

***Delineation of Sensorimotor Subtypes Underlying Residual Speech Errors
(C-RESULTS-SCED)***

Protocol NCT03736213

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Narrative Study Protocol

Overview. At the group level, children with RSE show poorer auditory-perceptual and oral somatosensory sensitivity than typical individuals, but individuals differ in the extent to which each sensory domain is impacted. Based on their grounding in sensorimotor models of speech production, biofeedback treatment approaches can be predicted to be more or less successful for a given individual based on whether the enhanced feedback matches that individual's major area of sensory impairment. The objective of this aim is to evaluate how distinct deficit profiles mediate relative response to different types of biofeedback intervention using a single-case randomization design. The same randomization design will be replicated across 8 individuals hand-selected to feature a high degree of asymmetry in auditory versus somatosensory domains of perception. Our hypothesis is that visual-acoustic biofeedback will produce larger gains in individuals whose deficit primarily affects the specification of the auditory target, while ultrasound biofeedback will produce larger gains in individuals whose deficit primarily affects the oral somatosensory target.

All 8 participants will receive an equal dose of both types of biofeedback treatment (10 hours of ultrasound biofeedback and 10 hours of acoustic biofeedback) but with the order randomized in each day. Participants in Study 3 will receive a total of 20 hours (10 days) of treatment over a 5-week period. Our prior single-case studies for both types of biofeedback suggest that this dosage is sufficient to observe within-session Acquisition of correct /r/.

Randomization. In this single-case randomization design, each participant will receive an equal number of sessions of visual-acoustic and ultrasound biofeedback, with randomized allocation of treatment types to individual sessions. Randomization will be blocked, with each of day of treatment serving as a block; within each day/block, one hour of treatment will be randomly assigned to feature visual-acoustic and one to feature ultrasound treatment. Based on each participant's sensory profile, we will define a congruent condition and an incongruent condition--that is, the biofeedback type that is expected to be more effective and the type that is expected to be less effective. We define visual-acoustic biofeedback as the congruent condition and ultrasound biofeedback as the incongruent condition for individuals with a primary auditory deficit; the reverse is true in the case of a primary somatosensory deficit.

Intervention Delivery. The text below describes elements of treatment that are shared across traditional and biofeedback conditions (both ultrasound and visual-acoustic). All sessions will feature the same dosage of treatment and will follow the same structure. Treatment conditions will differ only in the nature of cues and feedback provided. Differences across treatment conditions are described below under Interventions.

Participants will receive treatment structured similarly to the procedures described for Phase 1 (Acquisition) in the C-RESULTS RCT, which focuses on eliciting /r/ at the syllable level. However, participants in Aim 3 (who will be required to fall in the "low response" group from Phase 0 of treatment) will receive a longer duration of Acquisition training (20 hrs/10 days over a 5 week period). The first 30 minutes of each session will consist of relatively unstructured, highly interactive pre-practice, designed to provide instruction on the phonetic requirements for /r/ and shaping strategies to transform the child's current productions into accurate /r/. The next 30 minutes will elicit up to 200 syllables or 30 minutes of practice, whichever occurs first. (This high level of intensity has been successfully achieved by members of our research team in previous and in ongoing studies.) Practice will occur in blocks of 10 consecutive trials on the same syllable (e.g., 10 /ra/), after which a new syllable will

be addressed (e.g., 10 /re/). After every fifth trial, the clinician will provide qualitative (knowledge of performance) feedback appropriate for the current treatment condition (acoustic or ultrasound). In addition, one randomly chosen token in each block of 10 trials will be flagged for acoustic measurement and will be elicited in a no-feedback condition. Thus, biofeedback will be made available in 90% of trials. To limit variability of practice, only 5 different syllables will be treated for each participant in the first two sessions of treatment, and we will add one new syllable in each subsequent block (of two sessions). Syllables that are targeted in treatment will be based on those that are the least accurate during Phase 0 (and if all syllables are at 0% accuracy then a common set of 5 syllables will be chosen). Participants will not complete Phase 2 (Generalization) as part of the design of Study 3, but for ethical reasons, they will be offered the opportunity to receive Generalization Training after completion of the Aim 3 protocol. This training would fall outside of the context of the study and will not be analyzed for research purposes.