Official Title: Kindergarten Children Acquiring Words Through Storybook Reading (KAWStory)

NCT number: NCT03586479

Date of the Document: 8/31/2018

Study Information from https://osf.io/rh9ps

Title

Kindergarten Children Acquiring Words through Storybook Reading (DC012824), Study 3

Research Questions

3.1. What amount of testing during treatment (low, medium, high): (a) enhances learning during treatment and/or (b) reduces forgetting post-treatment? 3.2. What pre-treatment characteristics of kindergarten children with Developmental Language Disorder (DLD) are associated with (a) learning during treatment and/or (b) forgetting post-treatment? 3.3. At what point (a) during treatment can learning outcomes be accurately predicted; and (b) during post-treatment monitoring can retention outcomes be accurately predicted?

Hypotheses

3.1. (a) Lower testing during treatment will lead to steeper positive slopes during treatment than higher testing. The exact pattern of the treatment conditions is not predicted (e.g., low and mid better than high versus low better than mid and high versus low better than mid better than high) (b) Higher testing during treatment will lead to smaller negative slopes (i.e., less forgetting) post-treatment than lower testing. The exact pattern of the treatment conditions is not predicted (e.g., high and mid better than low versus high better than mid and low versus high better than mid better than low). 3.2. (a) Higher language (specifically vocabulary and narrative skills), working memory, and/or episodic learning scores will be associated with steeper positive slopes during treatment. (b) Better treatment learning and/or decay scores will be associated with smaller negative slopes post-treatment, indicating less forgetting. 3.3. (a) Accuracy in predicting learning outcomes will increase at each treatment point, and there will be a point during treatment when outcomes can be accurately predicted. The specific earliest point in treatment (reading 1, 2, 3, 4, or 5) when accurate predictions can be made is unknown without any specific hypothesis. (b) Accuracy in predicting retention outcomes will increase at each post-treatment point, and there will be a point during post-treatment when outcomes can be accurately predicted. The specific earliest point in post-treatment (immediate, 4-week, 8-week) when accurate predictions can be made is unknown without any specific hypothesis.

Sampling Plan

Existing Data

Registration prior to creation of data

Explanation of existing data

N/A -- Not using existing data

Data collection procedures

See attached file for details.

- Data collection procedures.pdf

Sample size

Sixty kindergarten children with DLD will participate. Children will be randomized to one of the 3 treatment manipulations (see manipulated variables) yielding 20 children per treatment condition. For each child definition and naming data will be collected for 30 treated words and 30 control words: 1 time pre-treatment, 6 times during treatment (repeated book readings 1-6), and 4 times post-treatment (immediate, 4-weeks, 8-weeks, and 12-weeks post-treatment).

Sample size rationale

3.1. Power Analysis for Research Question 3.1. Monte Carlo studies were conducted using Mplus to determine power to detect treatment differences in slope across 7 (treatment) or 5 (retention) data points. Slope reliabilities of .6 and .8 were considered in the specification of the population parameters. Both linear growth models and latent basis models with nonlinear growth were examined given that the expected shape of the trajectories is uncertain. Intraclass Correlation Coefficients (ICCs) from our prior studies indicated that between 10% and 30% of the variance in word learning was between persons. Thus, ICCs of both .10 and .30 were used in the power analysis. We will have .80 power or greater to detect moderate slope differences (d =.5) between two groups of 20 individuals in the treatment phase with 7 data points. In the post-treatment phase, with 5 data points, we will have .80 power to detect slightly larger slope differences (d =.6). Attrition has been minimal (1.9%). Thus, we will recruit additional children, as needed, to replace any children who do not complete the study. We will check the assumptions used in our power analysis yearly and update target sample size to maintain power. 3.2. Power Analysis for Research Question 3.2. Additional Monte Carlo studies were conducted using the same software, intraclass correlation coefficients, and slope reliabilities as for RQ3.1. Prior research by the team has indicated that correlations between predictors and learning are in the range of .4 and .5. Power to detect the relationship between level two predictors of this magnitude and slopes added to the treatment model will range from .70 to .85. Power to detect the main effect of each covariate at the last treatment point will similarly range from .73 to .87. Although power appears sufficient with a sample size of 60, an alternative approach if power is insufficient is to loosen our criteria for statistical significance and search for “promising” key moderators. Promising key moderators would need further testing as the

development of this treatment moves forward but would inform our understanding of which children with DLD may benefit from the treatment, addressing the research question. 3.3 There is no specific power analysis for research question 3.3.

Stopping rule

Power estimates based on simulations indicate that a total of 60 participants will be needed to detect the expected effects. Because we are interested in outcomes that are assessed one year after treatment, and there is minimal risk to treatment participation, we will not stop study recruitment until we have reached our recruitment goal.

Variables

Manipulated variables

See attached file for details.

- Manipulate Variables.pdf

Measured variables

See attached file for details.

- Measured variables.pdf

Indices

No indices of any type will be calculated. Rather we will use all of the scores described in the measures section for the proposed analyses.

No files selected

Design Plan

Study type

Experiment - A researcher randomly assigns treatments to study subjects, this includes field or lab experiments. This is also known as an intervention experiment and includes randomized controlled trials.

Blinding

- For studies that involve human subjects, they will not know the treatment group to which they have been assigned.
- Research personnel who interact directly with the study subjects (either human or non-human subjects) will not be aware of the assigned treatments.

- Research personnel who analyze the data collected from the study are not aware of the treatment applied to any given group.

Study design

The study is a three-group randomized design, with each participant being randomly assigned to one of three conditions. The design is mixed as there are both between participant (treatment condition) and within participant (word list) factors of interest. The factors will be counterbalanced to ensure that both word lists are represented in each treatment condition. Additional notes on blinding of research personnel who interact directly with subjects: The research assistant who administers the treatment cannot be blind to the treatment condition. They must know the treatment condition to correctly deliver it. This same research assistant collects during treatment because it would be cost prohibitive to send a second research assistant to every treatment to collect these data. Blinding of research personnel occurs in the following ways: (1) The research assistant (RA) administering pre- and post-treatment testing is blind to condition assignment to reduce bias. (2) All tests are scored by RAs who are blind to the treatment condition to reduce bias.

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Randomization

Random assignment to the three treatment condition occurs at the participant level. Participants will also be randomly assigned to one of two treated word lists within each treatment condition.

Analysis Plan

Statistical models

Research Question 3.1: We will use a multi-level modeling approach for (a) learning during treatment (7 observations: pre-treatment, repeated readings 1-6); (b) post-treatment forgetting (5 observations: reading 6, immediate, 4-week, 8-week, 12-week post). We will examine definition and naming data separately, yielding four models: treatment definition, treatment naming, post-treatment definition, post-treatment naming. For each model, observations at each test (level 1) are available for each participant (level 2). The expected shape of the trajectories is not known so the analytic approach will use either linear growth modeling or latent basis modeling, depending on which is most appropriate. Participants are randomly assigned to treatment (low, mid, high testing), and treatment will be included in the model as a fixed factor at level 2. The dependent variable is number of words correct. This count variable will likely not fit a normal distribution, and thus, an appropriate link function, such as a Poisson distribution, will be used. The research aim is to detect

differences between treatment conditions, therefore all possible pairwise comparisons will be conducted rather than an omnibus test. The slope by treatment condition interaction will be the effect of interest in determining whether there is differential learning or forgetting across low, mid, high testing. While the focus of our analyses is on treated words, a similar modeling approach will be used to model any learning of control words during treatment. We expect relatively flat trajectories for control words in all three treatment conditions and this will allow for inferences to be made about the effect of treatment rather than development or maturation Research Question 3.2: We will add pre-treatment measures as covariates to the models used in RQ3.1 to examine the relationship between these covariates and (a) learning slopes during treatment and (b) forgetting slopes post-treatment. Recall that there are several skills relevant for learning (language, attention, working memory, episodic learning) and forgetting (treatment learning, decay) and that we have multiple measures to tap different aspects of each skill (see measured variables table). Likewise, we also will examine biological and environmental variables as predictors. Previous research has indicated that the test measures are moderately correlated at around r =.50. Since these measures are theoretically and mathematically distinct (which we will confirm via correlations), we will examine the effect of each of these predictors individually. We hypothesize that higher language, attention, working memory, and/or episodic learning scores will be associated with steeper slopes during treatment. Similarly, we hypothesize that better treatment learning and decay scores will be associated with smaller slopes, indicating less decline post-treatment. These hypotheses are consistent with theories of learning and forgetting. However, it is likely that not all of these covariates will be significantly related to performance. Research Question 3.3: We will classify responses at the end of treatment (learner vs. non-learner) and post-treatment (rememberer vs. forgetter). Then, earlier performance will be analyzed to determine when treatment and post-treatment outcomes can be predicted. This yields empirically based benchmarks for progress and an understanding of the stability of learning and forgetting over time. As with RQ 3.1 and 3.2, we will separate treatment and post-treatment data as well as definition and naming data. Within each dataset, we will classify each child as having a negative or positive outcome based on performance at the last point in the series (i.e., reading 6 for treatment, 12-month post for post-treatment). We will use the accuracy range for the untreated control words to determine the cut-offs for this classification. Then, we will select an appropriate cut-off score at each earlier point during treatment or post-treatment. Because we have decided that the cost of false positives is greater than that of false negatives (see progress report), we will select cutoffs that minimize false positives. At each test point, measures of sensitivity, specificity, and positive/negative likelihood ratios and predictive values will be calculated. We will then determine the earliest point when we can accurately predict treatment and post-treatment outcomes

No files selected

Transformations

One of the primary dependent variables is a count of the number of words correct which will not fit a normal distribution. Rather than transforming the variable, an appropriate link function such as a Poisson distribution will be used. We will center time at the last intervention reading point for all models.

Follow-up analyses

The analysis plan for RQ 3.1 describes the pair-wise contrasts that will be used to follow-up on significant interactions. The analysis plan for 3.3 describes the subgroup analyses we will conduct for learners vs non-learners and forgetters vs. rememberers.

Inference criteria

Likelihood ratio tests will be used to compare nested models and determine what random and fixed effects are needed for the growth models as well as the significance of the treatment effects.

Data exclusion

We will analyze all available data. If extreme outliers occur, we will run the models both including and excluding the outliers and report both sets of models.

Missing data

The proposed analyses will be conducted within SAS Proc MIXED, SAS Proc GLIMMIX, or MPLUS using maximum likelihood estimation which will include all available data in the multidimensional likelihood function.

Exploratory analysis

If the there is evidence in the analysis for RQ3.1 that the amount of testing influences the number of treated words learned, we will examine whether there are differences between low, mid, and high testing in post-treatment broader vocabulary measures (DELV Semantic, CELF-4 Word Classes, CCC-2 Semantic, and vocabulary measures derived from interview/narrative tasks). The treatment is relatively short, which may limit broader change.