

Community Engagement in Hybrid Effectiveness-Implementation Studies

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HEALTH
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Shout out!



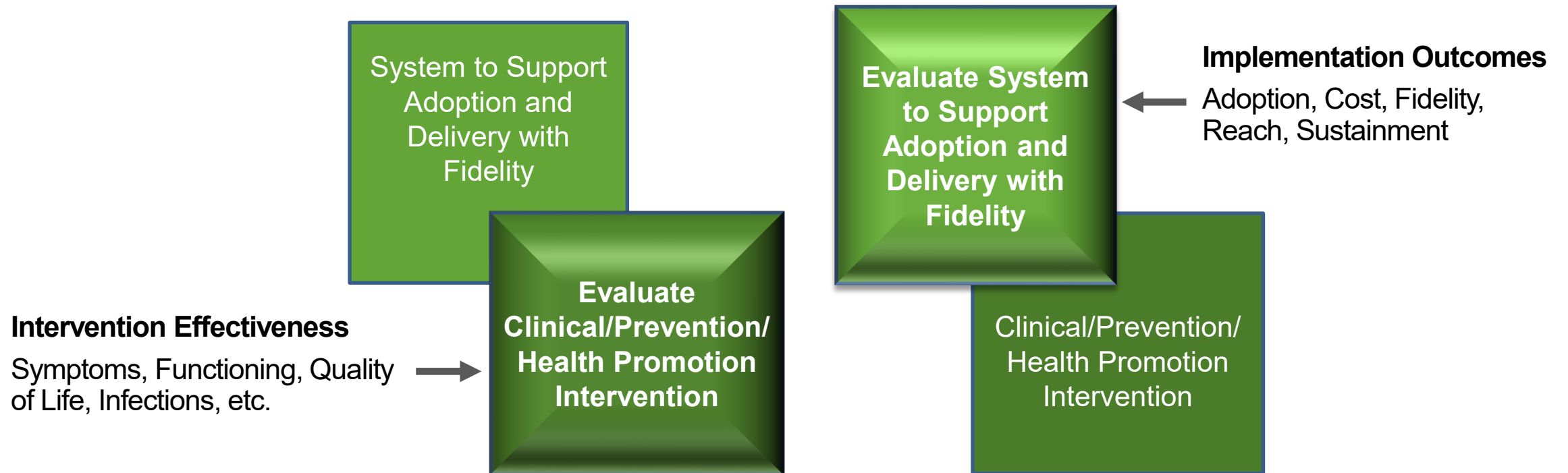
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Paradigm Shift

Implementation strategies are methods or techniques used to enhance adoption, implementation, sustainment, and scale-up/out of an EBI

- They do not have a direct effect on client/patient-level health outcomes



Why Hybrid Studies?

Can we hurry up please?

- Sequential examination can be slow

Don't wait for "perfect" effectiveness data before moving to implementation research

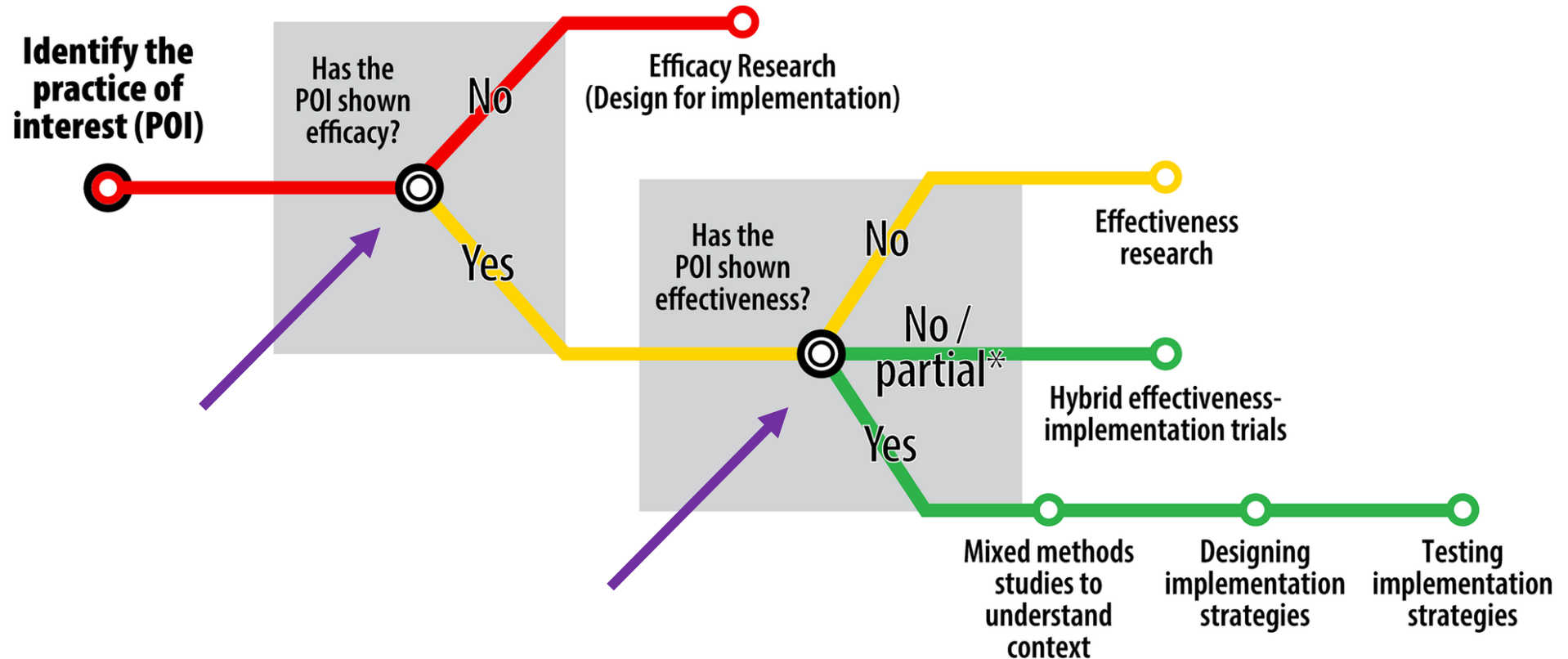
- We can "backfill" effectiveness data while we test implementation strategies

How do intervention outcomes relate to levels of adoption and fidelity?

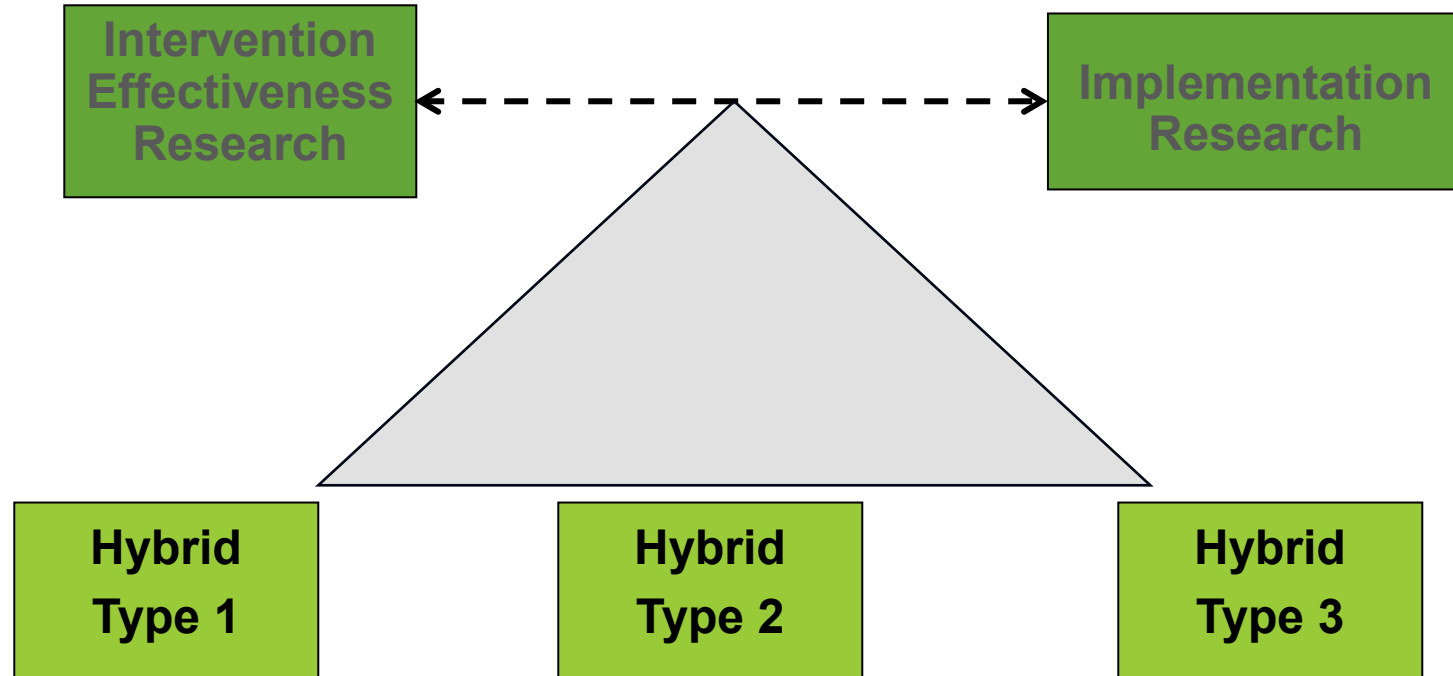
- How will we know this without data from "both sides"?

Hybrids help identify the knowledge gaps for the intervention of interest

What is it that you still need to know about “the thing”?



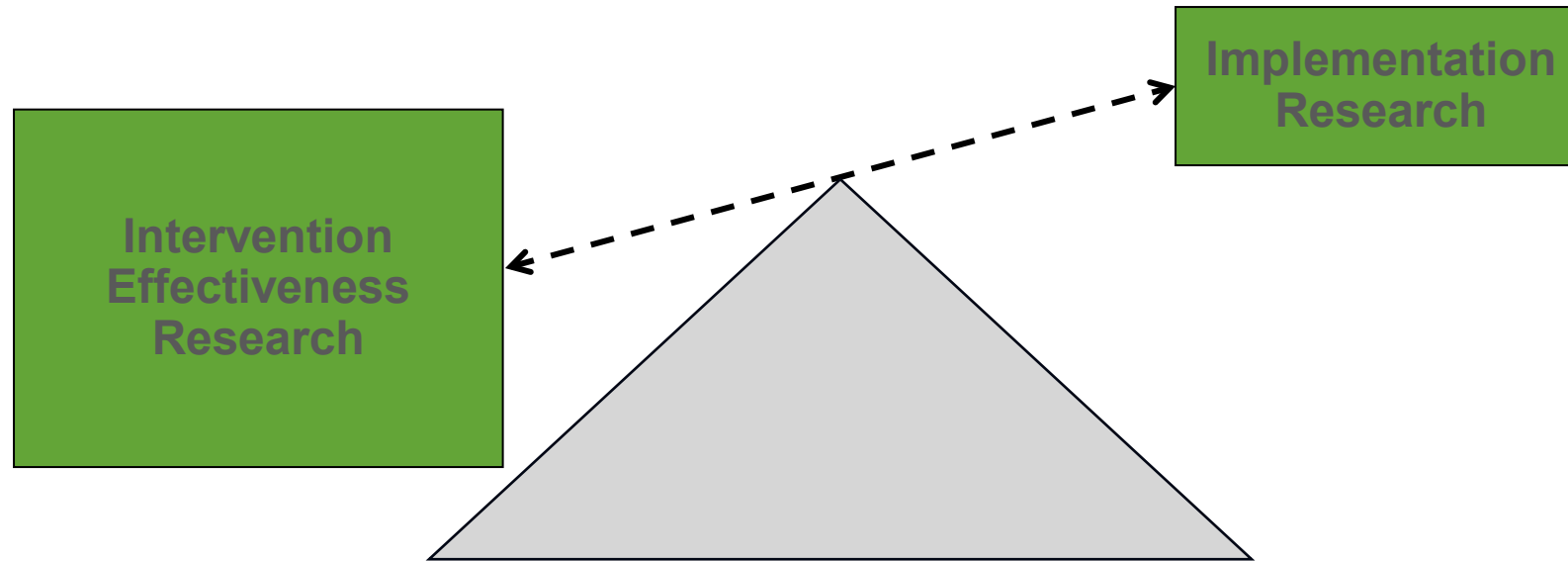
Hybrid Typology Continuum



Research Aims by Hybrid Study Type

Study Characteristic	Hybrid Type I	Hybrid Type II	Hybrid Type III
Research Aims	<p>Primary Aim: Determine effectiveness of an intervention (e.g., symptom change, parenting, etc.)</p> <p>Secondary Aim: Better understand context for implementation (e.g., barriers, acceptability, feasibility)</p>	<p>Primary Aim: Determine effectiveness of an intervention</p> <p>Co-Primary* Aim: Determine feasibility and/or (potential) impact of an implementation strategy</p> <p>*or “secondary”...</p>	<p>Primary Aim: Determine impact of an implementation strategy (e.g., reach, sustainment, adoption, cost)</p> <p>Secondary Aim: Assess clinical outcomes associated with implementation (e.g., functioning, parenting, etc.)</p>

Hybrid Type 1



Hybrid Type 1: “test”
intervention, gather information
on implementation

- Often a person-level RCT for intervention (“classic”)
 - Primary outcomes = intervention effectiveness
- PLUS implementation-focused process evaluation
 - “Implementability” of the intervention
 - Implementation determinants (B/Fs...)
- Often mixed methods
- NOT an explicit evaluation of “real world” implementation strategies
- Use data to prepare for development of future implementation approach

Hybrid Type 1 Considerations

All effectiveness trials use “implementation strategies” to support the delivery of the intervention, we just usually don’t call them that

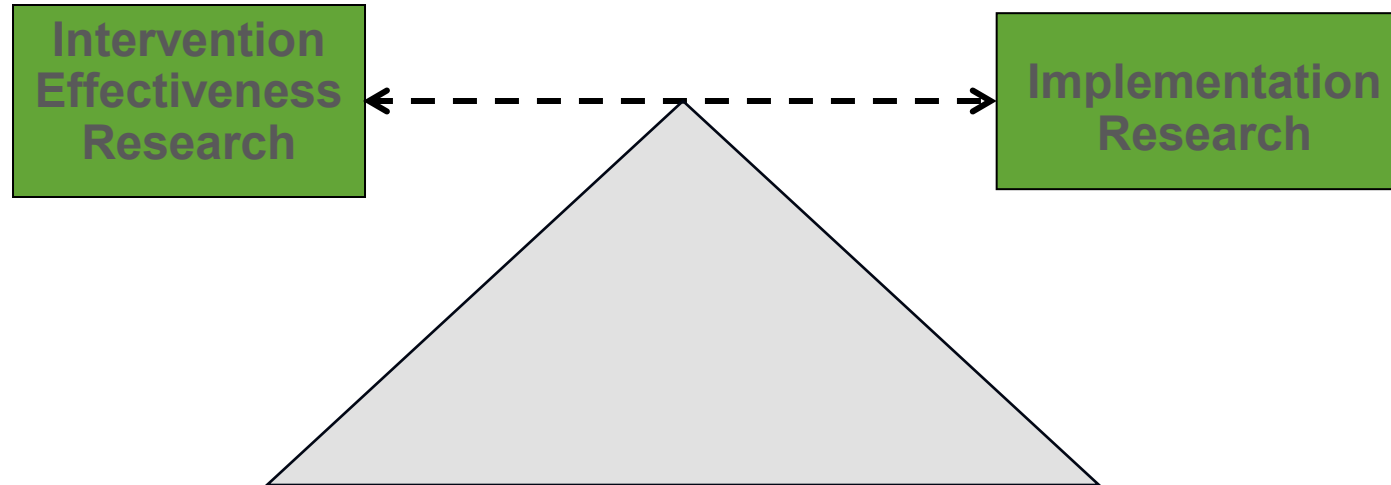
The are normally resource-intensive

- Paying clinics, paying interventionists, paying for care, frequent fidelity checks and intervening when it goes south...

We “know” that some/many the strategies used in effectiveness trials are not feasible for supporting wide-spread adoption

But, we can learn from the use of those strategies during the study

Hybrid Type 2



- Examining the performance of an intervention and implementation strategy simultaneously
- Implementation strategy is explicitly hypothesized to be “real world” ready
- Summative implementation outcomes like *reach*, *adoption*, *fidelity* are measured

Hybrid Type 2: “test” the intervention and the implementation strategy

- “Pilot” version (for implementation strategies)
 - Person-level RCT
 - “One arm” study of implementation strategy
- “Dual randomized” version
 - Testing/Comparing interventions and implementation strategies
 - Person- and place-level randomization

Hybrid Type 2 Considerations

Research design, not the hybrid type, dictates which outcome should be powered (effectiveness > both > implementation)

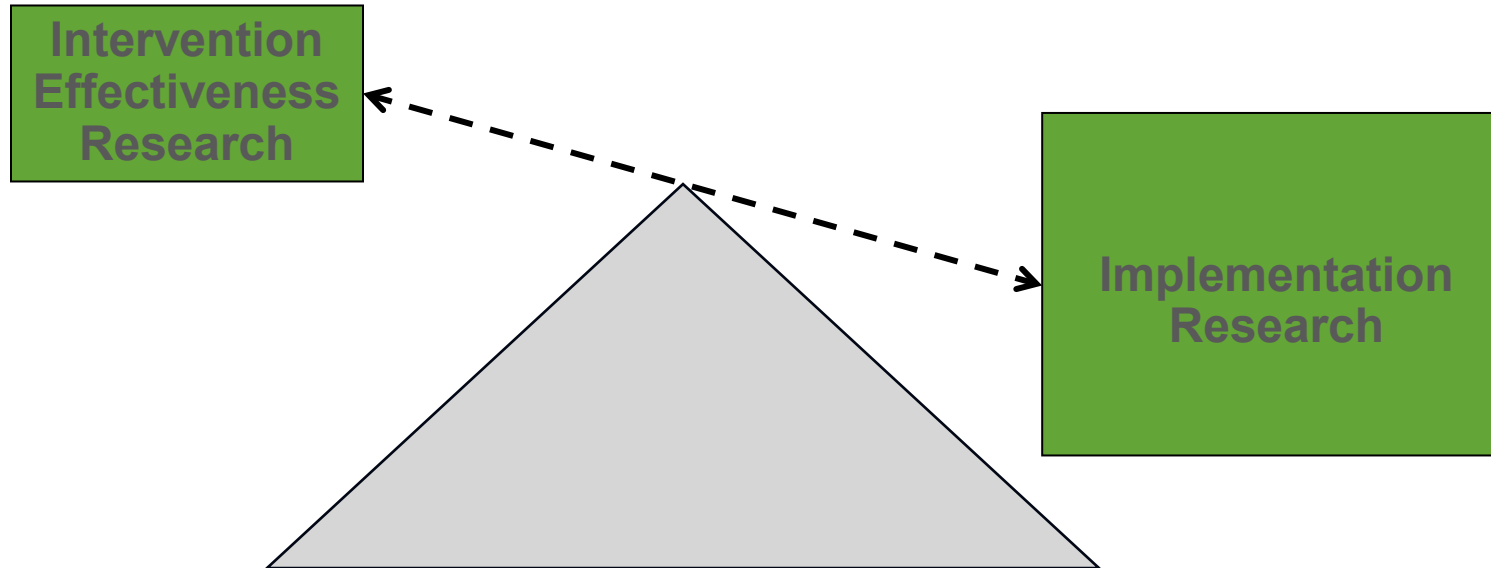
Important to have an explicitly described implementation strategy that is thought to be plausible in the real world

- Clear distinction from type 1

Explicit measurement of adoption, fidelity...

- Always happens in type 2

Hybrid Type 3



- Often cluster RCT for implementation strategy (“classic”)
 - Primary outcomes = implementation
- Intervention outcomes are secondary
- Stepped Wedge common
- Roll-out designs emerging
- Depending on type of intervention, collection of intervention effectiveness outcomes can be challenge
- Cost outcomes increasingly included
- Mechanisms (of strategies) analyses emerging

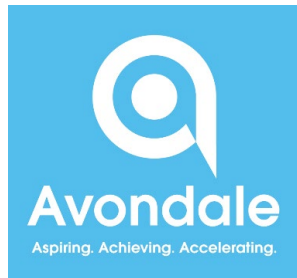
Hybrid Type 3: “test” implementation strategy, gather information on the intervention effectiveness



Family Check-Up 4 Health Program of Research

COMMUNITY ADVISORY BOARD (CAB)

Implementation Partners



Member Organizations



CAB Activities and Process

Established: 2014

Membership: 60+ individual members, 10+ implementation partners, ~25 organizations

Frequency: 2X Yearly, ~3hrs

Format: In-person → Virtual → Hybrid

Activities:

- Study findings report back, trouble shooting, sharing of lessons learned
- Members share with CAB (new programs, initiatives, etc.)
- Workgroups & Publications
 - Adaptation for sustainment: Berkel et al. (2020), *J Community Psychology* (3 CAB co-authors)
 - Economic analyses: Jordan et al. (2019), *Prev Sci*, & Harris et al. (2022), *Implement Sci Comm* (2 CAB co-authors)
 - Equity in outcomes: Berkel et al (under review) (8 CAB co-authors)

Type 2 Example

RAISING HEALTHY CHILDREN STUDY



Specific Aims

Aim 1

Finalize the adaptation of the FCU4Health, which was initially adapted and piloted in pediatric primary healthcare, based on input from a community advisory board (CAB) and partner clinics.

Aim 2

Evaluate the implementation outcomes of two delivery strategies: integrated/co-located care and coordinated care with referral.

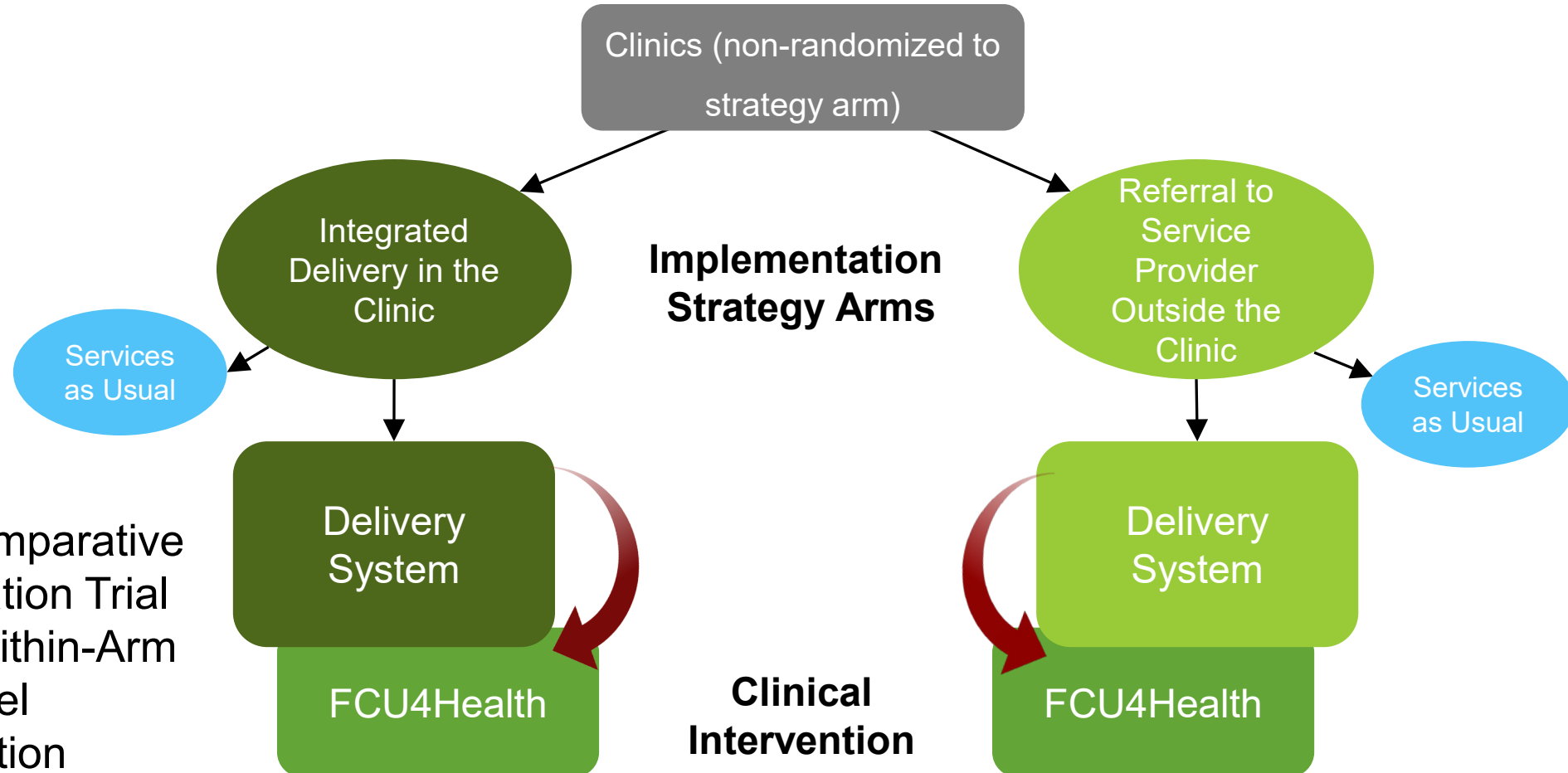
2a. Evaluate fidelity over time to the FCU4Health using a validated observational rating system and develop and test an automated fidelity coding system

2b. Employ behavioral intervention costing methods to evaluate the costs of installing and delivering the FCU4Health and conduct a cost-benefit analysis to evaluate the monetary benefits of program effects.

Aim 3

Test intervention effects on primary and secondary outcomes. Effects on proximal outcomes will be tested as mediators on the distal outcomes of child BMI and body composition.

Type 2 Example: FCU4Health



Design: Comparative Implementation Trial Involving Within-Arm Patient-Level Randomization



Type 3 Example

PREVAIL



Specific Aims

Aim 1

Examine the impact of strategies on implementation and child health outcomes. Test the effects of implementation strategies on:

- Aim 1a. implementation outcomes: MI fidelity ratings, parent home practice (engagement)
- Aim 1b. clinical outcomes: child and family health behaviors and child BMI

Aim 2

Determine the budget impact and cost-effectiveness of *implementation strategies*.

Aim 3

Evaluate the association between improvement between health behaviors and BMI. We will examine the association between improvements in health behaviors and changes in BMI from baseline to the 18-month assessment and examine the moderating role of baseline characteristics.

Study Design

12 behavioral health (BH) care teams

- ~10 BH clinicians in each team (n=~150 clinicians w/turnover and team expansion)
- Teams randomized to strategy conditions →
- All clinicians offered training

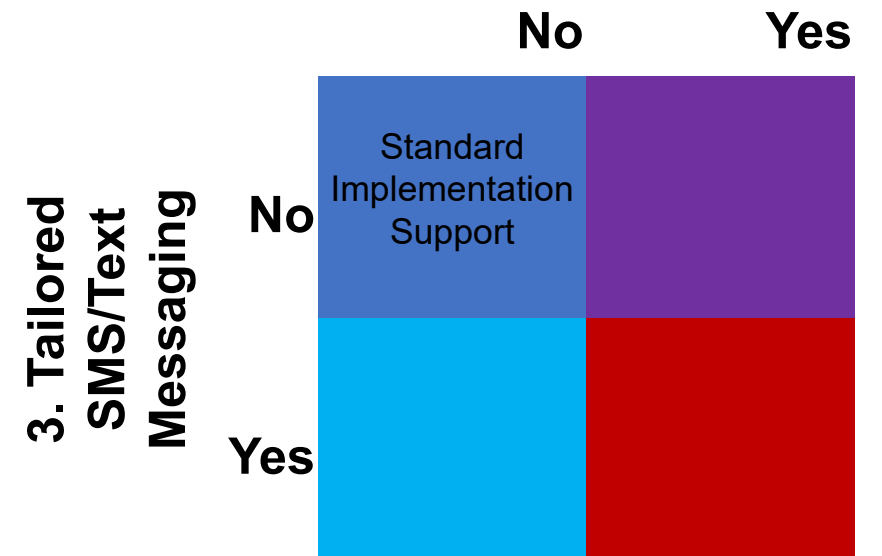
Enrollment & Inclusion

- All children ages 2-17 years in BH

FCU4Health is individually tailored based on ecological family assessment data to be “precision prevention”

Cluster-Randomized Multi-Level 2X2 Factorial

**2. Automated Fidelity
Monitoring & Feedback**



1. Clinical Decision Support Tool

PERSPECTIVE article

Front. Health Serv., 08 December 2022

Sec. Implementation Science

Volume 2 - 2022 |

<https://doi.org/10.3389/frhs.2022.1053496>

This article is part of the Research Topic

Hybrid Effectiveness-Implementation Trial Designs: Critical Assessments, Innovative Applications, and Proposed Advancements

[View all Articles >](#)

Reflections on 10 years of effectiveness-implementation hybrid studies



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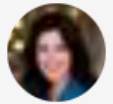
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Q1: Are they really “designs”?

Depends a bit on your definition...

Research design: Smith and colleagues defined research design as the planned set of procedures to: (a) select subjects for study; (b) assign subjects to (or observe their natural) conditions; and (c) assess before, during, and after assignment in the conduct of the study

BUT: 2012 paper’s focus on trial designs was too limiting

- Original paper talked about “where to randomize...”
- “Do they have to be trials?” No.
- Lots of folks took the basic idea and applied it to lots of research designs, program evaluation, QI, and other purposes

Let’s go with “**hybrid study**” instead

Q3: Which research design should I use?

Almost entirely depends on the research question(s)...

Research designs are not intrinsically linked to hybrid type, but...

- Type 1 studies favor intervention outcomes at a person level, so a lot of these studies have individual-level randomization or focus
- Type 3 studies favor implementation outcomes at a place level, so a lot of these studies use clustered designs or place-level focus
- Type 2 studies blend the two; hence relative emphasis tends to drive the design choice

Thank you!

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