BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
SYRACUSE UNIVERSITY
SUBJECT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: Biofeedback-Enhanced Treatment for Speech Sound Disorder: Randomized Controlled Trial and Delineation of Sensorimotor Subtypes
Protocol #: C-RESULTS-RCT, sub-study 1
Sponsor: National Institutes of Health (NIH) National Institute on Deafness and Other Communication Disorders (NIDCD)
Principal Investigator: Dr. Jonathan Preston
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Your child is being asked to be a subject in a research study because he/she has difficulty saying the English "r" sound. This consent form explains the research study. Before you decide to permit your child to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your child's speech-language pathologist. If you agree for your child to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

The NIH National Institute on Deafness and Other Communication Disorders, the sponsor of this study, is providing funds to Syracuse University for conducting this research study.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the effectiveness of different forms of treatment for errors affecting the "r" sound. In intensive motor-based treatment, a speech-language pathologist provides auditory models and verbal cues to help the child achieve a good "r" sound. In acoustic biofeedback treatment, a computer is used to create a visual representation of a child's "r" sound, which can then be compared against a model "r" sound. In ultrasound biofeedback treatment, ultrasound imaging is used to create a picture of a child's tongue, which can be compared against an ultrasound image of a correct "r" sound. All of the treatment methods used in this study have been shown to be effective in previous research. We want to compare these methods against one another to find out which is most effective.

NUMBER OF SUBJECTS AND LENGTH OF STUDY

About 180 subjects are expected to participate in this study at 3 research sites.

Your child's participation in this study is expected to last approximately 12 weeks (1-2 weeks testing, 10 weeks treatment).

STUDY PROCEDURES

Your child's participation will begin with an evaluation to determine if he/she fits all the criteria for our study. We will evaluate your child's hearing, oral-motor structure and function, language comprehension and production, and nonverbal IQ. We will also evaluate your child's perception and production of speech sounds, and we will test their oral tactile sensitivity (e.g., ability to discriminate forms with the tongue and awareness of the tongue's position in the mouth). The

evaluation process is expected to last up to three sessions, each up to two hours in duration. No treatment will be provided during this part of the study, but your child will be compensated for his/her time spent in evaluations at a rate of $20/hour.

If your child meets all of the criteria for inclusion in our study, we will ask you to bring your child for 1-3 treatment sessions per week for approximately 10 weeks. This study has three phases.

1. In the first phase (1 session, ~2 hours long), your child will work with a speech therapist who will verbally cue him/her to produce "r" in various contexts.

After the first phase, your child will be randomly assigned to one of three treatment conditions: intensive motor-based treatment, ultrasound biofeedback treatment, or visual-acoustic biofeedback treatment. Random assignment is like picking chances from a hat; your child has a 60% chance of being assigned to receive biofeedback treatment (with a 30% chance of receiving either the ultrasound or the visual-acoustic subtype) and a 40% chance of being assigned to receive intensive motor-based treatment.

2. In the second phase (3 sessions, ~1.5 hours each, over the course of roughly one week), your child will work with a speech therapist who will use the randomly assigned treatment method to cue your child to produce "r" in various contexts.
3. In the third phase (16 sessions, ~45 minutes each, over the course of roughly eight weeks), your child will continue to work with a speech therapist who will use the randomly assigned treatment method to cue your child to produce "r" in various contexts.

After completion of the study, we will ask your child to complete some of the same measures administered in the initial evaluation. Your child may be invited to return for an optional third session 1 – 2 hours in duration. Like the initial evaluation, your child will be compensated for his/her time in these sessions at a rate of $20/hour.

At the start and end of the therapy period, we will ask you to complete a questionnaire about your child's health and language history and how he/she is affected by his/her difficulty with the "r" sound. These questionnaires take roughly 15 minutes to complete.

During evaluation and treatment sessions, we collect audio recordings of your child's speech. If your child is assigned to the ultrasound biofeedback treatment condition, we will also collect video recordings of your child as part of this study. We use these recordings primarily for internal purposes, such as checking whether study staff are consistent in implementing our standard protocol. We will not release video of your child without explicit permission.

RESPONSIBILITIES

If you choose to enroll your child in this study, we will ask that you withdraw your child from any other therapy targeting the "r" sound for the duration of this study. However, speech therapy targeting goals other than "r" is permitted. We will be happy to speak with your child's speech pathologist to make sure your child will continue to receive services after the end of our study.

RISKS AND DISCOMFORTS

There are no more than minimal physical risks associated with participation in this study.

- Behavioral Testing: The risks associated with behavioral assessment are no greater than those involved during a standard speech-language evaluation in a school or clinic. These risks primarily include boredom or frustration with challenging tasks. To address the potential psychological discomforts such as frustration associated with challenging behavioral testing, participants will be given frequent breaks and will have the option to

discontinue testing at any time. Participating children do face very minor risks that are also present in everyday life, such as the risk of tripping on power cords or other equipment. During the measurement of oral sensation, there is a risk of transfer of communicable disease (such as the common cold) from one person to another if the strips used for measurement are not suitably disinfected between participants. To address this risk of communicable disease transmission, we sterilize the Teflon strips used for measurement in a UV Sterilizer after each use. Gloves are worn and sterile drapes are used to keep the strips sterile during the administration of the task. Finally, there is a slight risk of discomfort in connection with loud audio playback (approximately 80 dB) during two tasks used to measure sensory function. To address this risk, we allow participants to indicate what level of noise is comfortable for them and make adjustments accordingly.

- *If your child is randomly assigned to the intensive motor-based or visual-acoustic biofeedback treatment condition*: The risks associated with these treatments are no greater than in ordinary life. Use of acoustic analysis software (KayPentax Computerized Speech Laboratory) to provide biofeedback does not pose any additional risk beyond conventional therapy methods.
- *If your child is randomly assigned to the ultrasound treatment condition*: Ultrasound imaging is a safe and non-invasive technology that involves no radiation. The risks for ultrasound exposure are mitigated by the use of a B-mode ultrasound probe. Critically, we will follow the "as low as reasonably achievable" (ALARA) principle by not exposing the participant to ultrasound when they are not speaking or when they are not compliant or attending. To address the risk of communicable disease transmission, the probe is cleaned with transeptic spray and/or approved disinfecting cloths between participants. In a recent survey of participants undergoing ultrasound biofeedback treatment, the most commonly reported inconveniences reported by children were that the ultrasound probe positioning under the chin was mildly uncomfortable or that the gel was annoying (e.g. cold, gooey, sticky).

BENEFITS

Participating in this therapy may help your child produce a better "r" sound. There is no guarantee that your child's speech will improve as a result of their participation in this study. It may stay the same or worsen. However, the information learned from this study may help other people with speech disorders in the future.

If any new information is learned about this study that might affect your child's willingness to stay in this study, you will be told about it promptly.

COSTS OF PARTICIPATION

The sponsor will supply speech treatment to your child at no cost to you. Your child's participation in this study should not result in any additional costs.

REIMBURSEMENT

You/your child will be compensated $20/hour during evaluation sessions by check at the end of your participation in the study. Compensation will be prorated to the nearest 15 minutes. During treatment sessions, you and your child will receive $5 for each visit to defray study-related expenses such as travel and parking by check at the end of your participation. If you leave the study early, you will be reimbursed only for visits you complete.

CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you or

your child in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena. Exceptions include:

- A federal, state, or local law requires disclosure, such as information about suspicion of child abuse or neglect.
- Your explicit approval for the researchers to release personally identifiable information.

We protect your child's privacy by removing all identifiers from our records. Data that could identify your child will be kept separate from the data we report. All paper materials will be stored in a locked, secure place. Computer data will be stored in a password- protected database. Study records that identify your child and the consent and assent forms signed by you and your child will may be looked at by the Institutional Review Board and individuals responsible for overseeing the conduct of this research. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, your child will not be identified in these presentations and/or publications.

To track participant progress, we need to obtain outside listeners' ratings of participants' productions of words containing "r." We get these ratings by playing recordings of participants' utterances in a randomized, de-identified fashion for untrained individuals recruited to complete speech rating tasks in our lab or on the internet; these recordings will never contain identifying information such as your child's name. Below, we will ask for your permission to share recordings of your child's "r" productions as part of future research studies. Finally, we will ask permission to share de-identified audio recordings of your child in an academic context, like a conference or classroom. You are free to tell us not to store or share audio of your child in these ways. We will not release recordings of your child without your consent.

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

VOLUNTARY PARTICIPATION AND WITHDRAWAL

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 or loss of benefits. If you decide to leave the study, please tell the study staff. If you/your child choose to leave the study partway though, we may invite you to come back for one optional follow-up session at the time when all treatment sessions would have been completed. You are free to say no to this invitation.

ALTERNATIVES TO STUDY PARTICIPATION

Your child does not have to participate in this study to receive treatment for speech errors affecting /r/. He/she may instead seek treatment from another speech-language pathologist in the school or private clinic setting. He/she may also opt to have no treatment for "r" errors.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Jonathan Preston at 315-443-3143.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be

registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

STATEMENT OF CONSENT

By signing this form, I confirm the following:

- I have read all of 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 understand that the study team will store recordings of my child's speech and share them with outside listeners as part of this study.
- 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 give permission for my child's participation in this study. I understand that the study team will store recordings of my child's speech and share them with outside listeners as part of this study.

_____

Parent: Name (Print) Signature Date

_____

Person Obtaining Consent: Name (Print) Signature Date

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

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

   _____ YES (initials) _____ NO (initials)

2. Will you allow us to store audio recordings of your child and share them with outside listeners as part of **a future study**?

   _____ YES (initials) _____ NO (initials)

3. Will you allow us to use audio recordings of your child's speech in academic contexts, such as a conference or classroom?

   _____ YES (initials) _____ NO (initials)

4. Will you allow us to use video recordings of your child in academic contexts, such as a conference or classroom?

   _____ YES (initials) _____ NO (initials)