Need for Adaptive Research Designs in Speech Language Pathology

Christy L. Ludlow, PhD
Communication Sciences and Disorders
Email : ludlowcx@jmu.edu
Disclosures

- Receive research support and serve as a consultant to Passy Muir, Inc.
- Am an inventor on patents for devices for dysphagia
- Receive research support from National Institutes of Health
  - U54 NS065701
  - R43 DC012754
Drulia and Ludlow, “Relative Efficacy of Swallowing versus Non-swallowing Tasks in Dysphagia Rehabilitation: Current Evidence and Future Directions”

- **Initial search**: 1,546 citations
- **Review of each and identified**: 30 relevant
- **Determined 3 not acceptable**
- **Sorted 27 into 3 categories**

- **Direct Swallowing therapy (1)**
  - 1 RCT

- **Indirect therapy only (10)**
  - 1 RCT
  - 8 case series
  - 1 CCT

- **Combined Direct and Indirect therapy (16)**
  - 5 RCTs
  - 7 case series
  - 4 CCTs

**Notes**
- RCT = random controlled trial
- CCT = controlled clinical trial
Computed Cohen’s $d$ for therapy effect
Effect size ($d$) = Change in mean/ S.D.

<table>
<thead>
<tr>
<th>$d$</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>$&lt;.2$</td>
<td>no effect</td>
</tr>
<tr>
<td>$.2$ --</td>
<td>small</td>
</tr>
<tr>
<td>$.499$</td>
<td>moderate</td>
</tr>
<tr>
<td>$.799$</td>
<td>large</td>
</tr>
<tr>
<td>$&gt;.8$</td>
<td></td>
</tr>
</tbody>
</table>
Effect Sizes for Dysphagia Therapy alone

- Effect sizes are small for behavioral therapy alone (.3–.4) Mendolsohn during therapy

Effect sizes for other modalities alone

- Other single modalities of therapy have higher effect sizes (.45–.8) e.g. rTMS (5Hz), Icing, exercise alone (jaw opening), DBS, Levodopa
Effect sizes for Dysphagia Therapy Combined with Other Modalities

- Effects sizes range from .3 to 1.2,
  - Exercise plus swallowing therapy,
  - tDCS,
  - Videofeedback plus therapy
  - NMES plus swallowing therapy

- Spontaneous recovery alone has a 1.2 effect size during first 0–3 months
## Effect Sizes

- **Swallowing Therapy alone**  
  $ES = 0.4 - 0.5$ (Small)

- **Other therapies (Deep Brain Stim, LevoDopa, Transcranial Magnetic Stim) alone**  
  $ES = 0.4 - 0.7$ (Small to Moderate)

- **Other therapies + Swallowing Therapy Combined**  
  $ES = 0.6 - 1.2$ (Moderate to Large)

---

- **Spontaneous recovery alone post CVA**  
  $ES = 1.2$ (Large)
Current Therapy Regimens are infrequent and short

**Usual Dosage for Inpatient Rehabilitation**
- Dosage duration = 2 weeks
- Intensity = 1 hour per weekday
- Total exposure 10 hours
- # swallows = 600

**Usual Dosage for Outpatient Rehabilitation**
- Dosage = 4–6 weeks
- Intensity = 1 hour per week
- Total exposure 6 hours
- # swallows = 360
Methods for Optimizing Therapy

- Extending dosage by prolonging therapy program
- Increasing intensity by using multiple therapy sessions a day
- Shortening session duration to avoid fatigue
- Combining other modalities such as cortical stimulation with therapy
Adaptive Designs to Find the Most Effective Therapy Regimen

- Do adaptive studies before embarking on an RCT to determine optimal therapeutic program
  - Find most effective treatment intensity, # trials per day without patient fatigue
  - Find most effective session duration of treatment, shorter may be more effective
  - Find most effective treatment dosage, total # sessions
Questions to ask of adaptive designs

- **Sessions per day**, 1 per day is usual
- If therapy was in patient’s environment could have multiple sessions of short duration per day

![Graph showing increase in ES (effect size) with increasing sessions per day from 1 to 10.](image-url)
1 hour may not be optimal
Therapy period

- 2 weeks may not be optimal
When are Adaptive Designs useful?

- Conduct BEFORE designing an RCT
- Adaptive designs are used to identify optimal treatment regimen before doing a costly and lengthy RCT
- May need different regimens for different treatments for different types of patients
- Statistical analysis done independently by biostatistician and reported to DSMB