Randomized Designs for System Level Implementation Trials ?

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Here is One Perspective on Randomized Trials for Implementation Research

SCIENTIFIC PERSPECTIVE

- Strategies to implement "evidence-based" practices or programs necessarily involve organizational, community, or system level interventions.

- If we wanted to formally test **implementation strategies**, we would , at least on **scientific grounds prefer** to randomly assign implementation strategies at organizational levels, since randomized trials provide the strongest evidence.

ANOTHER PERSPECTIVE

- Randomized trials don't answer key implementation questions, too rigid, little generalizeability and low external validity...

Your Vote on Scientific Grounds

Randomized Implementation Trials at the Organizational Level would be scientifically useful for advancing Implementation Science -- if they could be carried out

How much do you agree?

1 - Not at All

2 - Somewhat

3 - Strongly

Here are some Practical Concerns about Trials Randomized at Organizational Levels

FINANCIAL, ETHICAL, and ORGANIZATIONAL PERSPECTIVE

- Carrying out a randomized trial at the organizational level is generally too expensive, as it requires many organizations to achieve sufficient statistical power
- Randomizing at the organization/community level is unlikely to be supported by these organizations or communities who are averse to withholding effective interventions, programs, or practices

CONCLUSION

- Randomized design strategies should rarely if ever be used for conducting large scale implementation evaluations.

Your Second Vote on Practical Grounds

On practical (or scientific grounds), we should **rarely if ever** use organization – level **randomized trials** to test/examine implementation strategies

How much do you agree?

1 - Not at All

2 - Somewhat

3 - Strongly

Outline

1. Introduction
   - What Methodologies are Important for the Field of Implementation Science?
   - Center for Prevention Implementation Methodology (Ce-PIM)
   - What is the role of a randomized implementation trial?
2. Two approaches: Randomize at a lower Level
   Randomize on Time of Implementation
3. Changing a Non-Randomized Design for Implementation Design to one that is Randomized:
   - "Timecasting"
4. Illustrative Randomized Design for Implementation Research
   - Example of the CAL-OH Randomized Implementation Trial
5. Roll-Out Randomized Implementation Trials
   - Statistically Useful?
   - Community Buy-In?
   - Conduct?
6. Conclusions

References at the end

Prevention Science – for Mental, Emotional, and Behavioral (MEB) Disorders

State of the Science

- **Conclusion: Lots of Effective Preventive Interventions**

Methodology for Effectiveness

- **Conclusion: Rigorous Randomized Preventive Trials Provided this Evidence**

Implementation

- ***Recommendations:*** **NIH charged with developing methodologies to address major gaps the study of dissemination and implementation of successful interventions.**

National Academy of Sciences (2009). Preventing Mental, Emotional, and Behavioral Disorders Among Young People: Progress and Possibilities

Center for Prevention Implementation Methodology (Ce-PIM) for Drug Abuse and HIV/Sexual Risk Behavior

Funded by NIDA and NIH/OBSSR

1. **Develop new methods** for Implementation Science
2. Partner with Implementation Researchers on the **Use of Innovative Methods in advancing Implementation Science**
3. Advance discovery in the **Practice of Implementation** by Partnering with Communities, Organizations, Practitioners, and Policy Makers

+ Mental Health, Depression, Suicide, Services

Our Methods Discussion Today is Limited to Trials of Implementation Strategies

Lots of Qualitative and Mixed Methods, QI designs

Landsverk, Brown, et al., 2012.

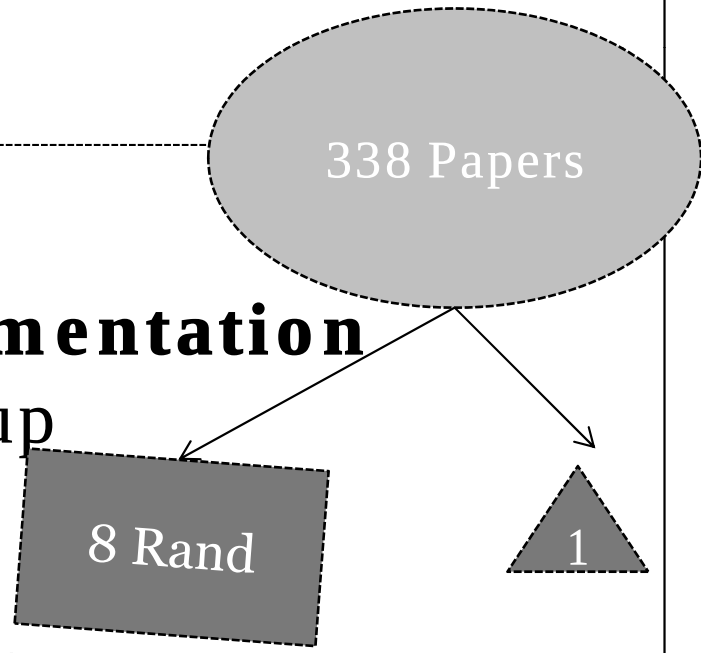
Limited Use of High Quality **Quantitative** Designs for Implementation Research

Review of research literature on behavior change related to healthy diets.

- **Among 2,872 studies, including 16 systematic reviews, only five studies were appropriately designed and/or reported on the range of outcomes so as to influence policy and practice.**

Schillinger, D. (2010). *An Introduction to Effectiveness, Dissemination and Implementation Research.* P. Fleisher and E. Goldstein, eds. From the Series: UCSF Clinical and Translational Science Institute (CTSI) Resource Manuals and Guides to Community-Engaged Research, P. Fleisher, ed. Published by Clinical Translational Science Institute Community Engagement

Randomized Trials In Fact Do Occur in Implementation



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. (2012)

Cluster/Group-Level Randomized Trials Published in Implementation Science

~ 44 / 193 Research and Study Protocols = 23%

- Some involve sizeable numbers of organizations

  40 counties in California (now 53)
  Wang, Saldana, Brown, Chamberlain. 2010, Implementation Science

- Many use small numbers of organizations

  6 oncology clinics
  Boveldt et al., 2011 Implementation Science

- **Many randomize at lower levels than the organization**

  37 first-grade classrooms in 12 elementary schools
  Poduska, Kellam, Brown et al. 2009 Implementation Science

Strategy 1: Randomize at a level lower than the organization

- When does this work? 3 requirements

1. "Unit of Implementation" you want to study is actually at a level below the organization level

   Ex: Coaching of teachers to deal with aggressive behavior

   Classrooms in a school randomly assigned to different coaching conditions

2. Amount of leakage of intervention is acceptable

Lower Level Implementation Strategies Represented in 3 Levels

	Education	Health	Health	Social Service	Governmental
	School District	Health Organization	AHRQ, VA, SAMHSA	County	State
Level 3	School	Clinic	Health Organization	Agency	County
Level 2 **Type of Implementation**	**Classroom:** **Coaching of an EBP**	**Clinician:** **Implement EB Practices**	**Clinical Practice:** **Reminders**	**Service Provider: Supervisor Training**	**Agency: $ Incentives**
Level 1	Child	Patient	Clinician	Client	Service Provider

Strategy 1: Randomize at a level lower than the organization

- When does this work? Third requirement

3. Level 2 units (classes) are similar to one another within Level 3 Groups (schools) OR Implementation is Strong

When does Randomizing at a Lower Level Affect Really Benefit Statistical Power: Similar Classrooms / Strong Intervention

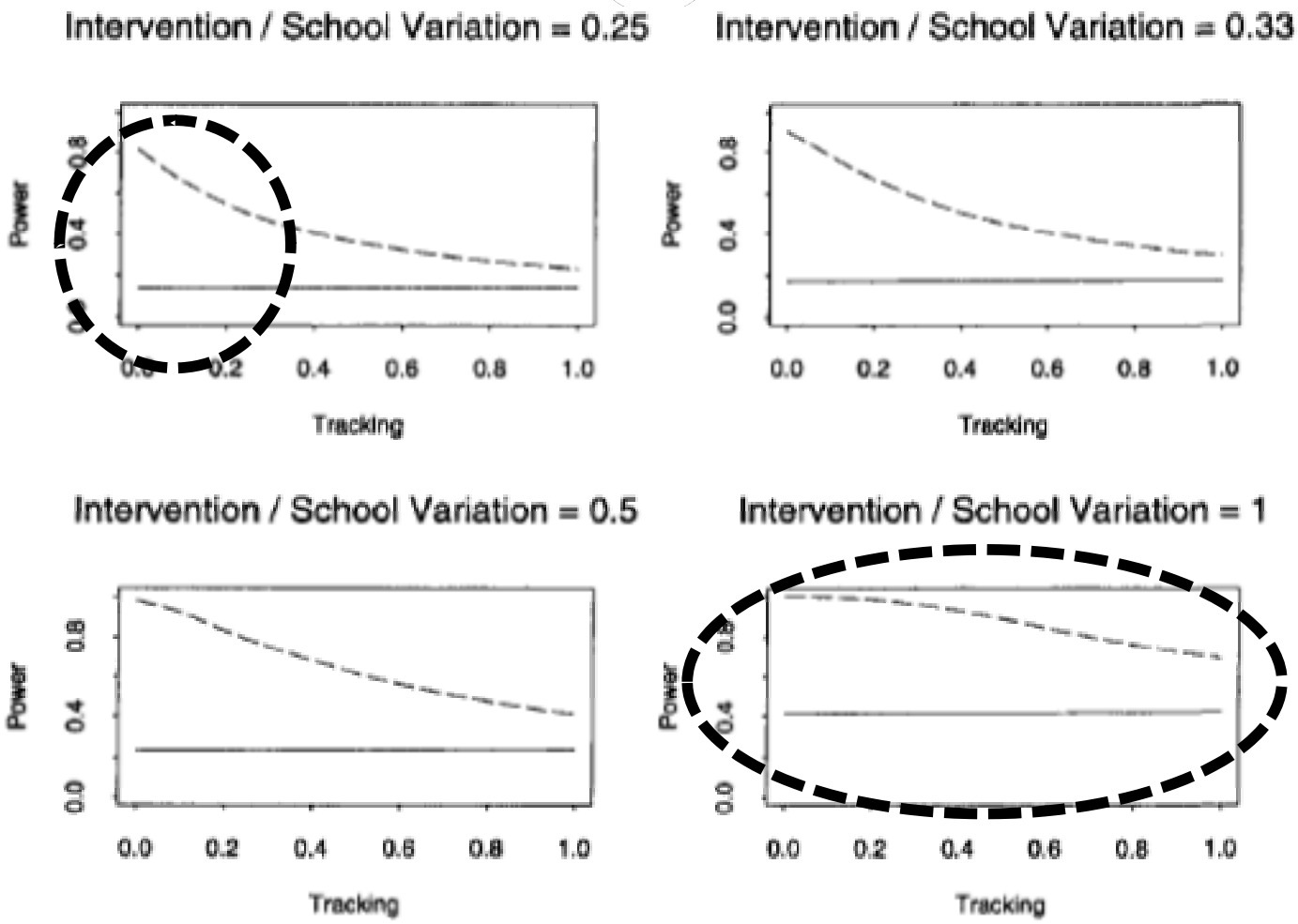


Fig. 3. Power as a function of tracking for varying strengths of intervention.

Brown & Liao, A J Commun Psychol, 1999

Magnitude of Effect
There are very few Broad Street Pump Handles Left to Remove

John Snow's Map of London

1849 proposed

1854 500 deaths
1855 ~ 0 deaths

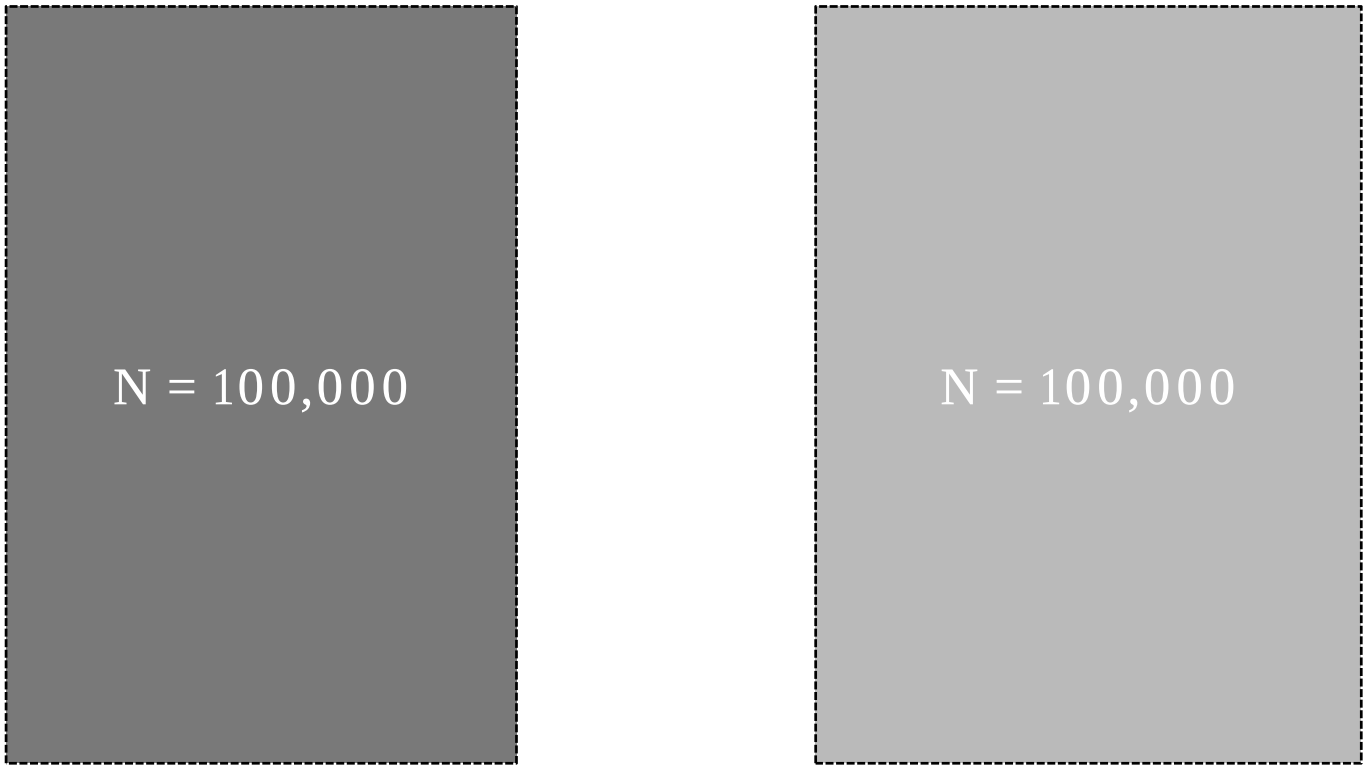
Removal of Pump Led to Immediate Reduction in Cholera Deaths

Strategy 2

- Motivation

Strategy 2: Using "Roll-Out" to Overcome the Challenge of Small Numbers of Organizational Levels

- **The Problem**: Effective Sample Size is # Org Units
- Implement in State 1 No Implementation in State 2



The Two Major Challenges with Organizational/System Level Interventions

- Small number of Organizations means low statistical power, even with very large individual sample sizes

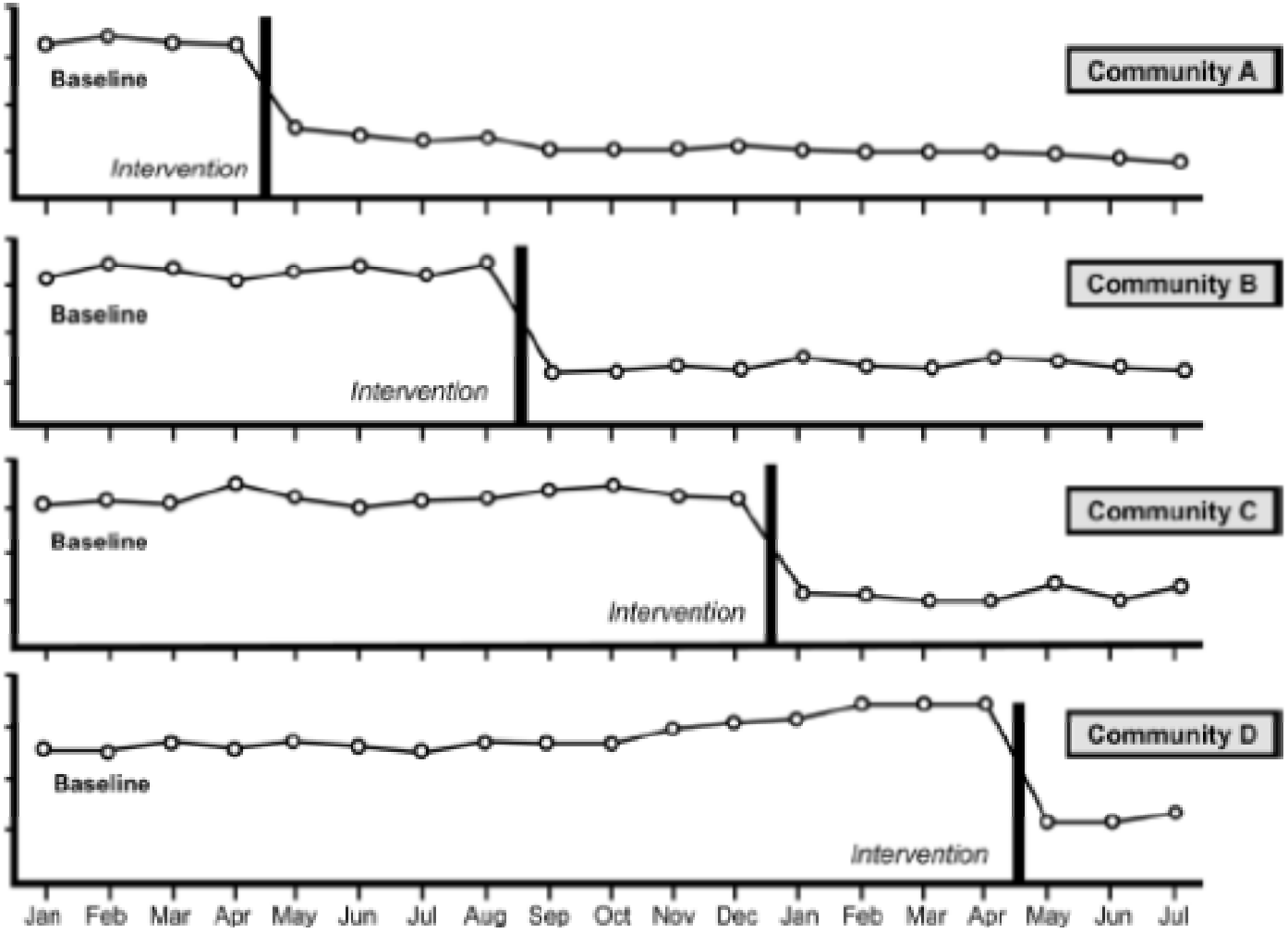
- High degree of organizational differences lowers power

Randomization can Sometimes Strengthen an Existing Design's Inferences, without Losing Anything

- Illustration of a Community-Level Implementation:

Initial Design

Hawkins NG et al., AJPM 2007: "Multiple Baseline, Interrupted Time Series"



A "Timecasting" **Nonrandomized** Designs for Dissemination/Implementation RE-AIM components

1. **Broadcast of an Intervention**

   Standardize Invitation and See Who Comes

2. **Narrowcast of an Intervention**

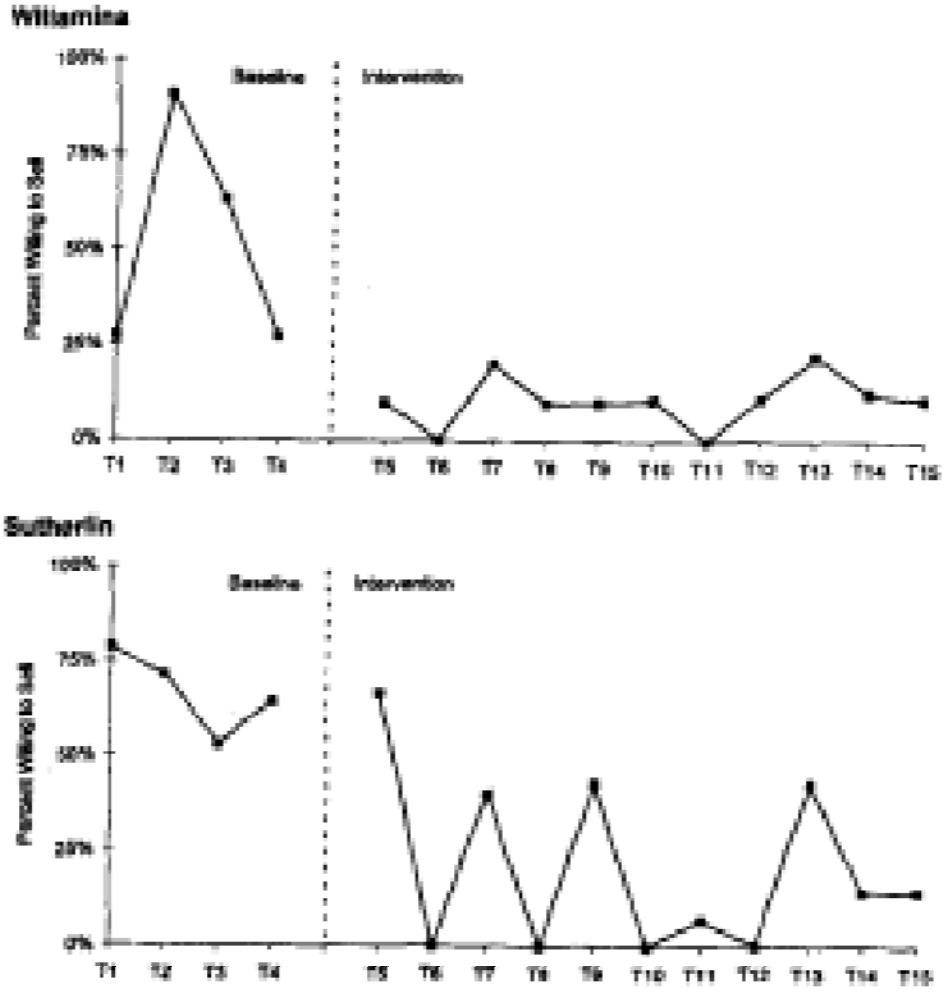
   Social Marketing to a Targeted Audience

3. **"Timecast" of an Intervention**

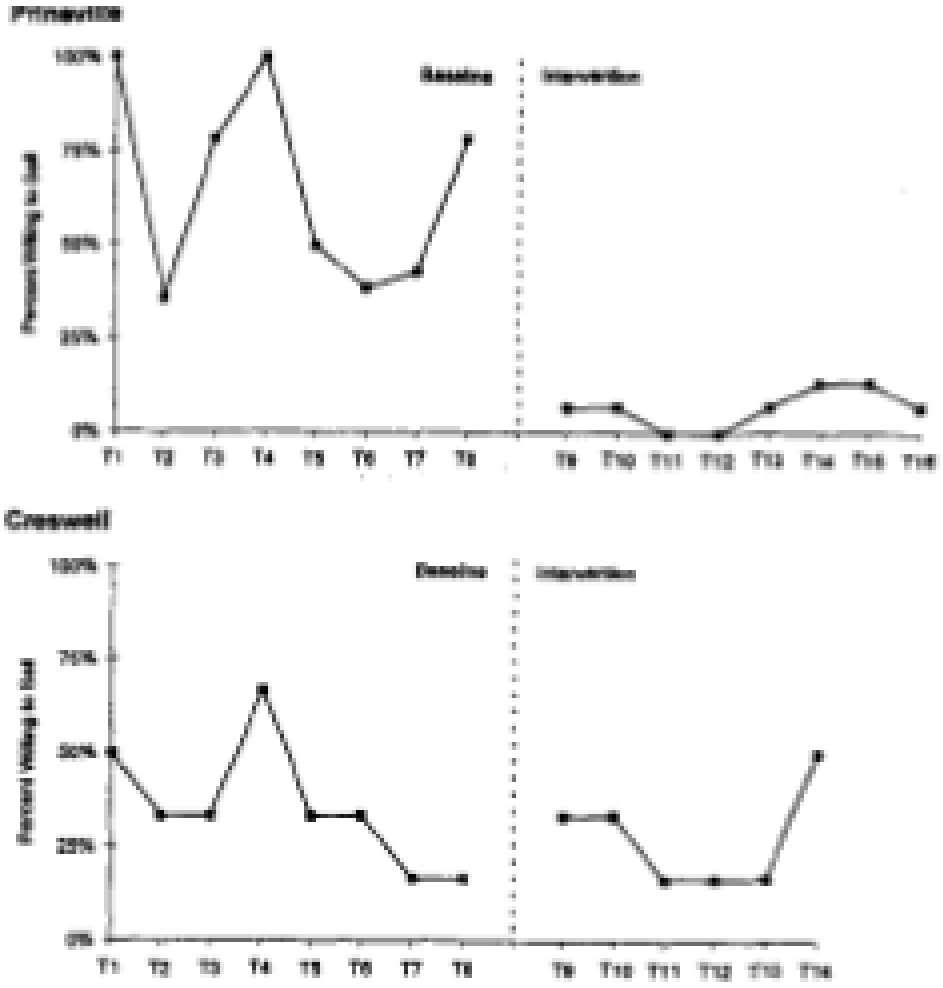
Multiple Baseline design = Interrupted Time Series

- Repeated measures over time of a community outcome
- Introduce an implementation to a community midway through
- Check whether community outcome differs before and after introduction

Biglan et al., AJCP 2006



Other Communities



Inferential Limitations with this Design

- What if and Exogenous Factor Happens at one of these Times of Transition?
  - Recession in CA – CAL-40 Randomized Implementation Trial
  - Dozens of deaths in Mexico – Implement of HIV Prev Sex Workers
- What if you Select the Most Promising Communities to Work with First?
- What if there are only a small number of communities?
- Hard to Conclude that Implementation Caused Change.

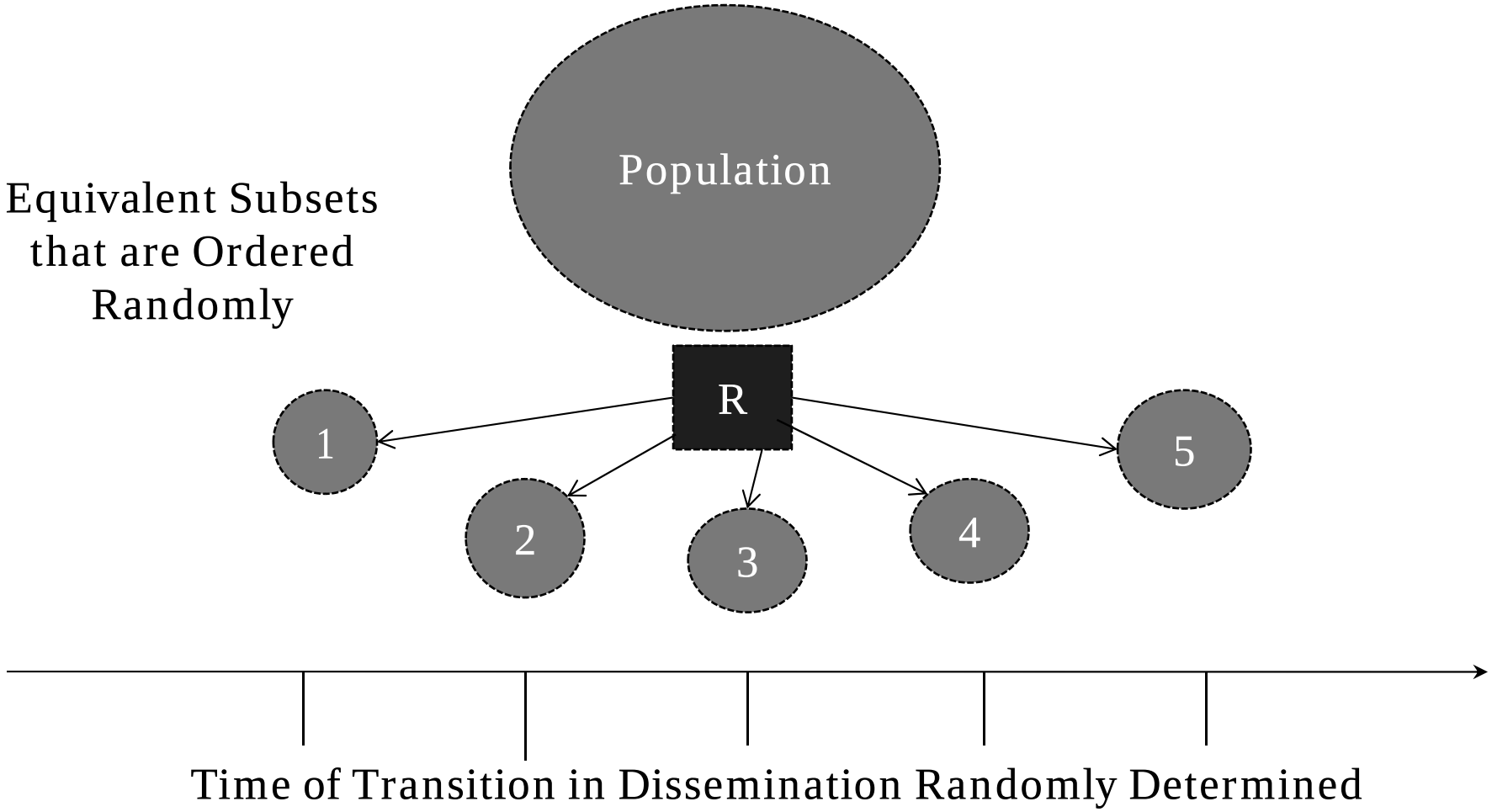
Turning a Multiple Baseline Design into a True Randomized Experiment: **Roll-Out Design**

ROLL-OUT DESIGN

- Divide Available Communities into Comparable Batches
- Start Measuring Outcomes for All Communities
- **Randomly** Assign Each Comparable Batch to WHEN the Dissemination Begins "Timecasting"
- 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 Dissemination Research (Brown et al., 2006 2008)



Timing of Implementation (0 to x)

- 1 0 0 x x x x x
- 2 0 0 0 x x x x
- 3 0 0 0 0 x x x
- 4 0 0 0 0 0 x x
- 5 0 0 0 0 0 0 x

Some Reasons to Consider Randomized Assignment

- Statistical Reasons
  - Statistical Precision/Power
  - Reduces Bias

Dynamic Wait-Listed Design (Roll-Out)

Brown, Clinical Trials , 2006

Randomized Assignment Can be Flexible

- Person
- Place/Group
- Time

Random Assignment of Schools to Different Times in an Effectiveness Trial

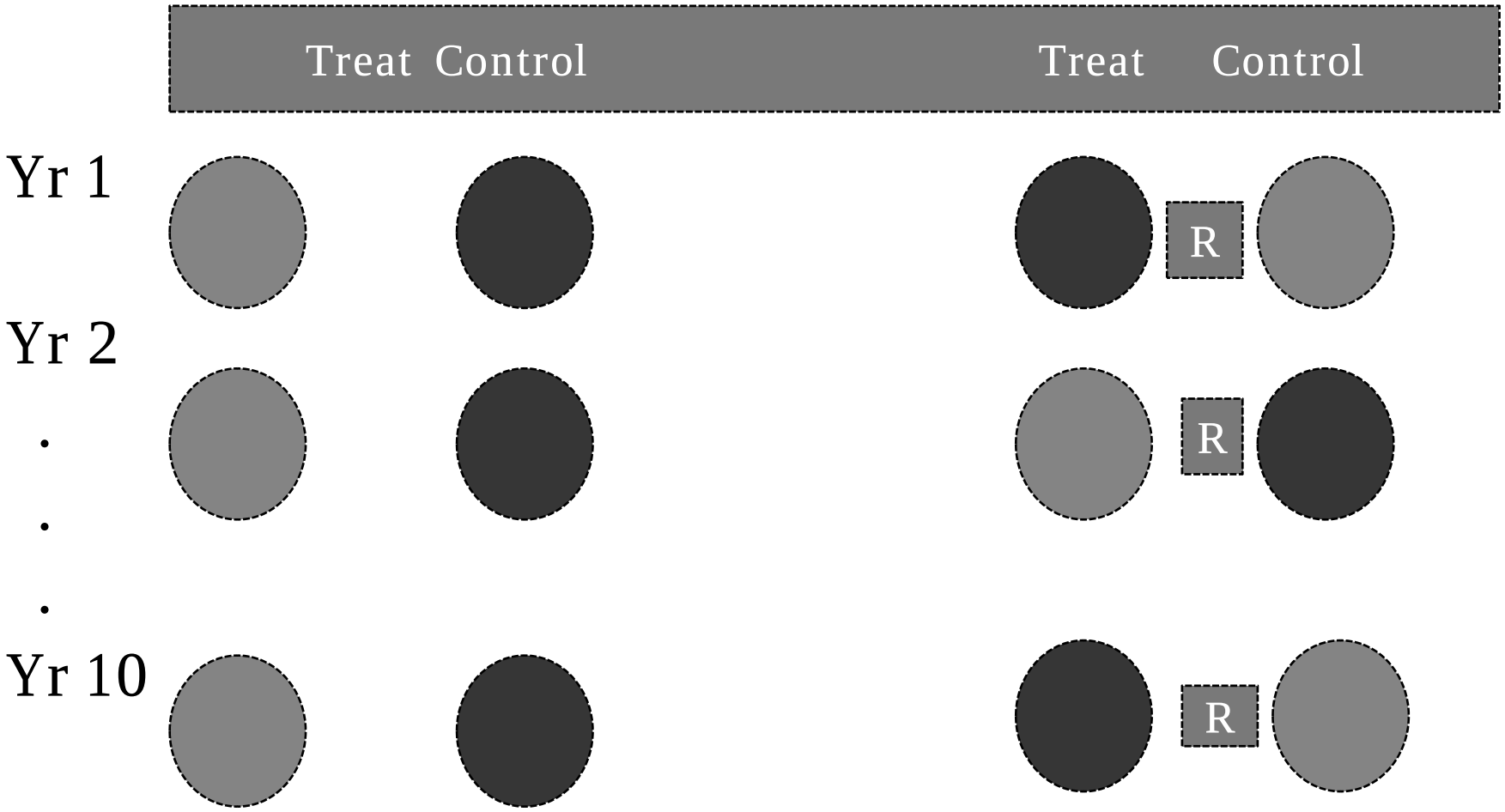
Brown et al., Clinical Trials, 2006

Random Assignment of **Counties** to Different **Times** of Implementation

Brown et al., 2008 Drug & Alcohol Dependence

How Random Assignment Reduces Bias in the Long Run

- Example: mPowerment Community Intervention



Implication of Roll-Out Designs for Community Research

- #Units (communities) to get randomized are Large but few are available at a time

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

SEQUENTIAL

- Randomize small numbers of communities now
- Randomize small numbers next year
- ...
- Randomize small numbers in following years
- Combine results across the years

- **Eventually you obtain sufficient statistical power**
  - Brown et al., Ann Rev Public Health 2009
  - Brown et al., Prev Science 2011

Randomized Roll-Out Implementation Trial

Are Randomized Trials Worth Doing in Implementation?

Probably NOT Without Some Changes in Usual Practice.

Main Idea in this Presentation is to use Roll-Out Designs

- What do they look like? -- CAL-OH Trial
- Are They Scientifically Useful?
- Can You Get Community Buy-In?
- Can They Be Conducted, Adhering to the Protocol?

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

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

Effectiveness Trial:

Roll-Out Trial:

Randomly Assign to Time that Intervention Begins, so ALL Communities Do Get Intervention

Advantage of going early: Thought to be useful

Advantage of going later: Intervention may be improved

Dynamic Wait-List: Brown et al., 2006, Clinical Trials

Will the Idea of Randomized Roll-Out Designs Be Accepted for Implementation Research As Well as for Effectiveness?

- For Implementation of an Empirically Supported Program, All Communities Get the SAME Evidence-Based Program, but Different Implementation

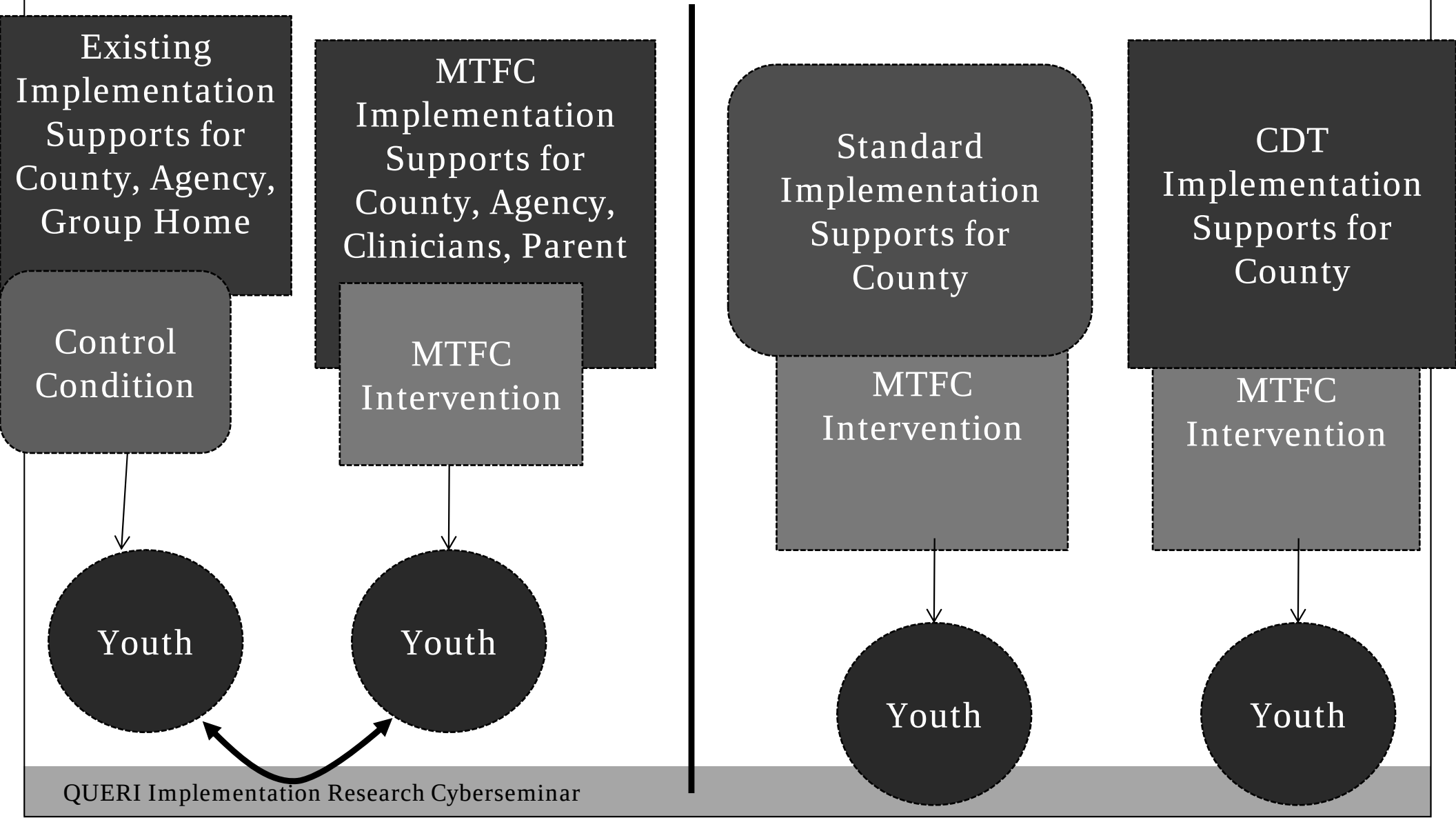
- Advantage for Waiting - Wait listed communities may get better implementation

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



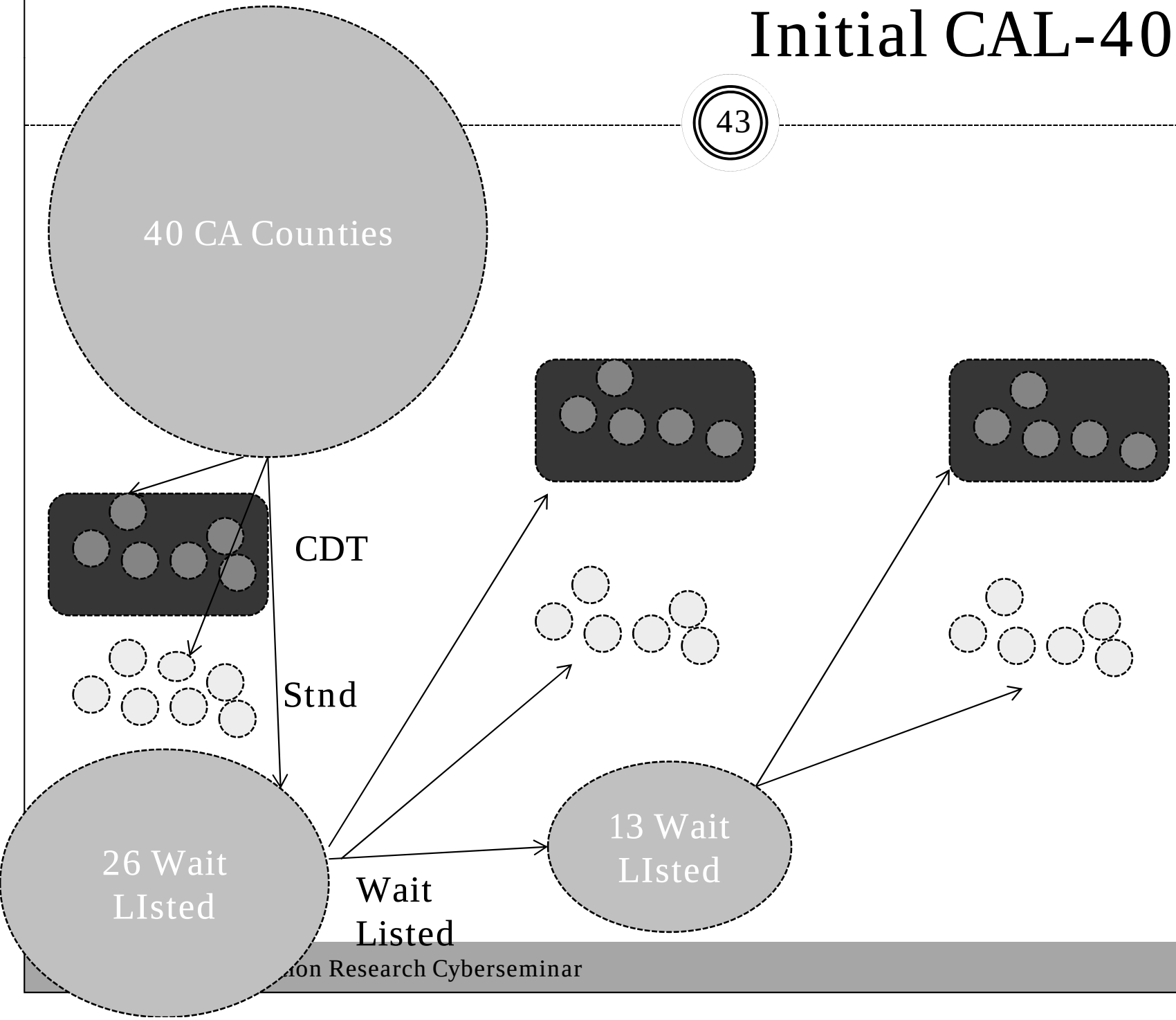
Detailed Illustration of the CAL-OH Randomized Implementation Trial

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.

Initial CAL-40 Design



Issues in the CAL-40 Design

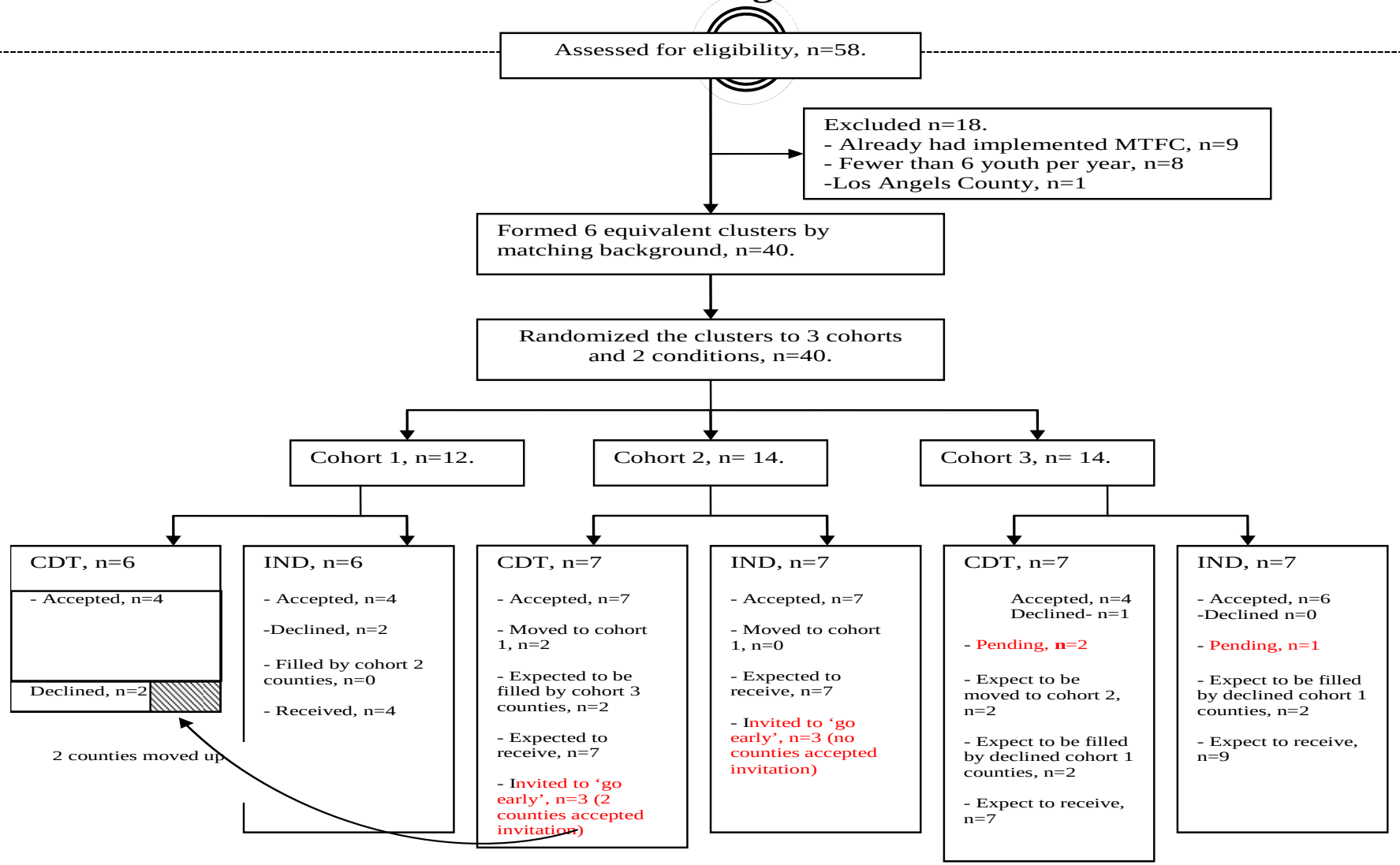
1. Acceptance of the Design was Complete
2. Some Counties Were Not Ready to take Part

   Moved Up Counties from Next Cohort, but remained in same implementation condition

Chamberlain et al., In press

3. Addressing Community Concerns with High Quality Alternatives to the Traditional Randomized Controlled Trial

Consort Diagram



Exogenous Factors in a Roll-Out Trial

Running Randomized Trials During a Recession

Solution: Added 13 counties in a second state, using equivalent inclusion/exclusion criteria

Summary: Randomized Implementation Designs

Randomized Implementation Trials in NOT a Panacea, but does have a place especially at the beginning

1. Some circumstances allow randomizing at lower level

"Unit of Implementation"
Limit implementation leakage
Somewhat comparable lower level units

2, Roll-Out Randomized Implementation Trials

- **Community Standpoint**

  Everyone gets active intervention with implementation
  Fair assignment of when intervention occurs

- **Scientific Standpoint**

  Can reduce bias, protect against external events, and improve statistical power, especially when expanded over time

  Valuable when there is LARGE Variation, at early stages and with highly variable organizations

- **RANDOMIZE EVEN FROM THE BEGINNING, EVEN IN PAIRS OF 2 BUT CONTINUE OVER TIME**

- Need to extend work on statistical properties and conduct of such trials

Related Papers

Aarons GA, Hurlburt M, Horwitz SM. Advancing a Conceptual Model of Evidence-Based Practice Implementation in Public Service Sectors. *Administration and Policy in Mental Health and Mental Health Services Research*. In press.

Brown, C. H., P. A. Wyman, et al. (2007). "The role of randomized trials in testing interventions for the prevention of youth suicide." International Review of Psychiatry **19**(6): 617-631.

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Related Papers

Chamberlain P, Saldana L, **Brown CH,** Leve LD. Implementation of MTFC in California: A Randomized Trial of an Evidence-Based Practice. In M Roberts-DeGennaro & SJ Fogel (Eds.) *Empirically Supported Interventions for Community and Organizational Change*. Lyceum Books, Inc, **In Press.**

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Flay, B, Biglan A, et al. (2005). Standards of Evidence: Criteria for Efficacy, Effectiveness and Dissemination, Prevention Sci, 6, 152-175.

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Related Papers

Wang, Saldana, Brown, Chamberlain (2010). Factors that influenced county system leaders to implement an evidence-based program: a baseline survey within a randomized controlled trial. Implementation Science.

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Books

Valente (2010), Social Networks and Health: Models, Methods and Applications

Palinkas and Soydan (2010). Translation and Implementation of Evidence Based Practice in Social Work: A Strategy for Research

1/12/2012	12:00pm	Randomized Designs for System Level Implementation Trials	QUERI Implementation Research	Brown, Hendricks

1) Regarding your comments on slide 35: can you explain why the left-hand-side method "confounds implementation with community readiness"?

If we only select those communities that are "ready" to offer the intervention first, then the less ready communities will always serve as controls, therefore perfectly confounding intervention status with readiness.

2) In the time cast design, how do you deal with a group that doesn't have a stable baseline when it's their turn to get the intervention?

This should go in the modeling, for example by modeling the developmental trajectory at the organization level in growth models, allowing a separate parameter for the variation in this baseline period, in pieces, for example, pre-intervention, during intervention, and after intervention. In growth modeling there are 3 standard ways the implementation can change outcome, the simplest is that there is just a difference in the mean of the growth trajectory, i.e., intervention causes more rapid change. The second is that the intervention affects the slope differently as a function of baseline, e.g., it may be that only those organizations that have a climate more inducive to implementation are ones that benefit from an implementation strategy. Third, there may be changes not just in the mean change or slope, but also in the variance, as this question suggests (i.e., variability may be important not just in baseline).

3) Is stepped wedge RCT another term for your roll-out RCT?

Yes. This idea was apparently first used in Cook and Campbell, 1979, but there are lots of times this design has been used without the name stepped wedge. Sometimes people use the name "stepped wedge design" even if timing is not randomized, which to me might better be called a multiple baseline study.

Here are a couple of relevant papers:

Hussey MA, Hughes JP: Design and analysis of stepped wedge cluster randomized trials. Contemparary Clinical Trials 2006. doi: 10.1016/j.cct.2006.05.007

Brown CH, Wyman PA et al. (2006). Dynamic wait-listed designs for randomized trials: new designs for prevention of youth suicide. Clinical Trials, 3, 259-271.

4) How should one determine the time period between additional rollouts, and how does this affect the analysis. Does it have anything to do with the time it takes for the intervention to be fully implemented? Or is that an independent issue?

In the work that I have done, the timing depends more on logistical issues, i.e. how long it takes to train or implement, but it clearly does affect power. In the work of Brown et la. (2006) Clin Trials and following, we have actually used every new training that occurs as a factor in the analysis, even if there are multiple trainings that occur at a single school once randomized.

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5) Also, what are the implications of a larger number of rollouts with smaller number of organizations in each wave, versus a smaller number of roll-outs with a larger number of organizations per roll-out?

Our calculations in Brown et al. (2006) Clinical Trials show pretty clearly that there is a large gain going from a standard wait-list (2 cohorts), to even 3 or 4 cohorts. But an additional gain with lots of time points that get randomized is the opportunity to control bias that might come from external factors.

6) So in summary, is it correct that having lower level randomization has more power than higher level randomization (as long as the variability between lower levels is low)

Yes, the statistical power for lower level randomization is very often much higher, even with a small number of lower level units per higher level. Also see Brown & Liao, 1999.

7) Do you have any suggestions for determining on which criteria to pair experimental and control groups (e.g., socio-economic status, urban vs. rural setting)? How do you decide which are the most important factors for determining similarity?

I would start with theoretically driven factors, and then add practical ones; the ones we used in the suicide roll-out effectiveness trial were high school vs. middle school and number of referrals in the previous year regarding suicide, the variable we wanted to change through our intervention. It would be possible to include some measures of context such as "readiness" but probably this is not really helpful unless you are confident you can measure this precisely enough.

8) Implementation studies in healthcare delivery often involve organization-level interventions, such as introduction of a new care model or other reorganization of care delivery processes, or delivery of group-level education and attitude-change strategies. The desired practice change is at the level of the individual clinician, however. Do we gain anything in statistical power by analyzing at the clinician level but adjusting for the organization-level clustering?

There are some important limitations about this clinical level analysis that adjusts for organize level clustering.

This won't allow for evaluation of the implementation components aimed at the organizational level.

If there is randomization at the level of the organization but analyzed at the level of the clinician, there can be a big cost in power relative to a design that randomized clinicians within organizations. But that's not always possible.

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9) In your experience are grant reviewers aware of these issues and accepting of "weaker" designs (such as roll-out or wait-list designs) or do they display more of a knee-jerk reaction that anything other than an RCT is flawed, despite the fact that randomized designs are essentially infeasible for the types of research questions you are addressing? How can we educate reviewers?

Good point, I think as implementation scientists we need to develop a strategy for this. One of the things I am trying to do is have the IOM commit do a new committee on Implementation Science. This might be of help. I think we need some key publications that lay these out for the field. Sound like a debate that would be interesting for Implementation Science?

10) Your work and many of the examples you cited involve communities, schools and other entities. Are there any differences to consider as we plan studies within a large healthcare system like VA, consisting of hundreds of hospitals and clinics?

I do think there are some major differences, but don't feel fully clear about them. One of the things that I found that distinguishes the settings that Patti C uses for foster care (which in my untutored view may be somewhat like the VA), and prevention in schools, for example, is that the programs that get implemented have different roles: for prevention the programs are often brought in to address distal outcomes that are not the primary mission of the organization; for social and health service systems we are often focused on the primary mission. This means the strategies for keeping such programs sustained over time, as well as adoption and fidelity, are often different.