

Official Title: Retrieval-Based Word Learning in Developmental Language Disorder During Book Reading

Grant #: R01DC014708

NCT#: NCT06026124

Date: October 31, 2022

Definition: Type of uploaded study document. Select one.

- Study Protocol: The written description of the clinical study, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations (if the protocol document includes the statistical analysis plan, use "Study Protocol with SAP and/or ICF" option). Note: All amendments approved by a human subjects protection review board (if applicable), before the time of submission and that apply to all clinical trial Facility Locations must be included.
- Statistical Analysis Plan (SAP): The written description of the statistical considerations for analyzing the data collected in the study. Includes how data are analyzed, what specific statistical methods are used for each analysis, and how adjustments are made for testing multiple variables. If some analysis methods require critical assumptions, the written description should allow data users to understand how those assumptions were verified.

Purpose

Word learning is one of the principal weaknesses in children with developmental language disorder (DLD). Our previous work has shown that special benefits accrue when these children must frequently recall newly introduced words during the course of learning. The goal of the study is to replicate the advantage that repeated retrieval holds over simple exposure to words and to demonstrate an increase in children's absolute levels of learning by implementing retrieval practice in the context of a story book. We include typically developing peers as a comparison group.

Participant selection

Preschool children with DLD are recruited through local speech-language pathologists and preschool teachers. Children with typical language development are recruited through advertisements in parent newsletters, preschools, and community events.

For interested families, a phone interview is used to screen for the following eligibility requirements:

- 1) current age between 4;0 and 5;11 (years; months)
- 2) monolingual English speaker; or bilingual speaker with significant English exposure from birth.
- 3) no significant neurological condition or neurodevelopmental disorder (e.g. ASD).

Informed consent is obtained at the first session and eligibility testing is then completed. To be eligible, the child must:

- 1) pass a pure tone hearing screening in both ears at 20 dB at 500, 1000, 2000, and 4000 Hz
- 2) score above 75 on a test of non-verbal intelligence (*Kaufman Assessment Battery for Children – Second Edition*).
- 3) complete the *Structured Photographic Expressive Language Test – Preschool 2* and receive a standard score in the following range:
 - a. To be included in the DLD group, children had a standard score below 87. This cutoff score has been found to show good sensitivity and specificity (Greenslade et al., 2009).

- b. To be included in the TD group, children had a standard score above 87.

All children also complete the Peabody Picture Vocabulary Test – Fourth Edition. Parents complete a questionnaire that includes mother's total years of education. The PPVT standard scores and years of maternal education are both used as covariates in all statistical analyses.

For eligible children, 6 sessions are scheduled to complete the study.

Word learning procedure

In the current study, the investigators aim to increase word recall accuracy levels by embedding the same words and retrieval schedules used in earlier studies into story contexts. Two artist-illustrated stories incorporate illustrations of the unfamiliar plants and animals that served as referents of novel nouns in an earlier study. Using a within-subjects design, children will learn eight novel nouns, four embedded in each of two stories. Along with each word form, children will learn a "meaning", that is, an additional piece of semantic information about the referent. The novel words are monosyllabic (consonant-vowel-consonant) and are matched across conditions according to phonotactic probability and neighborhood density (based on Storkel & Hoover, 2010).

In order to maintain the number of word exposures used in previous studies, the stories will be presented twice during each of the two learning sessions held on consecutive days. For each story, two words will appear in the repeated spaced retrieval (RSR) condition and two words in a repeated study (RS) condition, presented in alternating order. For novel verbs in the RSR condition, the first retrieval trial is an immediate retrieval trial. After the study trial (e.g., "This is called a nepp. It's a nepp. A nepp likes worms."), the illustration is re-presented and the child is prompted to retrieve word form ("What's this called?) and word meaning ("What does it like?"). After this, all retrieval trials are "spaced", that is, they appear after the other three novel words have intervened. All retrieval trials—immediate and spaced— are directly followed by another study trial for the same novel word. The novel words in the RS condition receive the same kinds of study trials but no retrieval trials. The second day is identical to the first. Across the two days, the same number of study trials (16) are provided for the novel words in the two conditions. There are 12 retrieval trials (four immediate, eight spaced) for each novel word in the RSR condition.

Outcome measures

Primary outcome measures:

Form Recall and Meaning Recall test at 5 minutes. For each story, after the child has completed the learning session of the second day, a five-minute break is given. Then a recall test of each word form and meaning is administered. Two items for each word form and meaning are used, with the second item for each word presented only after all four words had been tested once. Prompts used for the recall items are identical to those used in the retrieval trials ("What's this called?"; "What does this one like?"). The target image of the referent (without other visual context) is taken from the story book.

Form Recall and Meaning Recall at one week. The Form and Meaning recall test is re-administered one week after the first day of learning.

Form Recognition at one week. Immediately following the one-week Recall test, a picture-pointing recognition test is administered. The illustrated image of each novel word referent is shown along with two of the other referents in the set and the child was asked, "Which one is the e.g., /nep/."

Secondary outcome measures:

Peabody Picture Vocabulary Test – Fourth Edition is completed. Standard scores are obtained and used as a covariate in all statistical analyses.

Parents complete a questionnaire that includes mother's total years of education. Years of maternal education is used as a covariate in all statistical analyses.

Scoring

Word Form Recall measure: Eight items are used for the word form recall test for each set.

Several steps are used in the scoring of children's word productions:

- 1) Productions of real words alternatives to the novel word (e.g., "cactus") are scored as incorrect.
- 2) Productions that appear to be attempts at the novel word but are not accurate are submitted to the scoring system of Edwards et al. (2004). Each consonant is awarded one point each for correct place, manner, and voicing. For vowels, one point is given for each of length, height, and backness. An additional point is credited for correct syllable shape (CVC). Given that all novel words had the syllable shape CVC, all fully adult-like pronunciations earned 10 points. For any non-adult-like production to be scored as correct, the production is required to have a higher point total than the total that would be given if the child is instead trying to produce one of the other novel words.

Meaning Recall measure: Eight items were used for the meaning recall test.

Scoring of the children's responses on the meaning recall test as correct or incorrect is straightforward, as pronunciation, even when non-adult-like, is not a factor in distinguishing among the possible meanings (e.g., grass, butterflies, rain, sun).

Form Recognition measure: Eight items were used for the form recognition test.

The child's picture pointing response is recorded at the time of test. The score for the recognition test was the number of items in which the child pointed to the correct image in the three-image array.

Data analysis plan

Mixed-effects models will be used to evaluate the children's recall and recognition of the novel words. Models will be run with and without the covariates of PPVT-4 and maternal education in years. The number of items correct is the outcome measure for each analysis. The form and meaning recall test is administered five minutes after the learning period and one week later. For this test, diagnostic group (DLD, TD) is a between-participants variable and learning condition (RSR, repeated study), time (five minutes, one week) are within-participants variables. The word recognition test is administered only at the one-week mark and therefore does not include time as a variable. Random slopes for learning condition, item type, and time will be included when they do not approach zero.

Main-effects models and full factorial models with all possible interactions will be tested hierarchically. The main-effects models will be run initially with no interactions to provide a baseline of each model variable. Statistically significant interactions will be analyzed and relevant simple effects are reported. Effect sizes will be presented as partially standardized beta coefficients (b_{std}). To account for non-normal error terms, we will use boot-strapped standard errors with 1,000 replicates. Stata Version 18.0 (StataCorp, 2023) will be used for the mixed-effect model analyses.