Randomized Implementation Trials: Experience from the CAL-OH Project

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1. Is there a Role for Randomized Studies in Implementation Science? If So, Not the Usual Solution

2. Roll-Out Randomized Implementation Trials
   Statistically Useful?
   Community Buy-In?
   Conduct?

3. Illustrative Randomized Design for Implementation Research
   The CAL-OH Randomized Implementation Trial
   Evidence Based Intervention
   Multidimensional Treatment Foster Care (MTFC)
   Implementation Strategy to be Tested
   Community Development Teams (CDT) from CiMH
1. Is there a Role for Randomized Trials in Implementation?  
Why Randomized Trials May Not Work

- Set up to answer problems outside of implementation research
  Trials to determine efficacious or effective interventions
  Implementation: Examine a strategy
- Communities won’t stand for groups receiving only control condition
  Withhold an evidence-based program?
  Ethics of a Trial Relies on Equipoise
- Not possible to conduct randomized trial
  Too complicated?
  Simple to Randomize at community, county level
Why Randomized Trials Might Work

Randomized Assignment Can be Flexible

- Person
- Place/Group
- Time

Random Assignment of Schools to Different Times in an Effectiveness Trial

Brown et al., Clinical Trials, 2006

Random Assignment of Counties to Different Times of Implementation

Brown et al., 2008 Drug & Alcohol Dependence
Limited Use of Quality Designs for Implementation Research
Randomized Trials Are Well Represented

Child welfare/mental health implementation
• 9 of 338 studies had a comparison group
  ○ 8 of 9 used a randomized trial

Quality Improvement in Health Care
• Cochrane Collaboration Effective Practice and Organization of Care Review Group (EPOC) Reviews –
  ○ 57% exclusively Randomized Trials

Landsverk, Brown, Rolls Reutz et al (2011)
Landsverk, Brown, Chamberlain et al. (accepted for publication)
What Do You Get when a Study is Not Randomized

- Example: A Multiple Baseline Study Design
Inferential Challenge when Timing is Not Randomized

- What if and Exogenous Factor Happens at one of these Times of Transition?
- What if you Select the Most Promising Communities to Work with First?
- What if there are only a small number of communities?

- Harder to Conclude that New Program Implementation Caused Change.
2. Turning a Multiple Baseline Design into a True Randomized Experiment: **Roll-Out Design**

**ROLL-OUT DESIGN**

- Divide Available Communities into Comparable Batches
- Start Measuring Outcomes for All Communities
- **Randomly** Assign Each Comparable Batch to WHEN the Implementation Begins
- At the end, ALL Communities Are Exposed

- Analysis Uses All Communities and All Times
  - Communities Still Serve as Own Controls
  - Communities Compared by Exposure Status Across Time
Roll-Out Randomized Trials for Implementation Research (Brown et al., 2006 2008)

Equivalent Subsets that are Ordered Randomly

Communities

1 2 3 4 5

R

Time of Transition in Dissemination Randomly Determined

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Timing of Implementing (0 to x)

1. 0 0 x x x x x x 0 - baseline no tx
   x - implement

2. 0 0 x x x x x

3. 0 0 x x x x

4. 0 0 x x

5. 0 0 x

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Some Reasons to Consider Randomized Assignment

- Statistical Advantages
  - Statistical Precision/Power
  - Reduces Bias
  - Ability to Combine / Synthesize Findings Across Time
Random Assignment Reduces Bias in the Long Run

- Example: mPowerment Community Intervention

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Communities that get randomized are Large and often few are available at a time

A Single Trial with a Small Number of Communities is Nearly Always Underpowered

- Randomize small numbers of communities now
- Randomize small numbers next year
- ...
- Randomize small numbers in following years
- Combine results across the years
  - Brown et al., Ann Rev Public Health 2009
  - Brown et al., Prev Science 2011
Roll-Out Trial for Implementation Strategies

- Randomize WHEN communities get support to start implementation

Community
- Advantage for going early: program available
- Advantage for going later: may get a better program

Researcher
True, honest experiment
Changing Research Questions

Effectiveness vs Implementation

System to Support Adoption

Control

Intervention

Old System to Support Adoption

Intervention

New System to Support Adoption

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Buy-In: Will Communities Agree to be Randomized to Roll-Out Trials?

- Fair System
- Make Sure there Are Equal Advantages for Each Random Assignment

All communities get implementation of evidence-based program

Dynamic Wait-List: Brown et al., 2006, Clinical Trials
Cal-OH Implementation Trial Example

- Evidence-Based Program – Multidimensional Treatment Foster Care (MTFC)
- Two Implementation Strategies aimed at Counties in California and Ohio
  - Community Development Team (CDT)
  - Standard County Implementation (Stnd)
Two-Arm Trials
Effectiveness vs Implementation

- Existing Implementation Supports for County, Agency, Group Home
- MTFC Implementation Supports for County, Agency, Clinicians, Parent
- Control Condition
- MTFC Intervention
- MTFC Intervention
- Standard Implementation Supports for County
- MTFC Intervention
- MTFC Intervention
- CDT Implementation Supports for County
- MTFC Intervention
- Youth
- Youth
- Youth
- Youth

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Illustration of the CAL-OH Randomized Implementation Trial

**Objective**: Test the effectiveness of the Community Development Team (CDT), a theory driven model to promote the adoption, implementation, and sustainability for delivering the evidence-based Multidimensional Treatment Foster Care (MTFC) intervention in California counties that are not already using MTFC, relative to Standard County Implementation (Stnd).

**Method**: Randomize counties into 6 equivalent clusters, 3 of which receive CDT, other 3 receive standard implementation.

**Measures**: Time it takes to adopt, recruit staff, train, and place youth in MTFC homes.
Outcome(s) of a Randomized Implementation Trial

How fast do counties in the two conditions adopt, implement with fidelity, and sustain the intervention?
3. Addressing Community Concerns with High Quality Alternatives to the Traditional Randomized Controlled Trial

Issues in the CAL-40 Design

1. Acceptance of the Design was Complete
2. Some Counties Were Not Ready to take Part
   Moved Up Counties from Next Cohort, but remained in same implementation condition

Chamberlain et al., In press
Addressing Community Concerns with High Quality Alternatives to the Traditional Randomized Controlled Trial

Consort Diagram

Assessed for eligibility, n=58.

Excluded n=18.
- Already had implemented MTFC, n=9
- Fewer than 6 youth per year, n=8
- Los Angeles County, n=1

Formed 6 equivalent clusters by matching background, n=40.

Randomized the clusters to 3 cohorts and 2 conditions, n=40.

Cohort 1, n=12.
- CDT, n=6
  - Accepted, n=4
  - Declined, n=2
  - Filled by cohort 2 counties, n=0
  - Received, n=4
  2 counties moved in

- IND, n=6
  - Accepted, n=4
  - Declined, n=2
  - Expected to receive, n=7

Cohort 2, n=14.
- CDT, n=7
  - Accepted, n=7
  - Moved to cohort 1, n=2
  - Expected to be filled by cohort 3 counties, n=2
  - Expected to receive, n=7
  - Invited to ‘go early’, n=3 (2 counties accepted invitation)

- IND, n=7
  - Accepted, n=7
  - Moved to cohort 1, n=0
  - Expected to receive, n=7

Cohort 3, n=14.
- CDT, n=7
  - Accepted, n=4
  - Declined, n=1
  - Pending, n=2
  - Expect to be moved to cohort 2, n=2
  - Expect to be filled by declined cohort 1 counties, n=2
  - Expect to receive, n=7

- IND, n=7
  - Accepted, n=6
  - Declined, n=0
  - Pending, n=1
  - Expect to receive, n=9

2 counties moved into cohort 1

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Exogenous Factors in a Roll-Out Trial

Running Randomized Trials During a Recession

Solution: Added 13 counties in a second state OH, using equivalent inclusion/exclusion criteria
Summary
When Randomized Designs Are Valuable

- Magnitude of the Intervention Effect we are looking for is not Dramatic
- When other factors besides the Intervention can have strong effects on the outcome
- Roll-Out Implementation Trials are Often Statistically Valid, Accepted, Conductable
3. Addressing Community Concerns with High Quality Alternatives to the Traditional Randomized Controlled Trial

Advantages of “Roll-Out” Designs

- Community Standpoint
  Everyone gets active intervention
  Fair assignment of when intervention occurs
  Early – receive potentially beneficial intervention soon
  Later – may receive a better intervention

Researcher
  True randomized trial
  Comparatively simple
  May need to continue over multiple years/cohorts to obtain sufficient power