



Multilevel, Adaptive, Implementation Strategies (MAISYs)

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Data Science for Dynamic Decision-making Center
University of Michigan

Invited Presentation
Cincinnati Children's Hospital
18 Sept 2023



Super Outline

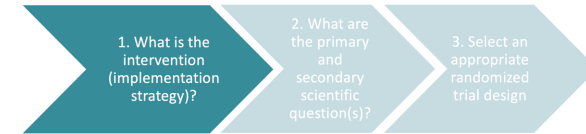
- Review: What is an intervention (e.g., an implementation strategy)?
- Review: Guidance on the Modern-day intervention Research Design Process, including how “optimization” fits into your research on adaptive interventions
- **Dr. Almirall’s MAISY Talk to be presented at Cincinnati Children’s Hospital Medical Center on Sept 18 begins on Slide 38, which lists the talk’s Learning Objectives.**

Outline of Pre-talk Slide Deck

- Review: What is an intervention (e.g., an implementation strategy)?
- Research Design Process

Outline of Pre-talk Slide Deck

- Review: What is an intervention (implementation strategy)?
- Research Design Process



What is an Intervention? “the thing”

- An intervention is an action, taken by an actor toward a target (from a population), intended to improve an outcome

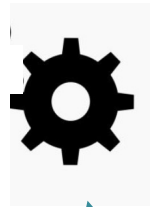
1. What is the intervention (implementation strategy)?

2. What are the primary and secondary scientific question(s)?

3. Select an appropriate randomized trial design

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Action
CBT

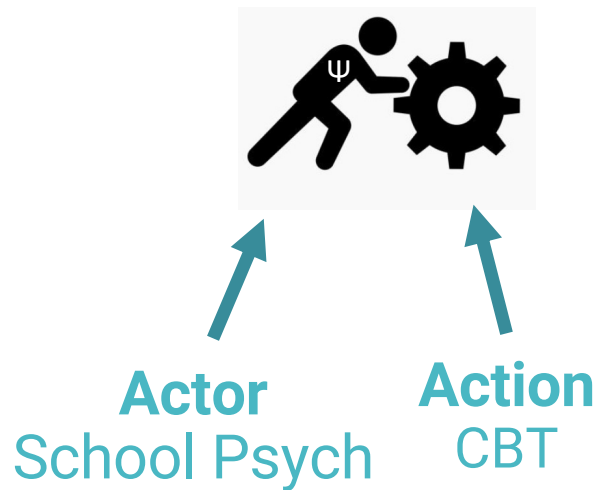
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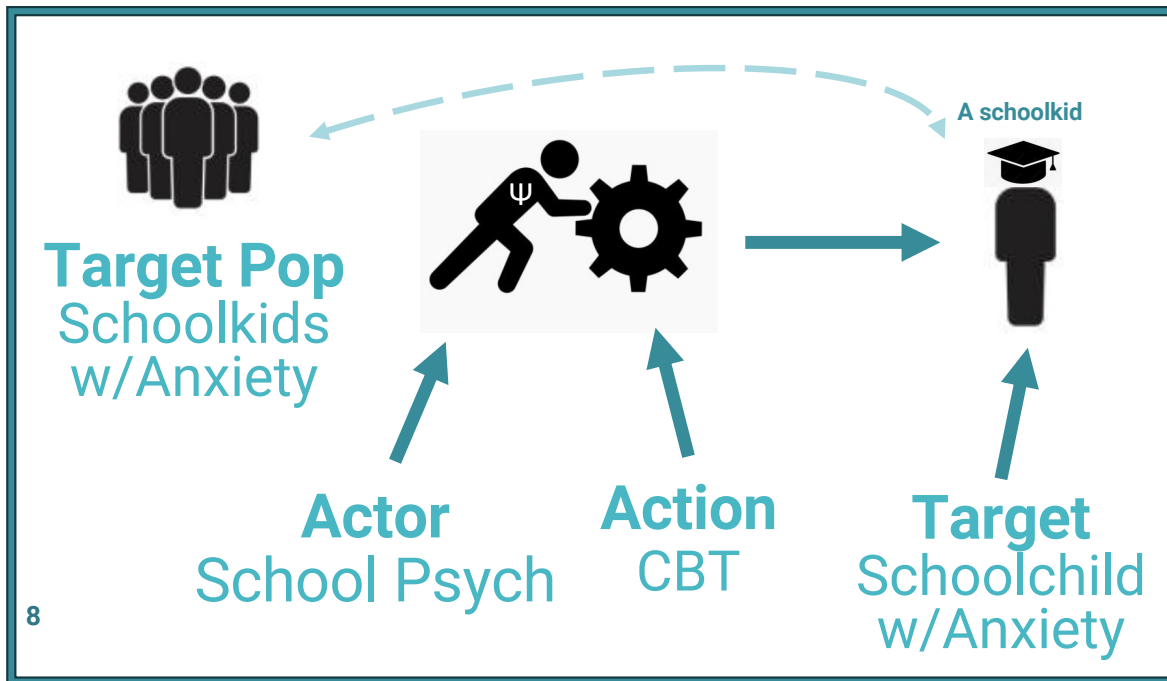
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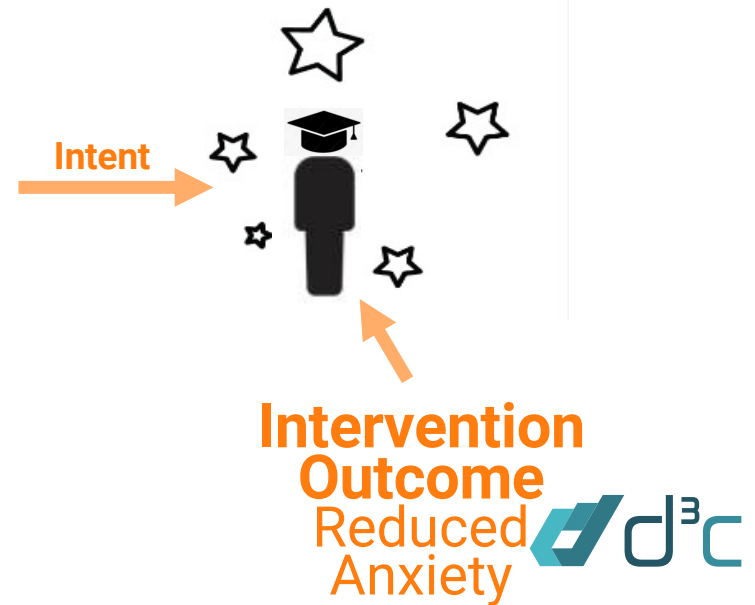
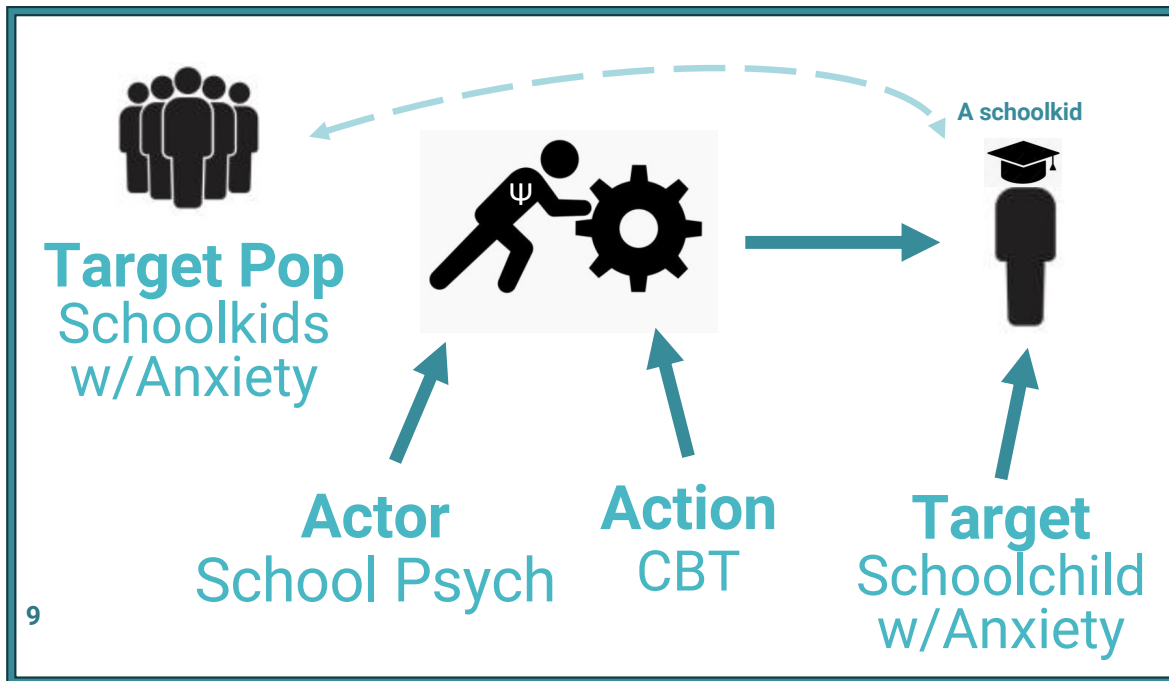
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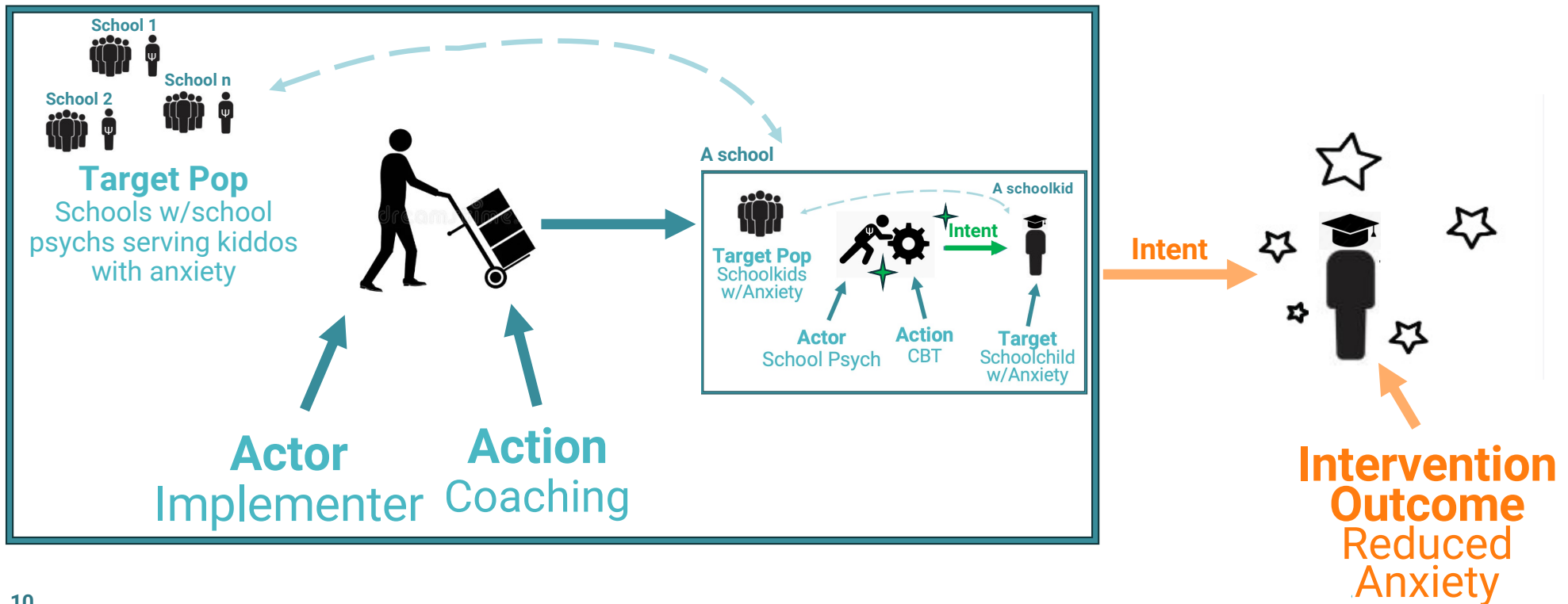


1. What is the intervention (implementation strategy)?

2. What are the primary and secondary scientific question(s)?

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An implementation strategy is a special type of intervention



Outline

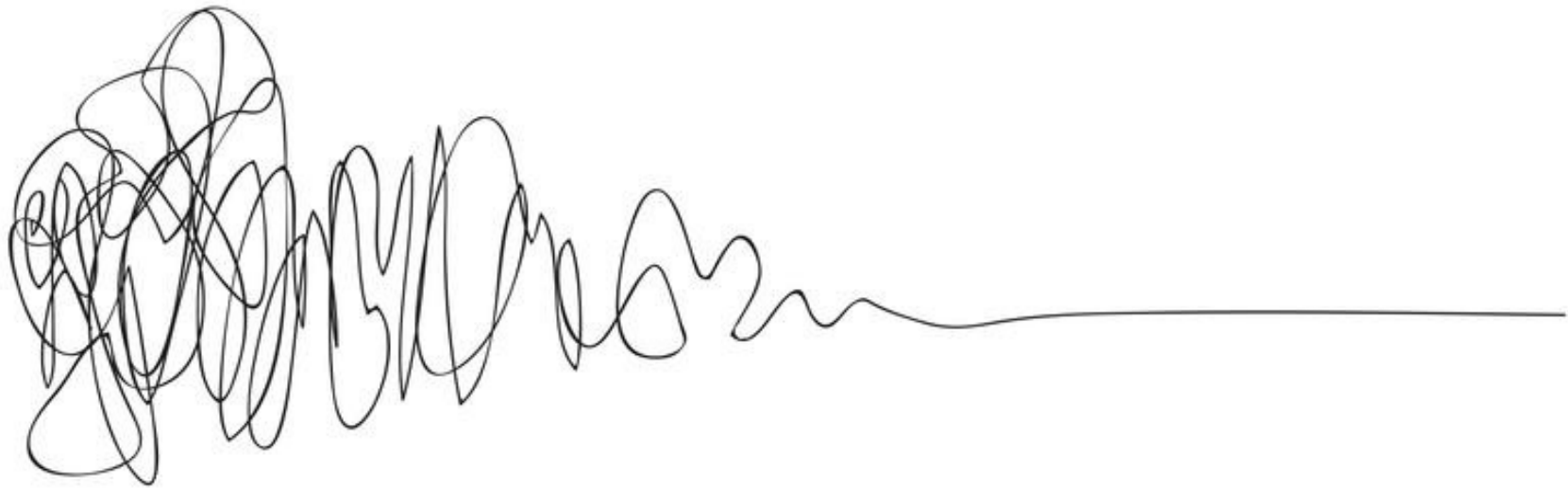
- Review: What is an intervention (implementation strategy)?
- Research Design Process

Research Design

1. What is the intervention (implementation strategy)?

2. What are the primary and secondary scientific question(s)?

3. Select an appropriate randomized trial design



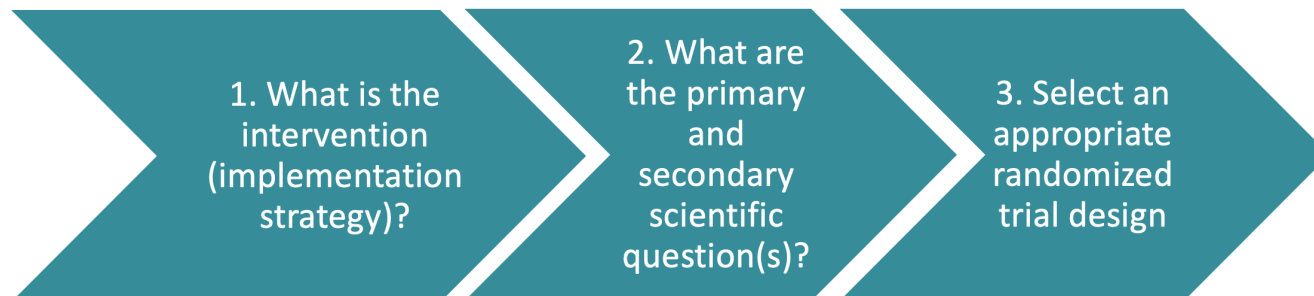
Design Squiggle by Damien Newman

Brought to my attention by Pedja Klasnja



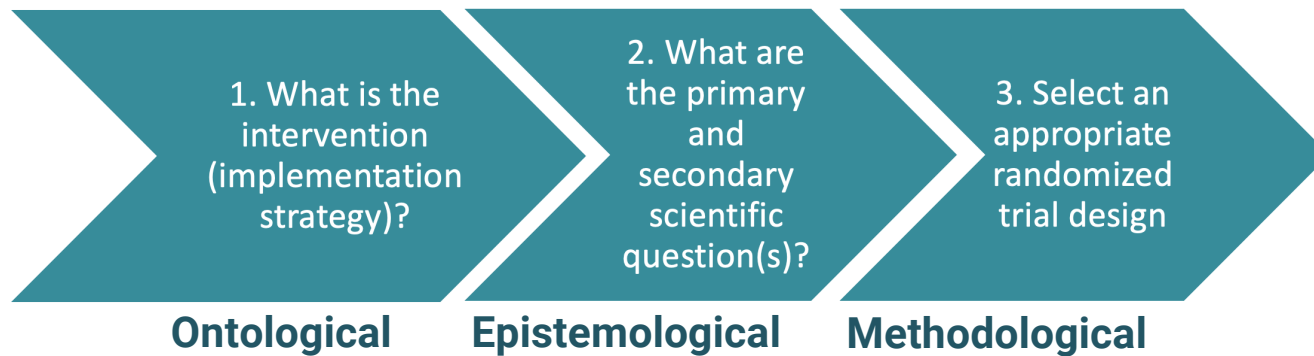
Research Design

Who? PI(s), Co-I(s), domain scientist, quant scientist, stakeholders, community co-creators, ...



Research Design

Critical Realism. This idea is courtesy of Elvin Geng.



Step 1. What is the intervention?

1. What is the intervention (implementation strategy)?

2. What are the primary and secondary scientific question(s)?

3. Select an appropriate randomized trial design



Step 1. What is the intervention?

Intervention Types
Single session intervention
Multicomponent Intervention
Adaptive Intervention
Just-in-time Adaptive Intervention
Multimodal Adaptive Intervention
...and so on...



Step 1. What is the intervention?

EXAMPLE

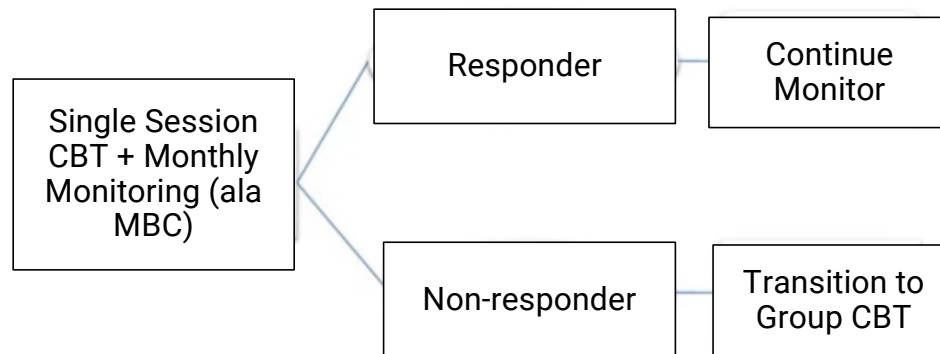
Intervention Types
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Multimodal Adaptive Intervention
...and so on...



Step 1. What is the intervention?

EXAMPLE

Action: Adaptive School-based CBT
Actor: School Psychologist
Target: Schoolkids with Anxiety
Population: Kids at school
Outcomes: To reduce anxiety --> improve academic performance





Step 1. What is the implementation strategy?

Implementation Strategy Types
Discrete implementation strategy
Multifaceted implementation strategy
Tailored implementation strategy
Adaptive implementation strategy
Multilevel adaptive implementation strategy
...and so on...

Step 2. What are the scientific questions?

1. What is the intervention (implementation strategy)?

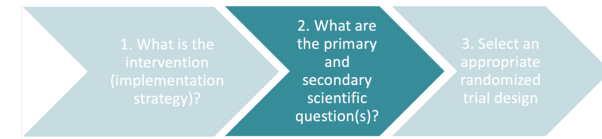
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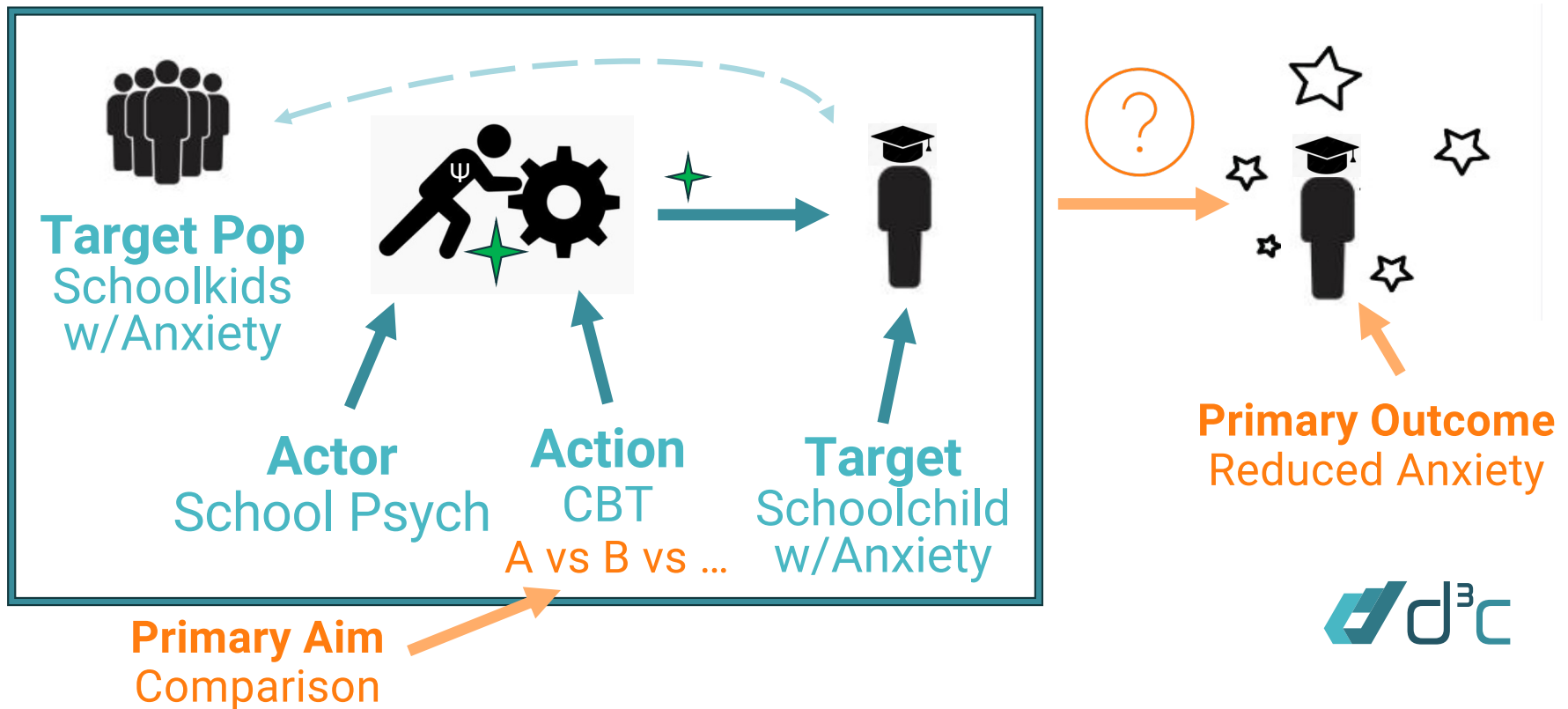


Step 2. What are the scientific questions?

Hybrid Type
(0) Intervention Effectiveness
(1) Implementation Strategy-Induced Intervention Effectiveness
(3) Implementation Strategy Effectiveness
(2) Dual Type [(1)+(3)]



Hybrid type 0: Intervention effectiveness

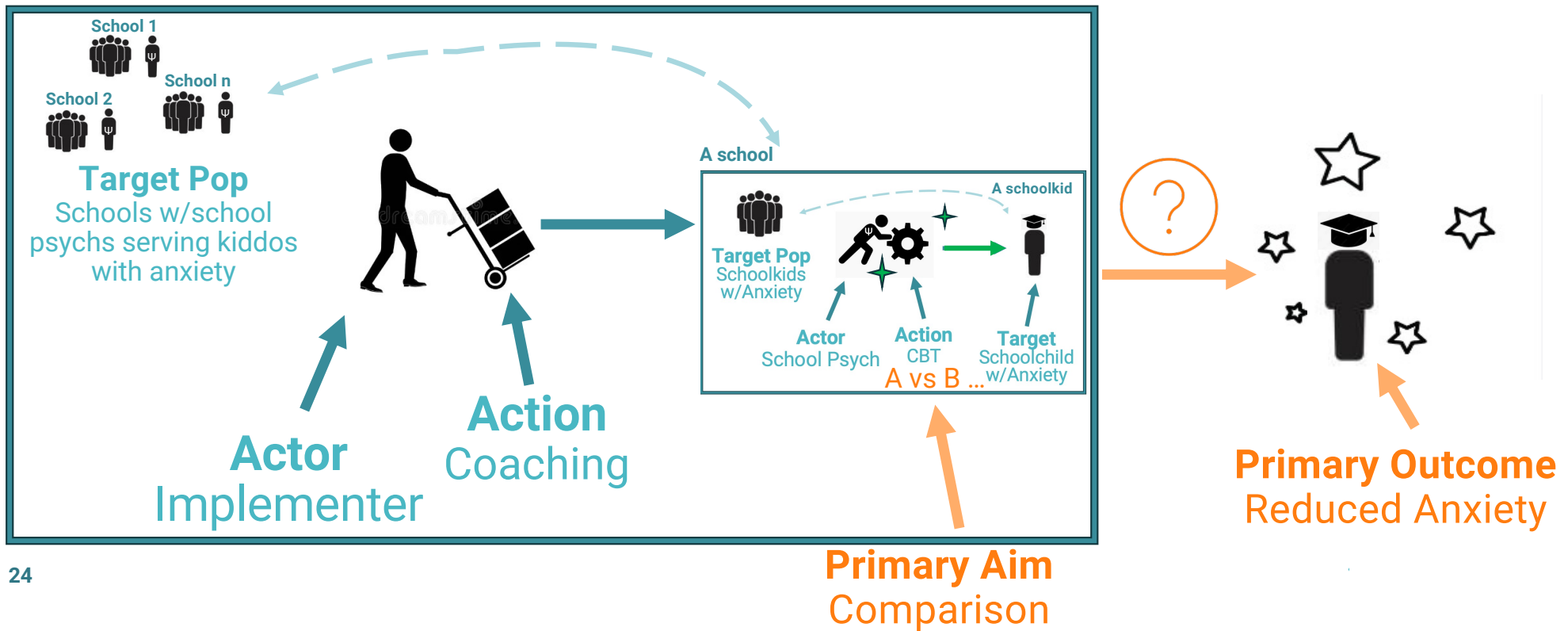


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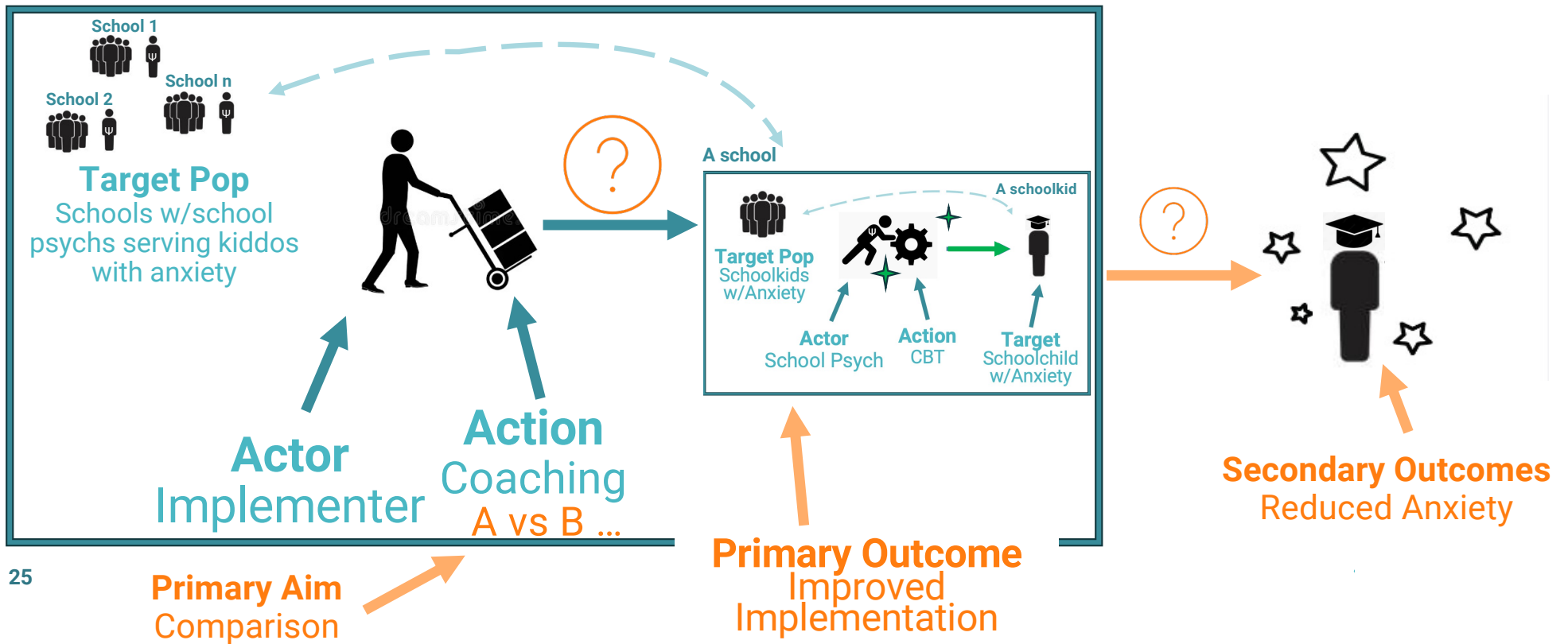
3. Select an appropriate randomized trial design

Hybrid type 1: Implementation strategy-induced intervention effectiveness



1. What is the intervention (implementation strategy)?
2. What are the primary and secondary scientific question(s)?
3. Select an appropriate randomized trial design

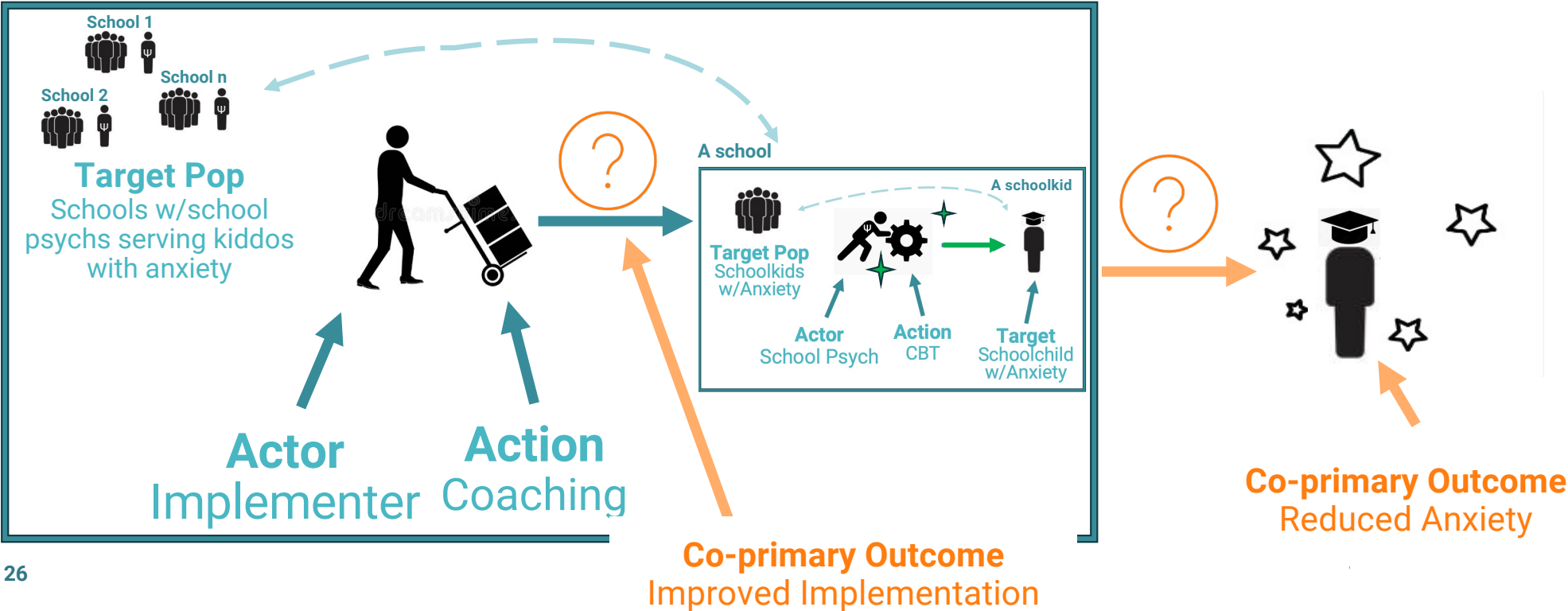
Hybrid type 3: Implementation strategy effectiveness



1. What is the intervention (implementation strategy)?
2. What are the primary and secondary scientific question(s)?
3. Select an appropriate randomized trial design

There are several possible comparisons in a hybrid type 2

Hybrid type 2: Dual-type





Step 2. What are the scientific questions?

Hybrid Type
(0) Intervention Effectiveness
(1) Implementation Strategy-Induced Intervention Effectiveness
(3) Implementation Strategy Effectiveness
(2) Dual Type [(1)+(3)]

X

Phase Type	
Prepare to Evaluate	Evaluate

In the ole days this is all we had, but things have changed for the better...





Step 2. What are the scientific questions?

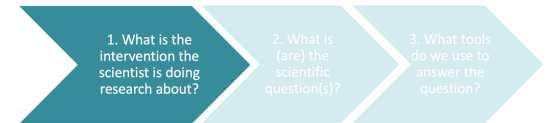
Hybrid Type
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(3) Implementation Strategy Effectiveness
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X

Phase Type	
Prepare to Optimize	Optimize
Prepare to Evaluate	Evaluate

Make the "thing" better





Step 2. What are the scientific questions?

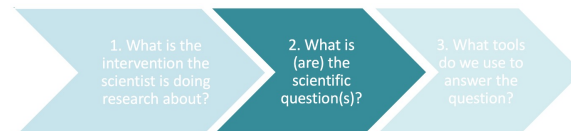
Hybrid Type
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(2) Dual Type [(1)+(3)]

X

Phase Type	
Prepare to Optimize	Optimize
Prepare to Evaluate	Evaluate

Evaluate the "thing"





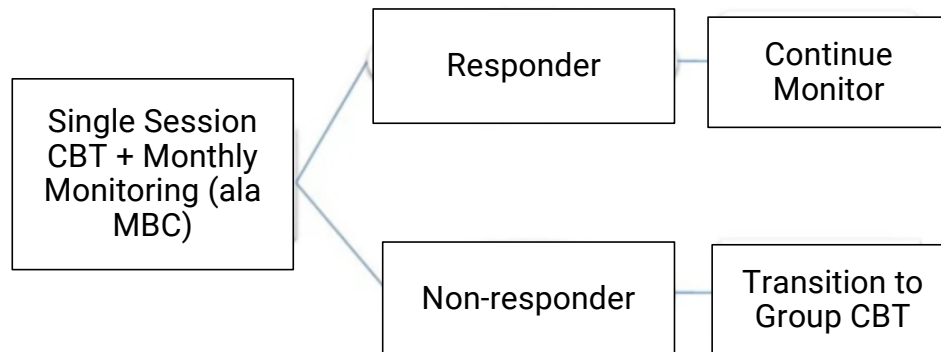
Step 2. What are the scientific questions?

Phase Type	
Optimize	Questions related to constructing the best possible intervention or implementation strategy
Evaluate	Questions relating to evaluating an already-developed intervention or implementation strategy
Prepare (to Optimize or Evaluate)	Measurement, determinants, feasibility and acceptability (i) of an intervention or implementation strategy, and/or (ii) of conducting an optimization or evaluation trial and/or (iii) so on....



Step 2. What is the question?

EXAMPLE



vs Usual Care

Step 3. What is the experimental design?

1. What is the intervention (implementation strategy)?

2. What are the primary and secondary scientific question(s)?

3. Select an appropriate randomized trial design

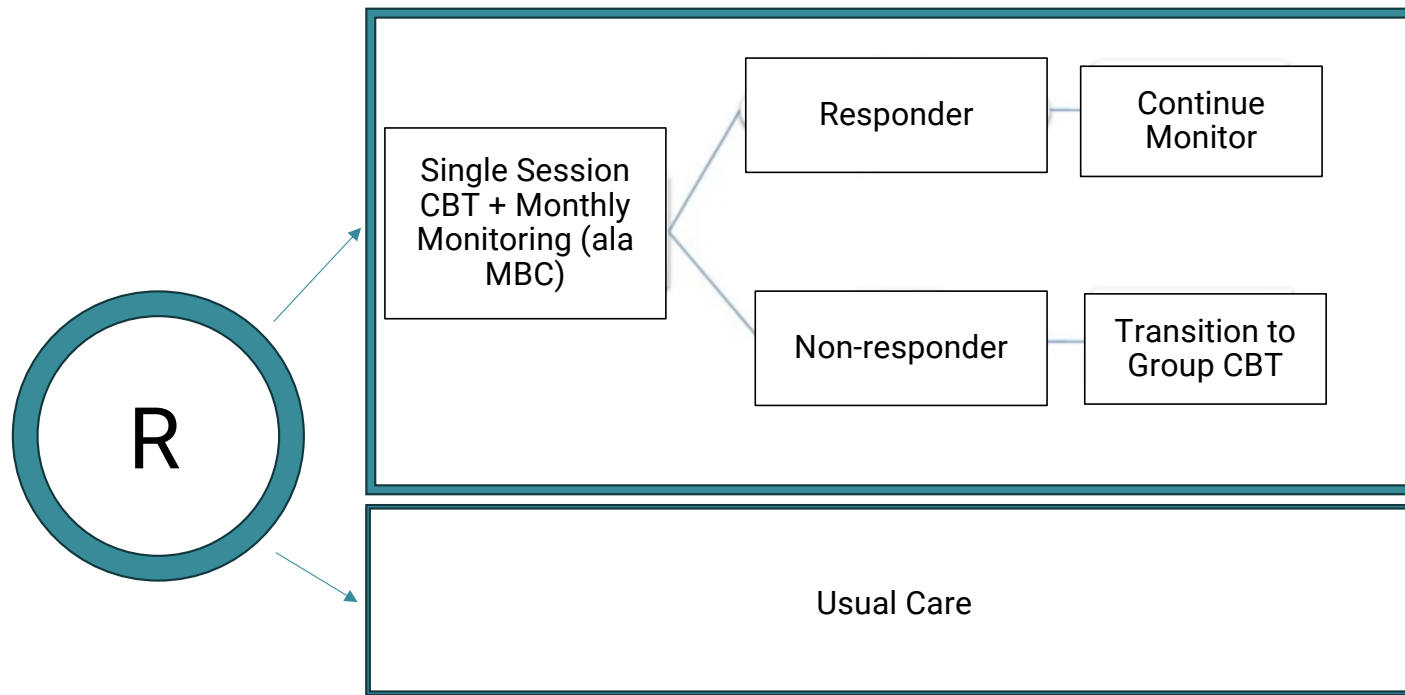
Step 3. What is the experimental design?

	Phase Type	
Optimize	Sequential multiple assignment randomized trial Multilevel SMART Micro-randomized trial Hybrid experimental design Enhanced non-responder trial ...and so on...[so many!!]	Spend a good bit of time here
Evaluate	Standard, two(multi)-arm, confirmatory RCT	Spend minimal time here
Prepare	Observational studies, Pilot randomized trials	Spend a lot of time here



Step 3. What is the experiment?

EVALUATION TRIAL



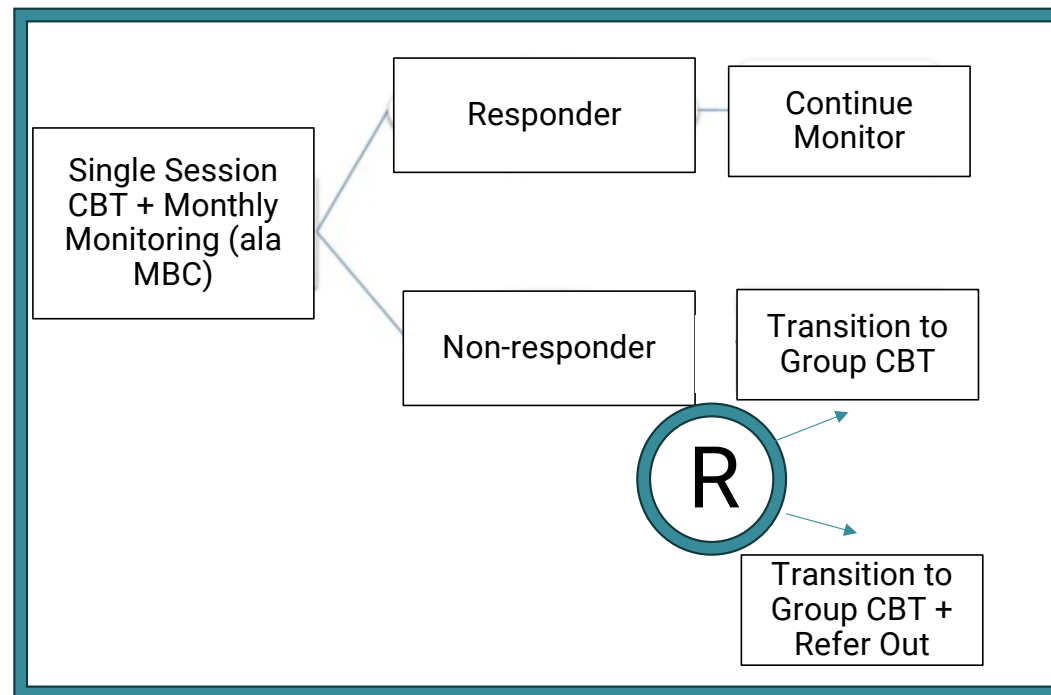
1. What is the intervention the scientist is doing research about?

2. What is (are) the scientific question(s)?

3. What tools do we use to answer the question?

Step 3. What is the experiment?

OPTIMIZATION TRIAL



Outline

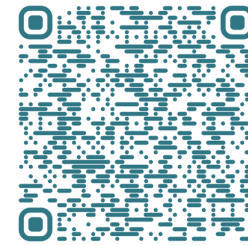
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Use these QR codes to learn more

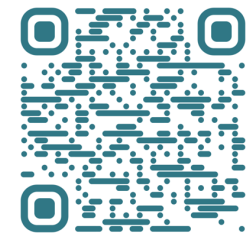
Introduction to Adaptive Interventions →



Introduction to SMART Designs →



A longer presentation about MAISYs →



Learning Objectives of the MAISY Talk

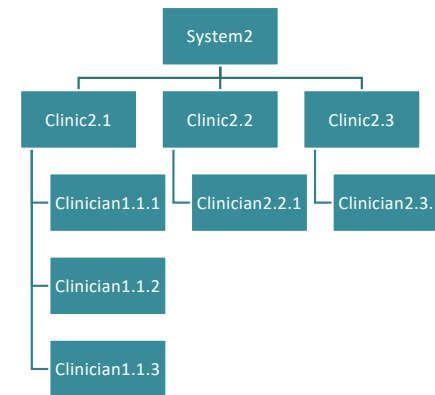
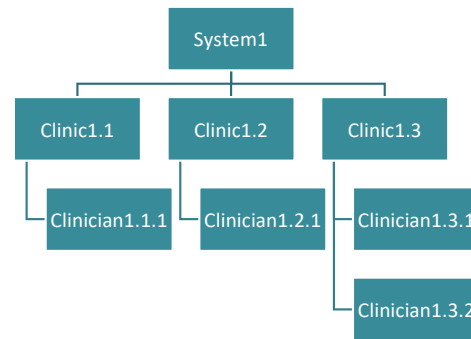
- You will learn why there is a need for multicomponent implementation strategies that respond to the needs of organizations
- You will learn about Multilevel Adaptive Implementation Strategies (MAISYs) as a possible solution to this
- You will learn about some novel randomized trials that aim to construct high quality MAISYs

Outline of the Presentation

- Implementers Have to Make Many Decisions @ Many Levels
- Multilevel Adaptive Implementation Strategies
- Using Randomization to Construct an Optimized MAISY
- Optimizing a MAISY is very different from Piloting or Evaluating a MAISY

Multiple Decision Levels

@System Level
@Clinic Level
@Clinician Level



Determinants to Implementation at Multiple Levels

Evidence-based practices fail to be implemented or sustained due to barriers at multiple levels. For example,

@System Level	Ineffective communication, monitoring practices, policies
@Clinic Level	Lack of support, workflow processes
@Clinician Level	Lack of skills

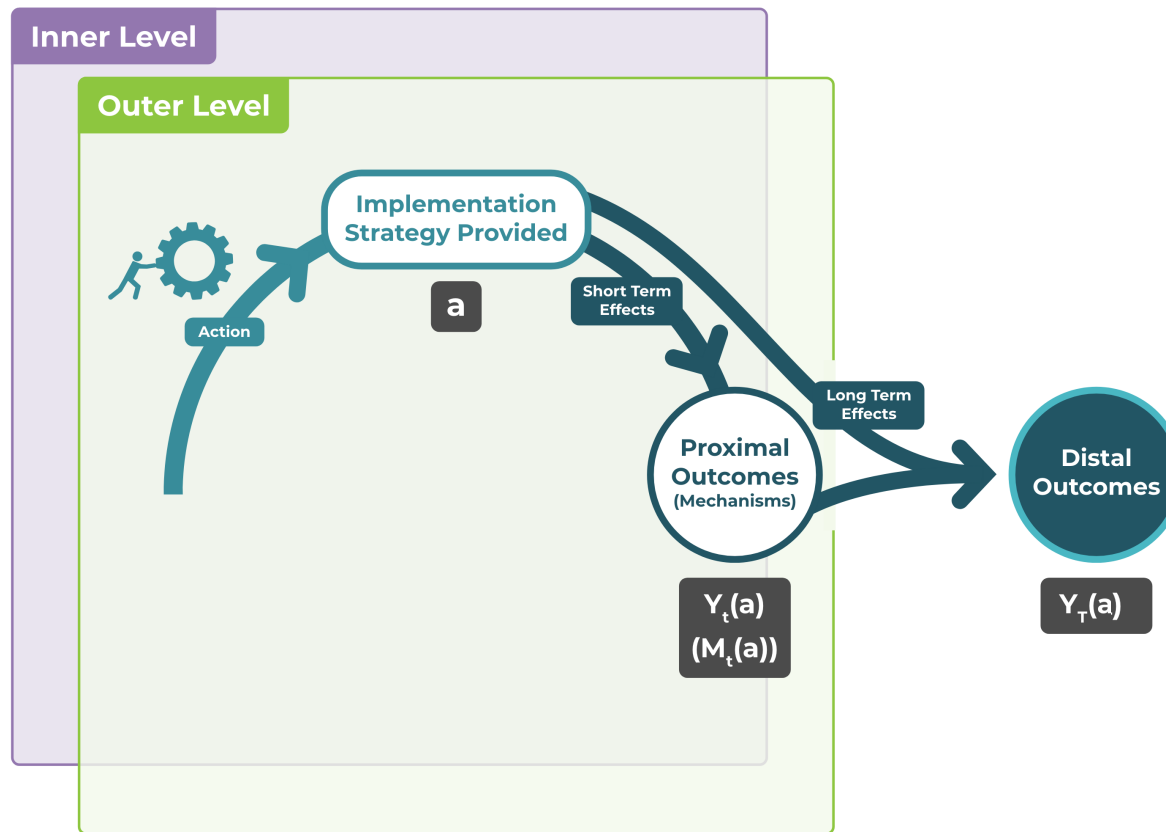
Implementation Strategies at Multiple Levels

A growing cadre of implementation strategies can help mitigate these challenges. For example,

@System Level	Audit & Feedback_S	Ineffective monitoring practices
@Clinic Level	Facilitation_{CC}	Lack of support
@Clinician Level	Coaching_{CN}	Lack of skills

Quick Review: What is an Implementation Strategy?

- Implementer
- Levels
- Targets
- Action
- Outcomes
- Rationale



Proctor, Powell, McMillen (2013), *Impl Sci*

From the Perspective of the Implementer

What works for one target may not work for another target

Between-target Heterogeneity

What works in the short-run may not work in the longer-run, or vice-versa

Within-target Heterogeneity

From the Perspective of the Implementer

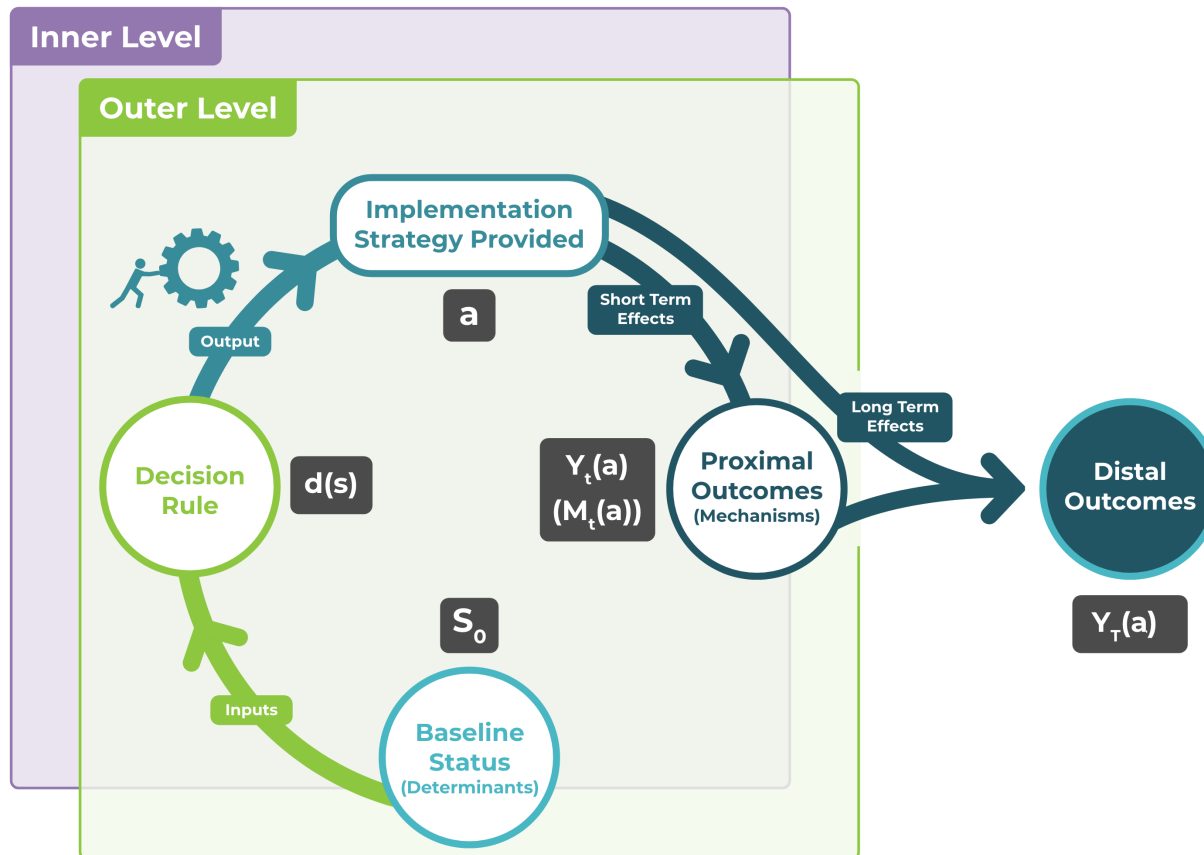


From the Perspective of the Implementer



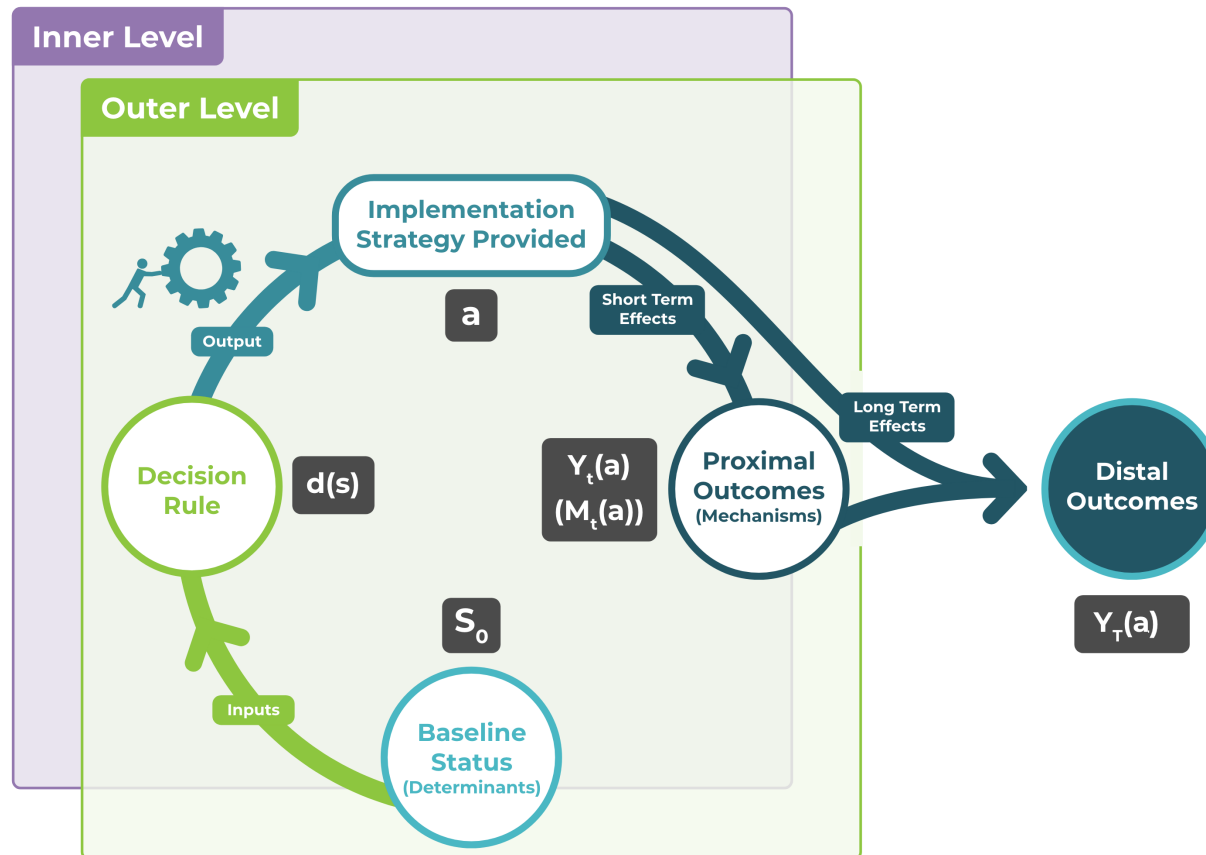
But a Decision is Not Just Any Action

What if we do this, instead?



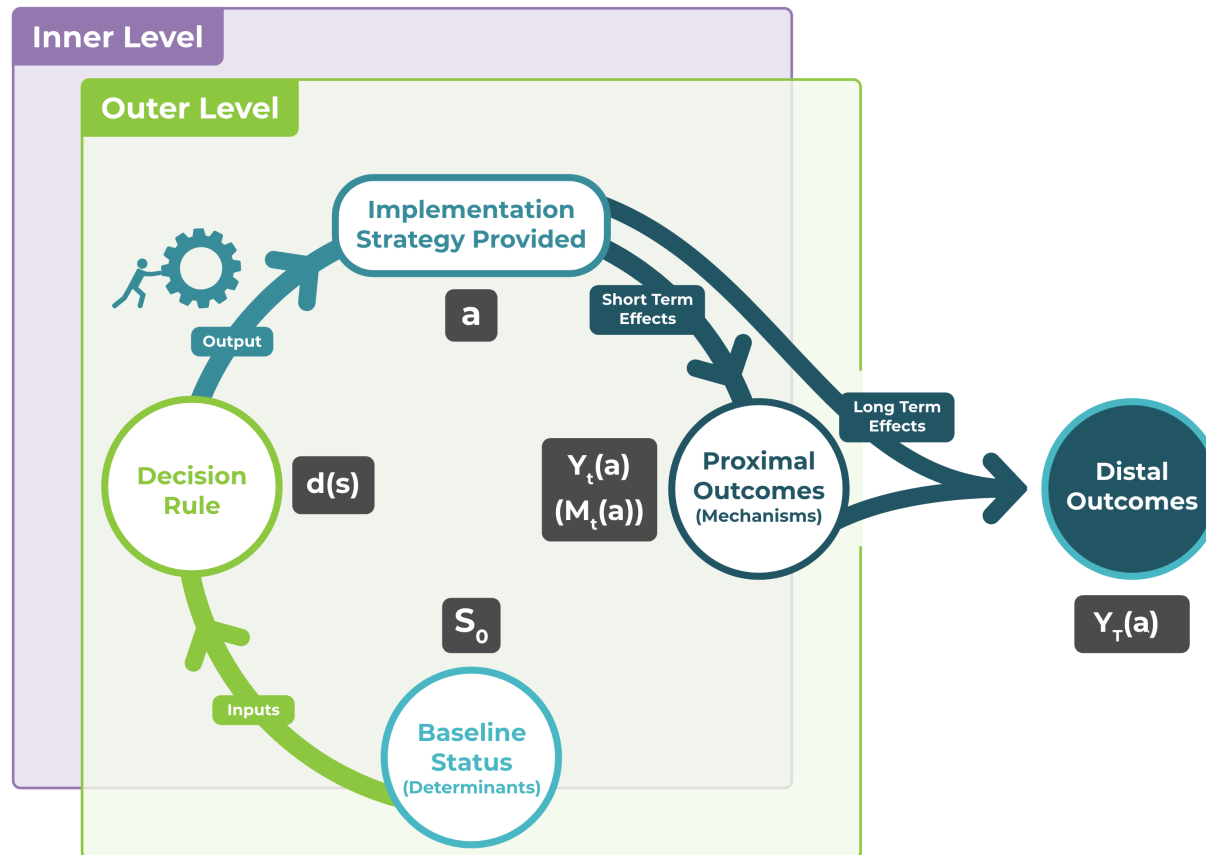
This strategy has these extra components

- Implementer
- Levels
- Targets
- Action Options
- Baseline Status
- Decision Rule
- Outcomes
- Rationale



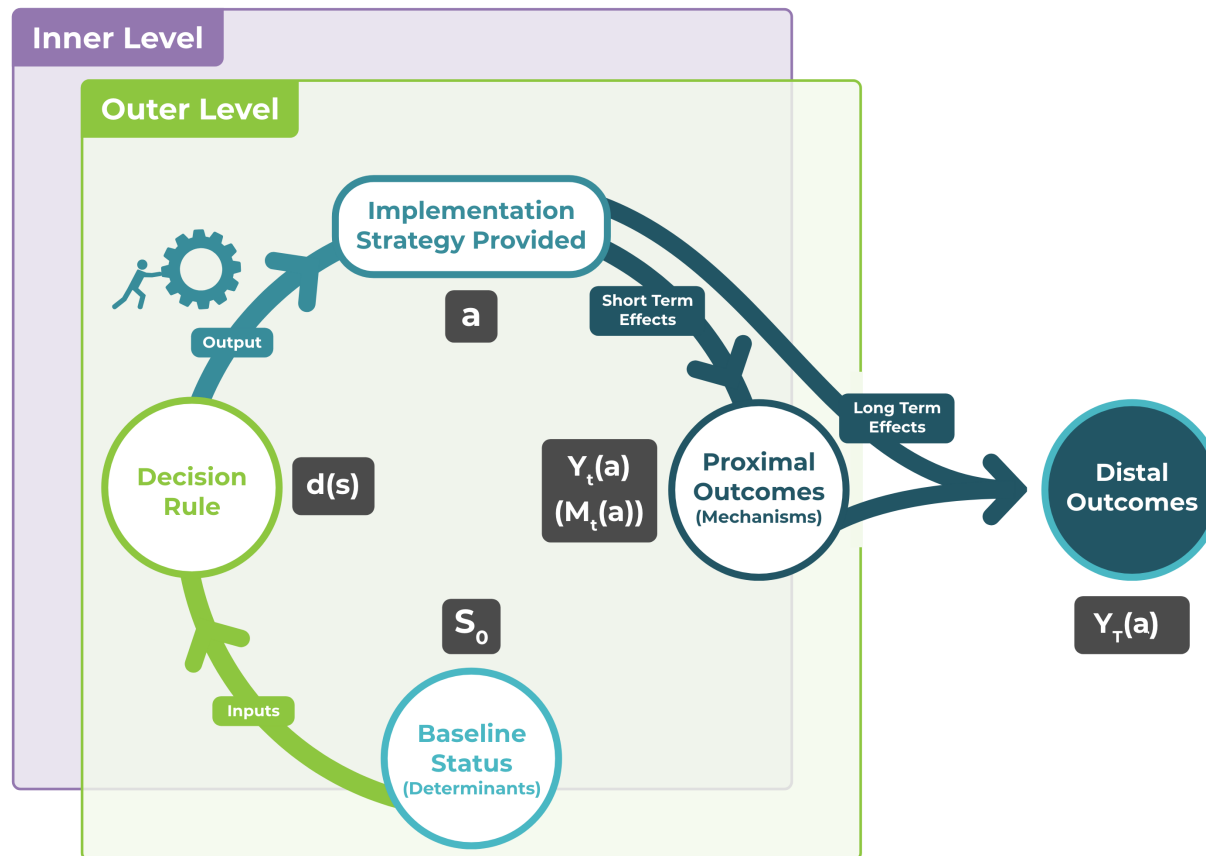
This strategy has these extra components

- Implementer
- Levels
- Targets
- Action Options
- Baseline Status
- Decision Rule
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- Rationale



The “determinant” here is the measure (the variable), which takes on different values.

Between-target Heterogeneity @ Baseline ✓
Within-target Heterogeneity ✗



In many settings, what implementers will need is

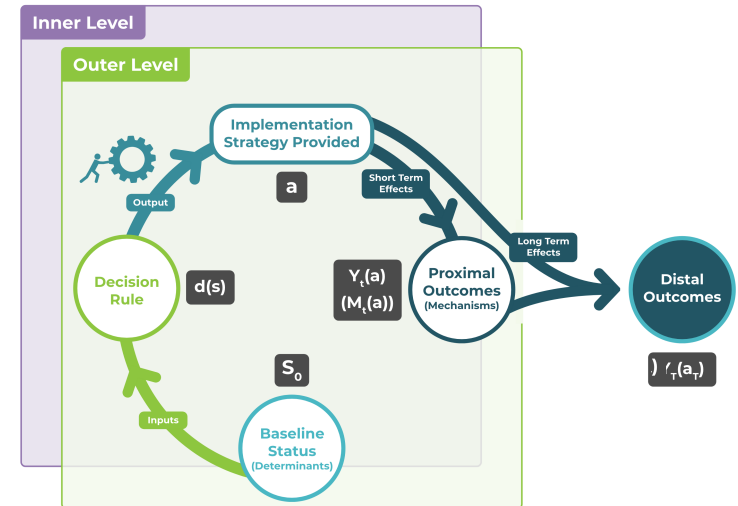
In many settings, what implementers will need is a **practical & intelligent guide** for how best to provide strategies across **multiple levels and multiple phases.**

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One that guides how best to adjust strategies given **both baseline and ongoing needs** of targets at the multiple levels of implementation.

Outline

- Many Decisions at Many Levels
- Let's Close this Loop using a Multilevel Adaptive Implementation Strategy
- Using Randomization to Construct an Optimized MAISY

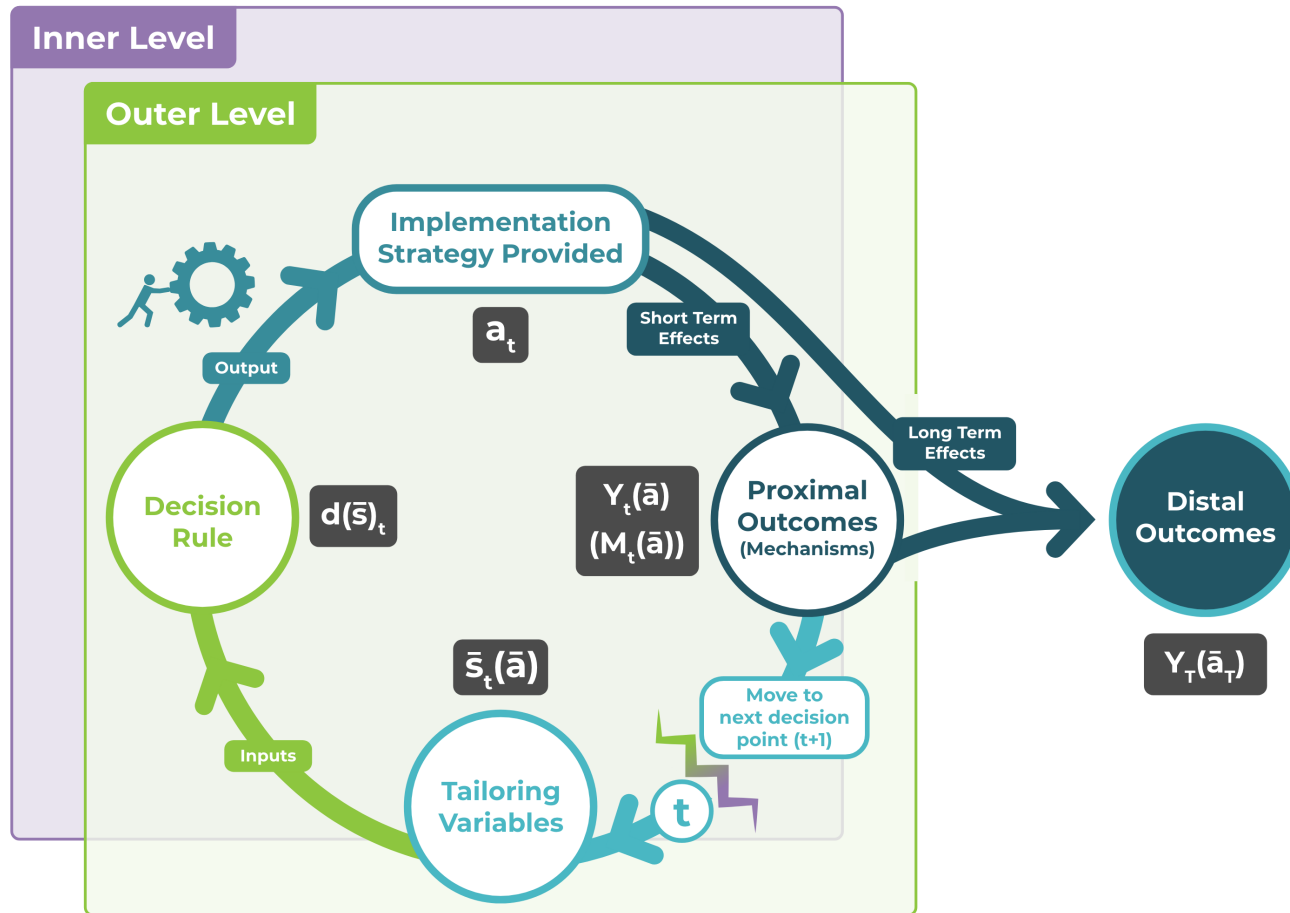


Multilevel Adaptive Implementation Strategy (MAISY)

A MAISY is a sequence of decision rules used to guide how best to adapt the provision of implementation strategies

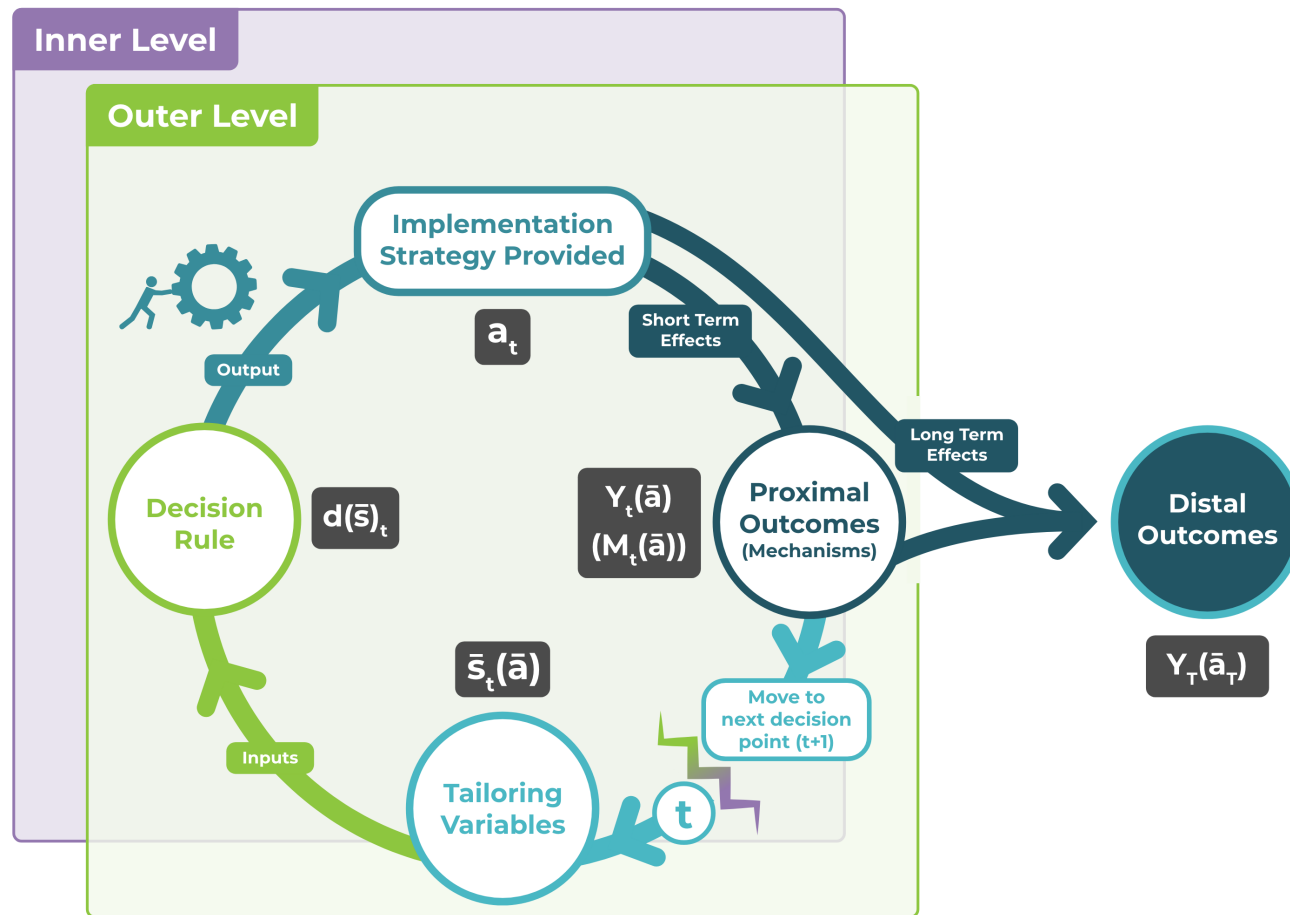
- (i) at critical decision points,
- (ii) across multiple levels,
- (iii) based on **both baseline and ongoing/changing status** of the targets in an organization.

Multilevel Adaptive Implementation Strategy (MAISY)



Multilevel Adaptive Implementation Strategy (MAISY)

- Implementer
- Decision Levels
- Targets
- Decision Points
- Action Options
- Tailoring Vars
- Decision Rules
- Outcomes
- Rationale

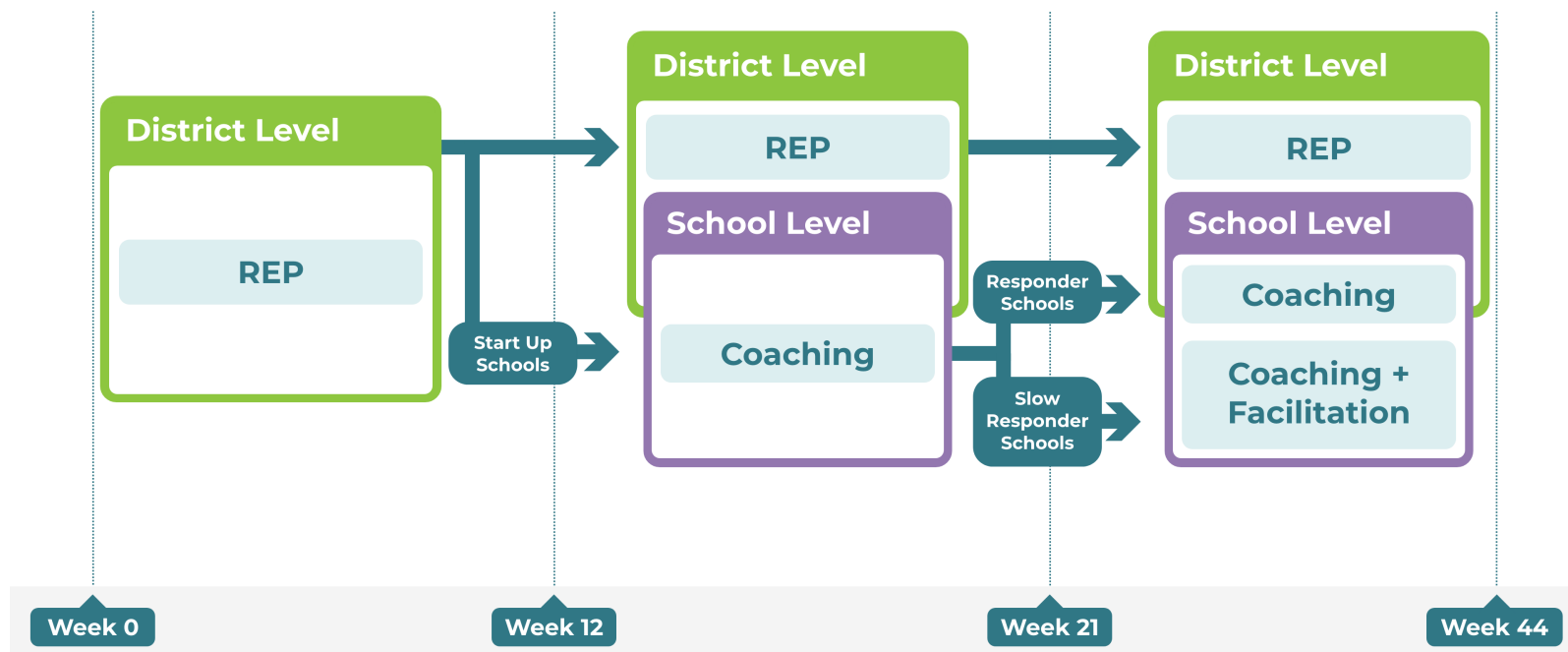


MAISY Example #1

Adaptive School-based Implementation of CBT (ASIC)

EBP: Cognitive Behavioral Therapy in Michigan Schools

Developer: Amy Kilbourne



Start-up School:

58

A school with school professionals who do not have training in CBT or have never provided CBT to any of their students.

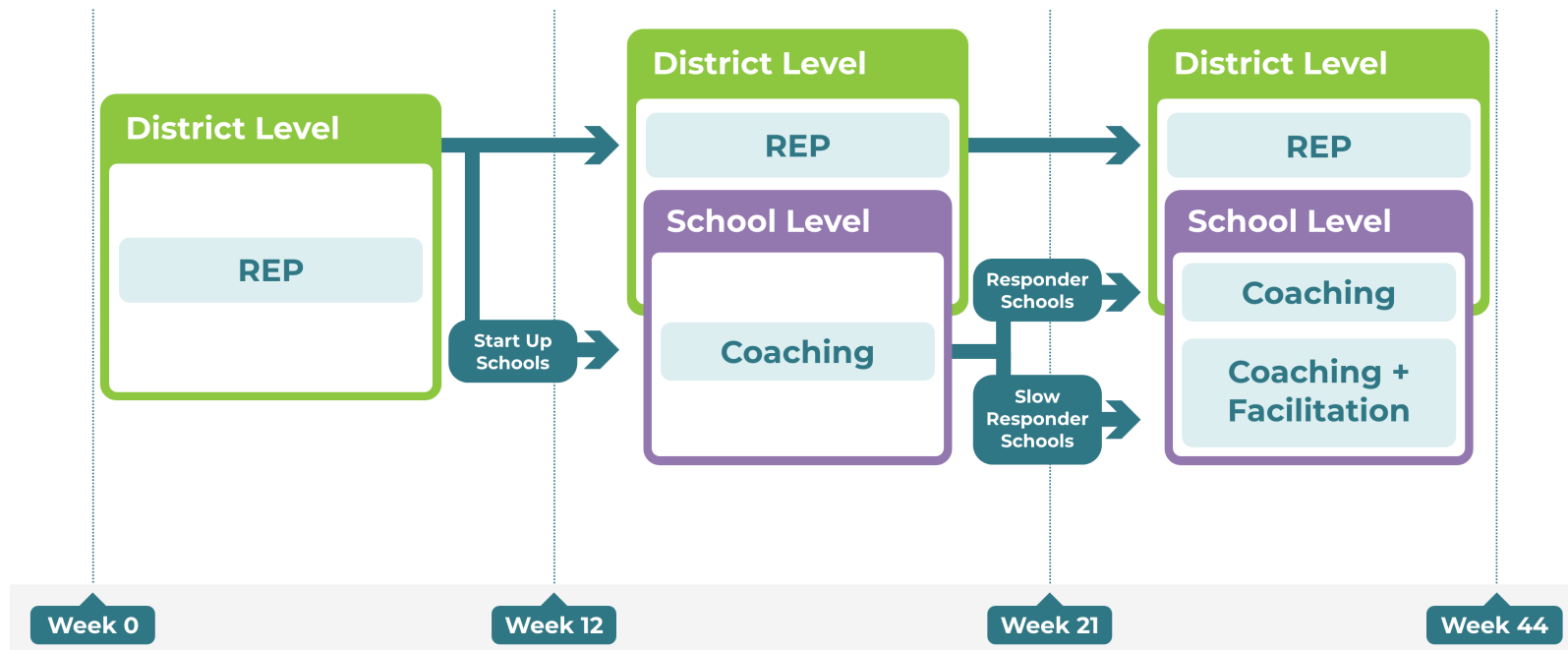


MAISY Example #1

Adaptive School-based Implementation of CBT (ASIC)

EBP: Cognitive Behavioral Therapy in Michigan Schools

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Slow-responding School:

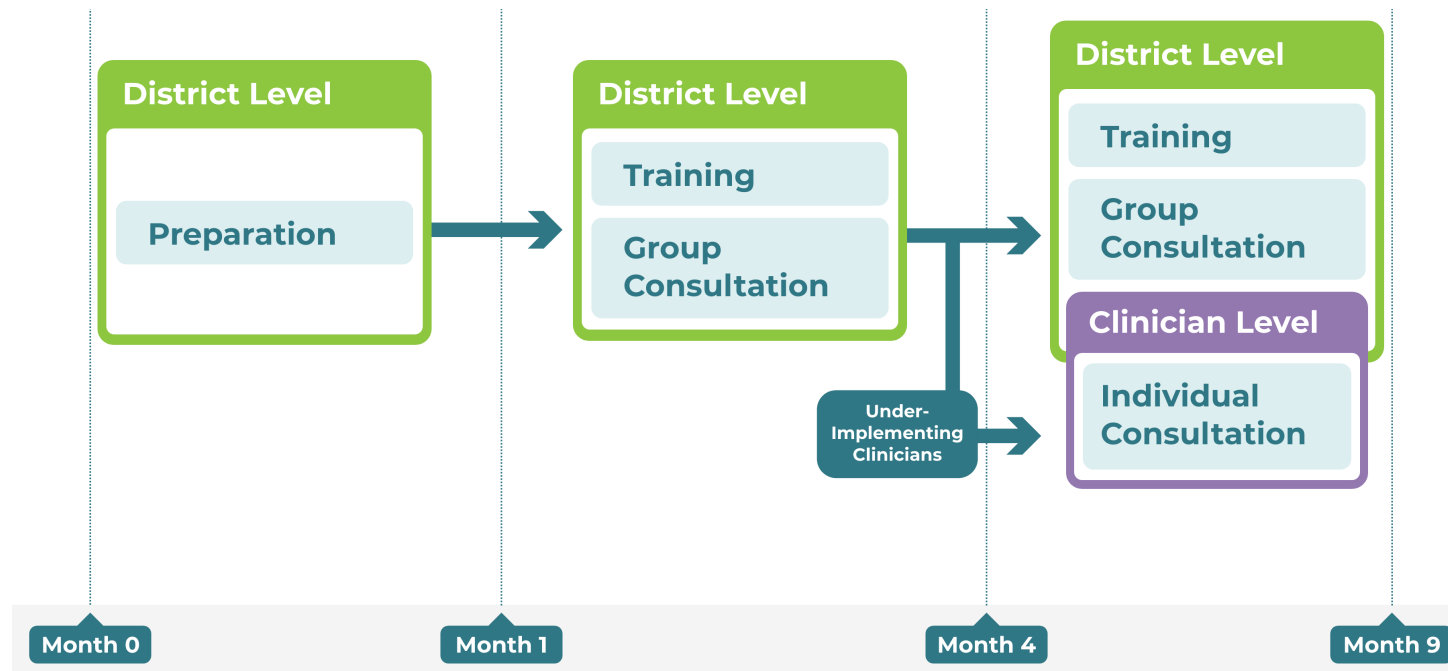
- (i) Any SP reports not providing 3+ CBT components to >10 students
- OR
- (ii) SPs report >2 barriers to CBT delivery (on average)

MAISY Example #2

Feedback & Outcomes for Clinically Useful Student Svcs (FOCUSS)

EBP: Measurement-based Care in Connecticut Schools

Developer: Elizabeth Connors



60

Under-implementing Clinician:
Collected 1+ outcome measure on <40% of students served in first 4 months



Why MAISYs?

Timing is important

Speed of adoption varies; not all targets are ready to take on more

Strategic sequencing

Lay a strong foundation for subsequent strategies, if needed

Health equity

MAISYs are consistent with “vertical health equity” principles



Why MAISYs?

Engagement is critical

In short-run, not just about fidelity or quant. of implementation

Often, more is not better

Kitchen sink strategies can lead to suboptimal implementation

Resource/Cost efficiency

Step-up for targets that need it; step-down for targets doing well

MAISYs are Guides for Implementers

- Implementation practitioners
- Community service providers
- Policy makers
- Clinical leaders
- ~~Researchers~~

MAISYs are Guides for Implementers, **not Researchers**

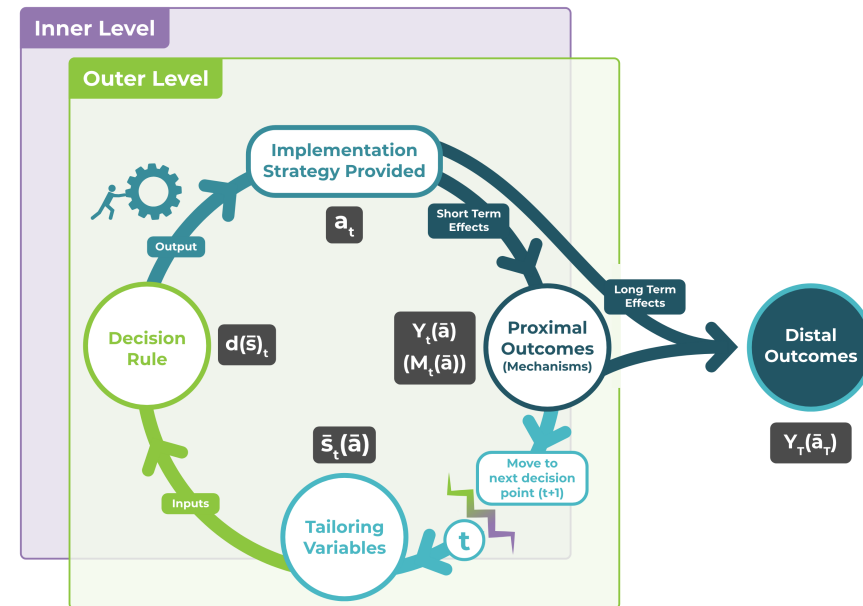
- Implementation practitioners
- Community service providers
- Policy makers
- Clinical leaders
- ~~Researchers~~ unless the Researcher happens to be in the role of the Implementer for purposes of the study, but let's hope the clinics and practitioners perceive it this way

A MAISY is not a Research Method

- Not an experimental design
 - There are no researchers in a MAISY
 - There are no randomizations
- Not an approach to conducting pilot studies
- Not an approach to data analysis
- Not an adaptive trial design

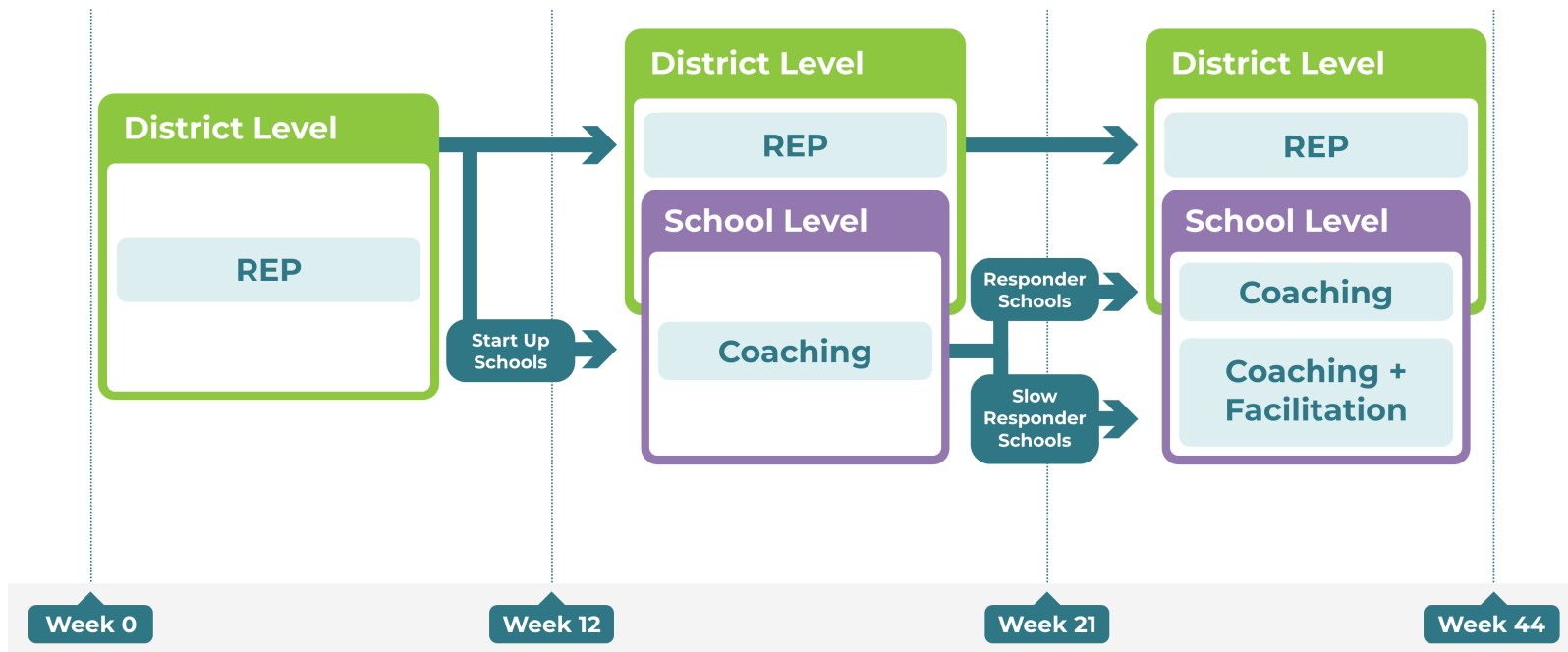
Jargon Buster Slide (~~Babel~~)

- Special case of what Byron Powell calls a “multifaceted multilevel implementation strategy”
- Special type of “adaptive implementation strategy”
- Certainly, MAISYs falls within the realm of “precision implementation strategies”



Recall MAISY Example 1

Adaptive School-based Implementation of CBT (ASIC)



Other Considerations

- Pre-specified (pre-planned)
- Mechanisms can be tailoring variables!!
- The tailoring variables are part of the MAISY
- Caution against conflating MAISYs and “adaptation”

Outline

- Implementers Have Many Decisions to Make
- Multilevel Adaptive Implementation Strategies
What? Why? Who?
- Developing an Optimized MAISY

**This is all about asking Optimization Questions
I am going to show you 13 of these.**

Outline

- Implementers Have Many Decisions to Make
- Multilevel Adaptive Implementation Strategies
What? Why? Who?
- Developing an Optimized MAISY

So put your researcher hats back on!



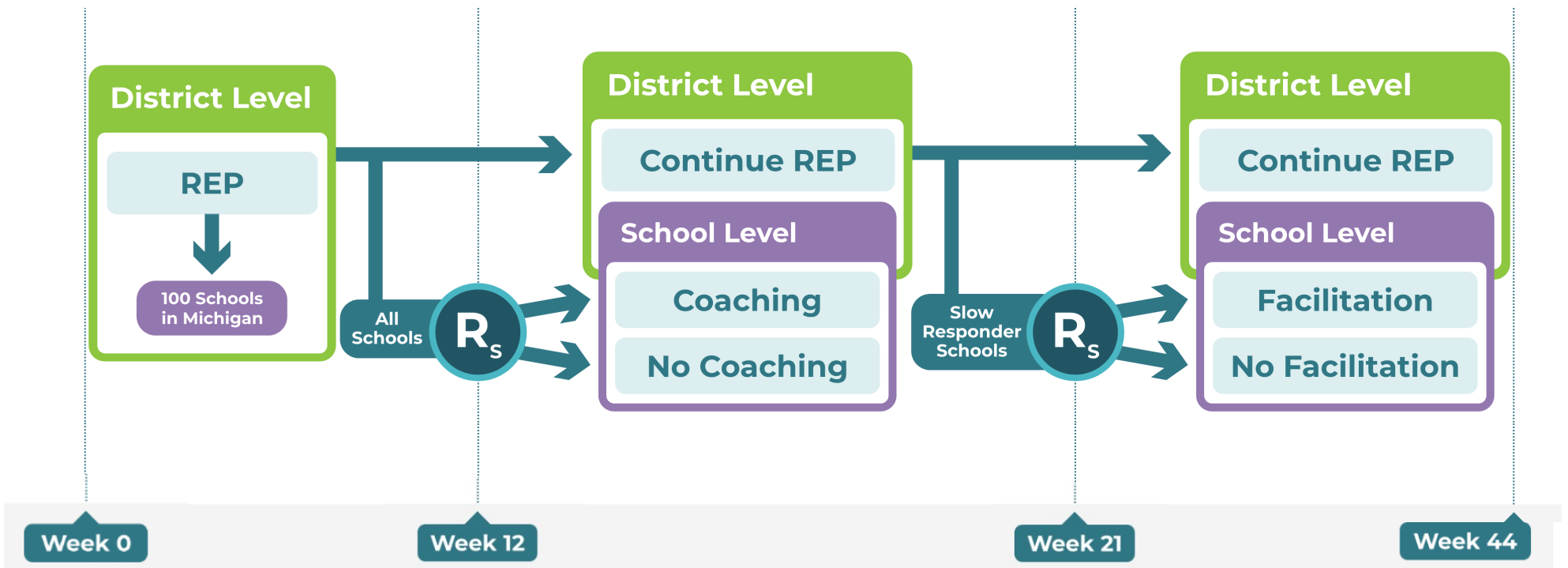
Optimization Questions: Basic, but important

	Type	In the context of ASIC
1	First stage strategies	What is the effectiveness of Coaching?
2	Later stage strategies	What is the effect of Facilitation among schools that are slower responders?
3	Interaction	Do Coaching and Facilitation interact to produce beneficial outcomes?
4	Adaptive versus not adaptive	What is the effect of the MAISY shown earlier vs only Coaching (not adaptive)?

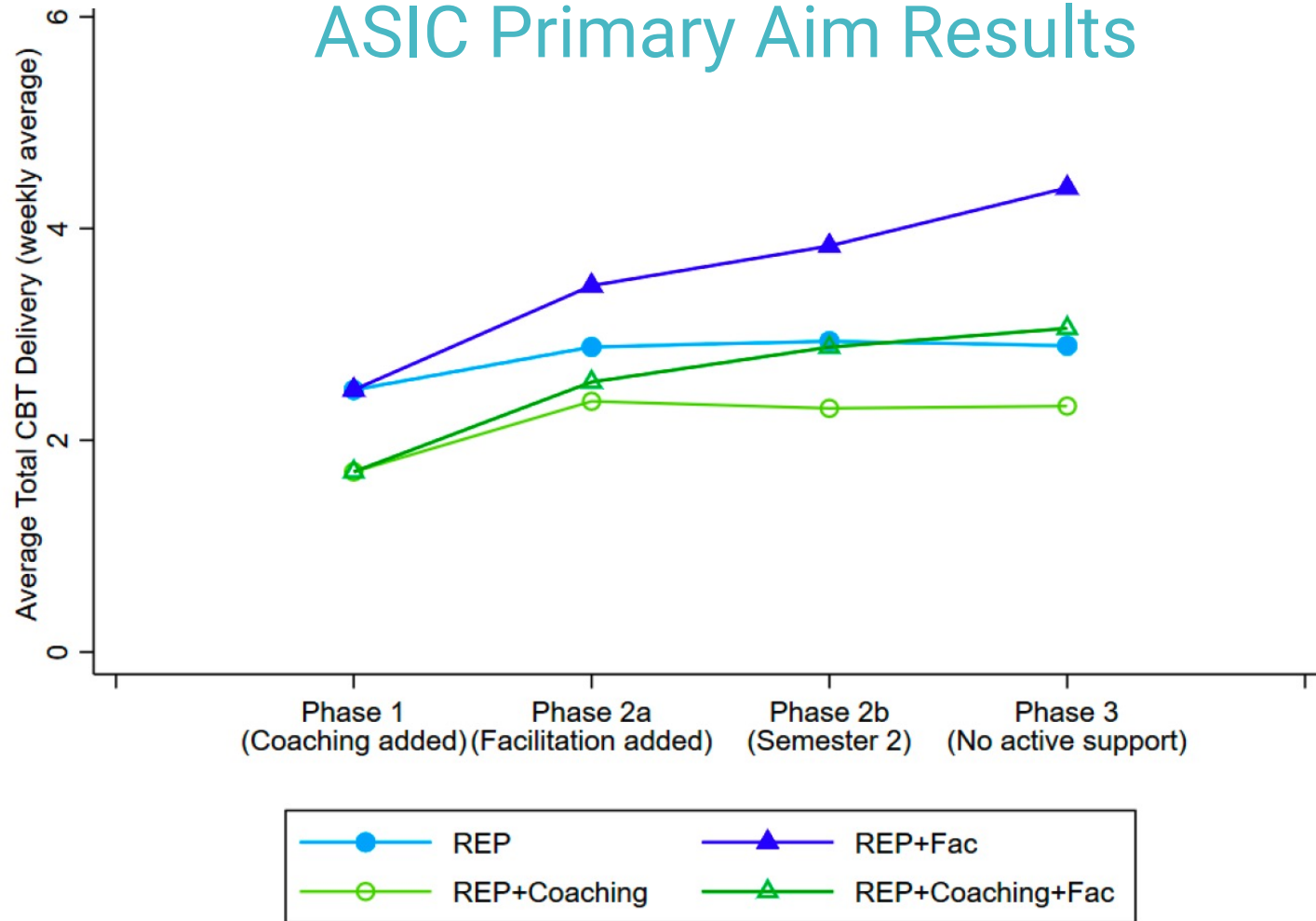
Sequential Multiple Assignment Randomized Trial

The ASIC SMART

PI: Amy Kilbourne



ASIC Primary Aim Results



Optimization Questions: All about tailoring

	Type	In the context of ASIC
5	Better way to define non-response?	Should we use a more lenient definition (a lower cut-off) for “Responding School”?
6	Other baseline tailoring variables?	Perhaps only start-up schools require Coaching?
7	Other ongoing tailoring variables?	Perhaps Facilitation should only be offered to sub-optimally responding schools that did not engage in Coaching?

Optimization Questions: More about tailoring

	Type	In the context of ASIC
8	Other multilevel tailoring variables?	Perhaps Facilitation should only be offered to sub-optimally responding schools within the lowest resourced school districts?
9	Is the putative mechanism aide in decision making?	Is Facilitation necessary in sub-optimally responding schools delivering higher-quality CBT as a result of Coaching?

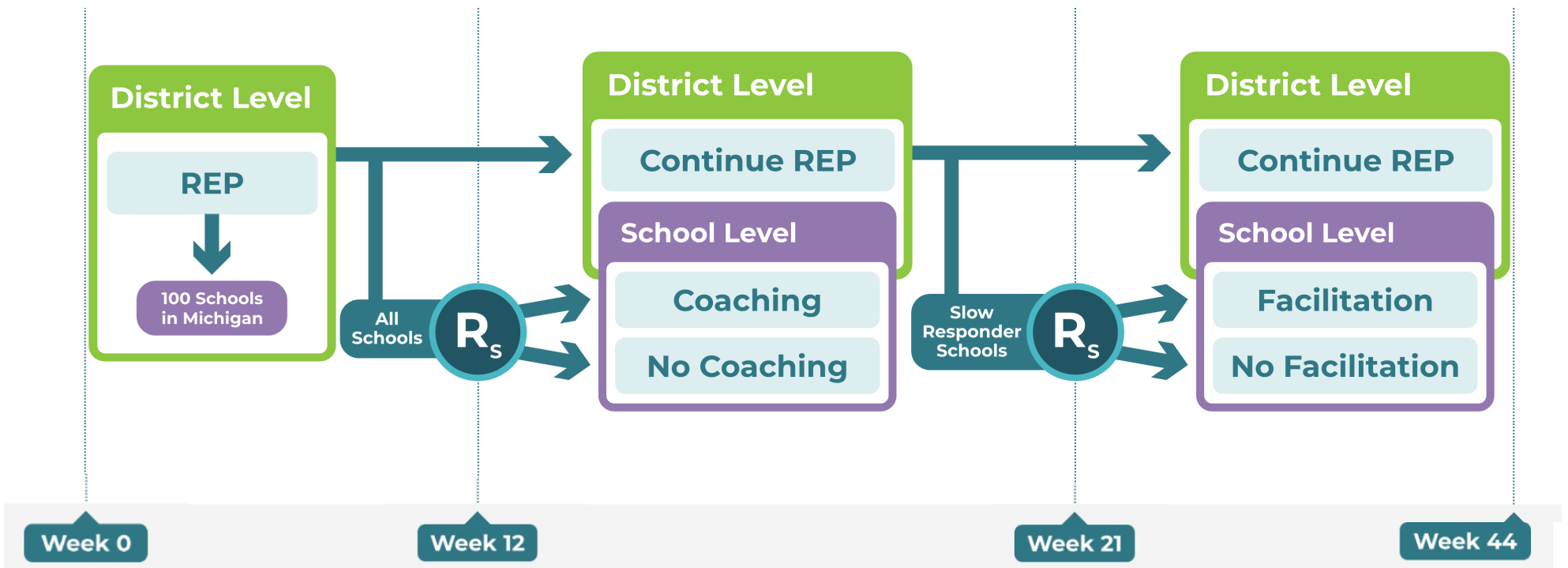
Optimization Questions: Some novel ones

	Type	In the context of ASIC
10	Sleeper effects of prior stage strategies?	Is it possible that first-stage strategies have no effect in the short-run, but have beneficial effects in the long-run when followed by a particular second-stage strategy?
11	Prescriptive effects?	Did we learn something from Coaching that can help decide whether to do Facilitation?

Sequential Multiple Assignment Randomized Trial

The ASIC SMART

PI: Amy Kilbourne

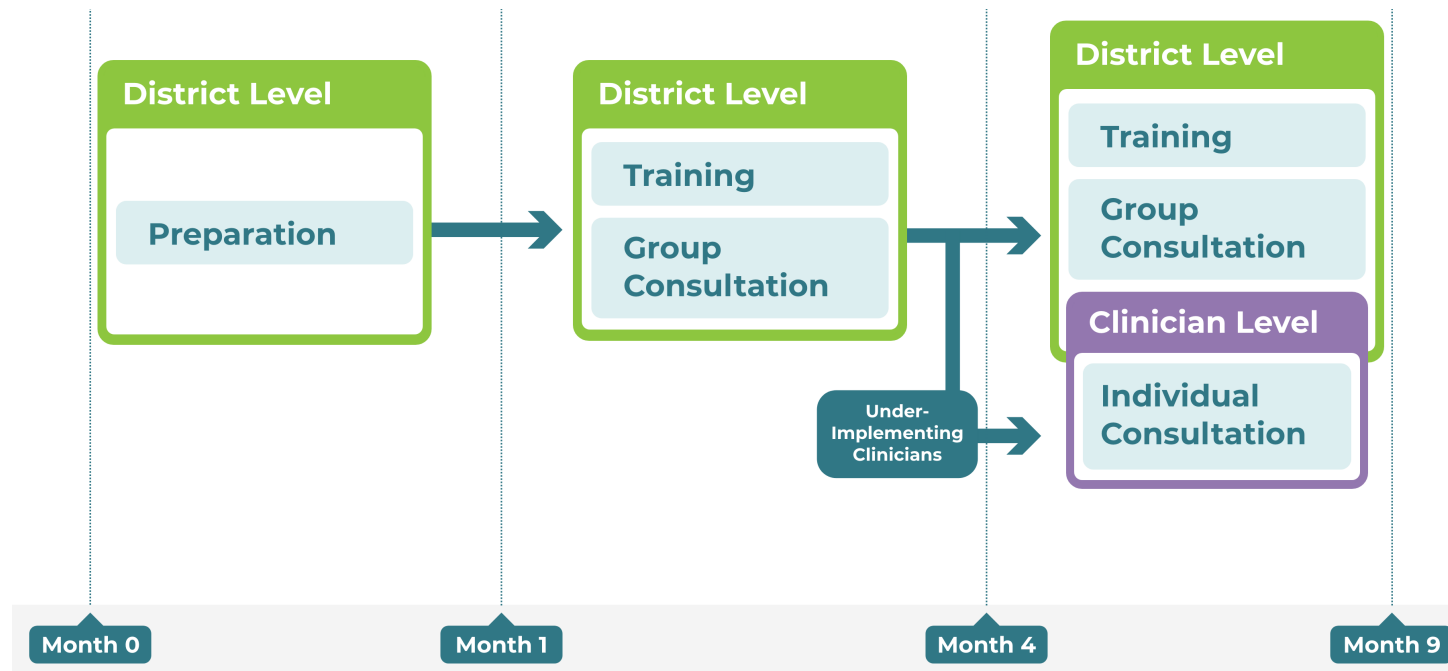


MAISY Example 2

Feedback & Outcomes for Clinically Useful Student Svcs (FOCUSS)

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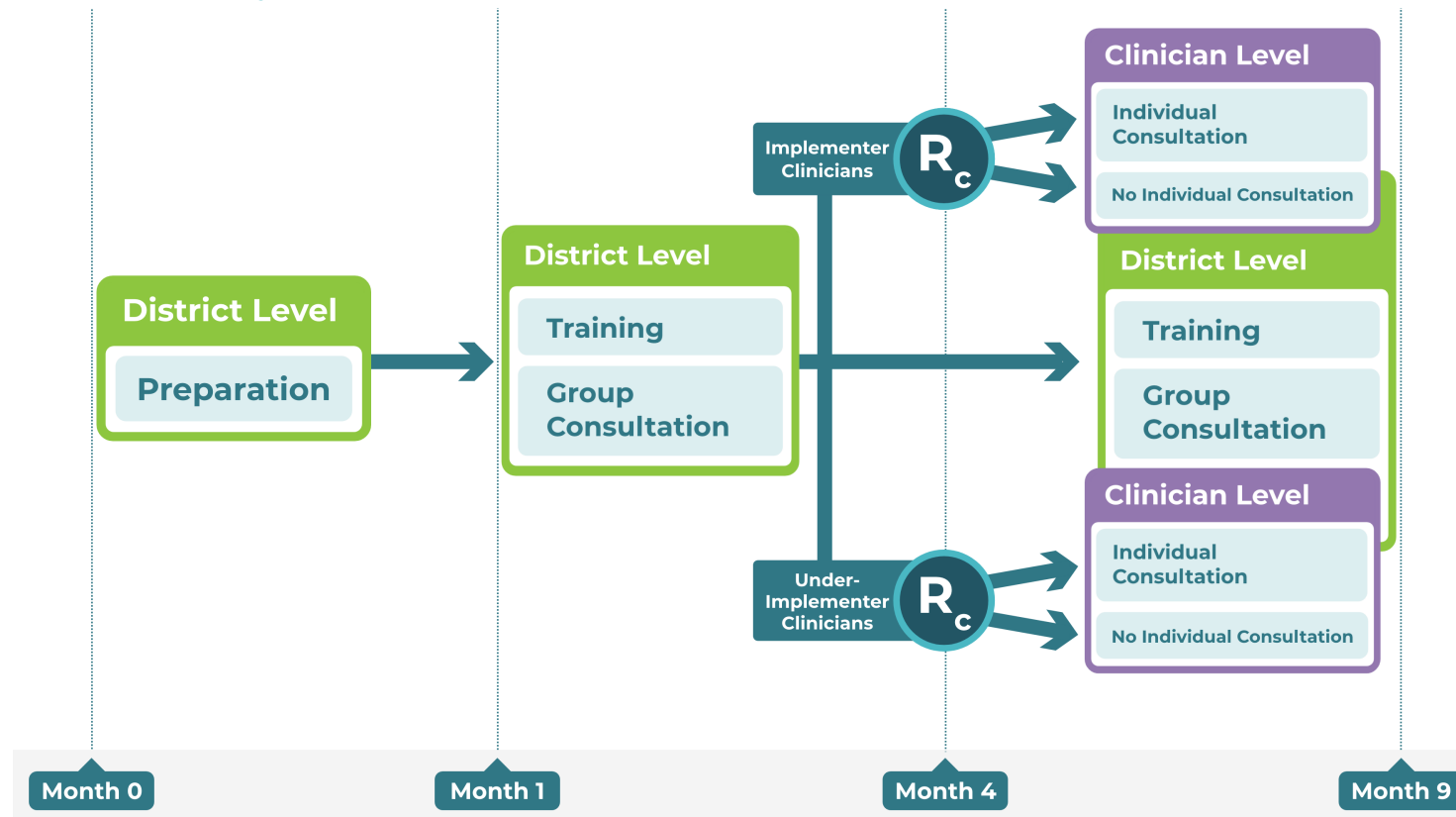
Back to Optimization Questions #2 and #7 in FOCUS

	Type	In the context of FOCUS
2	Later phase strategies	What is the average effect of clinician-level Individual Consultation?
7	Ongoing tailoring variables	How do we define “under-implementing clinician”?

Two-arm Optimization Randomized Trial

The FOCUSS Study

PI: Elizabeth Connors, Yale



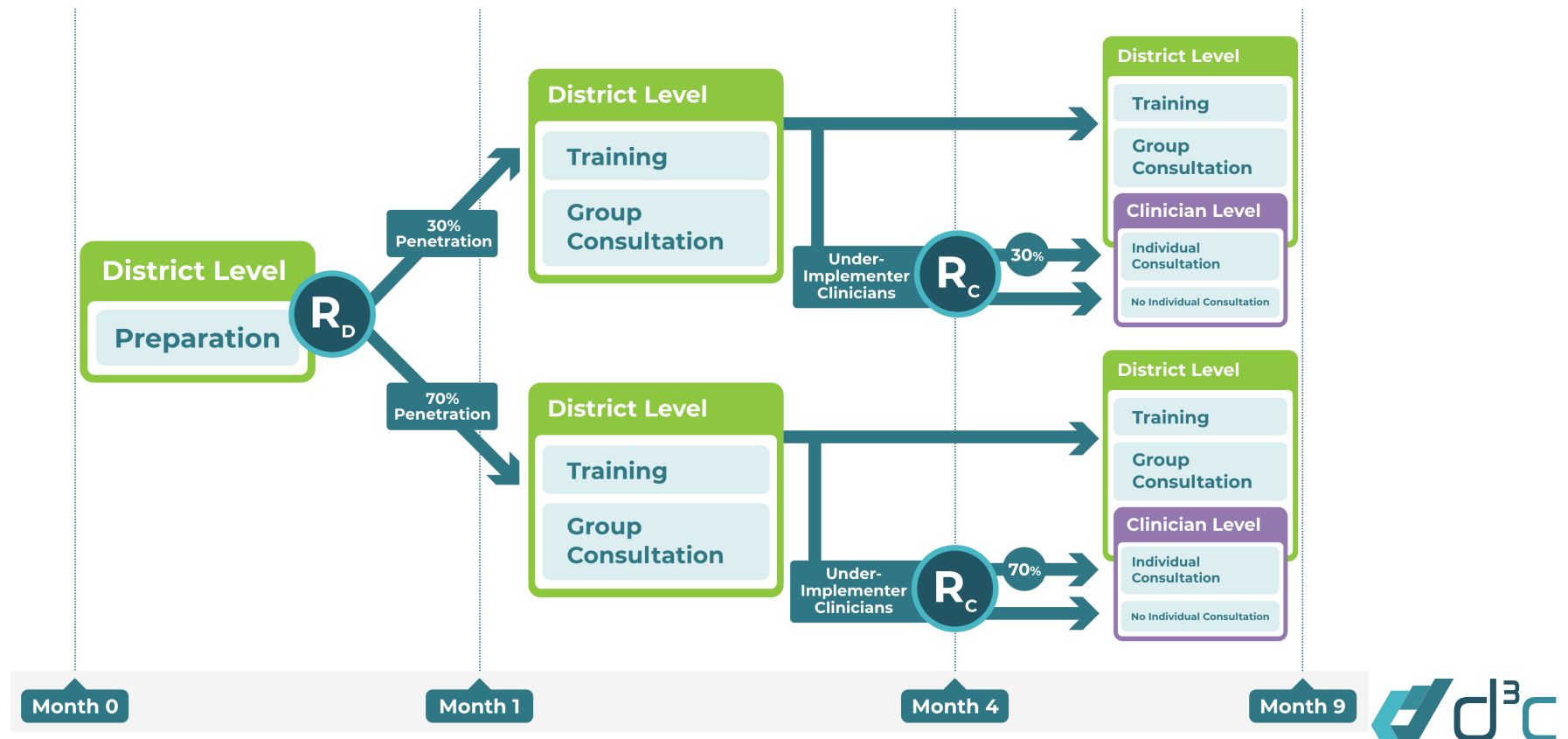
Optimization Questions: Concerning Spillover

	Spillover Questions!	In the context of FOCUSS
12	Optimal tipping point effect?	Effect of providing Individual Consultation to 30% vs 70% of under-implementers in a district?
13	Outer level strategies that engender beneficial spillover?	Target a random 1/2 of under-implementing clinicians vs up to 1/2 on a first-come first-serve basis?

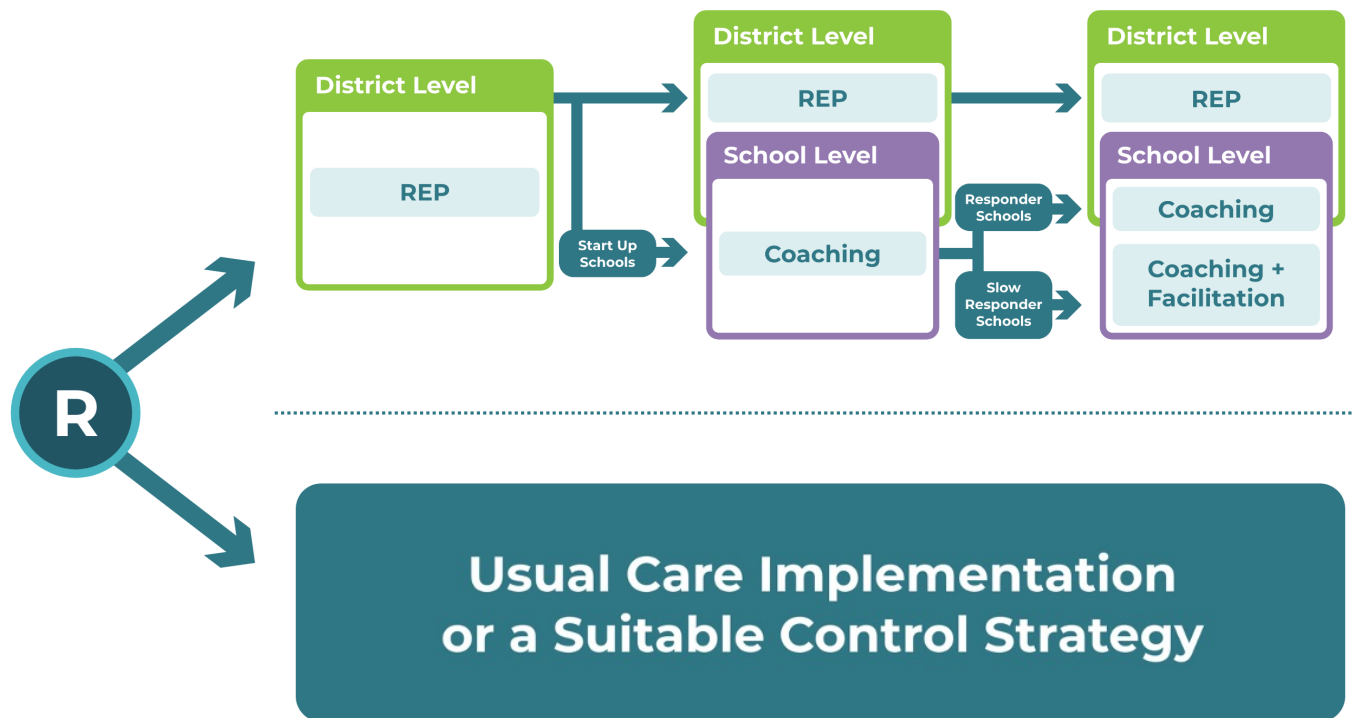
A Hypothetical, Multilevel SMART

Illustrated using FOCUSS

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Evaluation and optimization are very different.
This is evaluation. This is not optimization.



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R324B210001 (UMich, d3c);
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