Designs for Dissemination & Implementation Research

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Selected content adapted from presentations by:

Amy M. Kilbourne, PhD, MPH, & Karen M. Emmons, Ph.D.- TIDIRH, July, 2015, Pasadena, CA

Maureen Smith, Ph.D., Introduction to Translational Outcomes Research, Sept 2017, Madison, WI
I have a shareholder interest in CHESS Mobile Health, a web-based health care technology company that has developed software for patients and family members struggling with addiction.
Overview

- Translational research spectrum
- Designs for D&I research
- Group exercise- asking the right questions to get started with study design
The Continuum of Translational Research

Focus on the complete translational pathway

- Basic Research
- Methods Development
- Efficacy Trials
- Effectiveness Research
- Implementation Research
- Policy Research

Translational Research “Bench to bedside”

Translational Research “Bedside to curbside”
Randomized Clinical Trials

- Conducted to obtain safety and efficacy data on new treatments
- ClinicalTrials.gov currently has 198,792 trials with locations in 190 countries
- Application of scientific method to understand human biology
  - Test causality
  - Rigorously monitor and assess
  - Randomize assignment into groups
- Gold standard...for what conclusions?
Effectiveness Research

- Examine the gap between knowledge and usual community practice
- Includes reasons for and impact of the gap
- Presumption that having a gap may be fine...depends on impact
Implementation Research

- Develop, evaluate, disseminate behavioral interventions to improve practice and outcomes
- Strategies to close the gap
- Presumption that having a gap is bad
Commonly Used Designs

- Randomized controlled trial (RCT)
- Parallel assignment cluster RCT
- Stepped-wedge design
- Interrupted time series (ITS)
- Mixed-methods designs
- Hybrid/Implementation Effectiveness Designs

The Historically Prevailing Standard of Evidence: The Randomized Controlled Trial

Intervention tested by comparison with a control condition with random assignment → Change in outcome variable(s) Measured & compared Between experimental & control Groups

- Interventions highly standardized
- All else held constant
- Clients randomized, no choice

- Comparison based on average change for each group
- Subgroup analysis discouraged/limited
- Dropouts discounted, ignored

Green TIDIRH, 2013
Parallel Cluster vs. Stepped Wedge Designs
Stepped Wedge Design Benefits/Cautions

Preferable when:
- There is evidence in support of the intervention, or resistance to a parallel design where half receive the intervention.
- The intervention is service delivery or policy change that does not need participant consent.
- Logistical concerns mean that implementation must be staggered.

Deserves caution when:
- Methods for calculating power are murky.
- Clusters may not be able to follow randomization schedule.
### Interrupted Time Series Example: Coordinated Approach to Cancer Screening

<table>
<thead>
<tr>
<th>Interventions:</th>
<th>Interactive Voice Response Reminder System</th>
<th>Preventive Care Coach</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (6 months)</td>
<td>Intervention (18 months)</td>
</tr>
<tr>
<td>Site 1</td>
<td>oooooooooooooooo</td>
<td>IVR + PCC</td>
</tr>
<tr>
<td>Site 2</td>
<td>oooooooooooooooo</td>
<td>IVR</td>
</tr>
<tr>
<td>Site 3</td>
<td>oooooooooooooooo</td>
<td>IVR + PCC</td>
</tr>
<tr>
<td>Site 4</td>
<td>oooooooooooooooo</td>
<td>IVR</td>
</tr>
</tbody>
</table>

Mixed methods

Counts as “Mixed” when:
1. At least one QUAL and one QUANT method used
2. Each method is used rigorously
3. Data collection &/or analysis &/or results are integrated

➢ What
  ▪ Focus groups, structured interviews, ethnographic field techniques, etc.

➢ When & where
  – Throughout research process

➢ Why
  ▪ To inform development and refinement of interventions and implementation strategies
  ▪ To identify barriers and facilitators
  ▪ To illustrate context

Johnson, et al., 2007; Pluye & Hong, 2014
Hybrid Effectiveness/Implementation Designs

- Address limits of step-wise research (speed research → practice)
- Promote external validity
- Blended ability to test both intervention effectiveness and effectiveness of implementation strategies

Some important questions to address in hybrid designs

- What implementation strategies are most effective in improving the uptake of effective practices?
- What implementation barriers or problems emerge?
- What changes to implementation strategy, or clinical intervention, could be made to improve uptake?
Types of Hybrid Designs

- Clinical Effectiveness Research
  - Hybrid Type 1: test clinical intervention, observe/gather information on implementation
- Implementation Research
  - Hybrid Type 2: test clinical intervention, test implementation strategy
  - Hybrid Type 3: test implementation strategy, observe/gather information on clinical intervention outcomes
Sequential Multiple Assignment Randomized Trial (SMART) Designs

- Usually 2-3 critical decisions to address, e.g.,
  - **Sequencing decisions**: Which treatment to try first? Which treatment to try if sign of nonresponse?
  - Which treatment to try if subject doing well?
  - **Timing decisions**: How soon do we declare nonresponse? How soon do we declare response?

- Which decisions are most controversial or need investigation?

- Which decisions are likely to have the biggest impact on the outcome?

*The goal of a SMART is to inform development of adaptive intervention strategies*
ADEPT Design

### Run-In Phase
All sites offered REP to implement EBP; Patients start EBP by Month 3

- **REP**
  - **k=80 sites**
  - **Non-Responders** (<10 out of 20 enrolled patients receiving EBP or <75% sessions completed)
    - **k=60 sites**

### Month 6 Assessment
- **Add External Facilitation REP+EF**
  - **k=30 sites**
  - **N=600 patients**

### Phase 2
- **Responders**
  - **Continue follow-up assessments**
- **Non-Responders**
  - **Add IF (REP+EF/IF)**
  - **Continue REP+EF/IF**

### Month 12 Assessment
- **Responders**
  - **Continue follow-up assessments**
- **Non-Responders**
  - **Add IF (REP+EF/IF)**
  - **Continue REP+EF/IF**

### Follow Up
- **Month 18 and 24 Assessments**
  - **Continue follow-up assessments (A)**
  - **Continue REP+EF (B)**
  - **Continue REP+EF/IF (C)**
  - **Continue follow-up assessments (D)**
  - **Continue REP+EF/IF (E)**
  - **Continue follow-up assessments (F)**

- **Responders**
  - **k=20 sites**

- **6 Month follow-up assessment**
Why SMART Designs → Adaptive Interventions for Implementation Research?

- Heterogeneity of practices/providers
- Not all barriers/facilitators observable
- React to non-responsiveness/limited uptake
- Reduce implementation burden; use only what is necessary ("Chevy vs. Cadillac")
Pilot/feasibility research


<table>
<thead>
<tr>
<th>Method related</th>
<th>Pilot n = 6</th>
<th>Feasibility n = 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miniature RCT</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Testing recruitment</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Determining sample size/numbers available</td>
<td>3</td>
<td>0</td>
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<tr>
<td>Resources</td>
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<td>0</td>
</tr>
<tr>
<td>Randomization</td>
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<td>1</td>
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<tr>
<td>Outcome measures</td>
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<td>4</td>
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<tr>
<td>Data collection</td>
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<td>0</td>
</tr>
<tr>
<td>Follow up/dropout</td>
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<td>0</td>
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<tr>
<td>Intervention related</td>
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<td></td>
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<tr>
<td>Clinical outcomes</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Dose/efficacy/safety</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Acceptability</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Feasibility</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>
Pilot/feasibility research (cont.)

• Suggestion- ALWAYS include qualitative component in pilot-level research (since small studies will rarely provide convincing evidence of efficacy)

• Devil’s advocate- do you need to develop, test, and implement your own intervention?
Takeaway thoughts

• Mixing and matching terms is OK (i.e., your study could be described as a mixed-methods, Type III hybrid, cluster RCT design with an adaptive implementation strategy)

• Designs should seamlessly integrate implementation models/frameworks

• Find a way to build in qualitative components

• Hybrid designs seem to be winning the day in D&I research
Group exercise – introduction & example

- Basic building blocks of a D&I project:
  - Intervention (WHAT you are implementing)
  - Implementation strategy (HOW you are implementing the intervention)
  - Outcomes (your outcomes place you on the spectrum from efficacy research to implementation research)
  - Study design (how you will assess the effectiveness of the intervention and/or the implementation strategy)
Types of Hybrid Designs

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Group exercise

• At your table, please spend 20 minutes working through the 6 questions on the worksheet
• Afterwards, we will spend time reporting out and discussing
Selecting your intervention – key considerations

Is there evidence of efficacy of the intervention?

- Yes- Consider Type III hybrid
- No- conduct pilot efficacy research on the intervention before proceeding to implementation research, or consider Type I hybrid
If there’s no evidence of efficacy for your intervention- what about conducting a type II hybrid?

- Make sure your study design allows you to do simultaneous testing
- Avoid conflating the intervention and the implementation strategy
- Get feedback on your design (early and often)
Question: is there evidence of effectiveness of your implementation strategy?

• “Getting to Yes”: consult Powell’s taxonomy of implementation strategies; pick one or bundle them

• Conduct Type III hybrid trial?
• No: conduct pilot research of a novel implementation strategy, or consider type II hybrid
Thank you!

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