

Randomized Implementation Trials: Experience from the CAL-OH Project

1



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2

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3

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Outline

4

- 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

5

- **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

6

- 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

7

338 Papers

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

8

- **Example: A Multiple Baseline Study Design**

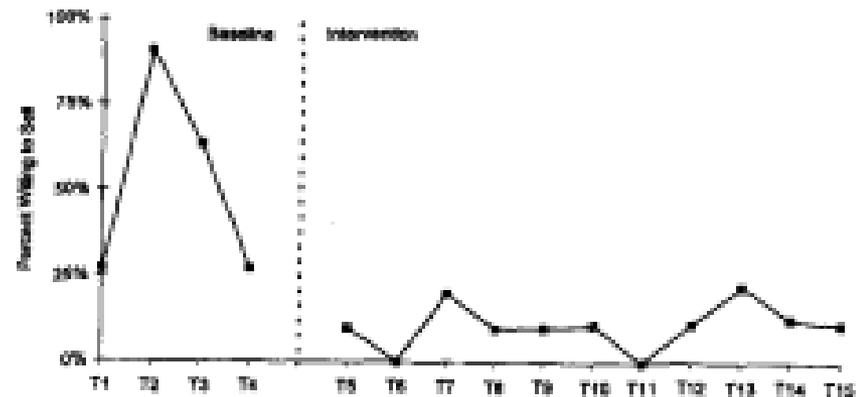
Biglan et al., AJCP 2006

9

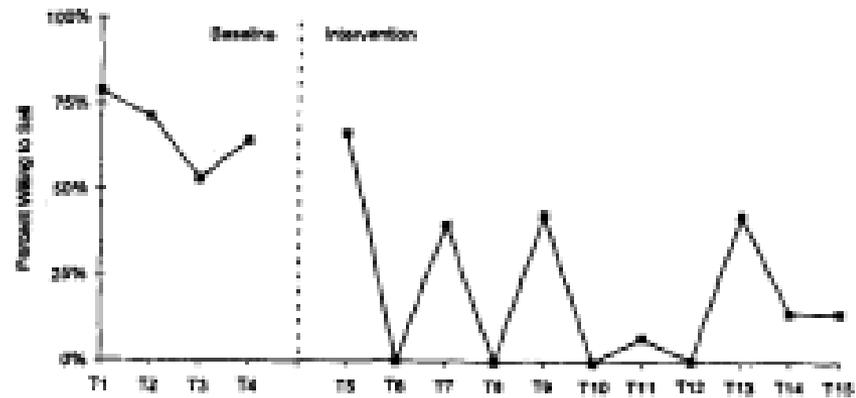
Illegal Tobacco Sales

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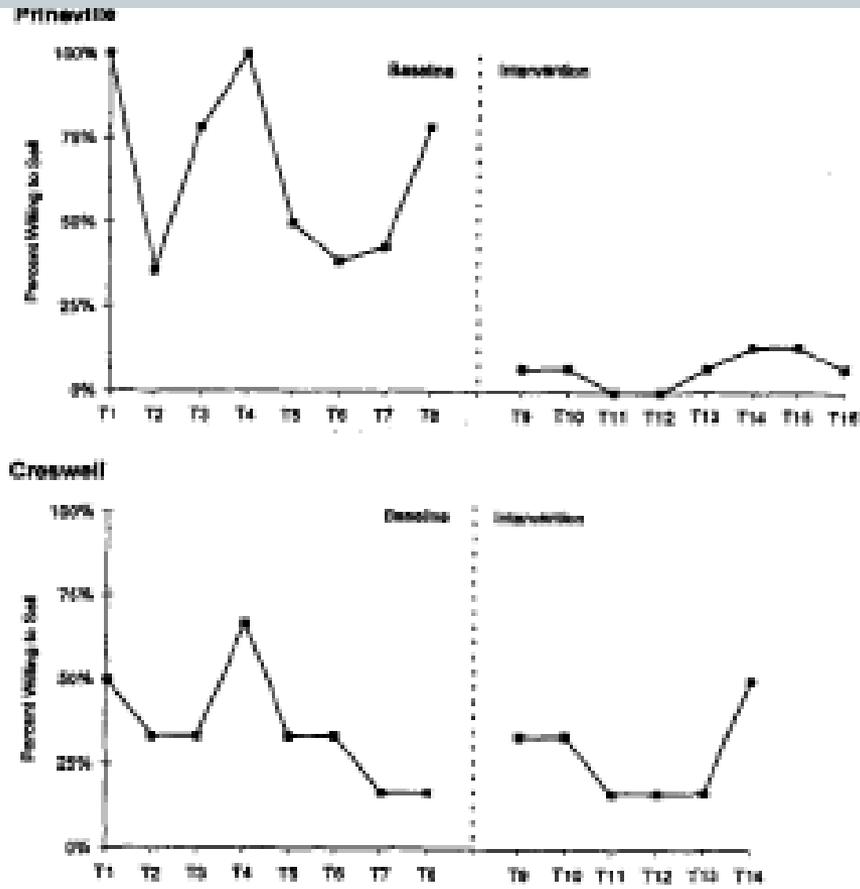


Sutherland



Other Communities

10



Inferential Challenge when Timing is Not Randomized

11

- **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**

12

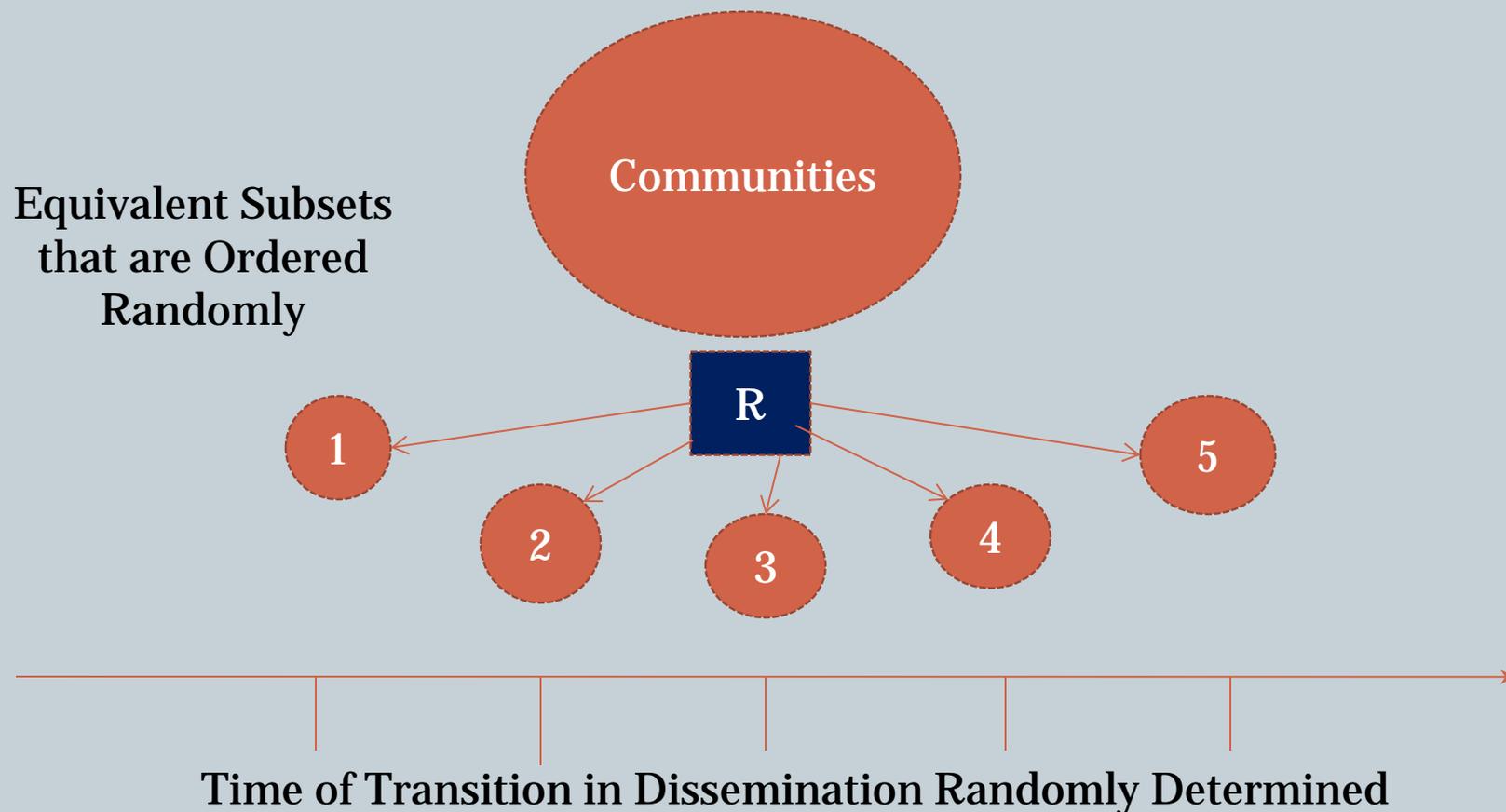
ROLL-OUT DESIGN

- 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)

13



Timing of Implementing (0 to x)

14

- 1 0 0 x x x x x 0 - baseline no tx
x - implement
- 2 0 0 x x x x
- 3 0 0 x x x
- 4 0 0 x x
- 5 0 0 x

Some Reasons to Consider Randomized Assignment

15

- **Statistical Advantages**

Statistical Precision/Power

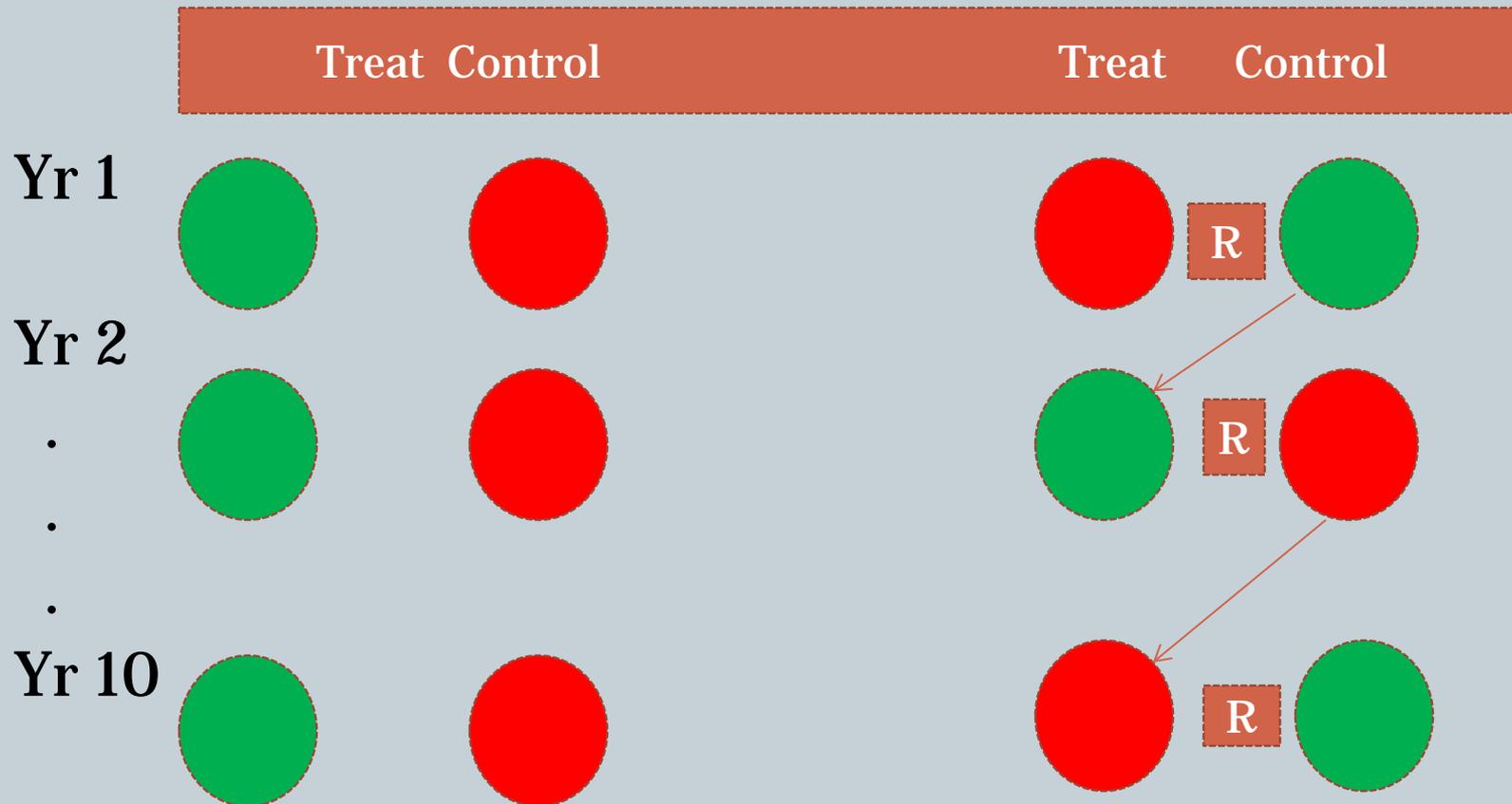
Reduces Bias

Ability to Combine / Synthesize Findings Across Time

Random Assignment Reduces Bias in the Long Run

16

- Example: mPowerment Community Intervention



Implication of Roll-Out Designs for Community Research

17

- **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

18

- 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

19

System to Support Adoption

Control

Intervention

Old System to Support Adoption

Intervention

New System to Support Adoption

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

20

- **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

21

- **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

22

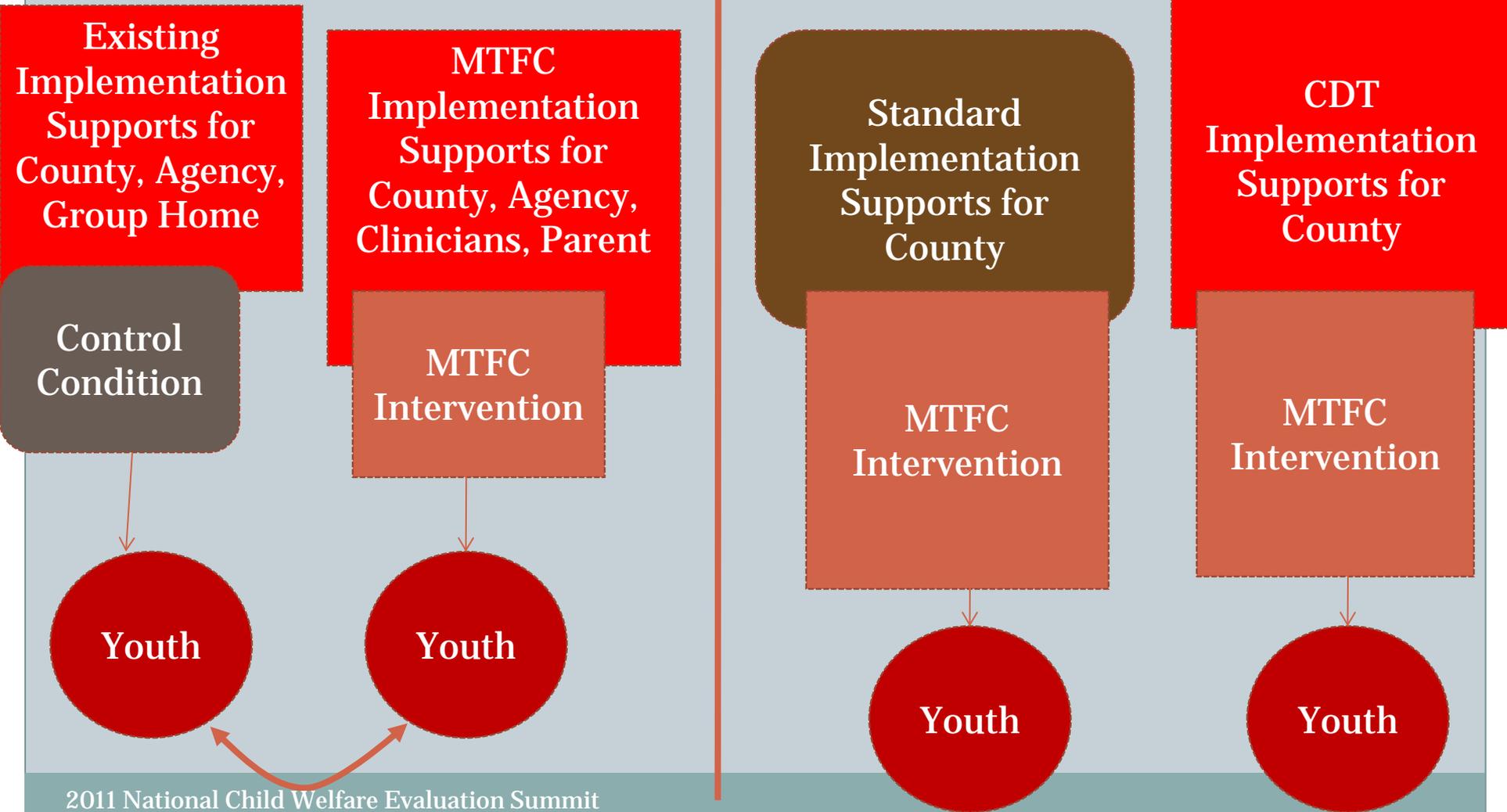


Illustration of the CAL-OH Randomized Implementation Trial

23

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

24

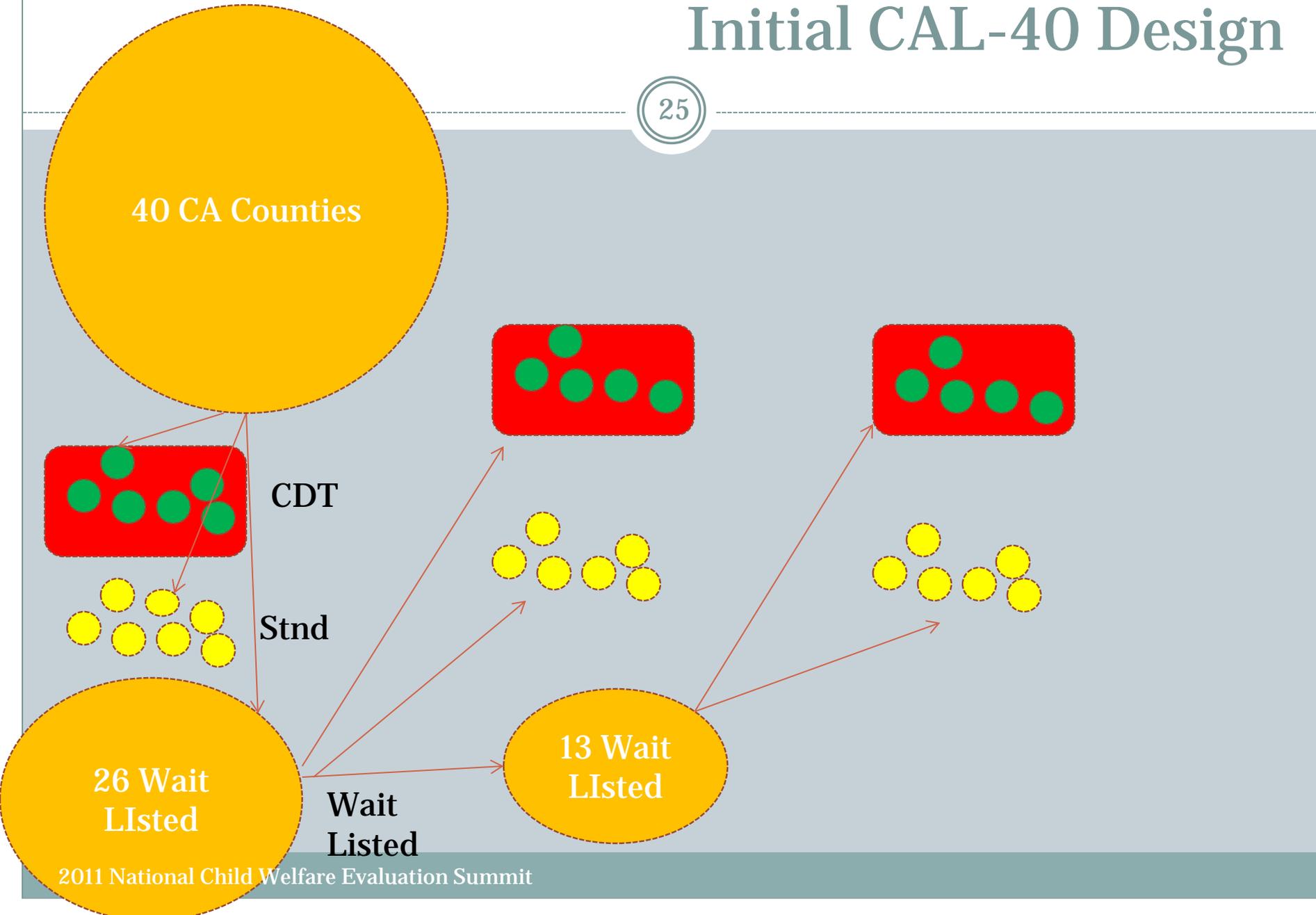
How fast do counties in the two conditions

Adopt

Implement with fidelity

Sustain the intervention ?

Initial CAL-40 Design



Issues in the CAL-40 Design

26

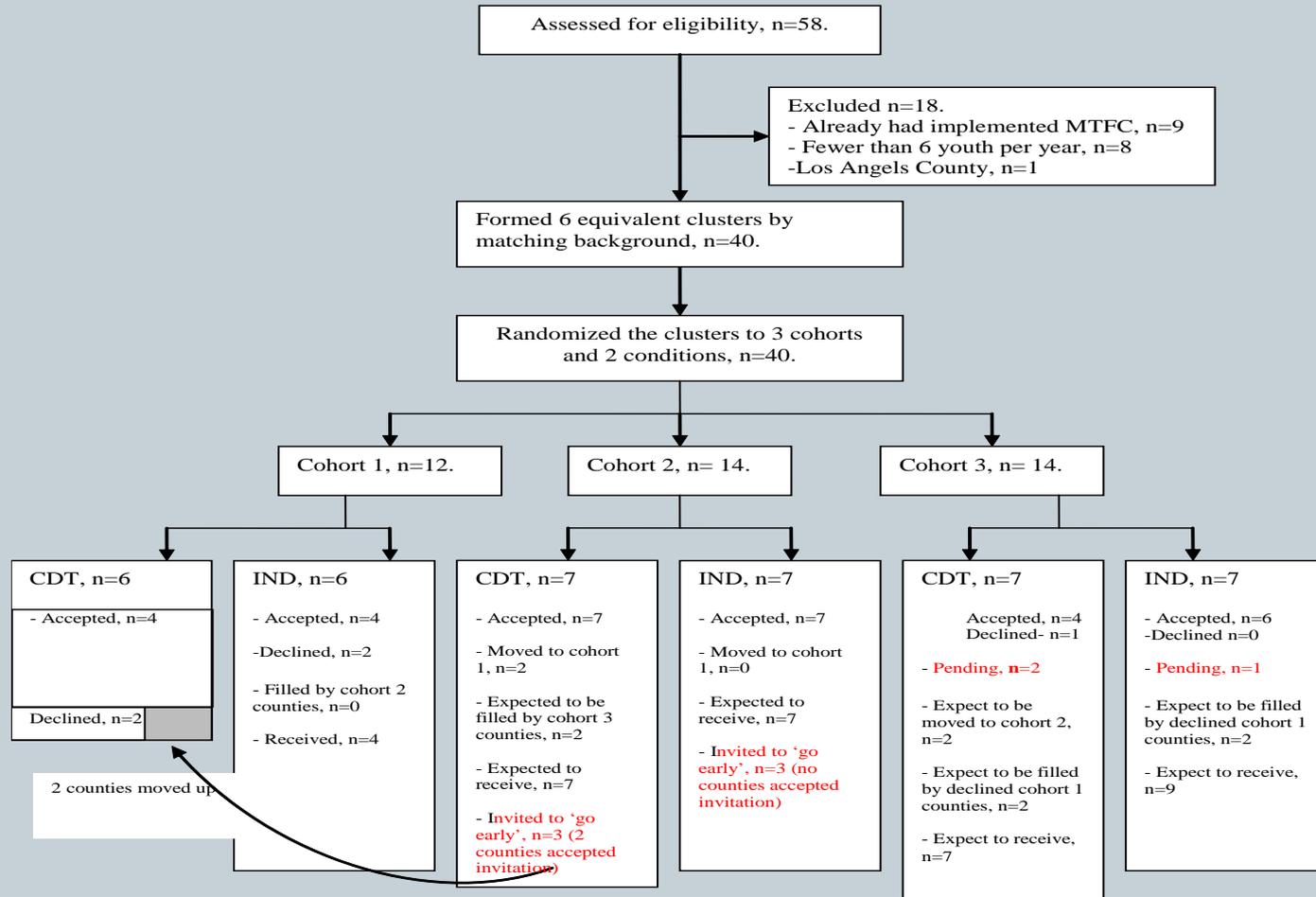
1. Acceptance of the Design was Complete
2. Some Counties Were Not Ready to take Part
Moved Up Counties from Next Cohort, but
remained in same implementation condition

Chamberlain et al., In press

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

27

Consort Diagram



Exogenous Factors in a Roll-Out Trial

28

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

29

- **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**

Advantages of “Roll-Out” Designs

30

- **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