

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



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*Supported by DC012824<sup>1</sup>*

# Disclosure:

## All authors received salary support from NIDCD 012824

See <https://wordlearning.drupal.ku.edu/presentations>  
for copy of these slides



Kindergarten Children Acquiring Words through STORYbook Reading



# Preliminary Clinical Trial

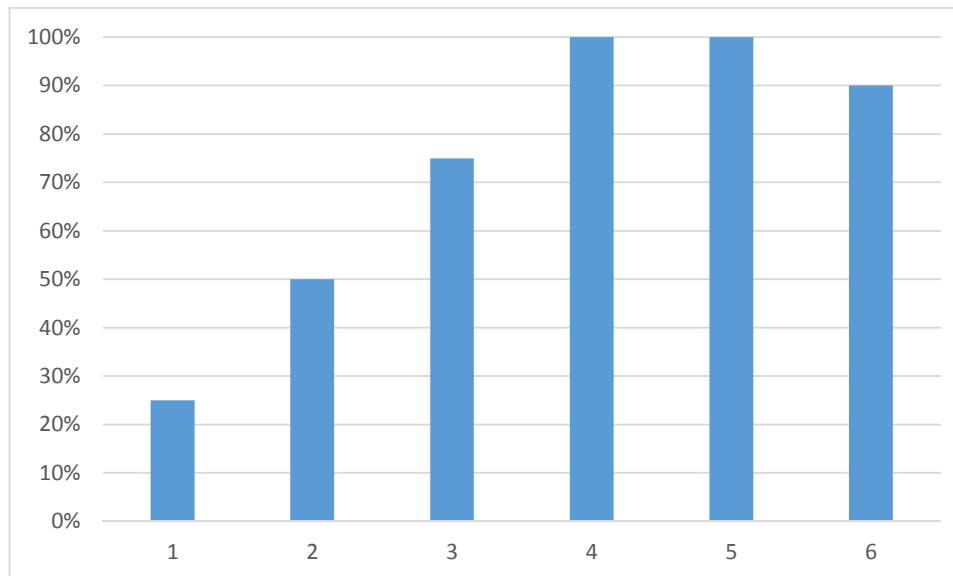
- ▶ Addresses core design and clinical issues
- ▶ Establish feasibility of Definitive Clinical Trial
- ▶ Intensity of treatment = key issue to be addressed early
  - ▶ *Treatment intensity* = cumulative number of properly administered teaching episodes (Warren, Fey & Yoder, 2007)
  - ▶ Standard in drug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

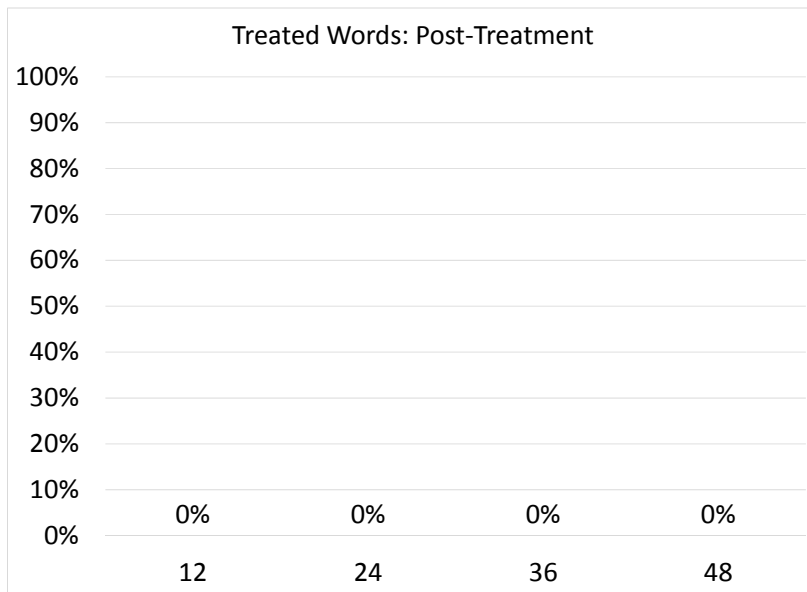
# Outcome Measure

- ▶ “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)

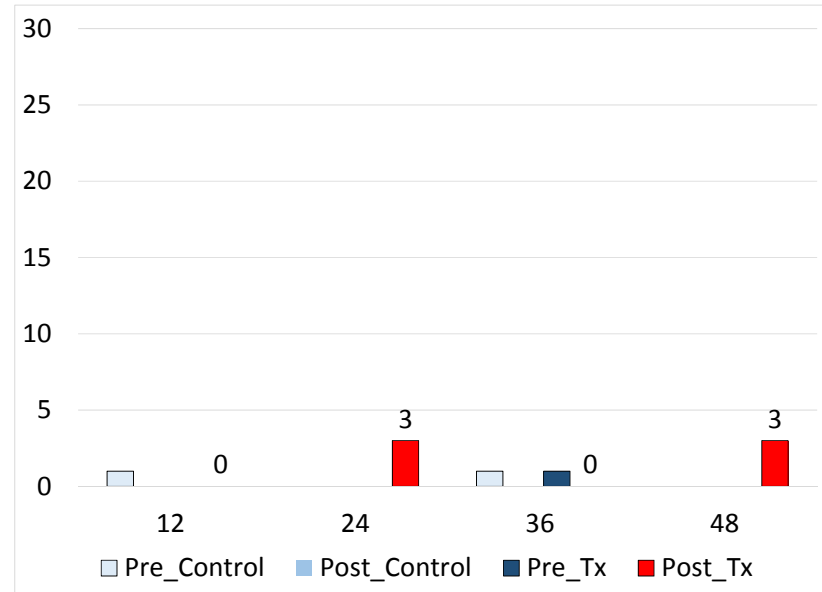


# Block 1: 1 child per intensity

## Primary: % Good Outcome

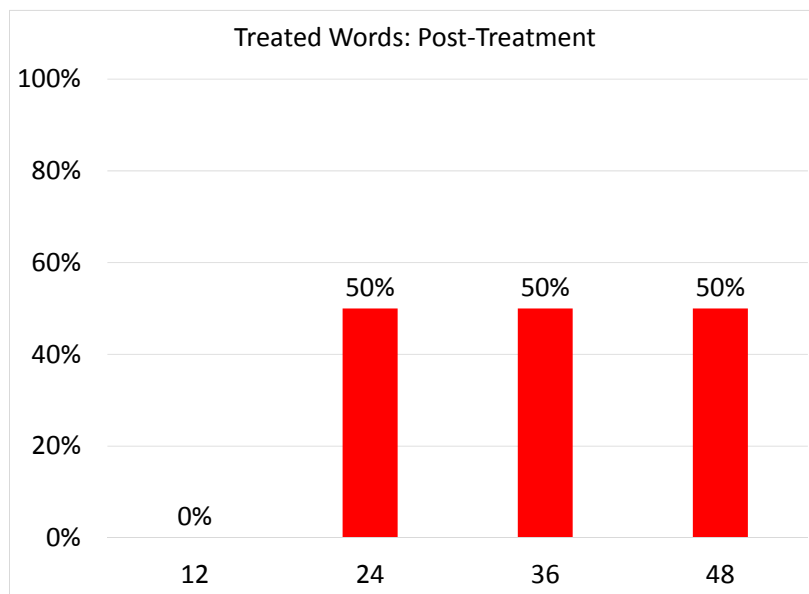


## Secondary: Words Correct for 1 Child

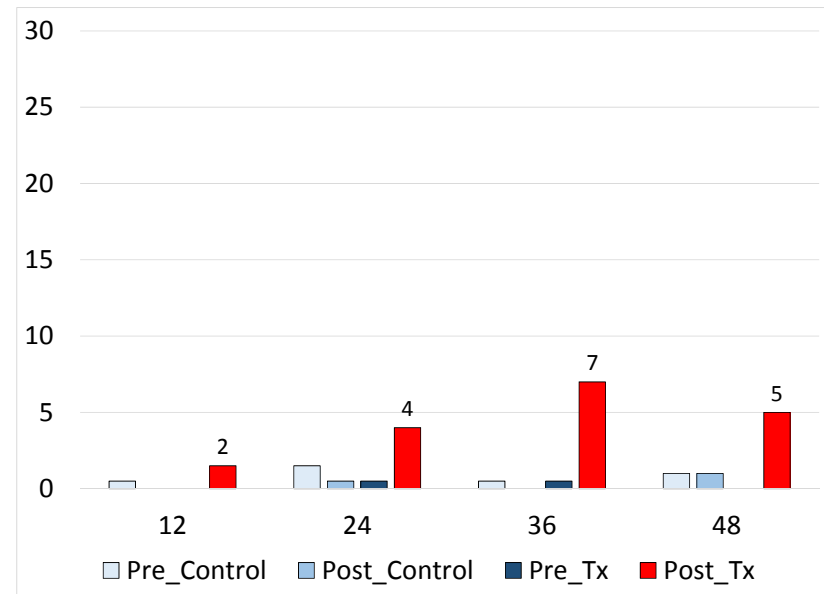


# Block 2: 2 children per intensity

## Primary: % Good Outcome



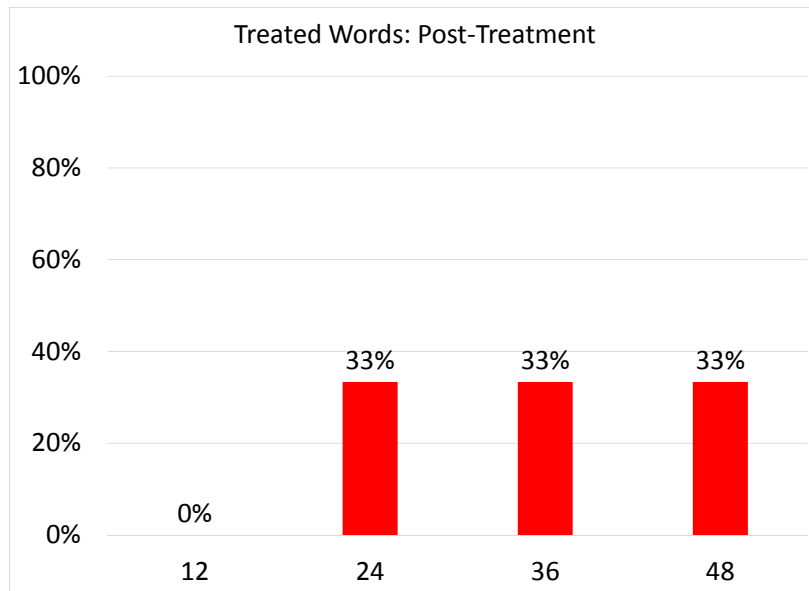
## Secondary: Mean Words Correct



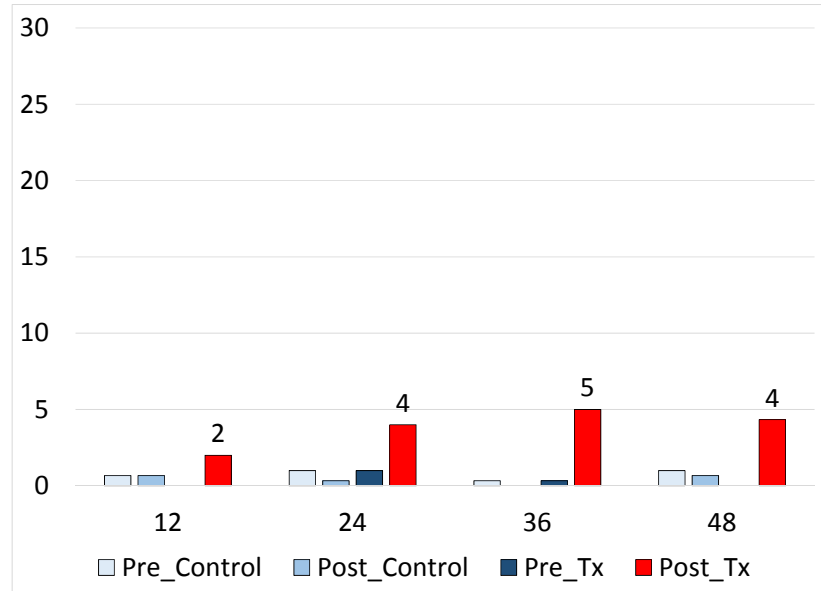


# Block 3: 3 children per intensity

## Primary: % Good Outcome

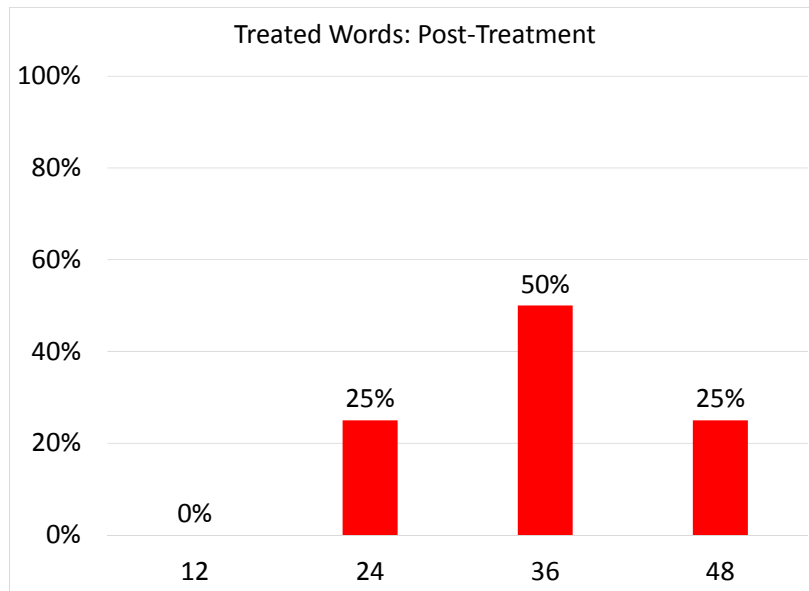


## Secondary: Mean Words Correct

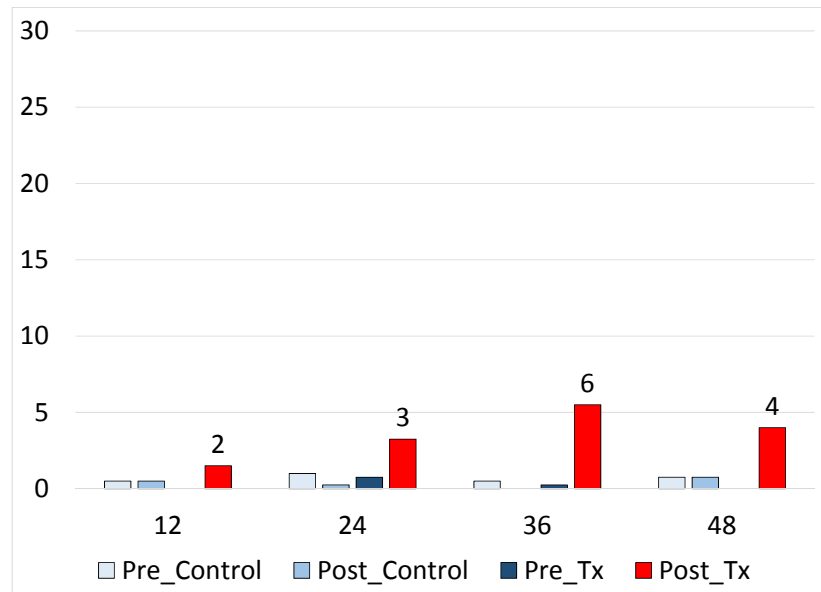


# Block 4: 4 children per intensity

**Primary: % Good Outcome**



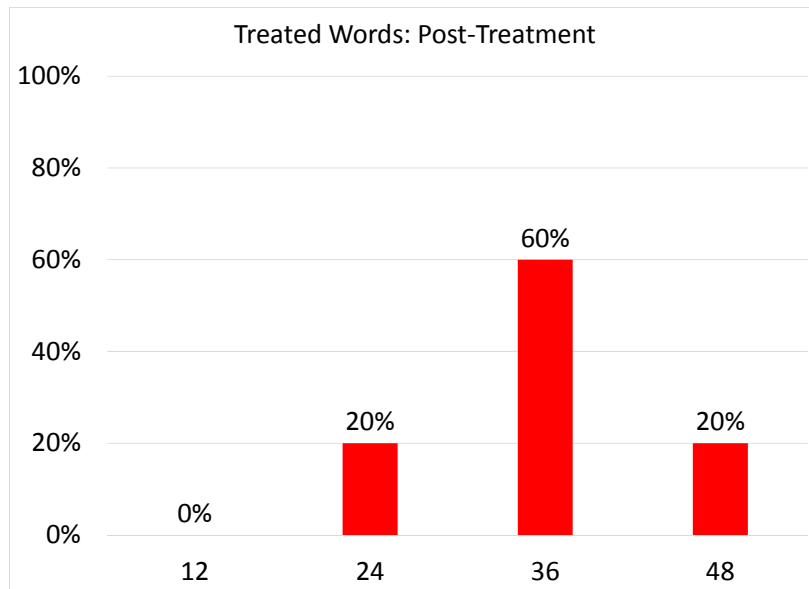
**Secondary: Mean Words Correct**



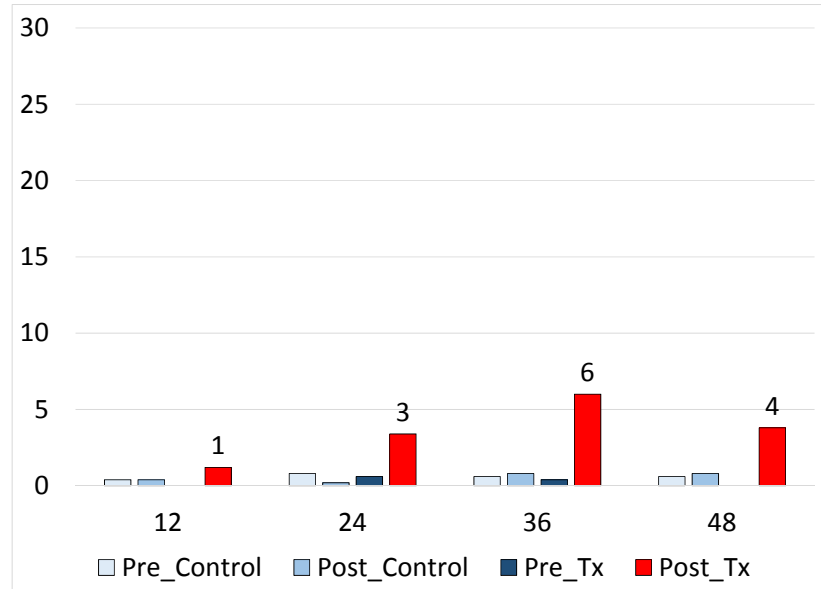


# Block 5: 5 children per intensity

**Primary: % Good Outcome**



**Secondary: Mean Words Correct**

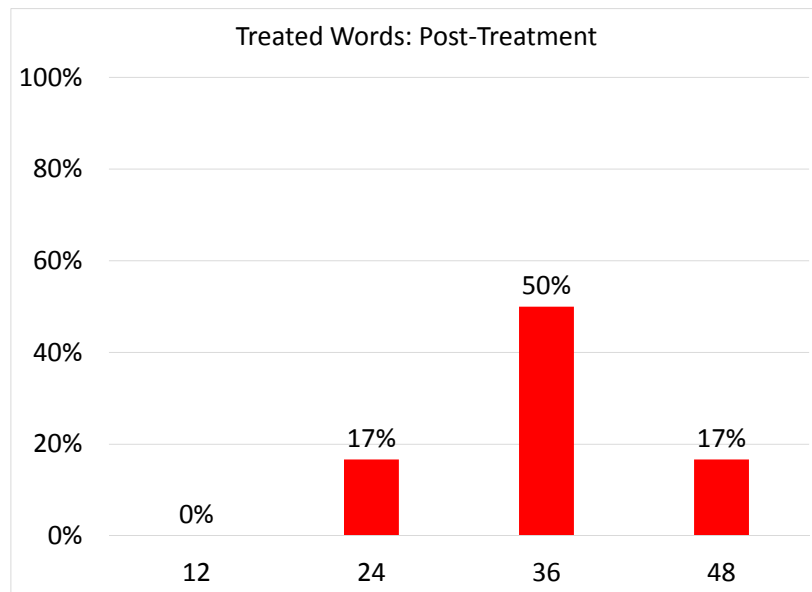


Dropped Intensity 12 after this block.

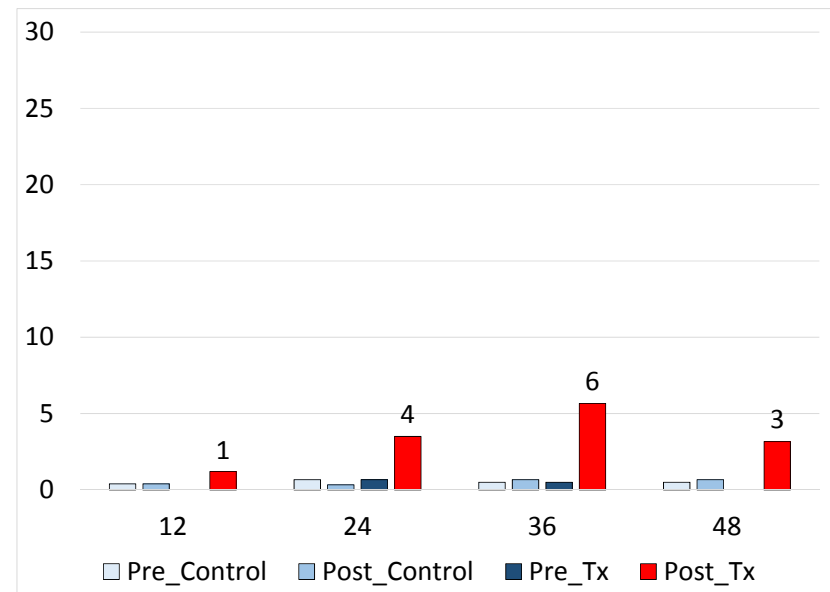
# Block 6: 6 children per intensity\*

\*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?

Contact: [hstorkel@ku.edu](mailto:hstorkel@ku.edu); [wordlearning.ku.edu](http://wordlearning.ku.edu)

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