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

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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
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

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

<table>
<thead>
<tr>
<th>Intensity</th>
<th>Treatment: 5 books (30 words)</th>
<th>Control: 5 books (30 words)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposures per Book per Session</td>
<td>Repeated Book Sessions</td>
</tr>
<tr>
<td>12</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>24</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>36</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>48</td>
<td>6</td>
<td>8</td>
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</table>

Intensity 12 = effective in Justice, Meier, & Walpole (2005); 77% of children showed “good” outcome.
Example: Intensity 12 vs. 48

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**

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<th>Treated Words: Post-Treatment</th>
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<tr>
<td>100%</td>
</tr>
<tr>
<td>0%</td>
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</table>

| 12 | 24 | 36 | 48 |

**Secondary: Words Correct for 1 Child**

<table>
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<th>12</th>
<th>24</th>
<th>36</th>
<th>48</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

Legend:
- Pre_Control
- Post_Control
- Pre_Tx
- Post_Tx
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

Treasured Words: Post-Treatment

<table>
<thead>
<tr>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
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<td>48</td>
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<td>33%</td>
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<table>
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<th>36</th>
<th>48</th>
<th>2</th>
<th>4</th>
<th>5</th>
<th>4</th>
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<th>Post_Control</th>
<th>Pre_Tx</th>
<th>Post_Tx</th>
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<tbody>
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</tbody>
</table>

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Block 4: 4 children per intensity

**Primary: % Good Outcome**

**Secondary: Mean Words Correct**

![Graph showing treated words' post-treatment percentages and mean words correct across different time points.]

- **Treated Words: Post-Treatment**
  - 0% at 12
  - 25% at 24
  - 50% at 36
  - 25% at 48

- **Mean Words Correct**
  - Pre-Control
  - Post-Control
  - Pre_Tx
  - Post_Tx
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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