Innovative Communication Intervention for Older Nonverbal Children with Autism

Connie Kasari
University of California Los Angeles

Developing Dynamic, Sequential Treatments that Optimize Mental Health Outcomes: Novel Clinical Trial Design and Data Analysis Strategies
NCDEU 2011
Disclosures

☐ None
Why Do a SMART Design in a Treatment Study for Autism?
Evidence Base for Autism Treatments?

- Applied Behavior Analysis considered most ‘evidence based’
  - Evidence base is mostly single subject design
  - 2 group RCTs (Dawson et al, 2009; Smith et al, 2004) – main outcome IQ
- Treatments are high dose (20+ hours per week) and comprehensive—covering all domains of development
- Outcomes for social and language weaker than IQ
Evidence Base for Autism Treatments…..most higher functioning

- Children excluded from most studies if nonverbal
- Evidence that speaking by age 5 is significant predictor of better long term outcome
- If not speaking by age 5, no known effective interventions
The Population

- 25-30% of children with ASD have not developed spoken language by age 5
- Children nonverbal despite involvement in at least 2-3 years of intensive ABA services
  - More of the same not indicated
Given that there are no effective treatments for nonverbal school age children with ASD…

- And no accepted outcome measures…..

- What treatments should be tested, what outcomes?

- Treatment sequencing considered?
  - No guidelines, no discussion
Potential Sequence of Interventions

- Need to provide ‘effective’ intervention for children who already have not responded to traditional interventions
- Use of alternative augmentative device---some evidence device can boost spoken language
- Parents feel they have given up if they go with device (so some push back)
Choosing the treatments

- Rely on what we know about younger children learning language
- 2 evidence based treatments merged
- Effect sizes for RCTs — $d=0.59-1.22$
- Issue of different mode of communication—ipad/dynavox or spoken language
- How many sessions, dose of treatment?
Specific Aims

☐ To examine initial communication treatment on child expressive language outcomes.

☐ For non-responders, to examine adaptive intervention effects on expressive language outcomes.

☐ To explore moderators of adaptive intervention outcomes.
Multisite Study

- 3 sites
  - UCLA, Vanderbilt, Kennedy Kreiger
- RCT of 96 kids (32 per site)
- Contrast the efficacy of a blended evidence based intervention with contrasting mode—spoken versus augmented (AAC)
CCNIA Treatment Flowchart

**A 'Responder' is Defined as: ≥25% improvement on ≥50% of the following variables:**

**Session Data (Average of Sessions 1&2 as compared to Average of 23&24)**
1. Total Social Communicative Utterances (Total SCU)
2. Percentage Communicative Utterances (% SCU)
3. Number Different Word Roots (NDWR)
4. MLUw
5. # Comments
6. Words per Minute (WPM)
7. Unique Word Combinations (only include if the child’s target talk is 2+ words)

**Language Sample (Screening compared to Month 3)**
8. Total Social Communicative Utterances (Total SCU)
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*Increased Intensity: Some participants may be able to come in for a 3rd session each week (45-60 minutes per session). A second option is longer sessions (i.e., 1.25 - 1.5 hours) twice a week to maintain the increased intensity. Target: 2.5 - 3 hours of treatment per week.*
Challenges

☐ Defining the population
  - Preverbal, nonverbal, minimally verbal

☐ Establishing responder status
  - Decisions on measures
  - What constitutes improvement?
Participants

- Children with ASD (clinical diagnosis and ADOS validation)
- 5-8 years old
- Above 24 months nonverbal cognition
  - 2 out of 3 assessments (TELD, PPVT, Leiter)
- 2 years of intensive intervention; minimally verbal
  - Fewer than 20 non-scripted words used functionally
Challenges in defining population—
Inclusion/Exclusion Criteria

- 96 participants screened; not all have data for each of the tests

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>Range</th>
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</thead>
<tbody>
<tr>
<td>Total N = 80</td>
<td></td>
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</tr>
<tr>
<td>CA (years) n=80</td>
<td>6.46 (1.07)</td>
<td>4.50 – 8.58</td>
</tr>
<tr>
<td>TELD Receptive (months) n=76</td>
<td>21.14 (9.67)</td>
<td>0 – 64</td>
</tr>
<tr>
<td>PPVT (months) n=74</td>
<td>29.72 (8.98)</td>
<td>18 – 68</td>
</tr>
<tr>
<td>Leiter-R Overall (years) n=53</td>
<td>3.62 (1.20)</td>
<td>2 – 7.58</td>
</tr>
<tr>
<td># Spontaneous Words Heard at Screening n=56</td>
<td>11.09 (18.57)</td>
<td>1 - 99</td>
</tr>
</tbody>
</table>
Demographics

<table>
<thead>
<tr>
<th>Treatment Condition: JA/EMT vs. JA/EMT/AAC</th>
<th>JA/EMT</th>
<th>JA/EMT/AAC</th>
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<tbody>
<tr>
<td>Total N = 41</td>
<td>N=20</td>
<td>N=21</td>
</tr>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Range</td>
</tr>
<tr>
<td>CA (years)</td>
<td>6.35 (1.08)</td>
<td>4.67 – 8.25</td>
</tr>
<tr>
<td>TELD Receptive (months)</td>
<td>21.75 (7.79)</td>
<td>0 – 38</td>
</tr>
<tr>
<td>PPVT (months)</td>
<td>31.70 (8.68)</td>
<td>23 – 52</td>
</tr>
<tr>
<td>Leiter-R Overall (years)</td>
<td>3.77 (1.31)</td>
<td>2 – 7.58</td>
</tr>
<tr>
<td># Spontaneous Words Heard at Screening</td>
<td>8.89 (9.88)</td>
<td>1 - 40</td>
</tr>
</tbody>
</table>

Leiter Nonverbal IQ range---38 to 121
A ‘Responder’ is Defined as: ≥25% improvement on ≥50% of the following variables

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# Responder Status Measures

<table>
<thead>
<tr>
<th></th>
<th>Responders</th>
<th></th>
<th></th>
<th>Paired Sample $t$-test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First Session</td>
<td>Mid-Point</td>
<td></td>
<td>$t$ = (-3.59^*)</td>
</tr>
<tr>
<td>Socially Communicative Utterance (SCU)</td>
<td>18.30 (14.68)</td>
<td>32.20 (11.95)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% SCU</td>
<td>22.63 (20.95)</td>
<td>31.27 (21.99)</td>
<td></td>
<td>$t$ = (-2.59^*)</td>
</tr>
<tr>
<td># Different Words</td>
<td>11.40 (11.30)</td>
<td>20.33 (13.31)</td>
<td></td>
<td>$t$ = (-4.34^*)</td>
</tr>
<tr>
<td>MLU</td>
<td>1.37 (0.40)</td>
<td>1.57 (0.49)</td>
<td></td>
<td>$t$ = (-2.76^*)</td>
</tr>
</tbody>
</table>

* denotes significant difference from Entry to Mid-Point at $p<0.05$. Mean (SD)
Intervention using AAC
Boy: age 5 1/2 years; no words, no sounds

Dynavox

ipad
Similar profile between responders and non-responders to initial treatment

<table>
<thead>
<tr>
<th>Entry Variables</th>
<th>Responders 75%</th>
<th>Non-Responders 25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronological Age (years)</td>
<td>6.75 (1.09)</td>
<td>6.29 (0.44)</td>
</tr>
<tr>
<td>Mental Age – Leiter-R (months)</td>
<td>47.33 (13.76)</td>
<td>46.75 (31.60)</td>
</tr>
<tr>
<td>IQ – Leiter-R</td>
<td>61.87 (13.72)</td>
<td>67.50 (37.33)</td>
</tr>
<tr>
<td>TELD Receptive Age (months)</td>
<td>25.40 (6.33)</td>
<td>24.25 (9.32)</td>
</tr>
<tr>
<td>TELD Expressive Age (months)</td>
<td>22.00 (5.92)</td>
<td>18.25 (0.96)</td>
</tr>
<tr>
<td>PPVT Age (months)</td>
<td>30.47 (7.15)</td>
<td>35.00 (12.73)</td>
</tr>
<tr>
<td>Frequency of Spontaneous Communication (words)</td>
<td>18.30 (14.68)</td>
<td>19.50 (18.58)</td>
</tr>
<tr>
<td>Percent of Spontaneous Communication</td>
<td>22.63 (20.95)</td>
<td>27.88 (26.53)</td>
</tr>
<tr>
<td>Number Different Word Roots (NDWR)</td>
<td>11.40 (11.30)</td>
<td>11.38 (9.71)</td>
</tr>
<tr>
<td>Mean Length Utterance (MLUw)</td>
<td>1.37 (0.40)</td>
<td>1.03 (0.72)</td>
</tr>
</tbody>
</table>
Compulsive Behavior Subscale
RBS-R at Entry—Potential Moderator?

<table>
<thead>
<tr>
<th></th>
<th>M (SD)</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responders</td>
<td>3.00 (2.78)</td>
<td>8.65</td>
<td>0.013</td>
</tr>
<tr>
<td>Non-Responders</td>
<td>8.00 (2.94)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Parent Report on a 0 – 3 rating--- Possible Range on Subscale 0 – 24.

Subscale Items include: Arranging/Ordering, Completeness, Washing/Cleaning, Checking, Counting, Hoarding/Saving, Repeating, Touch/Tap. (Bodfish et al., 2000, 1999)
Conclusion

- About 75% of participants are responders; others need greater intensity or adaptive intervention strategy
- Do not yet know the sequence of intervention mode
- Likely important moderators of treatment success
  - Repetitive behaviors (compulsive behaviors) seem to interfere
  - Others…..?
Lingering Concerns

- What level of response is right?
  - What is a meaningful change in communication?
  - Accounting for the heterogeneity in the population…..

- SMART design for treatments that are not well established on the population?
  - Increases participation, and does not penalize already non-responding children
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