Cover: Protocol

NCT #: NCT02332915

Title: Effect of Intensity of Treatment on Rehabilitation of Acquired Apraxia of Speech

Date: October 3, 2020

Protocol:

Participants

Inclusion Criteria:

- At least 4 months post onset of focal brain injury
- Chronic acquired apraxia of speech and aphasia
- Native English speaker
- Age: 21 – 90 years
- Pure tone hearing adequate to pass screening at 35 dB at 500, 1000, and 2000 Hz least one ear, or if aided, or verification from an audiological examination that hearing was adequate for conversational level speech.
- Negative histories for alcohol and/or substance abuse and neurological conditions other than stroke; self-reports verified by medical record review
- Performance within normal limits on the *Test of Nonverbal Intelligence-4* (Brown, Sherbenou, & Johnsen, 2010).

AOS diagnostic criteria (McNeil, Robin, & Schmidt,1997; 2009)

- Slow rate of speech
- Sound errors which included a predominance of distortions
- Syllable segregation
- Relatively consistent trial-to-trial articulation errors
- Prosodic abnormalities.

A battery of tasks was administered to elicit speech samples from which to judge presence/absence of AOS characteristics: 1) motor speech programming protocol (Duffy, 2013),

and 2) word and sentence repetition tasks (Wambaugh, Kalinyak-Fliszar et al., 1998; Wambaugh, West, & Doyle, 1998; and Mauszycki & Wambaugh, 2008). AOS symptoms were evident in at least some, but not necessarily all, of the preceding speech elicitation tasks. The diagnosis of AOS was initially made by each participant's primary clinician (one of the study research speech-language pathologists) and then was verified by the principal investigator.

Language assessments:

- *Western Aphasia Battery-Revised* (*WAB-R*; Kertesz, 2007)
- Nicholas & Brookshire Discourse Elicitation Battery (Nicholas & Brookshire, 1993)

Demographic data collected:

- Age
- Months post-onset
- Etiology
- Area of brain damage
- Years of Education
- Premorbid handedness
- Race/ethnicity
- Hemiparesis
- Marital status

Experimental Design

A combined group and single-case experimental design (SCED) was used. The group design component was a two-phase, cross-over design and the SCED component was a multiple

baseline designs (MBD) across behaviors and participants. This report is focused on the results of the group design.

Accuracy of articulation of two sets of experimental words (see "Experimental Stimuli") was measured repeatedly prior to treatment (see "Probes" for additional detail). For each participant, treatment (SPT-Traditional [SPT-T] or SPT- Intense [SPT-I]) was then applied to one set of experimental words while probing continued with both experimental sets. A two week, no-treatment interval followed the first treatment phase and a two-week maintenance probe was completed at the end of the interval. Repeated probing of the set of items to be treated in the second treatment phase during the no treatment interval (as part of the SCED) ensured that performance was stable prior to the application of treatment with that set. Then, the alternate treatment was applied to the remaining set of items. Follow-up probes were conducted at 2 and 8 weeks following the second treatment phase.

Treatment Order and Experimental Set Assignment. Quasi-randomized assignment was combined with participant matching to assign participants to one of two treatment orderings (i.e., SPT-I → SPT-T or SPT-T → SPT-I). We aimed to have a balance of aphasia severity and AOS severity reflected in the treatment orders. The first participant enrolled was randomly assigned to a treatment condition. Each subsequently enrolled participant was "matched" to a previously enrolled participant and assigned to the opposite group if he/she had the same aphasia type, had an AQ within 10 points of the match, and had the same AOS severity rating. When a match did not exist, then the participant was randomly assigned to a treatment order. Please note that the purpose of the investigation was not to compare performance relative to treatment order as all participants received both treatments. The matching and random assignment was conducted to minimize possible confounds associated with treatment order.

As indicated previously, each participant received both SPT-T and SPT-I. Two sets of experimental words were devised for each participant (described below). Those sets were randomly assigned to treatment condition to assist in controlling for influence of stimuli on treatment outcome.

Experimental Stimuli and Probe Procedures

Stimuli. As indicated, two sets of words were individually developed for each participant. For each set, there were three subsets, each of which represented a different sound target. Pretreatment assessment of word production was used to identify specific sounds that were difficult for the participant to produce. There were a total of 39 words per set, with 24 items designated for treatment and 15 items designated for generalization measurement. Across the participants, stimuli included monosyllabic words, multisyllabic words, and words in phrases.

Probes. Production of the experimental words was elicited in probes. During probes the examiner presented each word verbally, one at a time in random order, and asked the participant to repeat the word as accurately as possible. No feedback concerning accuracy of production was provided; only general encouragers (e.g., you're trying hard) were used. The treatment items were included in probes to measure the *acquisition effects* of treatment and the untreated exemplars of trained items were used to measure the *response generalization* effects of treatment (see Dependent Variable). All probe sessions were audio recorded.

Probes were conducted throughout all phases of the study. Prior to all treatment, three separate probes were completed with all stimuli. During each treatment phase, six probes were conducted. During the two-week no-treatment interval, the "to be treated" set was probed an additional three times to establish a second baseline before the second treatment. Follow-up probes were completed at 2 and 8 weeks post each treatment phase.

Dependent Variable

The dependent variable was accuracy of articulation of a target sound or sounds produced in words elicited in the probes. A single score of correct or incorrect was used for each experimental item. Scoring was completed using on-line, modified narrow transcriptions supplemented and verified with audio recordings. The target sound(s) for each experimental word was/were identified and determined to be accurately or inaccurately produced on the basis of the transcription. Then, the word containing the target sound(s) was given a score of "correct/incorrect". For each subset of items for each participant, the percentage of words in which the target sounds(s) was produced correctly was tallied from the verified, online productions; the subsets were further separated into trained and untrained subsets. These percentages served as the dependent variables for all analyses.

Target sounds were required to be produced without distortion in the correct syllable of the word. Multisyllabic words were required to have the correct number of syllables so that location accuracy could be judged. For words embedded in a phrase, the phrase word had to be attempted in order for the target sound (in the other word member of the phrase) to be scored as accurate. However, accurate production of the non-targeted phrase word was not required.

The *first complete* production was scored. If the entire target item was produced and there was an error on the target sound(s) and then the participant self-corrected the error, that item was scored as incorrect. However, if there was a false-start (the entire target item was not produced initially) followed by a correct production, then the complete production was scored as correct.

Treatment

The treatment under study was Sound Production Treatment (SPT; Wambaugh et al., 1998). SPT utilizes the therapeutic techniques of modeling/repetition, contrastive practice, orthographic cueing, integral stimulation, and articulatory cuing. These techniques are applied using a response-contingent hierarchy as follows:

1. The speech/language pathologist (SLP) produced a verbal model of the word or phrase and requested a repetition. If monosyllabic words were the treatment targets, sub steps were used for the purposes of contrastive practice upon an incorrect production (e.g., Wambaugh & Mauszycki, 2010; Wambaugh & Nessler, 2004). If multisyllabic words were the target, then contrastive practice was not used and the next step was attempted.
2. The SLP used printed letters/word to indicate the sound in error, directed the participant to attend to the target sound, provided another verbal model, and requested a repetition.
3. The SLP used integral stimulation - “watch me, listen to me, say it with me” - and attempted simultaneous production until a correct production was achieved, with a maximum of three attempts. In cases where a phrase is used, the entire phrase was attempted.
4. The SLP provided articulatory cuing appropriate for the sound production error and then repeated the procedures used in the previous step. Only the target word was practiced (not the entire phrase).
5. The SLP presented the next item.

Verbal feedback concerning the correctness of production of the sound target was provided immediately after each response. Since the hierarchy is response-contingent, ensuing steps of the hierarchy are completed *only* after an erroneous production. Following a correct response and provision of feedback, the next item was presented. The steps of the hierarchy are not reversed following a correct response.

The SPT hierarchy was applied to each treatment item repeatedly in a treatment session. The treatment sessions were approximately one hour long excluding probes. One treatment trial consisted of application of the SPT hierarchy to each of the 24 treatment items. As many treatment trials as possible were completed in a given treatment session. The number of treatment trials per session varied within and across participants and corresponded to the number of errors that occurred because more errors required use of more steps of the hierarchy. Although number of treatment trials varied, the length of each treatment session was carefully controlled to be between 50 and 60 minutes in length and was consistent within and across participants.

Number of treatment sessions was equivalent across treatment phases for each participant. Twenty-seven hourly sessions were completed in each treatment phase. For the intense treatment phase, SPT-I, three treatment sessions were conducted per day, for three days per week, for a total of three weeks. For the non-intense treatment phase, one treatment session was conducted per day, for three days per week, for a total of three weeks.

ASHA certified research SLPs conducted all treatment sessions. Accommodations to treatment schedule were made as needed (e.g., illness, vacations, holidays). Each participant selected his/her treatment location which remained constant throughout the study (i.e., participant's residence, research laboratory, or university clinic).

Reliability

Dependent Variable. Twenty percent of all probes (including all SCED probes) were quasi-randomly selected for rescoring by a research SLP who had not provided treatment; random selection occurred for all phases of the study. The audio recordings of probe sessions were used for rescoring. The reliability SLP was blinded to the assignment of lists to treatment phase and to assignment of items as treated or untreated. Point to point agreement was calculated for scoring of each item and percent agreement was calculated for each probe. Agreement for scoring each word/target as correct/incorrect ranged from 81% to 97%, with the average being 90%.

Independent Variable. A research SLP who had not participated in a given participant's treatment scored audio recorded treatment sessions for accuracy of implementation of treatment. Ten percent of all treatment sessions were randomly selected and were scored for administration of specific treatment components: 1) accurate administration of steps of the treatment hierarchy – 99 %; 2) presentation of all treatment words in each trial – 99%; 3) correct utilization of randomization and blocking – 98%, and 4) treatment session length of 50-60 minutes within +/- 5 minutes – 98%.