

Preliminary Clinical Trials in Language Intervention: An Interactive Book Reading Example



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Kindergarten Children Acquiring Words through STORYbook Reading

Preliminary Clinical Trial

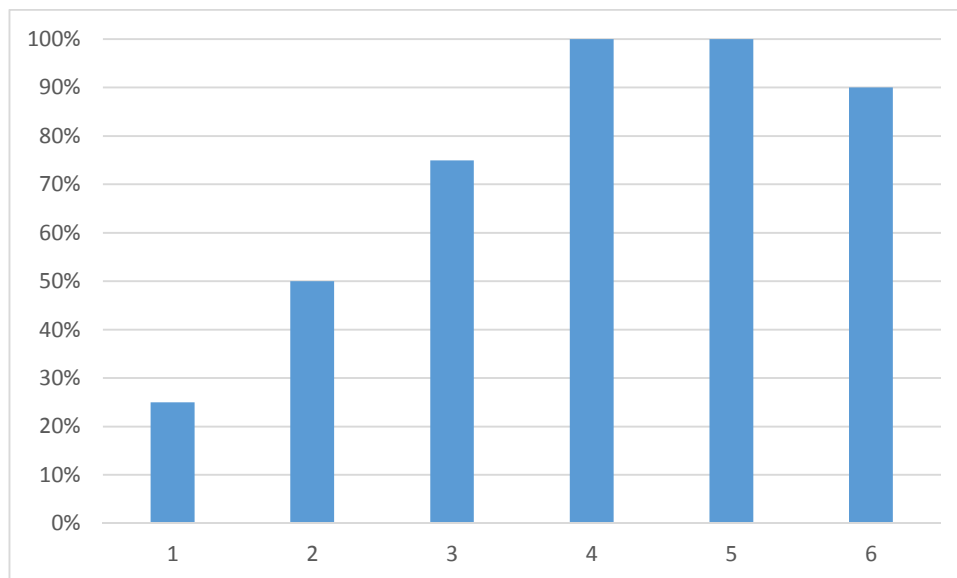
- ▶ Addresses core design and clinical issues
- ▶ Establish feasibility of Definitive Clinical Trial
- ▶ Intensity of treatment = key issue to be addressed early
 - ▶ *Treatment intensity* = cumulative number of properly administered teaching episodes (Warren, Fey & Yoder, 2007)
 - ▶ Standard in drug trials
 - ▶ Rare in behavioral interventions

Drug Trial Designs: Escalation Strategy

- ▶ Basic Tenets
 - ▶ Use as few participants as possible ~ limits receipt of ineffective treatment
 - ▶ Identify 'adequate' or 'promising' intensity rather than 'optimal'
- ▶ Toxic Drug Trials
 - ▶ Increase intensity until toxicity is unacceptable
- ▶ Non-Toxic Drugs Trials
 - ▶ Increase intensity until benefit plateaus

Drug Trial Designs: Escalation Strategy

- ▶ Hunsberger, Rubinstein, Dancey & Korn (2005)
- ▶ Set a threshold for “good” vs. “poor” outcome
- ▶ Assign participants to different intensities
(Various methods: typically 1 or 3 or 6 participants per intensity)
- ▶ Plot % of participants with good outcome by intensity



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Purpose

- ▶ Apply this escalation strategy to a behavioral intervention
- ▶ Identify the 'adequate' or 'promising' intensity of interactive book reading for kindergarten children with SLI



Interactive Book Reading to Facilitate Word Learning

- ▶ Adult reads storybook to child
- ▶ Deviates from text to provide additional information
 - ▶ Synonym of a word
 - ▶ Definition of a word
- ▶ Effective method for teaching new words
 - ▶ Typically developing children
 - ▶ Children with low vocabulary associated with low SES
 - ▶ See Marulis & Neuman, 2010 and Mol, Bus, deJong & Smeets, 2008 for meta-analysis
- ▶ Children with SLI need more exposures to learn words
 - ▶ Need a higher intensity of the treatment
 - ▶ What intensity?

Participants: 23 Kindergarten Children with SLI

Demographics:

52% Male; 78% Not Hispanic; 87% White

Caregiver's Education:

22% High School; 35% Some College; 35% College Degree

	Mean	SD	Range
Age	5;8	0;6	5;0 - 6;5
CELF Core Language Percentile	3	3	<0.1 - 12
DELV Semantic Subtest Percentile (83%)	9	8	0.1 - 25
RIAS Nonverbal IQ Percentile	54	25	23 - 99
CELF Understanding Spoken Paragraphs Percentile	6	7	0.1 - 25
CTOPP Phonological Memory Percentile	14	13	<1 - 45

Interactive Book Reading

(based on Justice, Meier, & Walpole, 2005)

▶ Stimuli:

- ▶ 10 commercially available books (from Justice, Meier, & Walpole, 2005)
- ▶ 6 target words in each book
- ▶ 5 books (n = 30 words) selected for treatment
- ▶ 5 books (n = 30 words) selected for monitoring (control)

▶ Basic Treatment Session:

- ▶ Book 1: Preview (picture) - Book Reading - Review (picture)
- ▶ Book 2: Preview (picture) - Book Reading - Review (picture)
- ▶ All conditions: At least one exposure to
(1) book text; (2) synonym; (3) definition; (4) context sentence

Overview of Escalation Design

- ▶ Select “reasonable” intensities
 - ▶ Four selected a priori
- ▶ Enroll children in blocks of 4
 - ▶ Within block, one child randomized to each intensity
- ▶ Look at the data as we go
 - ▶ % of children with “good” outcome
 - ▶ # of words learned
- ▶ Eliminate or add intensities as we go
 - ▶ If an intensity doesn’t look promising, drop it
 - ▶ If no response plateau, add higher intensities
- ▶ Stop when the pattern is clear
 - ▶ Pattern stops changing across blocks

Intensities Tested

Intensity	Treatment: 5 books (30 words)		Control: 5 books (30 words)	
	Exposures per Book per Session	Repeated Book Sessions	Exposures per Book per Session	Repeated Book Sessions
12	3	4	0	0
24	4	6	0	0
36	6	6	0	0
48	6	8	0	0

Intensity 12 = effective in Justice, Meier, & Walpole (2005);
77% of children showed "good" outcome

2 x Intensity 12 = 24

3 x Intensity 12 = 36

4 x Intensity 12 = 48

Example: Intensity 12 vs. 48

Hunter, A. (1998). *Possum and the peeper*. Boston: Houghton Mifflin
<https://wordlearning.drupal.ku.edu/appendix-master-treatment-word-list>

Intensity 12:

3 exposures x 4 ssns

- ▶ Preview: *Marsh* is like a swamp. It means a low, wet land, often thick with tall grasses.
- ▶ Book Reading: They came down to a *marsh* where they saw a muskrat spring-cleaning his house.
- ▶ Review: Ducks and beavers live in a *marsh* because they like the water

Intensity 48:

6 exposures x 8 ssns

- ▶ Preview: *Marsh* is like a swamp. *Marsh* means a low, wet land, often thick with tall grasses.
- ▶ Book Reading: They came down to a *marsh* where they saw a muskrat spring-cleaning his house. *Marsh* is like a swamp.
- ▶ Review: Ducks and beavers live in a *marsh* because they like the water. *Marsh* means a low, wet land, often thick with tall grasses.

Outcome Measure

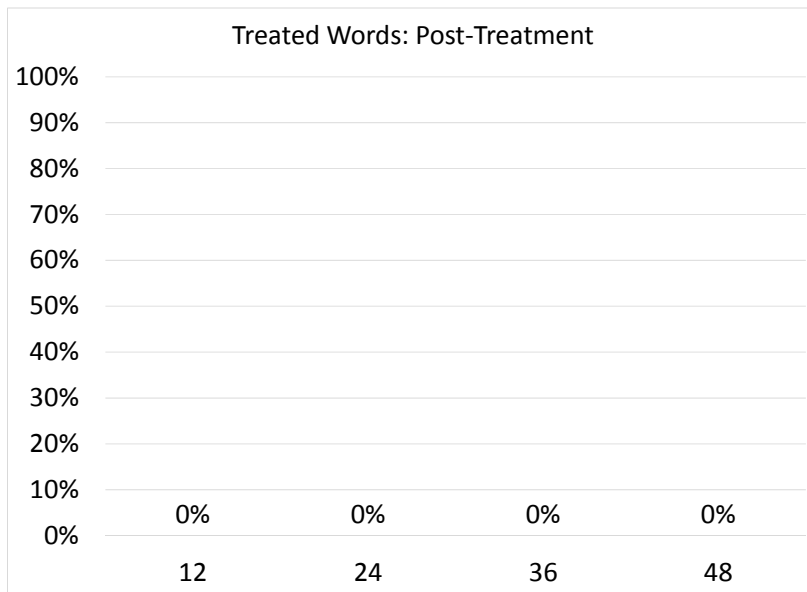
- ▶ Definition Task: Tell me what XXX means?
- ▶ Scoring (McGregor, Oleson, Bahnsen, & Duff, 2013)
 - ▶ 0 = no response, inaccurate response
 - ▶ 1 = vague definition or an appropriate context sentence
 - ▶ 2 = partial definition (accurate but lacks detail)
 - ▶ 3 = detailed definition
- ▶ Example: Flashing - a sudden bright light that goes away fast
 - ▶ 0 = flashlight; when it's dark
 - ▶ 1 = change (transient); you're flashing your camera on & off (example of transient light)
 - ▶ 2 = lights go on (light but no transient)
 - ▶ 3 = light is off and on (light + transient)
- ▶ For comparison to Justice et al, final score =
 - ▶ 0-1 counted as incorrect
 - ▶ 2-3 counted as correct

Outcome Measure

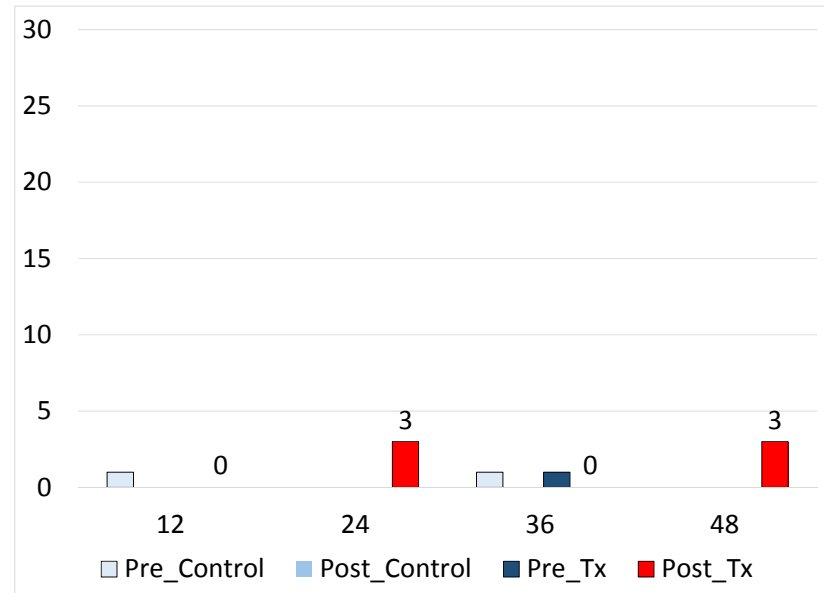
- ▶ “Good” outcome
 - ▶ Post-test score of 5 or greater for treated words (i.e., 5+ words with correct definition)
 - ▶ Score for control words (pre & post) = 0-4 with $SD = 0.9$ ($M = 1$)
 - ▶ Similar to Justice et al.’s definition (which was 4+)
- ▶ Primary Outcome: % of children achieving good outcome
- ▶ Secondary Outcome: Mean # of words correct (i.e., definition score of 2-3)

Block 1: 1 child per intensity

Primary: % Good Outcome

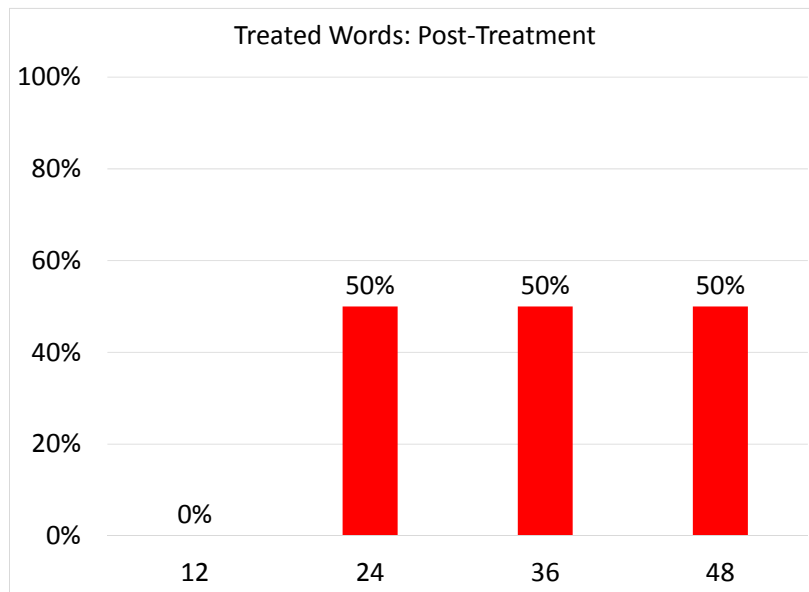


Secondary: Words Correct for 1 Child

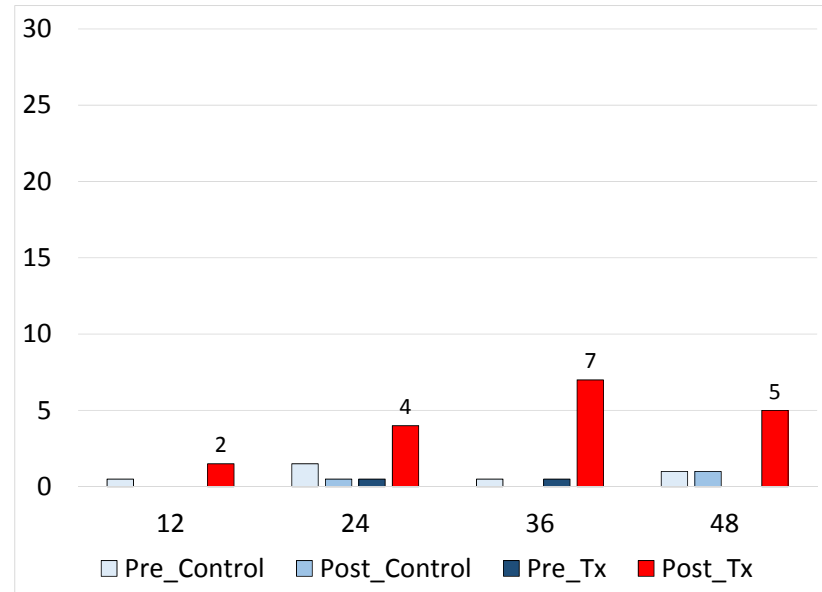


Block 2: 2 children per intensity

Primary: % Good Outcome

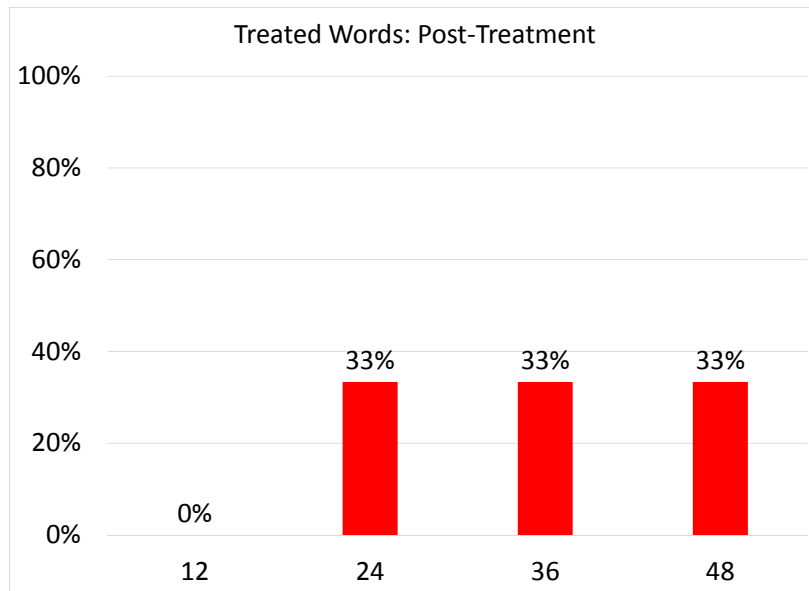


Secondary: Mean Words Correct

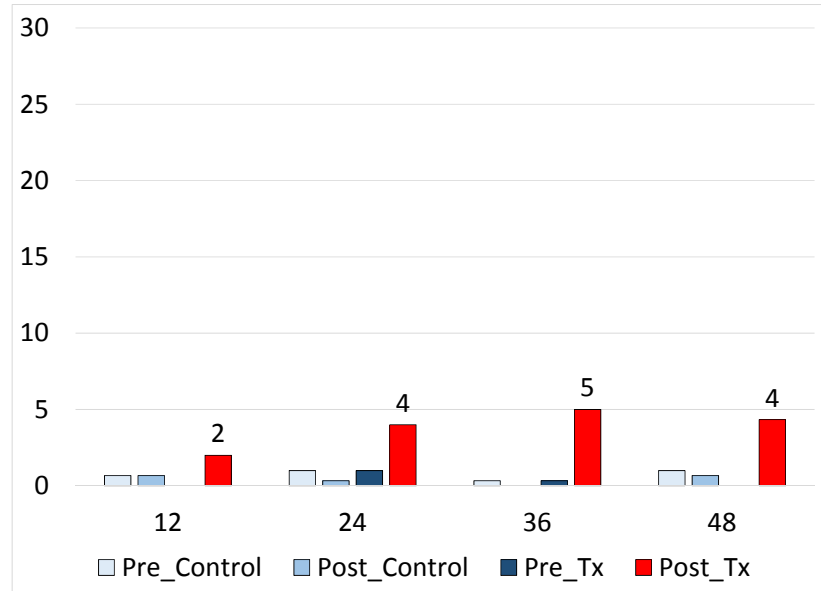


Block 3: 3 children per intensity

Primary: % Good Outcome

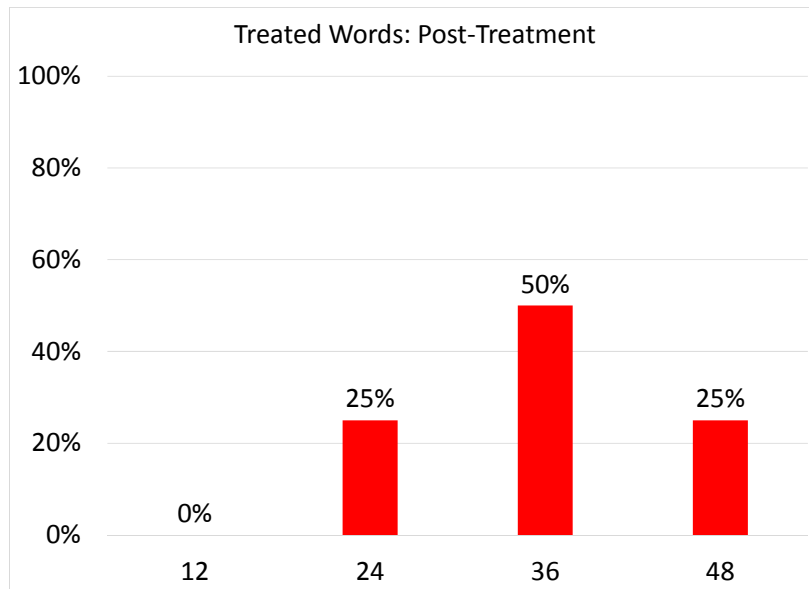


Secondary: Mean Words Correct

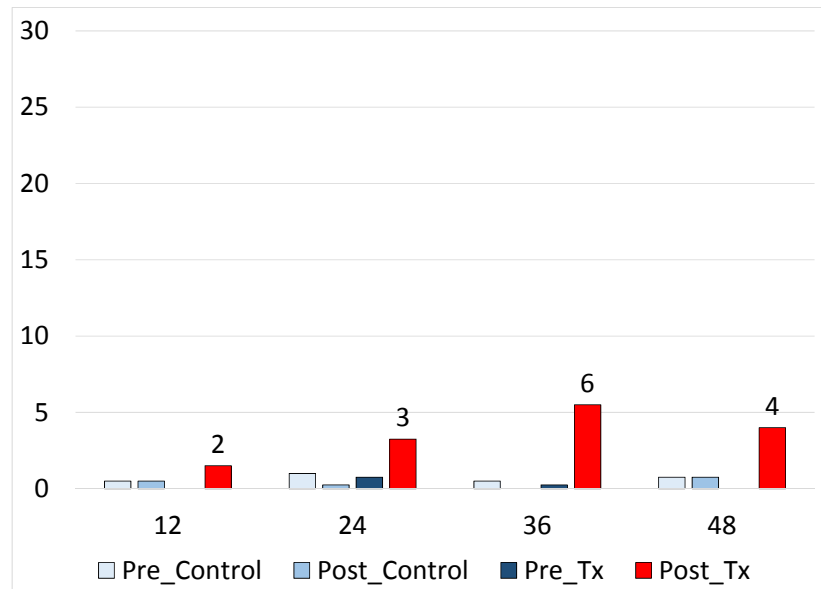


Block 4: 4 children per intensity

Primary: % Good Outcome

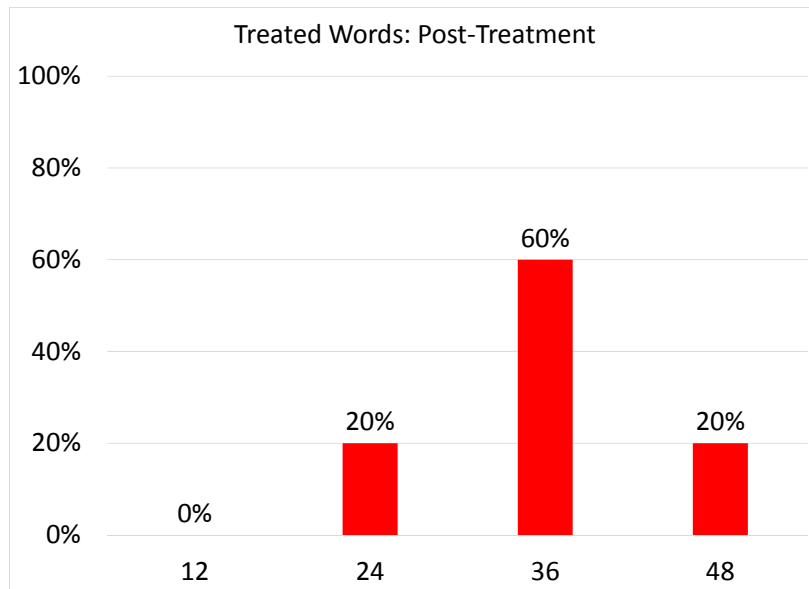


Secondary: Mean Words Correct

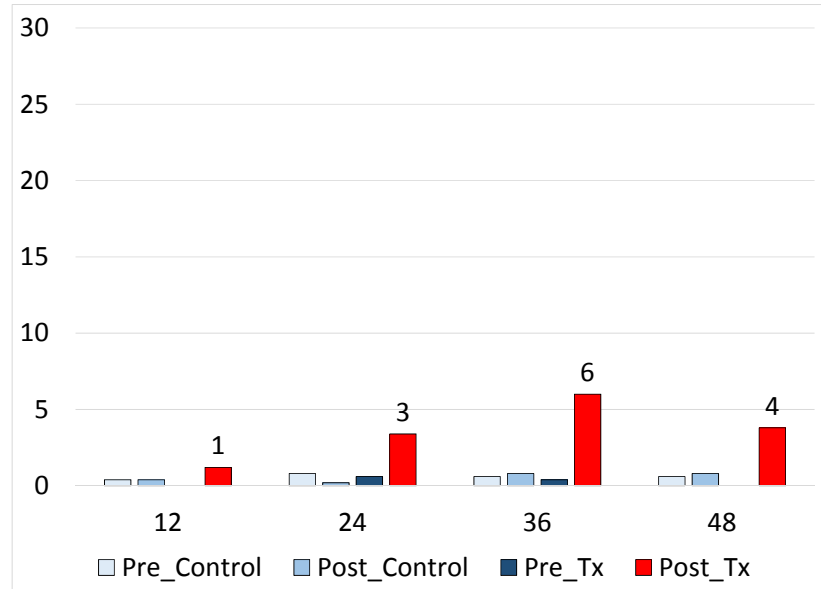


Block 5: 5 children per intensity

Primary: % Good Outcome



Secondary: Mean Words Correct

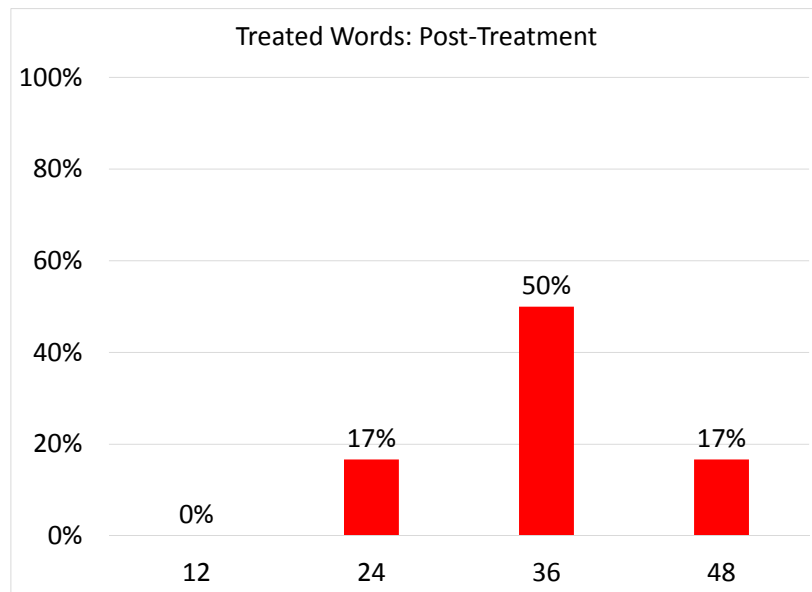


Dropped Intensity 12 after this block.

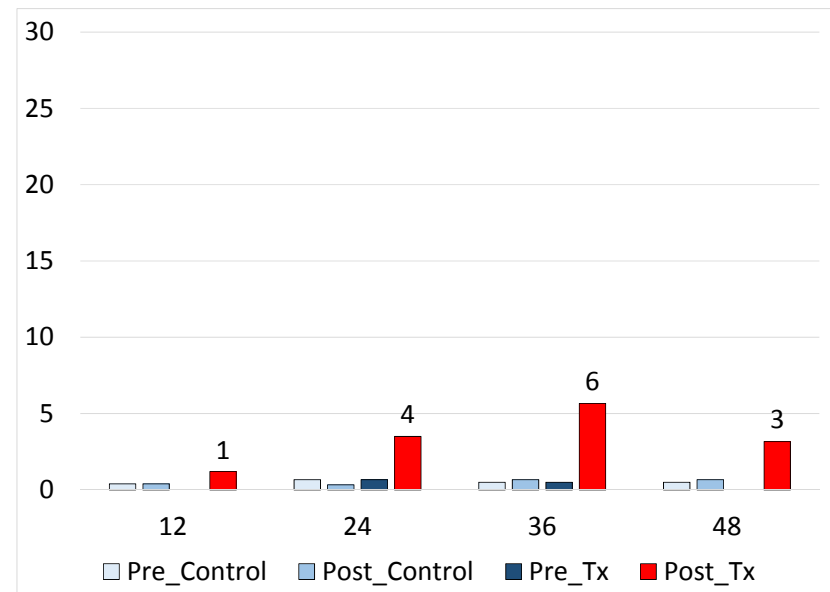
Block 6: 6 children per intensity*

*Exception: 5 children in Intensity 12

Primary: % Good Outcome



Secondary: Mean Words Correct



Block 7 is in progress

Interactive Book Reading: Preliminary Conclusions

- ▶ Intensity 36 = most promising
 - ▶ Replicated across 3 blocks
- ▶ However, only 50% of children show “good” outcome
 - ▶ May want to further enhance the treatment in other ways to boost outcomes
 - ▶ Need to look at low and high responders for ideas re: potential enhancements
 - ▶ Treatment data may yield insights

Escalation Strategy for Behavioral Interventions

- ▶ Looks promising
- ▶ Defining a threshold response to treatment seems reasonable
 - ▶ Sets a minimum acceptable response to treatment
 - ▶ Still allows for variation
 - ▶ Highlights the promising intensity
 - ▶ Highlights need for further development
- ▶ Plan to analyze our data more formally to determine whether “rules of thumb” can be generated
 - ▶ e.g., run simulations similar to non-toxic drug trials



Questions?

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