Brief Title: Training Grammar With Meaning

Unique Protocol ID: DLD-Tx2

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1) Study Population

Participants will be between the ages of 4 and 6 years old and have a language impairment. Children will include both boys and girls. Given that boys are more often affected by this condition, we expect a slight excess of boys in the sample (e.g. 2:1 m:f). Subjects will be recruited from Tucson area preschools, kindergartens, daycare centers, and treatment programs. We intend to sample from geographic regions that are likely to produce a diversity of racial and ethnic backgrounds.

We anticipate that up to 300 children will participate over 6 years. Children will reflect all socio-economic levels (as indexed by mother's/guardian's educational level) with racial and ethnic distribution roughly equivalent to that of the Tucson population of children.

Power analyses indicate that between 16 and 24 children are required per study to find significant effects. Sample sizes may be adjusted to reflect actual effects as studies proceed. To get these numbers, we typically need to test 50 participants a year, with children not meeting the criteria for language impairment, children having insufficient numbers of potential treatment targets (speech/language errors) withdrawn after testing.

Inclusion criteria include:

Between ages 4 years 0 months and 6 years 11 months at the time of treatment onset.
Native English language development, with exposure to other languages acceptable.
Normal hearing as indicated by a pure-tone audiometric screening.
Normal nonverbal skills as indicated by the nonverbal scales of the Kaufman Assessment Battery for Children.
Impaired language as indicated by the Structured Photographic Language Test (monolingual English speakers) or the BESA (English/Spanish bilinguals).

Exclusion criteria include

Other handicapping conditions that could cause poor language skills (e.g., autism, intellectual disability, blindness, genetic disorders, neurologic disease or injury), by parent report.
Native language skills other than English.
Lack of functional English proficiency by *both* parents or *any* guardian.

2) Recruitment Methods and Consenting Process

a. Recruitment Process:

1) Recruitment flyers will be provided through preschools and daycares that include children with language impairments. The flyer is attached.

2) Parents can contact us directly (e.g., word of mouth referral, response to flyers. finding information on their own [e.g., past UA News items]. This item (UA News Items) covered only the preschool summer camp program as a community engagement piece. It is not used by us for recruitment, but parents do find it on the UA website.

3) Parents of children on waiting lists from previous years will be phoned to invite their child to enroll in the current year (if still age-eligible).

Parents contacting us through any means will be screened via telephone so that we can determine the likelihood of their child qualifying for the study.

b. Informed Consent:

A consent form will be used to obtain Parental Permission. Parents will be provided the consent form to read, and the points covered in the written document will be reviewed orally with the parents by the project staff (see VOTF). Parents will have the opportunity to ask questions at any time before or after providing consent. Parents will be provided both written and oral notification of major changes to the project (e.g., the nature of the treatment procedures used; project location) and oral notifications of minor changes (e.g., changes in start date, holidays).

Assent will be waived due to the ages of the children, as children are under the age of 7. We are asking for one parental signature. Please see Appendix A.

The consenting parent must have functional English skills for their child to participate [diagnosis of the disorder presumes adequate English exposure]. Therefore, no translators or translated documents will be used.

Consent and HIPAA documents are appended.

3) Research procedures involved in the Human Research

Total participation will last no more than 14 months. Participant qualification testing will occur over 1-4 days (depending on the child's ability to cooperate) up to 10 months prior to treatment.

Treatment will occur over a 6-week period with daily participation. Treatment-related procedures will last up to one hour per day. In addition to the treatment itself, children's language will be sampled periodically to determine which aspects of speech and language are in error and should be treated, as well as to track progress. Testing of verbal and nonverbal characteristics are obtained during the treatment period for 15 additional minutes approximately twice a week. To facilitate participation of low SES children [whose parents cannot miss work for their child's treatment], all children will be offered supervised day care, provided separately from the treatment, for up to 5 hours per day. Parents are

asked to return with their children between 2 and 4 months post treatment to measure retention of treatment effects.

This study will compare two variants of the same treatment. In one, children will be told the meaning of verbs that they will be prompted to use along with their grammatical target. In the other, children will not receive information on word meanings.

Treatment sessions will be audio and video recorded. This will apply to all children as a condition of participation. The recordings are needed to assess accuracy of treatment delivery and accuracy of the coding of children's responses to the treatment. We will request permission to use video recordings for training future students and clinicians. Consent will be indicated by the parent's initials on a line giving this consent on the PHI consent form. This consent is not required for the child to participate.

Participant qualification testing includes:

A pure-tone audiometric screening.

The nonverbal scales of the Kaufman Assessment Battery for Children. materials appended

The Structured Photographic Language Test (monolingual English speakers) or the BESA (English/Spanish bilinguals). materials appended

Treatment methods:

Treatment methods occur in an adult-child context in which the two are engaged in child-appropriate activities (e.g., board games, structured play, book reading, craft projects) and conversation. This treatment is known as Conversational Recast which is known to have an overall positive impact on children's language skills, based on published research by our group and others (going back into the early 1980s) Clinicians elicit language from the child by prompting them to use particular words, phrases, or sentences. After a child's response to the clinician's prompt, the clinician provides a correct model of the child's attempted utterance. Children are provided with at least 24 opportunities per session to attempt a treatment target and to receive feedback in the form of a correct repetition of the utterance or praise. No negative feedback is used.

It is not possible in advance to provide the exact words, phrases, or sentences used in treatment for multiple reasons. First, the linguistic units targeted for treatment are tailored to the errors of omission or commission for each individual child enrolled. These are never uniform across all children. Second, research considerations such as balancing particular targets across treatment groups influence the decision on what to treat, and therefore, the words used. Third, the treatment is not scripted and should not be scripted (scripted treatments have yielded poor effects in the previous literature). Fourth, our previous research has found that clinicians must use a large variety of words and contexts to train language for it to generalize to new linguistic and environmental contexts. It is not unusual for clinicians to use 75 different activities and well over 200 different

target words over the course of a treatment period. Finally, since treatment occurs in a conversational context with the child, treatment doses (the words spoken to children thought to effect change) often follow from what the child says, which is not predictable in advance.

Sessions are video and audio recorded so that the accuracy of treatment administration and coding of child utterances can be checked. These are used so that paper records can be checked for accuracy against a recorded record. Entire sessions are never transcribed, although individual words may be when it is important to record the exact sounds used in a child's production (e.g., him vs. he; bringed vs. brought, wabbit vs. rabbit).

Analysis plan

In this study, the dependent variable is expressed as change from baseline performance in units of standard deviation. This was designed to address the question of whether the treatment produced positive change overall. For this, we consider performance on the generalization probes from the first three pretreatment and final three end-treatment probe sessions. We calculate a single-subject effect size *d* metric that reflects gains in morpheme use from baseline levels, for each individual child. This is calculated for each of the Target and Control morphemes as follows:

$$\text{Generalization } d = \frac{\text{(end treatment probe mean – pretreatment probe mean)}}{\text{end treatment standard deviation}}$$

We note that when the end treatment standard deviation was zero, we used the minimum possible standard deviation to avoid dividing by zero. We will compare the effect sizes of Target morpheme use to Control morpheme use for each group to determine the effects of treatment in terms of generalization to untreated words.

We used a Bayesian statistical approach to data analysis, using JASP software (JASP Team, 2021). For all tests, we will use the Bayesian equivalent of a Mann-Whitney U test for between group comparisons and a Wilcoxon signed-rank test for within-subject comparisons. Bayesian statistics do not require data to meet the assumptions of other parametric tests (e.g., t-tests), which the types of small samples used in early efficacy studies are unlikely to meet. Another important difference is that Bayesian statistics do not test for statistical significance but express the probability that two distributions are different. This probability is expressed as a Bayes Factor (BF), which can range from 0 to infinity, signaling that probability of a difference is highly unlikely to near certainty. A Bayesian approach can also evaluate the probability that two distributions are equivalent (1/[BF] for group differences), which is not possible for traditional parametric statistics. For tests of within- or between-group differences, this expresses the range of effect sizes from within which the true effect is likely to fall. For correlations (Kendall's tau here), it expresses the range of correlations from which the true correlation is likely to fall.

As BFs increase above 1.0, support for the experimental hypothesis (e.g., group or condition differences) also increases. Guidance on the strength of support was provided by van Doorn et al., (2021), who suggested that BFs between 1 and 3 can be interpreted as providing

weak or incremental support for a hypothesis, moderate support indicated by BFs between 3 and 10, and strong support for BFs above 10. Although these values were suggested in the context of experimental research. We note, however, that comparison of two treatment methods that are each known to be efficacious, as will be the case here, is unlikely to result in a BF large enough to meet this criterion for "strong support".

To address the effectiveness of the treatment, we will compare the treatment d for treated and control grammatical forms, collapsed across treatment conditions. To address whether providing semantic support improves learning, we will compare the treatment d for children who did and did not receive semantic support during treatment. To address the degree to which children retained learning after treatment concluded, we correlated (Bayesian Kendall's Tau) the mean performance on the average of the final 3 generalization probes with performance at follow-up.