

Official Title: Interactive Book Reading to Accelerate Word Learning by Children with SLI

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Purpose. The goal was to determine whether interactive book reading outcomes for children with SLI were affected by manipulation of dose (i.e., the number of exposures to the target word during a book reading session) and dose frequency (i.e., the number of repeated book reading sessions) and whether pre-treatment factors predicted treatment response variation.

Participant Selection. Kindergarten children are recruited through community language screenings, referrals from speech-language pathologists, or advertisements. At first contact with an interested family, an informed consent document and background questionnaire are provided. The background questionnaire gains information about demographic characteristics of the child/family and assesses some of the inclusionary/exclusionary criteria.

Exclusionary Criteria: a child is excluded from participation if he/she:

- (1) speaks more than one language, as determined by background questionnaire;
- (2) has a health history indicating neurologic or other disorders that would exclude a diagnosis of SLI (e.g., autism), as determined by background questionnaire.

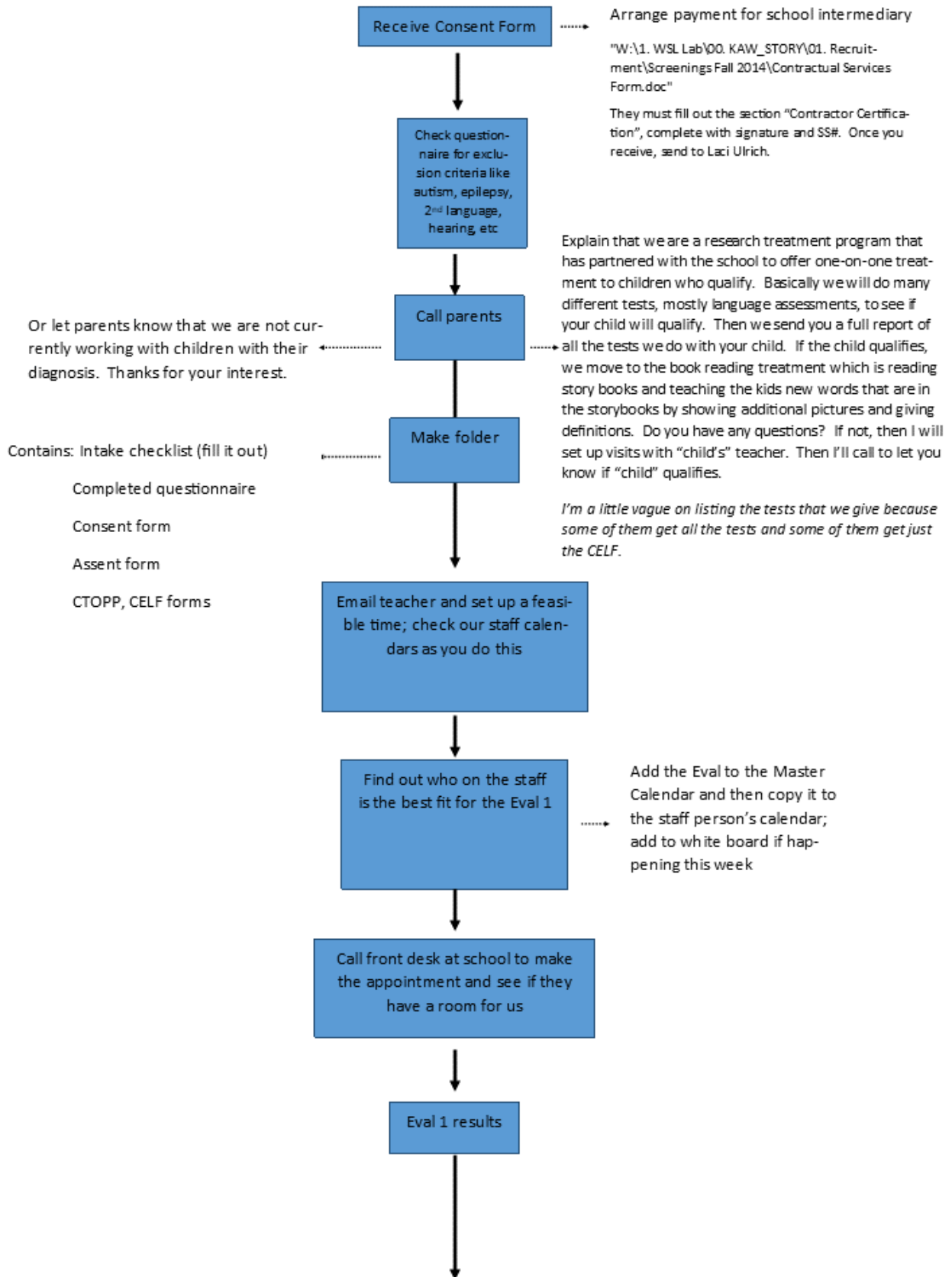
Inclusionary Criteria: children will

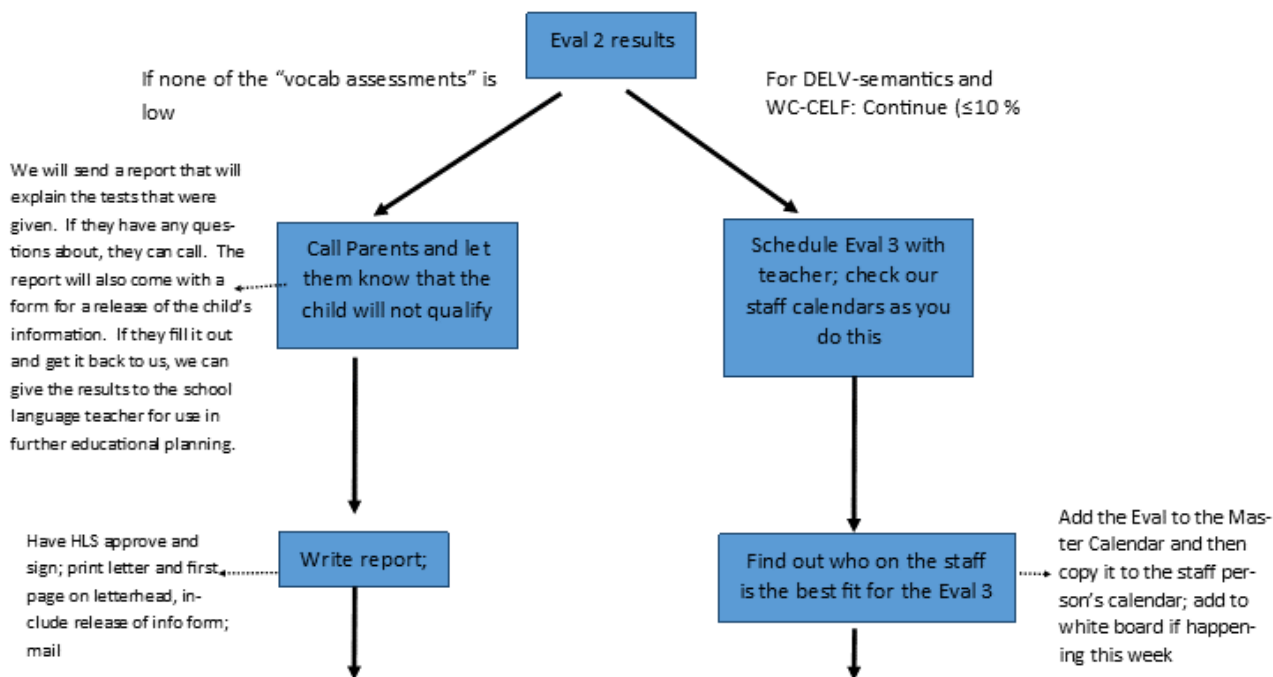
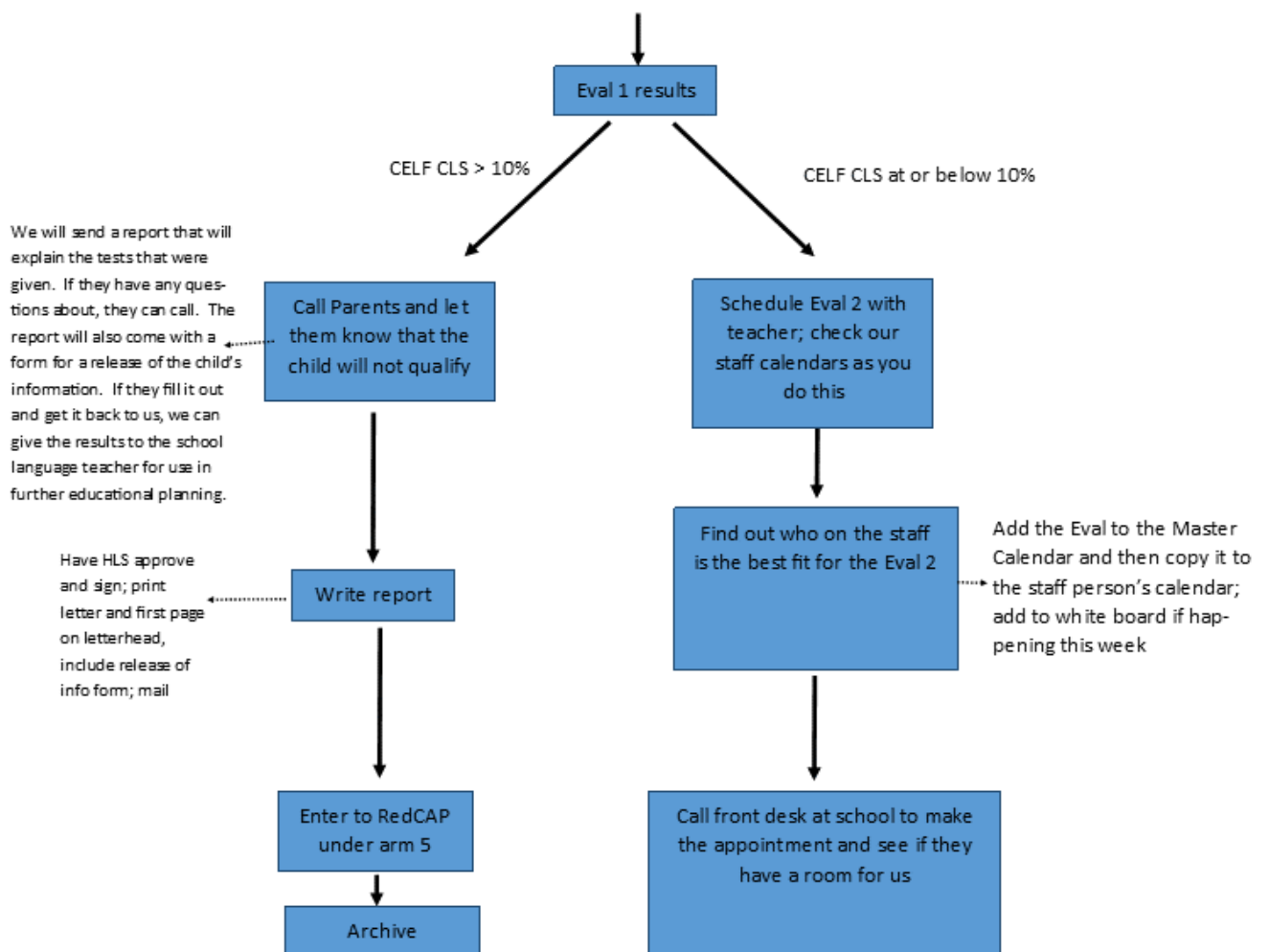
- (1) be at least 5-years-old and in/eligible for kindergarten, as determined by background questionnaire;
- (2) pass a hearing screening;
- (3) have nonverbal IQs at or above the 16th percentile on the *Reynolds Intellectual Assessment Scale-2* to rule out cognitive deficits;
- (4) have a Core Language Score at or below the 9th percentile (standard score = 80, 1.3 SD below mean) on the *CELF-4* to document language impairment;
- (5) score at or below the 9th percentile (standard score = 6) on the semantics subtest of the *DELV* or the word classes subtest of the *CELF-5* to document a vocabulary deficit. Score cut-offs are based on classification accuracy reported in the manuals (when reported).

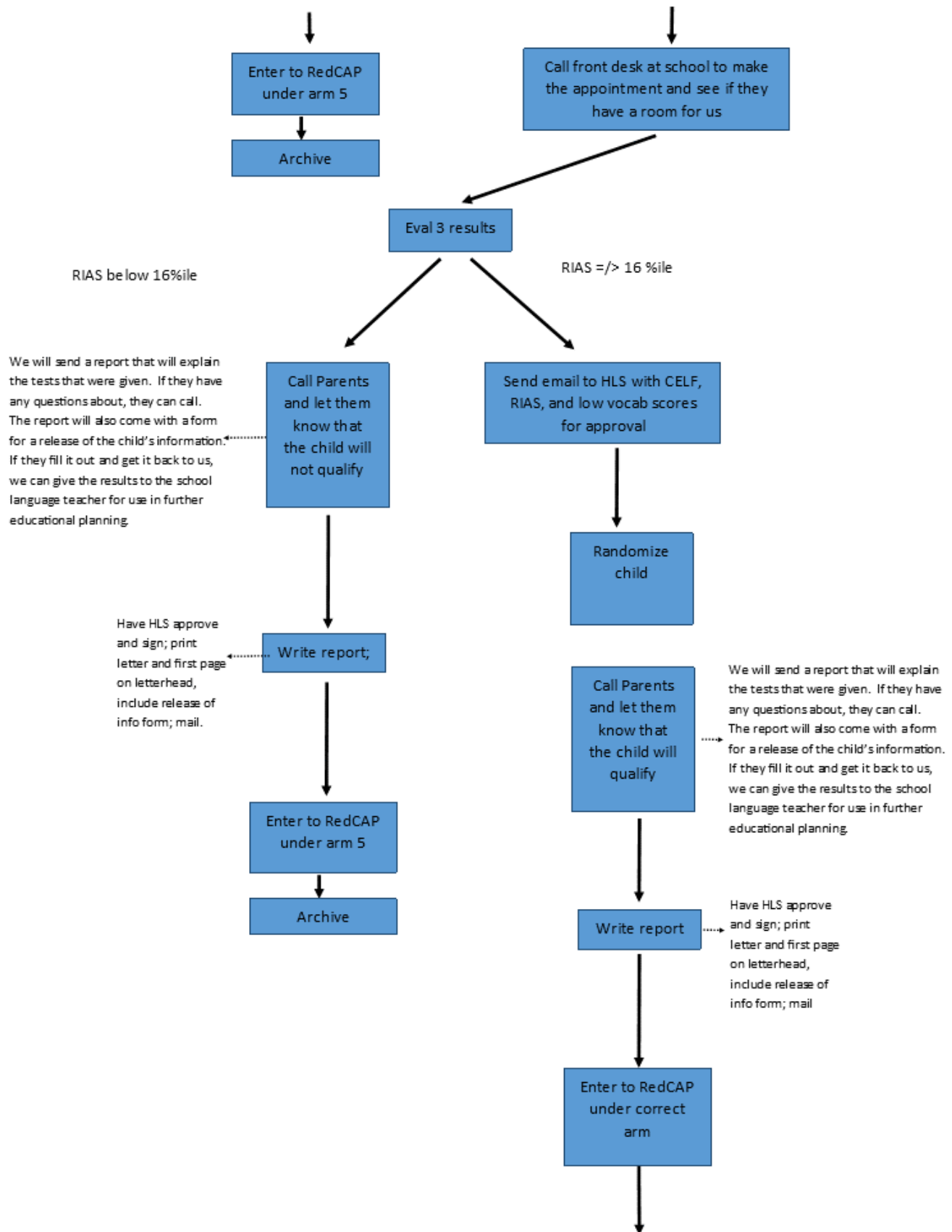
Procedural flowchart. Is shown in the following multi-page figure. Each major procedure is described below.

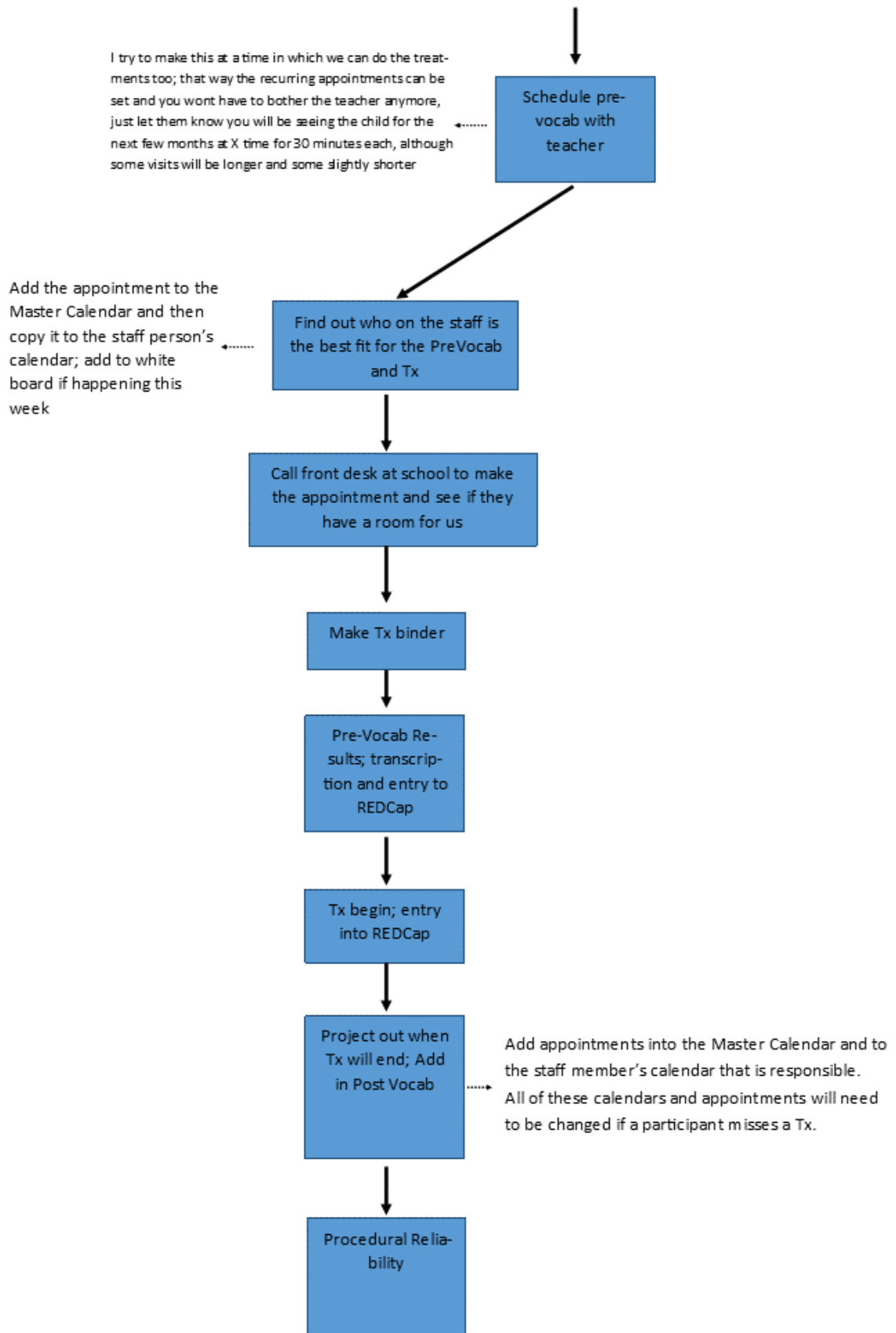
Standardized Testing: Once informed consent is attained, standardized tests are administered to assess inclusionary criteria and gain additional information to further characterize the participants and potentially predict their performance in treatment.

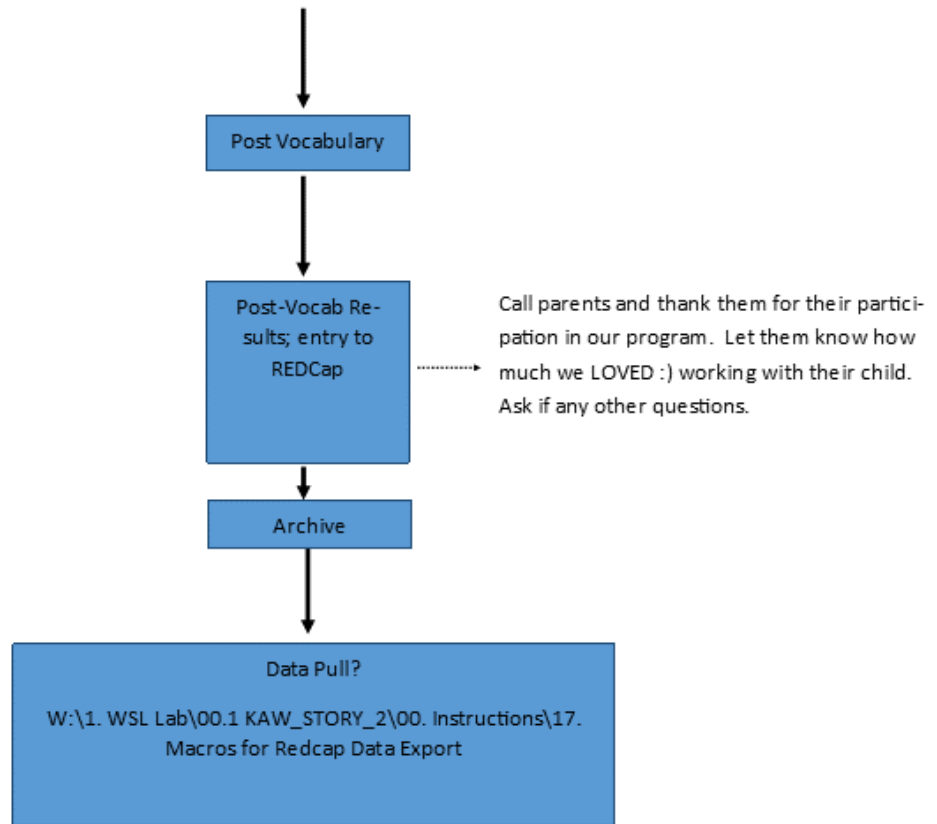
- Pre-Session 1
 - Signed consent form (could be completed at Session 1)
 - Completed background questionnaire (could be completed at Session 1)
- Session 1
 - CELF-4: Core Language Subtests (inclusionary criteria)
 - CTOPP-2: Phonological Awareness – Elision subtest (further characterize participants)
- Session 2
 - DELV Semantic subtest (inclusionary criteria)
 - CELF-4: Word Classes subtest (inclusionary criteria)
 - CTOPP-2: Phonological Awareness – Sound Matching subtest (further characterize participants)
- Session 3
 - Hearing screening (inclusionary criteria)
 - RIAS (inclusionary criteria)
 - CTOPP-2: Phonological Awareness – Blending subtest (further characterize participants)
 - CTOPP-2: Phonological Memory subtests (further characterize participants)
 - GFTA-2: Articulation (further characterize participants)











Randomization. Once children have met all criteria to be included in the study, they are randomized to one of the 4 treatment arms, shown in the next figure. Treatment arm randomization also includes assignment of Set A and Set B books to each treatment. Stratified randomization was used such that children with DELV standard scores 6 and higher are randomized separately from children with DELV scores 5 and lower because it was hypothesized that treatment outcomes would differ based on the ability to quickly learn new words, as indexed by the DELV.

Treatment. See https://asha.figshare.com/articles/Dose_Dose_Frequency_Storkel_et_al_2019_/9745181_Supplemental_Material_S4_Treatment_scripts_for_each_treatment_condition_and_each_word_set for the treatment protocol (session-by-session list of activities and treatment scripts) corresponding to each arm and word set.

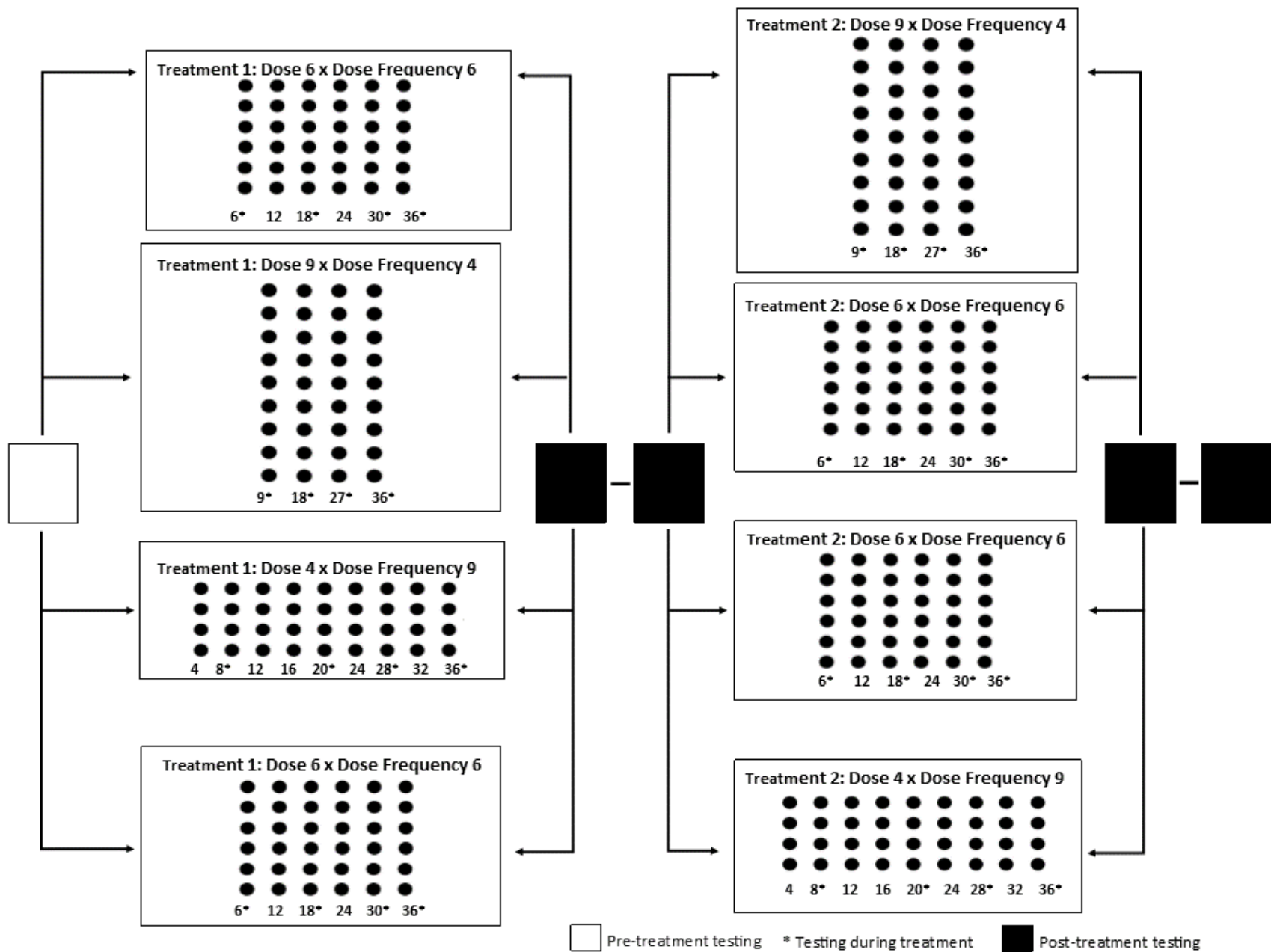
Outcome Measures.

Primary outcome measure: Definition task. As in our prior preliminary clinical trial (Storkel, Voelmle, et al., 2017), the primary outcome measure was a definition task. We chose a definition task for two reasons: (1) to afford comparison to our past research with this treatment to determine whether continuing changes to the treatment improve outcomes; (2) to ensure that the treatment is helping children establish the rich word knowledge needed to support a variety of linguistic tasks. Although this task sets a high bar for word learning, our past research shows that it is sensitive enough to detect changes between different treatment conditions. The definition task was administered before treatment, immediately following the conclusion of each treatment, and 2 weeks following the conclusion of each treatment

Research assistants administer the task across two sessions with 15 Set A and 15 Set B words tested in each session. For each word, the child received the prompt, "Tell me what [word] means." Prompts were pre-recorded and presented with computer software so that pronunciations of the words were consistent across tasks. Children's responses were audio recorded and transcribed for later scoring. The children first hear three practice words (*bed, ball, candy*), which were words likely to be known by them to ensure that they understood the task. Then, the 30 target words are presented in random order along with familiar words ($n = 10$, e.g., *chair, teacher, apple*). In terms of training the testers, all testers are shown how to use the computer software and the recording device. Testers practice administering the definition test to other trained testers until they are comfortable with the equipment and protocol. Testing script is available at https://asha.figshare.com/articles/Dose_Dose_Frequency_Storkel_et_al_2019_/9745181_Supplemental_Material_S7_Testing_script.

The definition scoring procedures from our prior preliminary clinical trial (Storkel, Voelmle, et al., 2017) are used. In the prior study, the research team followed the procedures of McGregor, Oleson, Bahnsen, and Duff (2013) and consulted dictionaries to create a scoring rubric that listed common elements of an accurate and complete definition for each word (e.g., *pouted = negative emotion + lips/face*). Possible scores were: 0 points for an incorrect or absent definition (e.g., *pouted = face*), 1 point for an appropriate use of the word in a sentence (e.g., *pouted = pouted because you don't want to eat and your mom makes you*) or for a vague definition (e.g., *pouted = cry*), 2 points for a conventional definition containing at least one critical element but lacking other critical elements (e.g., *pouted = mad*), and 3 points for a complete and accurate definition including all critical elements (e.g., *pouted = feel mad and push your lips out*). Two raters independently score each response following the rubric guidelines. The raters compare their scores and resolve disagreements through consensus.

In the analyses, children's definitions scored as 2 or 3 (i.e., a partially or completely accurate definition) are counted as correct and definitions scored as 0 or 1 (i.e., incorrect definition, absent definition, correct use of a word in a sentence, or vague definition) are counted as incorrect. This was done to afford comparison to prior studies (Justice et al., 2005; Storkel, Voelmle, et al., 2017).



Secondary outcome measure: Interim definition. Learning also is tracked during treatment. The research assistant who provides the treatment prompts children to provide definitions or name the target words at four points during each treatment. The words are assessed in a fixed order while the child views the pre-reading pictures for each word. The research assistant asks, "What does [word] mean?". Specific feedback is not provided but the correct definition always is provided after the child's response regardless of the accuracy of the response. This is shown in the scripts at https://asha.figshare.com/articles/Dose_Dose_Frequency_Storkel_et_al_2019_/9745181. Definition responses were scored by two independent raters unaware of children's treatment assignment following the procedures described above.

Secondary outcome measure: Interim naming. For naming prompts, the research assistant shows the child the post-book reading picture without the orthographic label and asks a question meant to elicit the phonological form of the target word (e.g., "What is the lightning doing?" to elicit flashing). Specific feedback is not provided but the correct orthographic label and context sentence always are provided after the child's response regardless of the accuracy of the response. This is shown in the scripts https://asha.figshare.com/articles/Dose_Dose_Frequency_Storkel_et_al_2019_/9745181. Naming responses were scored as correct or incorrect. Correct responses included the word itself (e.g., glared), the word in its bare form or with a different ending (e.g., glare, glaring) or an acceptable phonological substitution of the word (e.g., gwarding, judged on an individual basis). One independent judge scored naming responses and scores were verified by another judge.

Summary of the Design. The preceding figure provides a summary of the design. Upon meeting the selection criteria, children were randomized to 1 of 4 treatment arms. Pre-treatment definition testing was conducted for all 60 words, as indicated by the white box in Figure 1. Treatment 1 then was initiated for 30 words (Set 1 words with Set A or B being randomized to Set 1 or Set 2). Set 1 words were tested via naming and definition tasks four times during Treatment 1, as indicated by asterisks in the figure. Upon completion of Treatment 1, all 60 words (Set 1 and Set 2) were tested immediately and 2-weeks after treatment via the definition task. Note that Set 1 words have received treatment but Set 2 words have not yet received treatment and serve as untreated control words. Treatment 2 was then initiated for the remaining 30 word (Set 2 words). Set 2 words were tested via naming and definition tasks four time during Treatment 2, as indicated by the asterisks in the preceding figure. Upon completion of Treatment 2, all 60 words (Set 1 and Set 2) were tested immediately and 2-weeks after treatment via the definition task. Note that Set 2 words have just received treatment, whereas Set 1 words received treatment much earlier. Thus, for Set 1 words, these test points indicate longitudinal maintenance of learning following 5-12 weeks of treatment on a different word set.

Data Analysis Strategy. A series of multilevel longitudinal models were evaluated using SAS Proc Mixed to describe the change in number of Set 1 and Set 2 words accurately defined over seven test points: pre-treatment, 36 exposures in Treatment 1 (i.e., last Treatment 1 session), immediate post-Treatment 1, 2-week post-Treatment 1, 36 exposures in the second treatment (i.e., last Treatment 2 session), immediate post-Treatment 2, and 2-week post-Treatment 2. Because the number of exposures varied for the interim definition tests, only the 36-exposure interim definition test data, which was consistent for all treatment conditions, were used. We expected significant slopes for Set 1 words during Treatment 1 when they were the target of intervention. We had no hypotheses about whether Set 1 words would decline or would be maintained after Treatment 1 ended and monitoring continued during Treatment 2. We expected non-significant slopes for Set 2 words during Treatment 1, when those words were not the focus of intervention, and significant slopes for Set 2 words during Treatment 2 when they were the target of intervention. Because the number of words defined were counts, the natural log of the words defined was modeled resulting in a model equivalent to a generalized linear mixed model with a negative binomial link function.

The significance of fixed effects was evaluated using Wald tests, and the significance of random effects was evaluated using likelihood ratio tests and information criteria between models with the same fixed effects. We evaluated models with time coded as days since the start of intervention as well as categorically by intervention point. The categorical model fit the data better. The final categorical coding of time is shown in Table 7. Because there were two treatment phases (Treatment 1 vs. Treatment 2) with different expectations for change in Set 1 versus Set 2 words in each phase, we examined a piecewise model of change in which the change related to the first treatment phase (i.e., pre-treatment, 36 exposures in Treatment 1, immediate post-

Treatment 1) was described by one linear slope and change related to the second treatment phase (i.e., 2-week post-Treatment 1, 36 exposures in the second treatment, and immediate post-Treatment 2) was described by a second linear slope. This allows the slope for each word set to differ across each phase, as predicted.

Results. Results are reported fully in Storkel, H. L., Komesidou, R., Pezold, M. J., Pitt, A. R., Fleming, K. J., & Romine, R. S. (2019). The impact of dose and dose frequency on word learning by kindergarten children with developmental language disorder during interactive book reading. *Language, Speech, and Hearing Services in Schools, 50*, 518–539. https://doi.org/10.1044/2019_LSHSS-VOIA-18-0131 - open access

Summary of Results. Results showed that children with DLD learned a significant number of words during treatment regardless of the dose and dose frequency format, but that significant forgetting of newly learned words occurred in all formats once treatment was withdrawn. Individual differences in word learning were related to CELF Core Language and CELF Understanding Spoken Paragraphs scores.

Conclusion. When administered at an adequate intensity, variation in the dose and dose frequency of interactive book reading does not appear to influence word learning by children with DLD. Although interactive book reading continues to show promise as an effective word learning intervention for children with DLD, further development is needed to enhance the effectiveness of this treatment approach.