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Clinical Trials: C2068-P
Apraxia of Speech: A Comparison of EPG Treatment & Sound
Production Treatment

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Statistical Analysis Plan
& Treatment Protocols

Statistical - Data Analysis Plan

Conservative Dual Criterion (CDC) method

The CDC method was used as an objective method to assist in assigning treatment effects (Fisher et al., 2003). Application of the CDC method involved using the baseline probe values to create a trend line and a mean (level) line for each set of data. These criterion lines were then adjusted upwards in the direction of the expected treatment effect by 0.25 standard deviations and were extended into each corresponding treatment phase. That is, the lines serve to predict continued performance, in the absence of treatment, based upon the baseline data. Assigning positive treatment effects requires that a pre-specified number of data points fall above both lines (see Fisher et al., 2003; Swoboda, Kratochwill, & Levin, 2010 for a more detailed explanation of the CDC method). For example, with five data points per treatment phase, all five points must fall above both CDC lines (Fisher et al., 2003). For this investigation, each treatment phase had 12 data points (i.e., probes), at least nine data points are required to be above both lines to assign positive treatment effects (Fisher et al., 2003).

Effect sizes were calculated to estimate magnitude of change that was associated with treatment. d-Index values (Bloom, Fischer, & Orme, 2006; Cohen, 1988) were calculated for each target speech sound for the treated and untreated stimulus items to measure the changes associated with the *treatment phase* and the *follow-up phase* (in comparison to the baseline phase). The d-index is a modification of Cohen's d formula that allows for greater precision in calculating effect sizes when there are a smaller number of baseline data points (Bloom et al., 2006). For effect size calculations associated with changes that occurred in the treatment phases, the five data points immediately preceding the application of treatment and the last three data points at the end of the treatment phase were used. For effect size calculations associated with changes in the follow-up phases, all baseline points in the initial baseline phase

(i.e., all data points preceding the start of the first treatment phase) and the three follow-up data points were utilized (i.e., 2, 6, 10 week probes).

Effect sizes are reported for the purpose of comparison within and across participants. Benchmarks have been established for SPT (Bailey, Eatchel, & Wambaugh, 2015) and benchmarks for treatment involving VBFB may be established in the future.

Treatment Protocols

Electropalatography Treatment Protocol: Phases 1, 2, & 3

EPG: Treatment Phase 1

Both the clinician and participant wear their pseudopalate

Feedback on all (100%) treatment items (Knowledge of Results (accuracy in producing the stimulus item) & Knowledge of Performance (accuracy in articulation [correct tongue placement])

1. The clinician will model/produce the treatment item (word) three times via EPG (i.e. visually displaying production) while the participant observes

Three unison productions of the treatment item (word) by the clinician and participant

- If correct, give feedback → **Go to Step 6**
- If incorrect, give feedback → **Go to Steps 2**

2. The clinician will model the target sound & vowel three times via EPG (i.e., visually displaying production) while the participant observes

Three unison productions of the target sound & vowel by clinician & participant

- If correct, give feedback → **Go to Step 5**
- If incorrect, give feedback → **Go to Step 3**

3. Breakdown Target Sound

- First practicing tongue placement *up to 5 times* → **Go to Step 4**

4. The clinician will model the target sound & vowel three times via EPG (i.e., visually displaying production) while the participant observes

Three unison productions of the target sound & vowel by clinician & participant

- If correct, give feedback → **Go to Step 5**
- If incorrect, give feedback → **Go to Step 5 (try again at word level)**

5. The clinician will model/produce the treatment item (word) three times via EPG (i.e. visually displaying production) while the participant observes (*Step 5 – same as Step 1*)

Three unison productions of the treatment item (word) by the clinician and participant

- If correct, give feedback → **Go to Step 6**
- If incorrect, give feedback → **Go to next item**

6. The clinician will model/produce the treatment item (word) one time

The participant will produce the treatment item (word) three times after model is provided

- If correct or incorrect, give feedback → **Go to the next treatment item**

EPG: Treatment Phase 2

Both the clinician and participant wear their pseudopalate

Feedback on 66% of treatment items (i.e., 20 of 30 treatment items will receive verbal feedback specifically Knowledge of Results & Performance) on steps 1-3 (Items that receive feedback will be randomly selected by the clinician).

1. The clinician will model/produce the *word* or *phrase* (one word with treatment word) treatment item *three* times via EPG while the participant observes the screen.

Three unison productions of the word or phrase by the clinician and participant

- If correct, provide feedback - if item is selected for feedback → **Go to Step 4**
- If incorrect, provide feedback - if item is selected for feedback → **Go to Step 2**

2. The clinician will model/produce the *syllable with target sound* (word level target) or *treatment word* (phrase level target) three times via EPG while the participant observes the screen

Three unison productions of the target three times by clinician & participant

- If correct, provide feedback - if item is selected for feedback → **Go to Step 3**
- If incorrect, provide feedback - if item is selected for feedback → **Go to next treatment item**

3. The clinician will model/produce the *word* or *phrase* (one word with treatment word) treatment item *three* times via EPG while the participant observes the screen.

Three unison productions of the *word* or *phrase* by the clinician & participant

- If correct, provide feedback - if item is selected for feedback → **Go to Step 4**
- If incorrect, provide feedback - if item is selected for feedback → **Go to next treatment item**

4. The clinician will model/produce the *word* or *phrase* one time

The participant will produce the treatment item three times after model is provided

- The participant will self-evaluate the perceptual accuracy of **all** (i.e., 100%) their productions with a particular focus on the *final* production
 - If the participant judges production accurately – **Go to next treatment item**
 - If the participant inaccurately judges/unable to judge production – spatial/temporal (S/T) goals demonstrated by clinician via visual feedback
 - Correct production – incorrect evaluation: SLP reviews S/T goals & how they were **met**
 - Incorrect production – incorrect evaluation: SLP review S/T goals & how they were **not met**

5. If inaccurate evaluation of production:

- a. Participant attempts target three times & again evaluates the accuracy of their final production compared to spatial/temporal goals
 - i. Regardless of accuracy of production or evaluation, SLP gives feedback → **Go to next treatment item**

EPG: Treatment Phase 3

Only the participant will wear their pseudopalate

*Current treatment list is treated in conjunction with filler list (i.e., alternate back & forth randomly)

Feedback on 66% of treatment items (i.e., 20 of 30 treatment items will receive verbal feedback specifically Knowledge of Results & Performance) on steps 1-3 (Items that receive feedback will be randomly selected by the clinician).

1. The clinician will model/produce the *word* or *phrase* (one word with treatment item) treatment item *one* time while the participant observes.

Three productions of the *word* or *phrase* by the participant.

- If correct, provide feedback - if item is selected for feedback → **Go to Step 4**
- If incorrect, provide feedback - if item is selected for feedback → **Go to Step 2**

2. The clinician will model/produce the *syllable with target sound* (word level target) or *treatment word* (phrase level target) one time while the participant observes

Three productions of the *syllable* or *word* three times by the participant

- If correct, provide feedback - if item is selected for feedback → **Go to Step 3**
- If incorrect, provide feedback – if item is selected for feedback → **Go to Step A**
 - **A) Three unison productions of target word, feedback given → Attempt two word combination again with Step 3**

3. The clinician will model/produce the *word* or *phrase* (one word with treatment word) treatment item three time via EPG while the participant observes.

Three productions of the word or phrase by the participant.

- If correct, provide feedback - if item is selected for feedback → **Go to Step 4**
- If incorrect, provide feedback - if item is selected for feedback → **Go to next treatment item**

4. The clinician will model/produce the *word* or *phrase* one time

The participant will produce the *word* or *phrase* three times after model is provided

- The participant will self-evaluate the perceptual accuracy of **all** (i.e., 100%) their productions with a particular focus on the *final* production
 - If the participant judges production accurately – **Go to the next treatment item**
 - If the participant inaccurately judges/unable to judge production – spatial/temporal (S/T) goals demonstrated by clinician via visual feedback
 - Correct production – incorrect evaluation: SLP reviews S/T goals & how they were **met**
 - Incorrect production – incorrect evaluation: SLP reviews S/T goals & how they were **not met**

5. If inaccurate **evaluation** of production:

- a. Participant attempts *word* or *phrase* **three times** & again evaluates the accuracy of their **final** production compared to spatial/temporal goals/SLPs production

- i. Regardless of accuracy of production/evaluation, give feedback → **Go to next treatment item**

Sound Production Treatment – Protocol

Instructions: I'm going to say a word (or phrase) and I would like you to repeat the word (or phrase) as accurately as you can

Treatment Hierarchy:

- 1) **Say word or phrase** and request repetition
 - a) If correct, request 5 repetitions, go to the next item.
 - b) If incorrect, give feedback and go to step 2.

- 2) **Show word or phrase**, indicate target word and underline the target sound, **say word or phrase**, and request repetition
 - a) If correct, request 5 repetitions, go to the next item.
 - b) If incorrect, go to step 3.

- 3) **Integral stimulation** – “Watch me, listen to me, and say it with me” up to 3 times. Say word or phrase with the word with the target sound that is the focus
 - a) If correct, request 5 repetitions, go to the next item.
 - b) If incorrect, go to step 4.

- 4) Give **Articulatory Placement Cues**, attempt **word again (for phrase level stimuli only the word with the target sound is attempted here) after** cueing using **integral stimulation**
 - a) If correct, request 5 repetitions of **word or phrase**, go to the next item
 - b) If incorrect, go to the next item

**Feedback: Initially 100%. Fade as appropriate. Clinician's discretion as to the amount of feedback provided (can decrease to 50-60%). Items that receive feedback will be randomly selected by the clinician (i.e., approximately 15 to 20 out of 30 treatment items will receive feedback). Clinician's feedback is always verbal.