

Online assessment and enhancement of auditory perception for speech sound errors

Protocol NCT04858035

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STUDY 2:

Narrative Study Protocol

Randomization

Children with RSE may vary in pre-treatment severity, and the extent to which they can approximate /r/ may be an important indicator of subsequent treatment response. Therefore, a blocked randomization procedure will be used to protect against a situation where treatment groups are unbalanced with respect to pre-treatment severity. Based on the treating clinicians' perceptual ratings of participants' performance in /r/ word probes administered in the pre-treatment evaluation phase, participants will be categorized as High Accuracy (>5% accuracy) or Low Accuracy (\leq 5% accuracy). These groups will be referred to as “response groups.” Following this categorization from Phase 0, participants from each response group will be separately randomized to the waitlist-first or treatment-first condition.

Randomization will be supervised by statistician J. Hill at the NYU site. The following approach will be used:

- (1) Participants will be randomized after providing informed consent, meeting eligibility requirements, and completing the baselines that determine response group (High, Low). Clinical sites will notify the statistician of each participant's response category for the purpose of blocked randomization.
- (2) For each site, NYU will develop two batches of 10 concealed envelopes for assignment, one for high responders and one for low responders. Each will contain 10 participant assignments in random order: five treatment-first, five waitlist-first. Although NYU will be involved in the randomization process, participants will be given one code for randomization and another for data collection. Thus, when clinical results are transmitted back for data analysis, the NYU team will not be able to link the outcomes data with the original randomized allocation.
- (3) We cannot fully predict the exact proportion of high/low responders, so it is possible that we will encounter significantly more in one group than the other. Once we have recruited the first 10 participants for one subgroup (e.g., Low Responders), another batch of 10 envelopes will be generated to allocate the next 10 children in that subgroup.

Intervention/Delivery

All treatment will be provided individually by a certified speech-language pathologist via Zoom videoconference using a unique password-protected room for each participant. Each session will begin with 10 minutes of relatively unstructured, interactive pre-practice to provide instruction on the phonetic requirements for /r/ and strategies to shape accurate productions. The remainder of the session will include up to 150 syllables/words or 50 minutes of practice, whichever comes first. Practice will occur in blocks of 10 consecutive trials on the same item (e.g., 10 /ra/), followed by a new item (e.g., 10 /re/).

During each block, the clinician will provide qualitative (knowledge of performance) feedback as prompted by our open-source software, Challenge Point Program (CPP). CPP guides clinician actions, increasing treatment fidelity across sites and enabling adaptive changes in practice difficulty based on participant performance. After each block of 10 trials, the clinician scores each response (0 or 1), and CPP adjusts difficulty accordingly. Participants with at least 80% cumulative

session accuracy will advance from syllable to word-level practice; those dropping below 50% will return to syllable-level practice to reduce difficulty.

In word-level practice, feedback frequency (80%-50%-20%-0%), clinician modeling, and word shape complexity will be systematically adjusted based on performance. Qualitative feedback—either biofeedback or verbal clinician input—will start at 80% of trials and decrease based on participant success.