

Improving the Academic Performance of First-Grade Students with Reading and Math Difficulty

NCT03991234

Study Protocol and Statistical Analysis Plan

10/27/2025

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Study Protocol

Summary: The main purpose of this clinical trial is to explore short-term effects of coordinated intervention versus the business-as-usual school program on the primary endpoints of post-intervention word-reading fluency and arithmetic fluency. The study population is students who begin 1st grade with delays in word reading and calculations. Students who meet entry criteria are randomly assigned to coordinated intervention across reading and math, reading intervention, math intervention, and a business-as-usual control group (schools' typical program). The 3 researcher-delivered interventions last 15 weeks (3 sessions per week; 30 minutes per session). Students in all 4 conditions are tested before researcher-delivered intervention begins and after it ends.

Eligibility: The student attends a participating school in the Metropolitan-Nashville Public Schools and is a member of a first-grade classroom whose teacher has agreed to let his/her students participate. The student must have the available school schedule to participate and adequate English proficiency to be reliably assessed in English on study entry screening measures. The student must score at or below the 25th percentile on the study's screening math test, score at or below the 25th percentile on the study's screening reading test, and score at or above the 7th percentile on at least one of the study's two measures of cognitive performance

Detailed Description: First-grade students who meet study entry criteria are identified near the start of the school year using a 3-stage screening process. Students who enter the study complete the pretest battery.

Then, students are randomly assigned at the individual level to coordinated intervention, reading intervention, math intervention, or a business-as-usual control group (the schools' typical classroom instruction with supplemental intervention schools choose to provide). Research staff deliver intervention in the coordinated intervention condition, in the reading intervention condition, and in the math intervention condition 1:1 for 15 weeks (three 30-min sessions per week, scheduled in line with teacher input to avoid students missing

important content). Adherence to the researcher-delivered interventions is monitored via audio recordings and live observations.

The content of each researcher-delivered intervention is aligned with the school district's 1st-grade foundational reading & math learning standards; relies on explicit instruction; and incorporates fluency-building activities word reading and/or arithmetic problems; incorporates procedures designed to build engagement and perseverance. Reading intervention is designed to build skill in letter-sound associations, decoding, sight words, and contextualized reading. Math intervention is designed to build number knowledge, counting strategies, and arithmetic skills. Coordinated intervention addresses the same instructional objectives as reading intervention & math intervention.

When researcher-delivered intervention ends, students in all four conditions complete the posttest assessment battery. Testers are blind to students' study conditions. Adherence to testing protocols is monitored via audio recordings. The primary endpoints are posttest word-reading fluency and arithmetic fluency.

Statistical Analysis Plan

For the analyses, we pooled data across the cohorts. Intra-class correlations (ICCs), indicating dependence due to clustering ranged from .010-.133 at the classroom-level (level-2) and from .001-.044 at the school-level (level-3). Therefore, for each outcome measure, we conducted fit a three-level multilevel model with students (level-1) nested within classrooms (level-2), nested within schools (level-3). For each model, we adjusted for pre-test performance at level-1 and cohort at level-2, and accounted for missing data using full information maximum likelihood estimation. All analyses were conducted in Mplus 8.4 (Muthen & Muthen, 1998-2025).