Comparing Traditional and Biofeedback Telepractice Treatment for Residual Speech Errors (C-RESULTS TPT)

Protocol NCT04625062

Document generated July 1, 2020

Protocol: C-RESULTS TPT

Narrative Study Description

Randomization. In this single-case randomization design, each participant will receive an equal number of sessions of visual-acoustic biofeedback and traditional treatment (n = 10 each), with randomized allocation of treatment types to individual sessions. Randomization will be blocked, with each week of treatment serving as a block; within each week/block, one session will be randomly assigned to feature visual-acoustic and one to feature traditional treatment.

Intervention Delivery. The text below describes elements of treatment that are shared across traditional and biofeedback conditions. 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**. All treatment will be provided on an individual basis by a certified speech-language pathologist. Treatment will be delivered over Zoom videoconference calls using a unique password-protected room for each participant. The first 10 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 remainder of the session will elicit up to 150 syllables/words or 50 minutes of practice, whichever occurs first. (This level of intensity has been successfully achieved by members of our research team in previous and ongoing studies, including pilot studies of telepractice treatment.) Practice will occur in blocks of 10 consecutive trials on the same item (e.g., 10 /ra/), after which a new item will be addressed (e.g., 10 /re/). Within each block, the clinician will provide qualitative (knowledge of performance) feedback as prompted by our custom software.

In all conditions, stimulus presentation will be managed with our custom open-source software, Challenge Point Program (CPP). The CPP software prompts clinician actions such as delivery of knowledge of performance (KP) feedback, promoting increased fidelity in treatment implementation both within and across sites. It also enables systematic changes in practice difficulty based on participant performance. After the software presents a stimulus and the participant attempts to produce it, the clinician scores the response as 0 or 1 based on their clinical impression of an incorrect or correct production of /r/. Following each block of ten trials, the software automatically tallies the scores entered by the clinician and uses them to make adaptive changes in practice difficulty. When a participant demonstrates at least 80% cumulative accuracy at the session level, they will be advanced from syllable to word-level practice; if the cumulative session-level accuracy drops below 50%, they will be dropped back to the syllable level to decrease difficulty. In word-level practice, parameters are adjusted on a rotating basis so that as accuracy increases, either the frequency of feedback is reduced (80%-50%-20%-0%), clinician models are faded, or word shapes increase in complexity. Qualitative feedback (either biofeedback or verbal clinician feedback) will begin at 80% of trials and, contingent upon the participant's performance, will be systematically decreased to 0%.

Primary Purpose: Treatment

Interventions

Intervention Type: Behavioral

Name: Traditional articulation treatment

Description: Traditional articulation treatment involves providing auditory models and verbal descriptions of correct articulator placement, then cueing repetitive motor practice. Images and diagrams of the vocal tract will be used as visual aids; however, no real-time visual display of articulatory or acoustic information will be made available. Knowledge of performance feedback, when prompted by the CPP software, could describe either the desired articulator placement or the auditory quality of the target sound. Specific cues and strategies are publicly available as supplements to the published protocol of the parent study (McAllister, Preston, Hitchcock, Hill, 2020).

Intervention Type: Behavioral

Name: Biofeedback–visual-acoustic

Description: In visual-acoustic biofeedback treatment, the elements of traditional treatment (auditory models and verbal descriptions of articulator placement) are enhanced with a dynamic display of the speech signal in the form of the real-time LPC (Linear Predictive Coding) spectrum (Sona-Match module of KayPENTAX Sona-Speech software). Because correct vs incorrect productions of /r/ contrast acoustically in the frequency of the third formant (F3), participants will be cued to make their real-time LPC spectrum match a visual target characterized

by a low F3 frequency. They will be encouraged to attend to the visual display while adjusting the placement of their articulators and observing how those adjustments impact F3. Knowledge of performance feedback will typically involve reference to the location of the third peak on the visual display. Specific cues and strategies are publicly available as supplements to the published protocol of the parent study (McAllister et al., 2020).

Study Phase: Phase 1
Intervention Model: Other
Masking: Yes; Outcomes assessor
Allocation: Randomized

Outcome Measures

Name: Acoustically measured accuracy of /r/ in syllables
Type: Primary
Time Frame: Before and after each session of treatment
Brief Description: Probes of words and syllables containing /r/ in various phonetic contexts will be elicited at the start and end of each treatment session. We will follow a semi-automated protocol developed in the parent project to demarcate intervals of interest in a Praat textgrid. Textgrids and recordings will be submitted to a forced aligner, followed by automated extraction of formant frequencies (F1, F2, F3) at the center of each /r/ interval identified. F3-F2 distance, which is smaller in correct /r/, will serve as the primary acoustic correlate of accuracy.
Name: Perceptually rated accuracy of /r/ production
Type: Secondary
Time Frame: Before Phase 0 and again after the end of all treatment (10 weeks later)
Brief Description: To assess generalization of treatment gains to untreated words, participants will read a 50-word probe and a 10-sentence probe list eliciting /r/ in various phonetic contexts. Stimuli in each probe will be presented individually in randomized order. No auditory models will be provided; for children with reading difficulty, semantic cues will be provided to elicit the intended word. Individual words will be isolated from the audio record of each word probe and presented in randomized order for binary rating (correct/incorrect) by 9 naive listeners who are blind to treatment condition and time point (but will see the written representation of each target word). Sentences will be rated in a similar fashion, but raters will hear the whole sentence and will be instructed to rate only a single word cued orthographically. We will use the proportion of “correct” ratings for each token (McAllister Byun, Harel, Halpin, & Szeredi, 2016) as our primary measure of perceptually rated accuracy.

Subject Participation Duration

13 weeks (3 week baseline/maintenance, 10 weeks treatment)

Will the study use an FDA-regulated intervention?

No