Presented by

Daniel Almirall, PhD

Multilevel Adaptive Implementation Strategies

MAISYs

Outline

Implementation Support Professionals Have Many Decisions to Make @ Many Levels

Multilevel Adaptive Implementation Strategies

Using Randomization to Construct an Optimized MAISY

For now, **take off** your “researcher hats.”

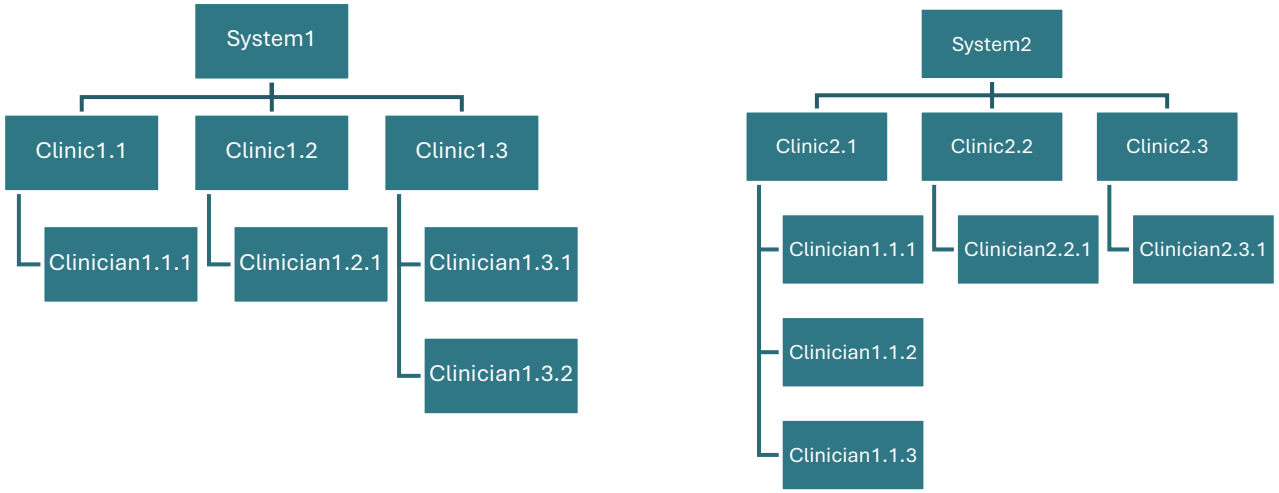
You are now an **Implementation Support Professional**.

Implementing any Intervention Requires Action at Multiple Levels

@System Level

@Clinic Level

@Clinician Level



These are the targets we are trying to help: the clinician and the organization(s) they work in.

Barriers to Implementation at Multiple Levels

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

@System Level	Ineffective communication, Ineffective policies, …
@Clinic Level	Lack of support, Poor workflow processes, …
@Clinician Level	Constraints on time for growth, Lack of skills, …

This is why we need Implementation Support Professionals.

Implementation Strategies at Multiple Levels

A growing cadre (>100) of implementation strategies can help mitigate these challenges. For example,

@System Level	**Audit & Feedback**	Ineffective monitoring practices
@Clinic Level	**Facilitation**	Lack of support
@Clinician Level	**Coaching**	Constraints on time for growth

These are the things Implementation Support Professionals can use to do their work.

Sounds great, but Implementation Support Professionals

have a difficult job ahead.

The challenges are steep.

What works for one target may not work for another target

Between-target Heterogeneity

What works in the short-run for one target may not work in the longer-run for another, or vice-versa

Within-target Heterogeneity

The challenges are steep.

What works for one target may not work for another target

Between-target Heterogeneity

What works in the short-run for one target may not work in the longer-run for another, or vice-versa

Within-target Heterogeneity

At every level.

Outline

- Implementers Have to Make Many Decisions @ Many Levels
- Multilevel Adaptive Implementation Strategies
- 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.

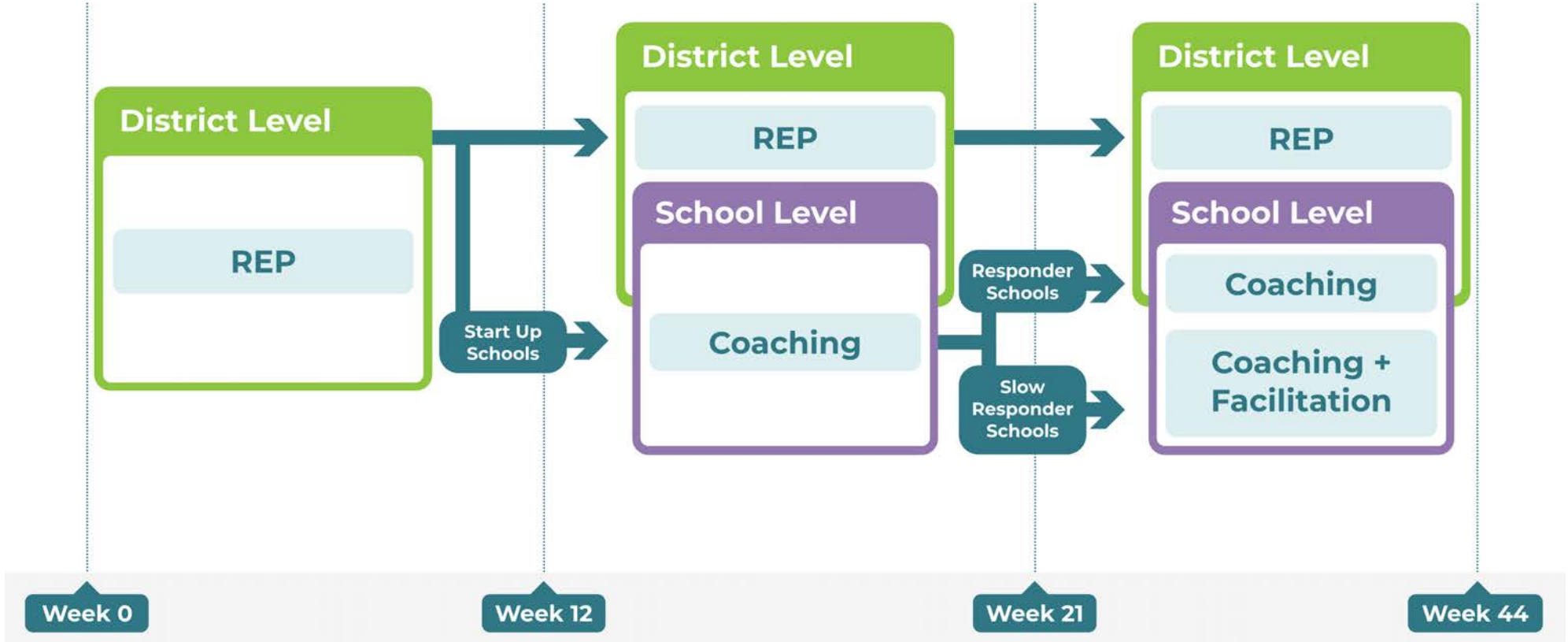
MAISY Example #1

MAISY Example #1

Adaptive School-based Implementation of CBT (ASIC)

EBP: Cognitive Behavioral Therapy in Michigan Schools

Joint work with: Amy Kilbourne



REP $$

(1) Weekend Training, (2) Website access, (3) Newsletter, (4) Monitoring Protocol & Engagement, (5) Technical Assistance Phone Number (pull only)

MAISY Example #1

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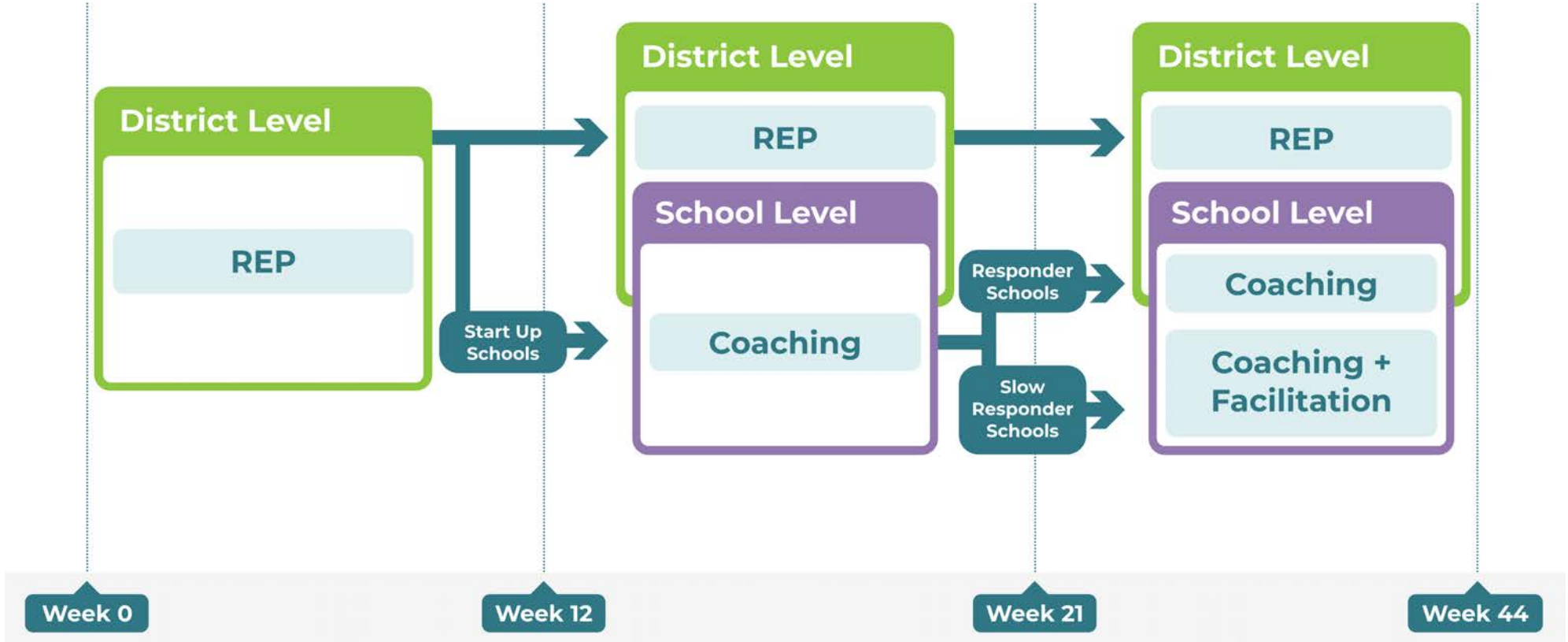

Start-up School:

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

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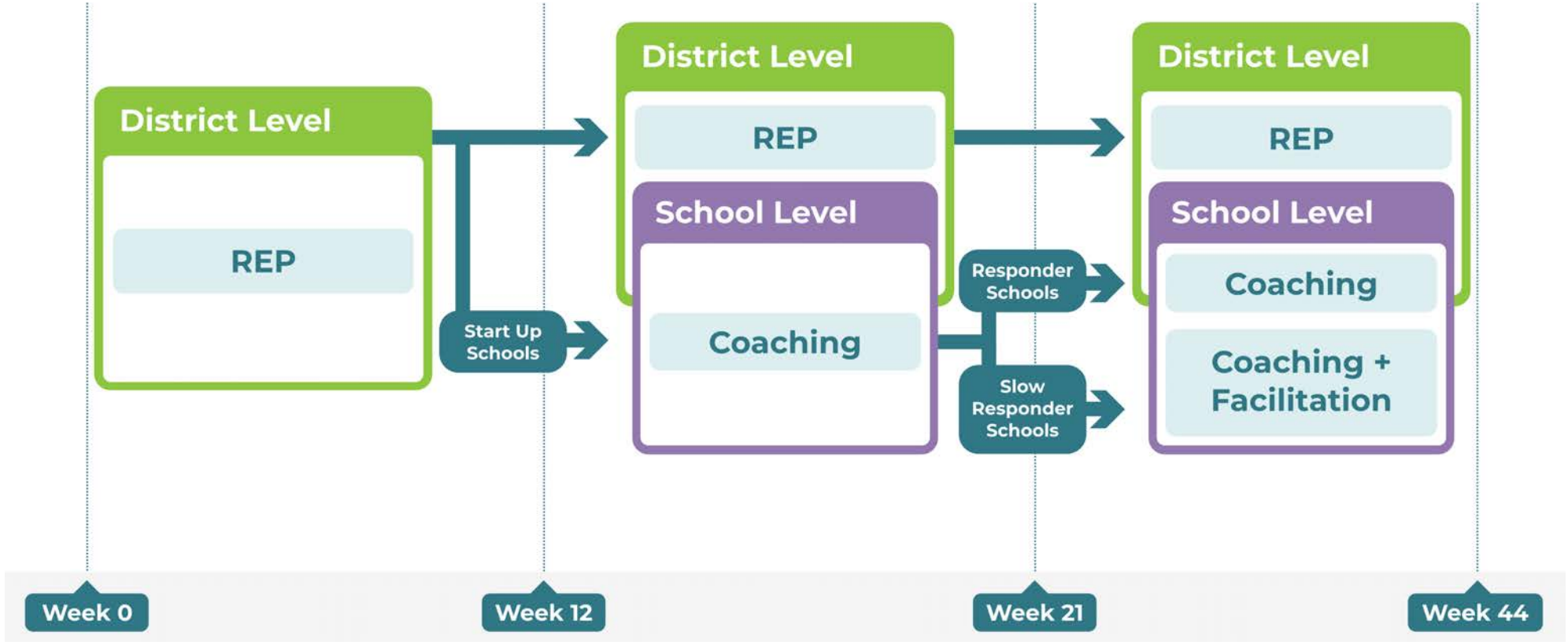

Coaching $$$$

CBT Skills Coaching; In-person; Very expensive

MAISY Example #1

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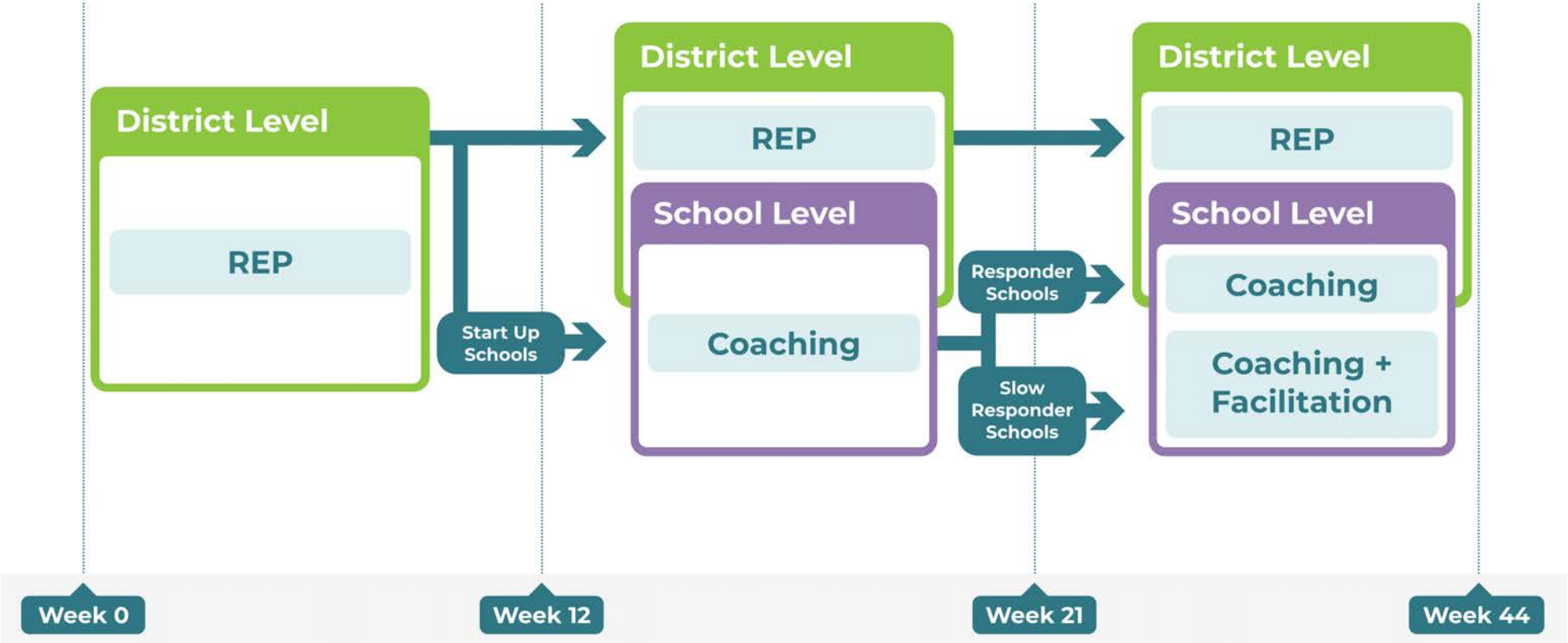

Slow-responding School:

(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 #1

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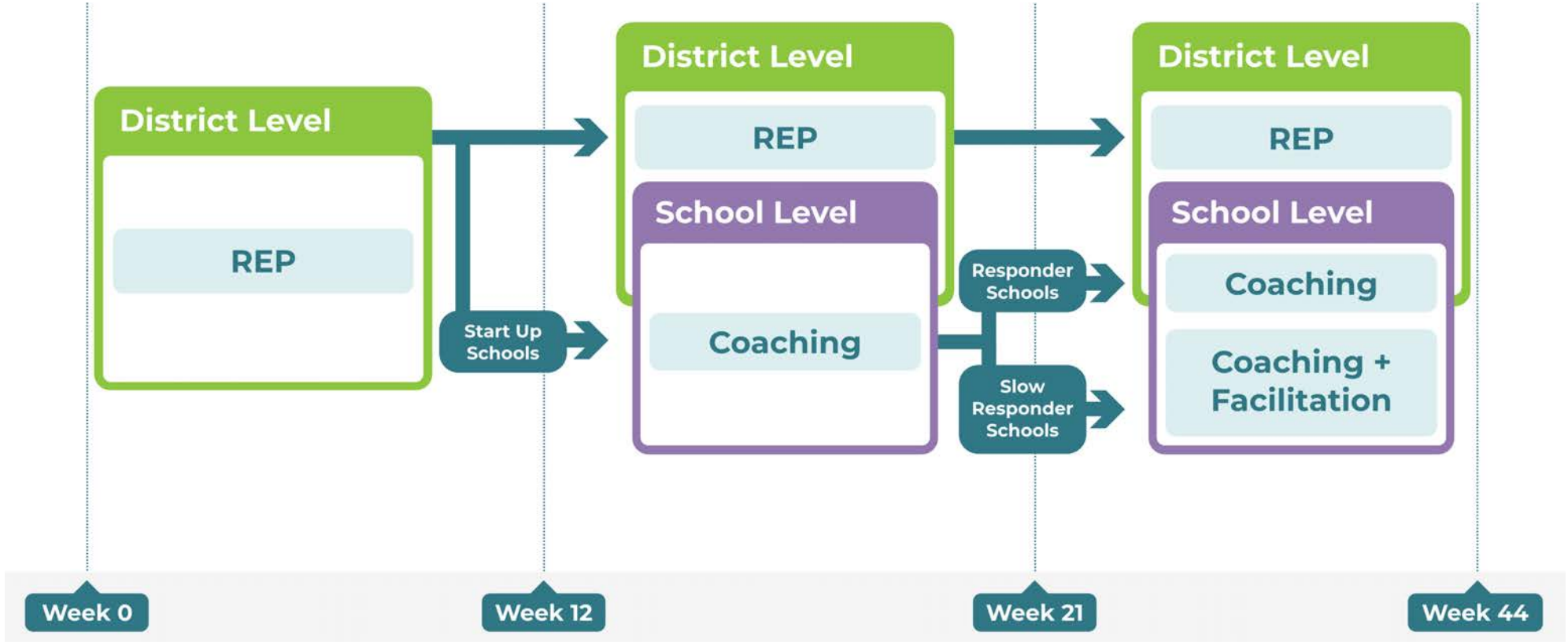


Facilitation $$$:
Business/Executive Coaching, via the phone

Why MAISYs?

At all levels, these are all important…

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

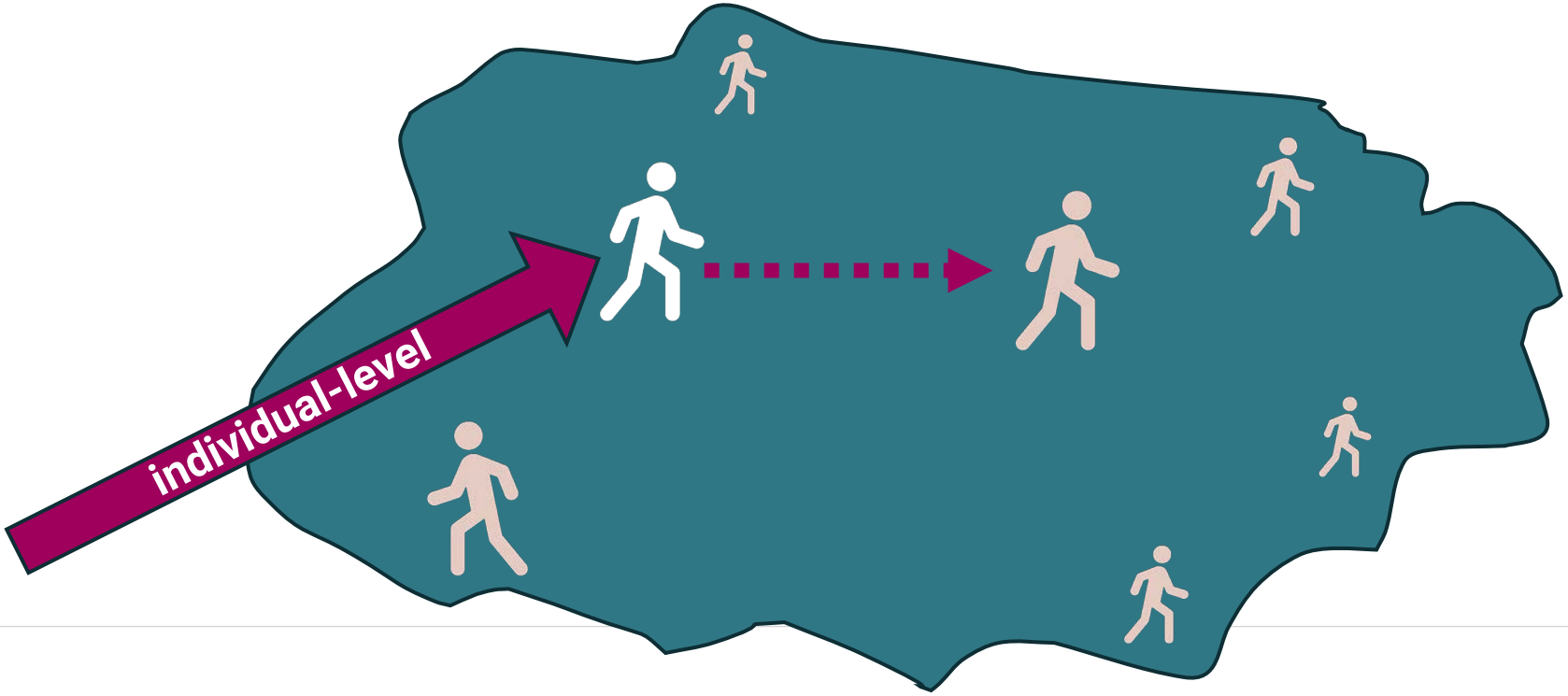
Why MAISYs?

At all levels, these are all important…

Near always, More is not better	Kitchen sink strategies can lead to suboptimal implementation
Resource Efficiency	Step-up for targets that need it; step-down for targets doing well

Why MAISYs?

Spillover …individuals directly targeted with intervention influence the outcomes of other individuals not directly targeted



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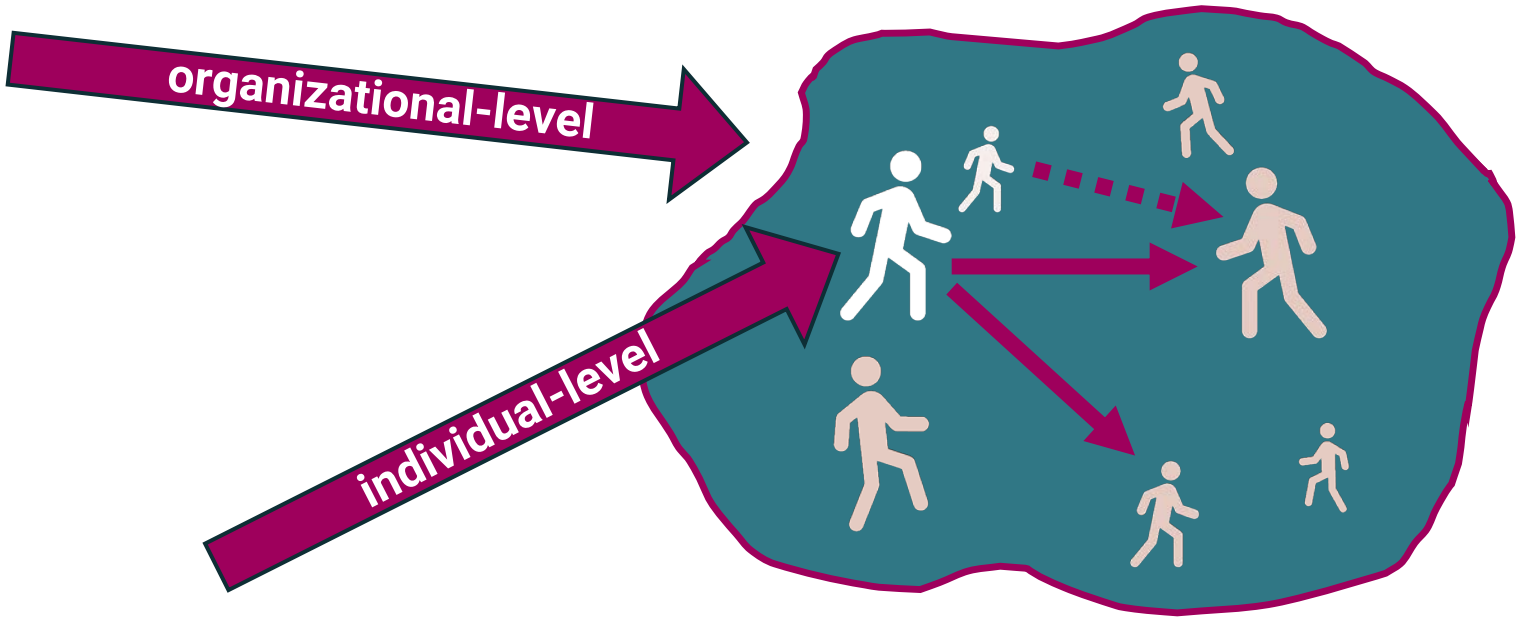
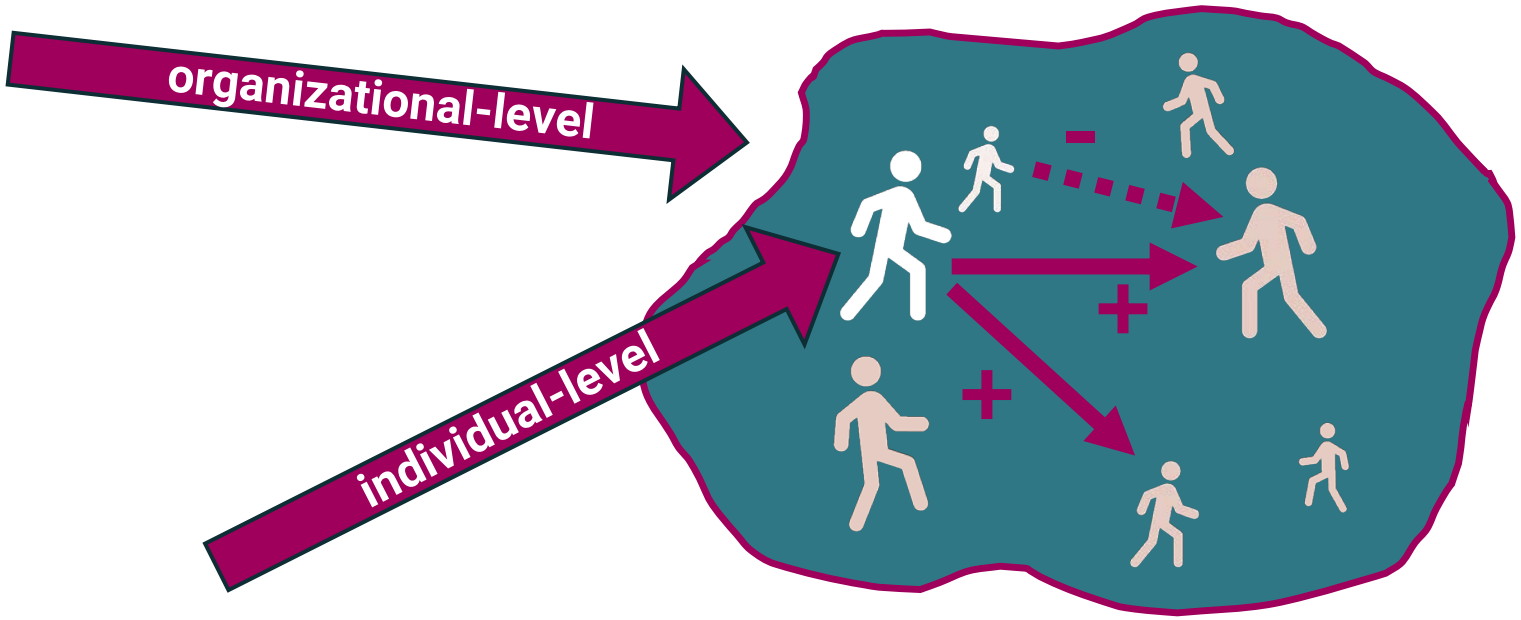


Why MAISYs?

Spillover **MAISYs can be designed to impart maximal positive spillover.**



Outline

- Implementers Have to Make Many Decisions @ Many Levels
- Multilevel Adaptive Implementation Strategies

Now put your “researcher hats” back on…!

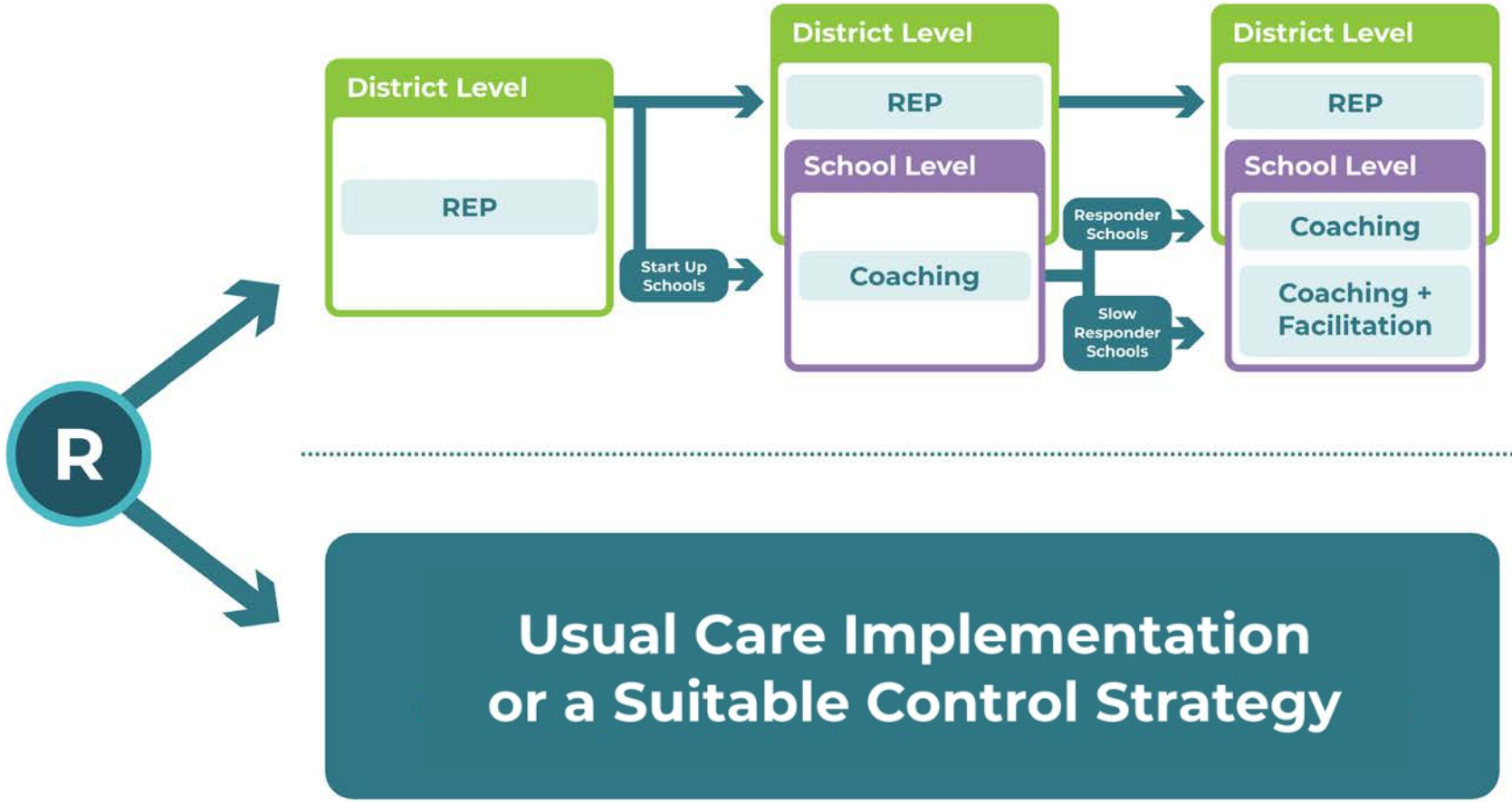
POP QUIZ #1:

What type of randomized trial design would you use if you wanted to **evaluate** the MAISY we just presented?

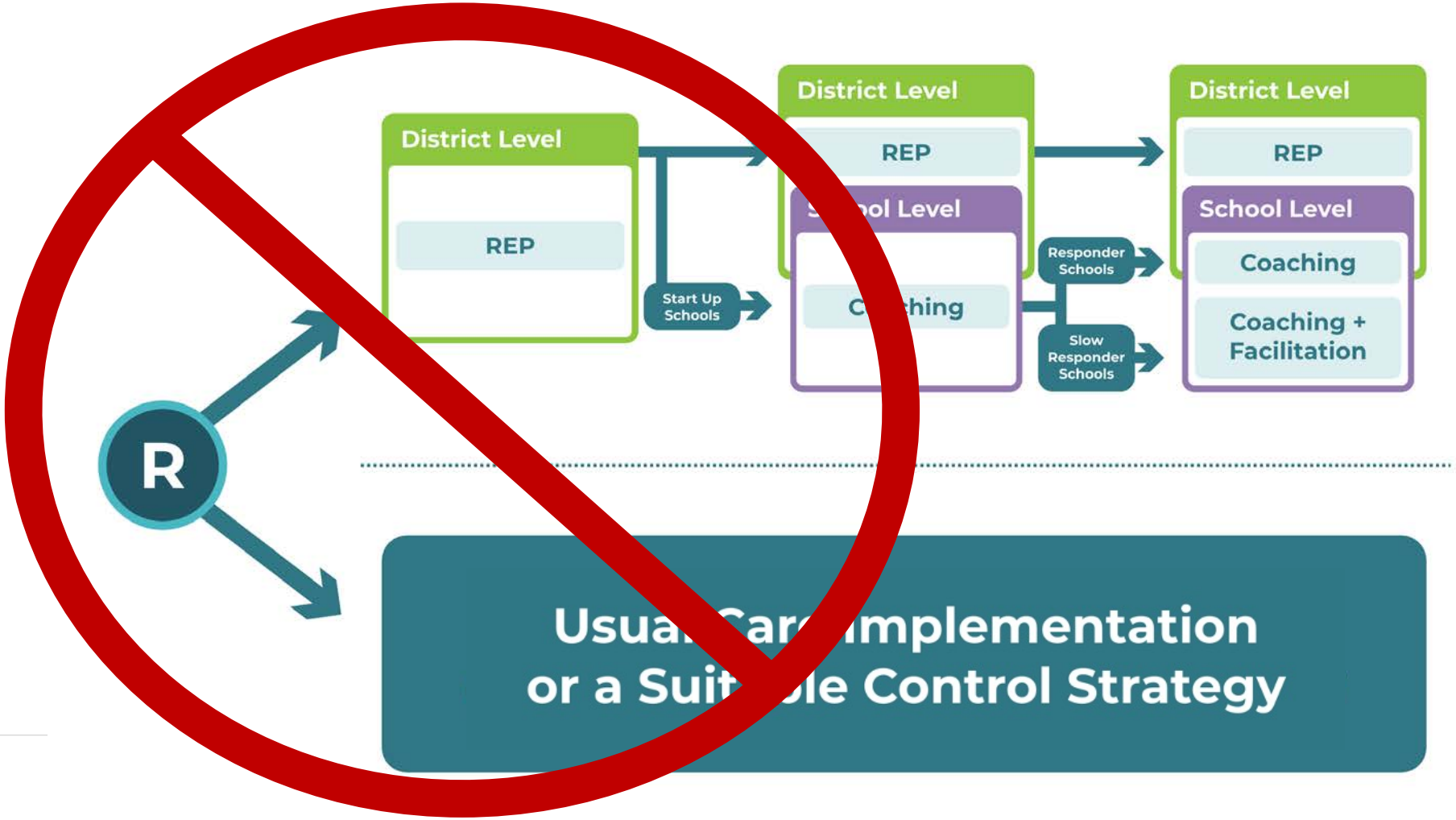
R01 MH114023; PI: Kilbourne

ANSWER:

A standard, 2-arm, confirmatory clustered randomized trial.



My focus concerns optimization randomized trials!



Outline

- Implementers Have to Make Many Decisions @ Many Levels
- Multilevel Adaptive Implementation Strategies
- Using Randomization to **Construct an Optimized MAISY**

Now put your “researcher hats” back on…and hold on!

A Decision Aide for Selecting the Appropriate Type of Optimization Trial

This decision aide below presupposes that the

- ☑ scientist has a set of two or more optimization questions; and, for simplicity,
- ☑ MAISY has two levels: individual i within organization j; and
- ☑ primary outcome $Y_{i,j}$ is defined at the level of the individual i within organization j.

Regarding the set of optimization questions:		**Comparisons at a single level or across multiple levels of the MAISY?**		
		Single level		**Multiples levels**
		Individual *i*	**Organization *j***	**Both Individual *i* and Organization *j***
Comparisons at a single decision opportunity or across multiple decision opportunities?	**Single**	Single level Factorial	Clustered Factorial	Multilevel Factorial
	Multiple	Single level SMART	Clustered SMART	Multilevel SMART

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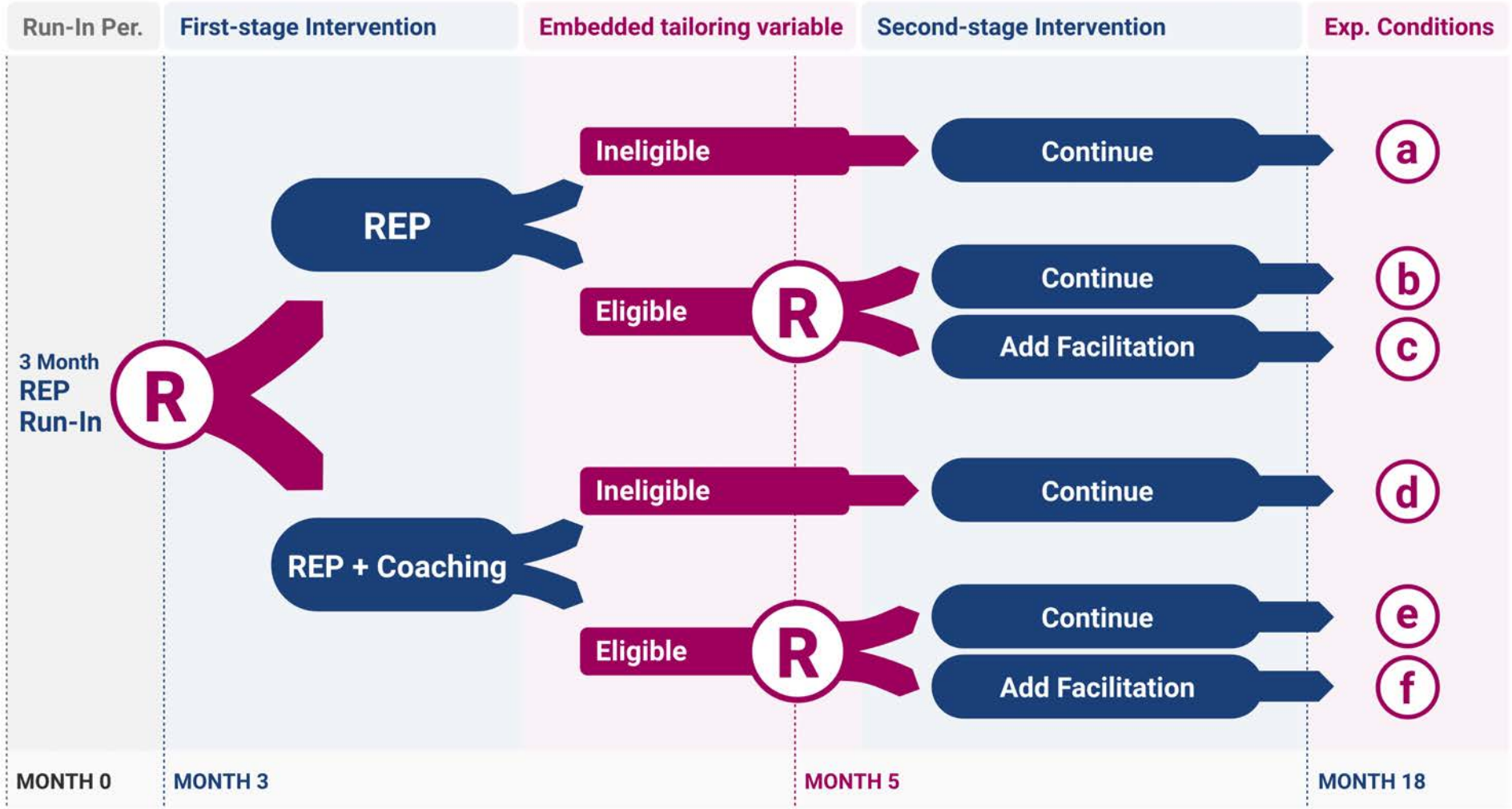
Comparisons at a single decision opportunity or across multiple decision opportunities?	**Single**	Single level Factorial	Clustered Factorial	Multilevel Factorial
	Multiple	Single level SMART	Clustered SMART	Multilevel SMART

Optimization Questions: Basic, but important

Type	In the context of ASIC
Effectiveness of earlier stage strategies	What is the effectiveness of Coaching?
Effectiveness of later stage strategies	What is the effect of Facilitation among schools that are slower responders?
Between-stage Interaction Effects	Do Coaching and Facilitation interact to produce beneficial outcomes?
Adaptive versus not adaptive	Adaptive vs non-adaptive, ala REP only vs the MAISY shown earlier

Clustered SMART Example



REP →

Replicating Effective Programs; low-level implementation strategy that provides manualization of intervention (e.g., CBT), didactic training, & technical assistance

Coaching →

In-person coaching during CBT groups at the school for a minimum 12 weeks

Facilitation →

Phone calls with an expert in CBT & strategic thinking for a minimum 12 weeks.

Clustered SMART Example

4 Embedded Interventions (aka Implementation Strategies)

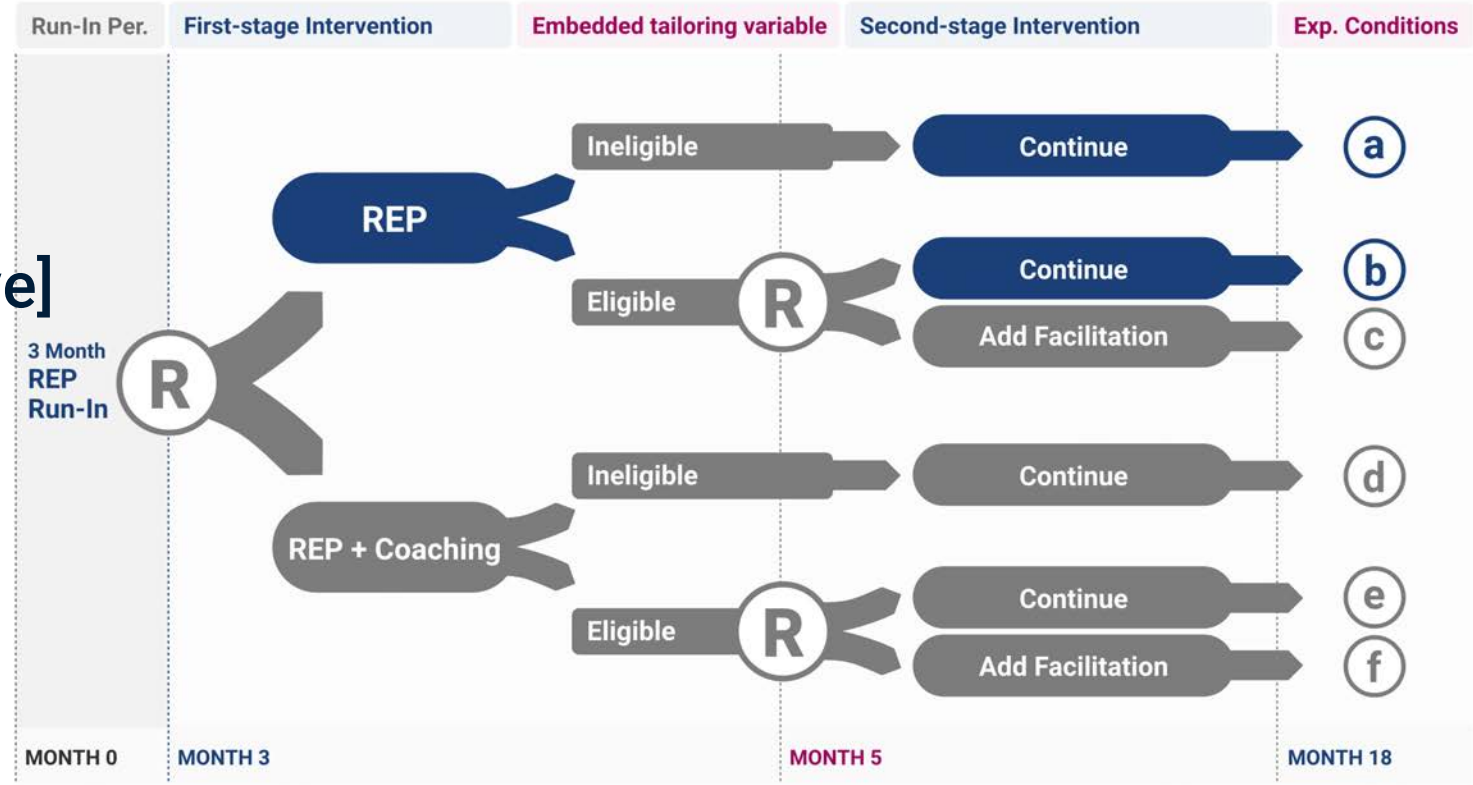
[2 are MAISYs, 2 are not adaptive]

Clustered SMART Example

4 Embedded Interventions

Intervention #1 [not adaptive]

Always do **REP**

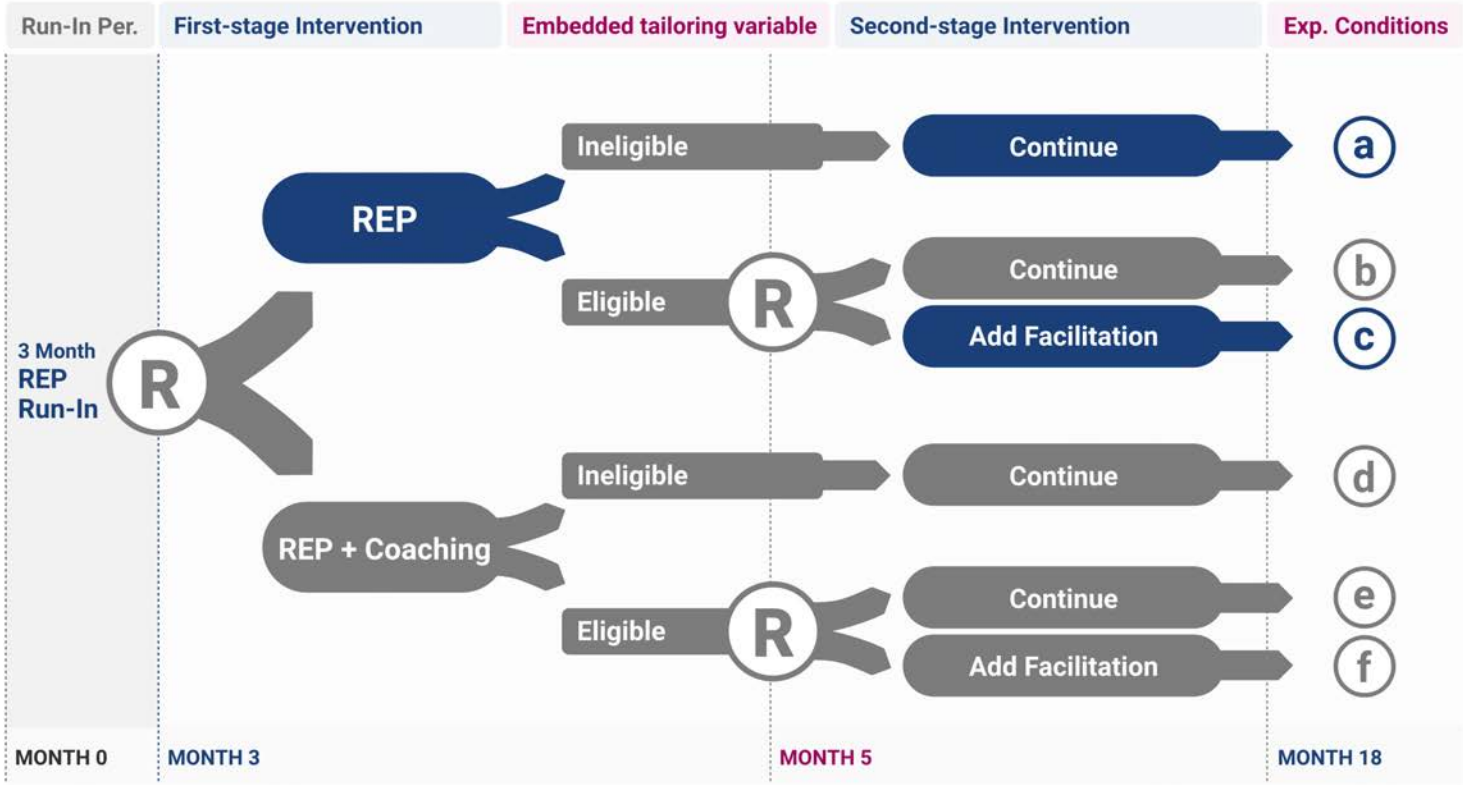


Clustered SMART Example

4 Embedded Interventions

Intervention #2 [a MAISY]

Start with **REP**;
if **ineligible, continue REP**;
else **add Facilitation**

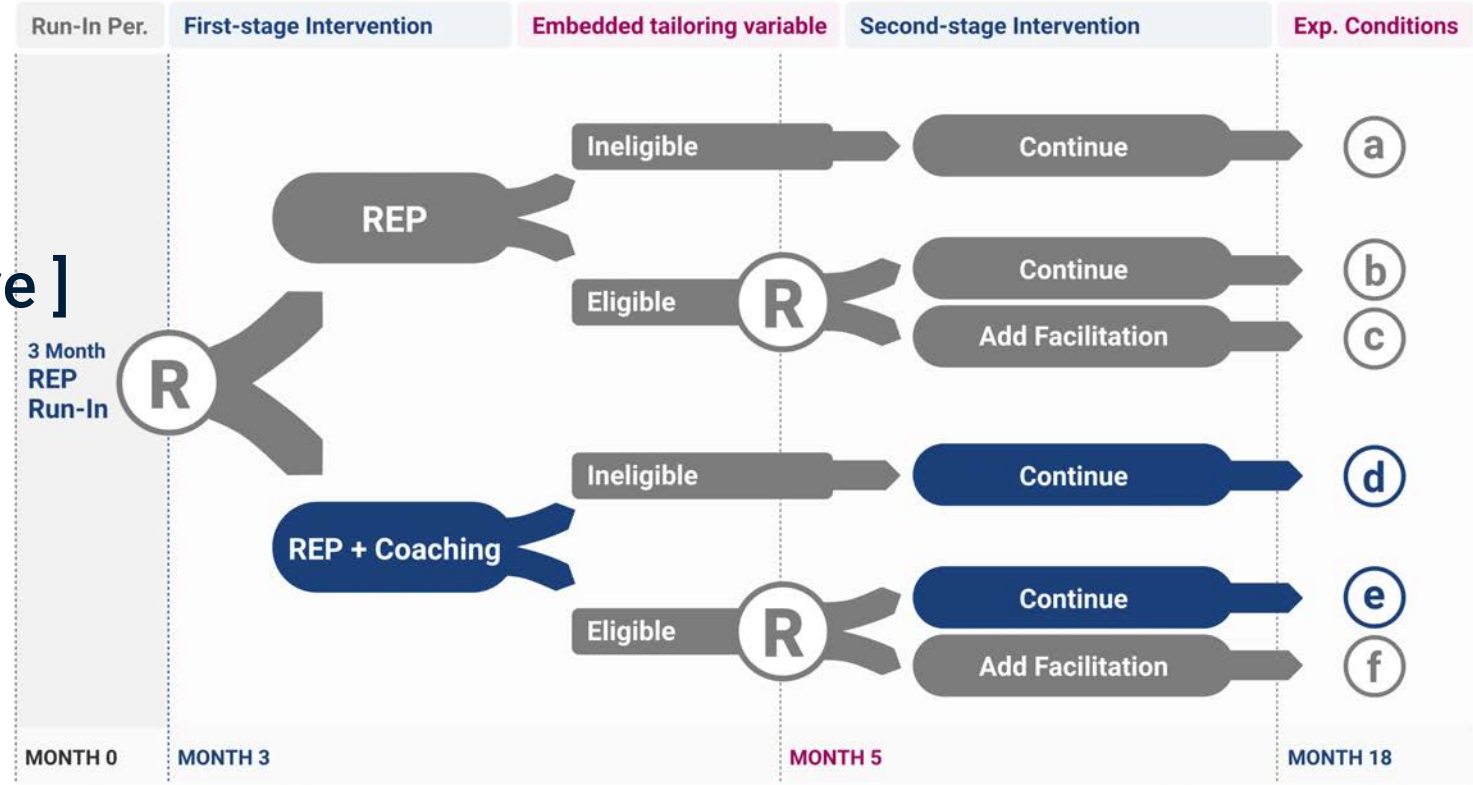


SMART Example

4 Embedded Interventions

Intervention #3 [not adaptive]

Always do **REP + Coaching**

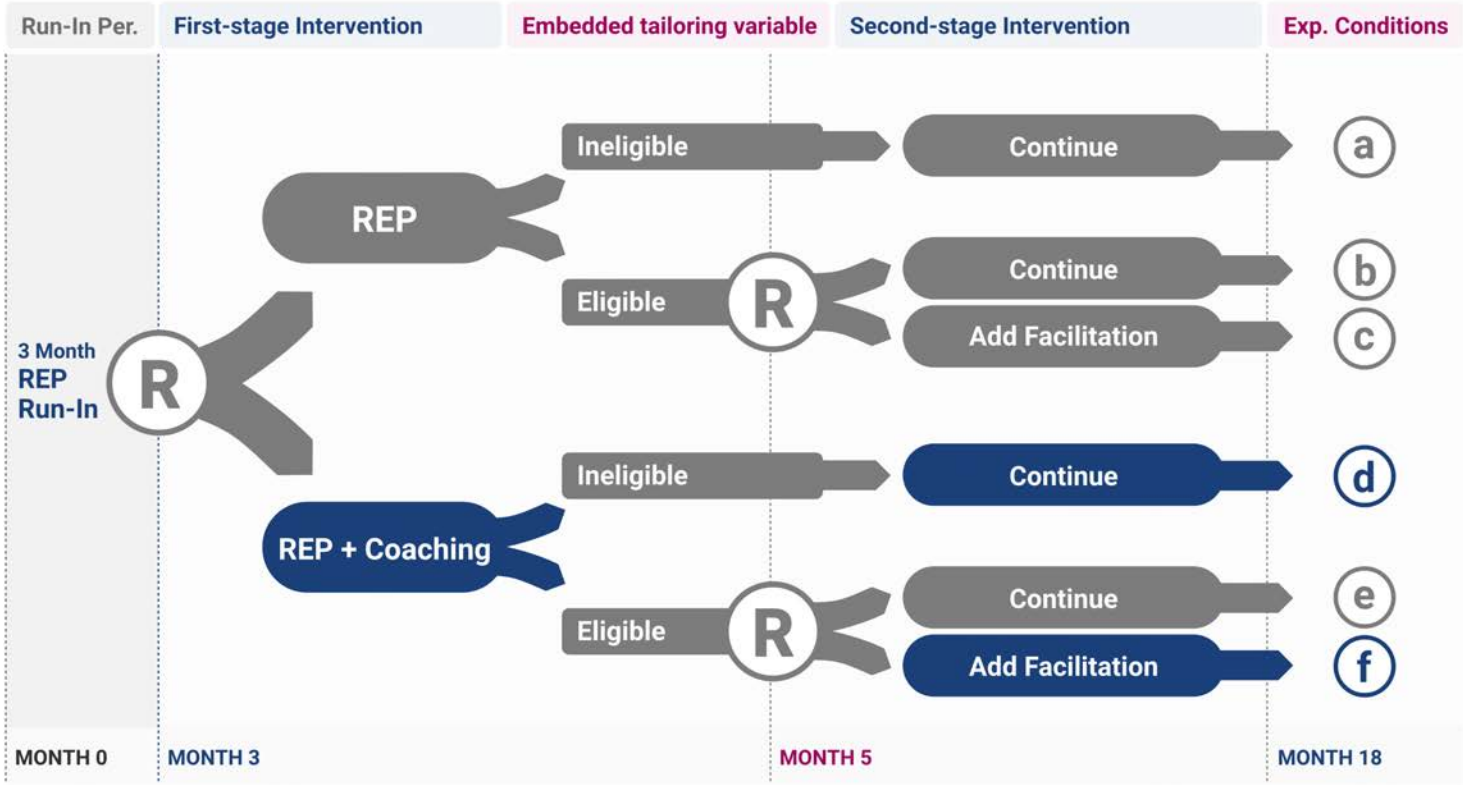


SMART Example

4 Embedded Interventions

Intervention #4 [a MAISY]

Start with **REP + Coaching**;
if **ineligible**, **continue REP**
+ Coaching;
else **add Facilitation**



SMART Example

Primary Aim

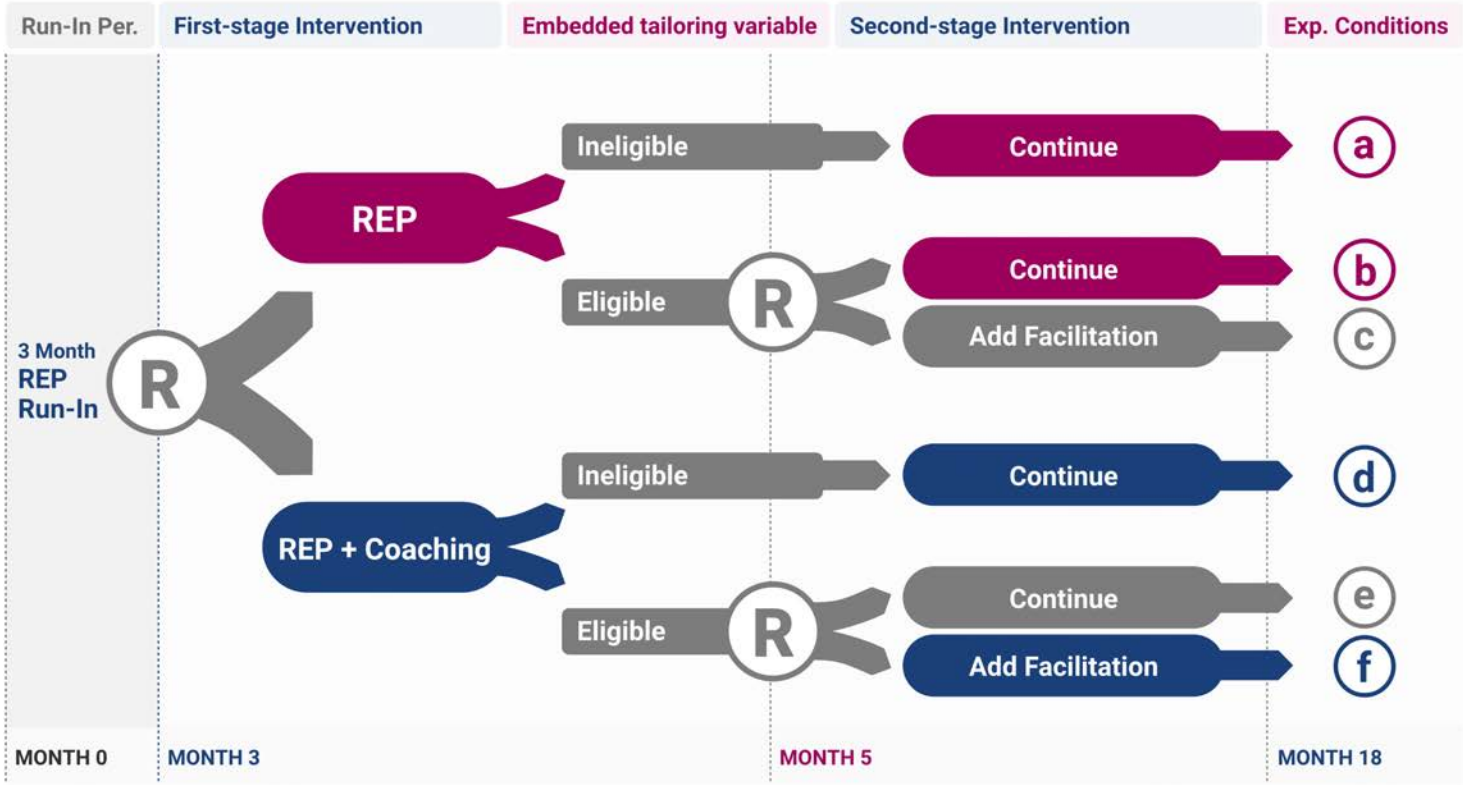
To compare

Always do **REP**

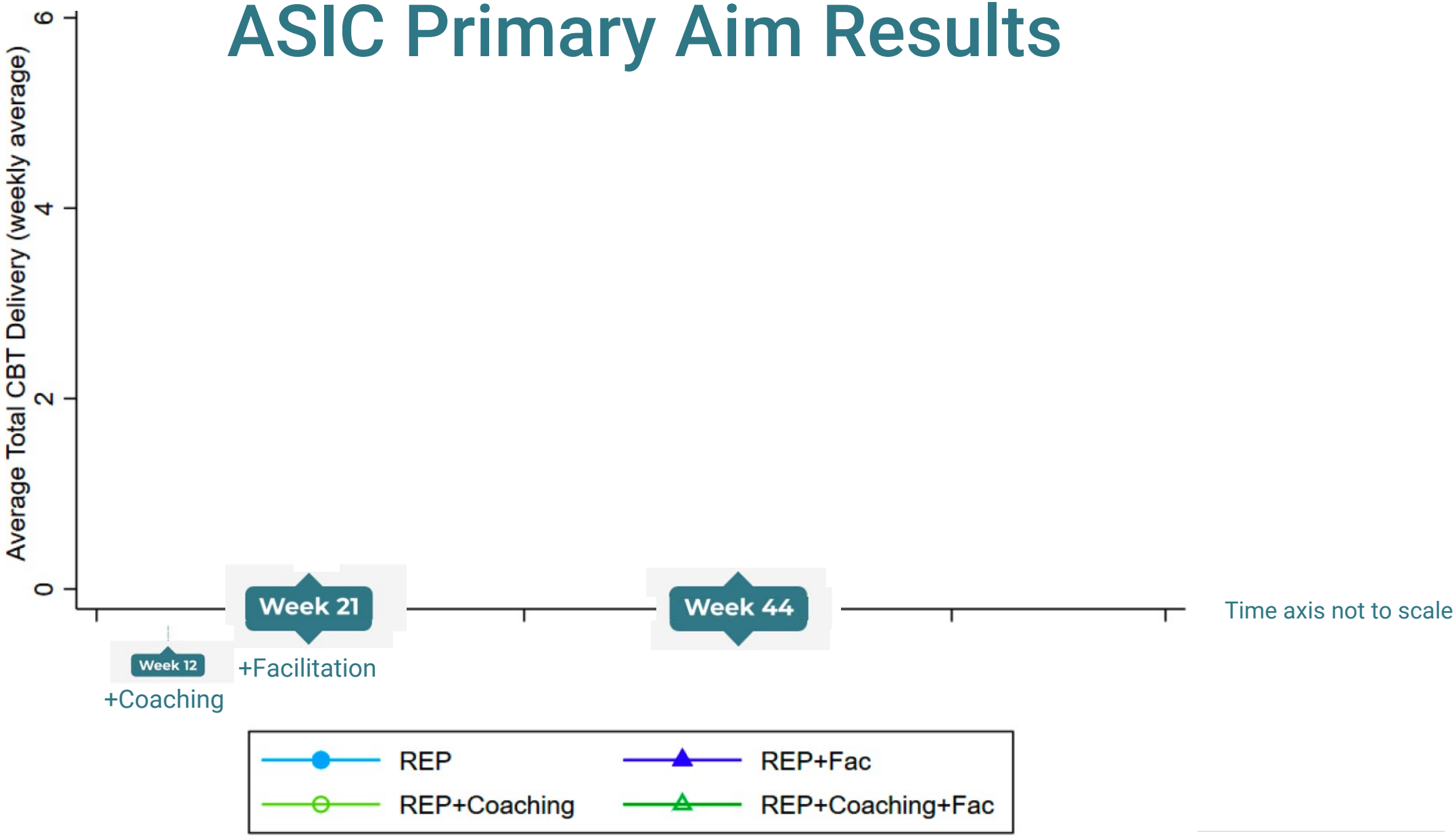
versus

REP + Coaching + Facilitation
MAISY

in terms of the average number of CBT sessions delivered by SPs over 18 months.



ASIC Primary Aim Results



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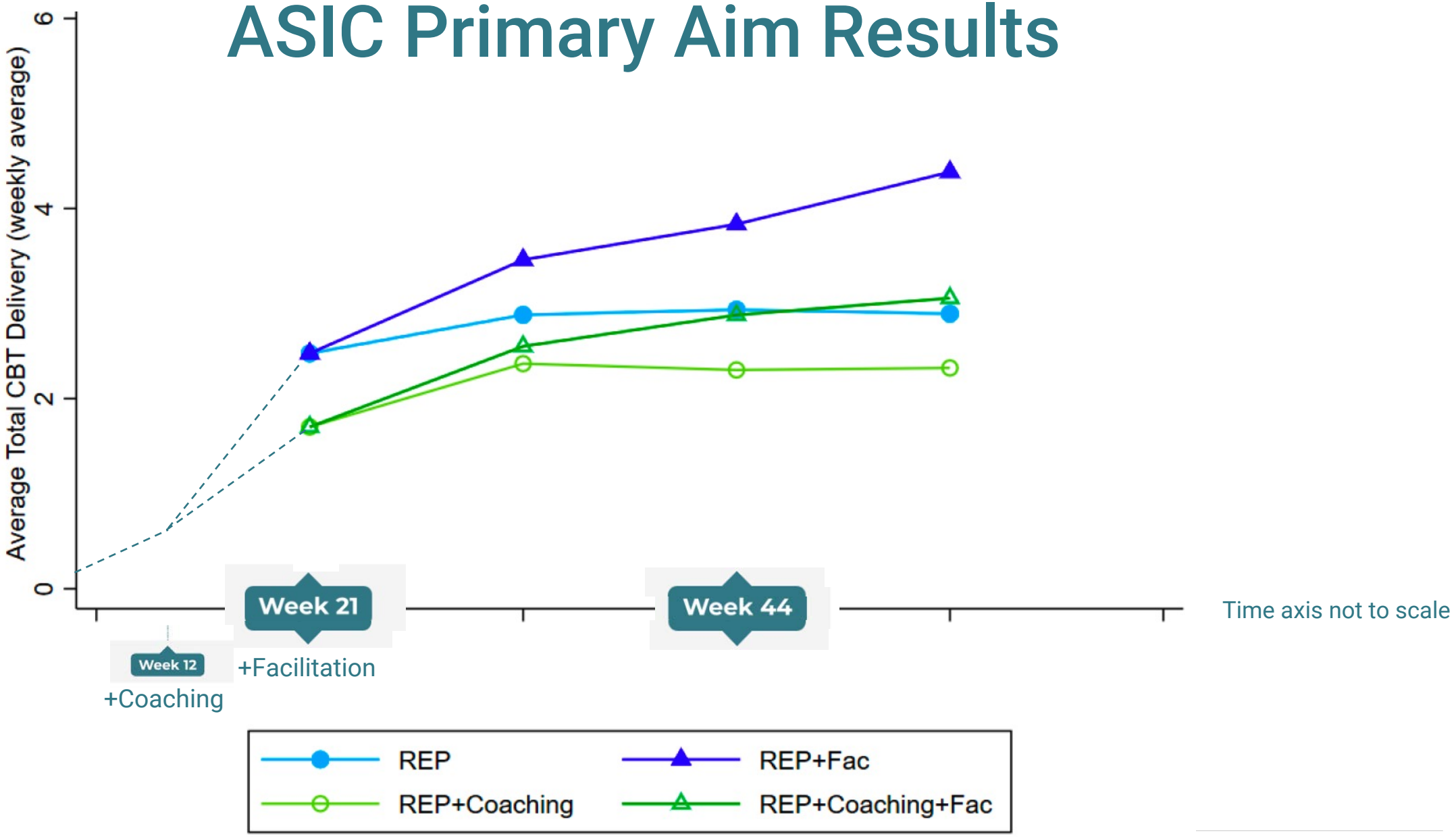
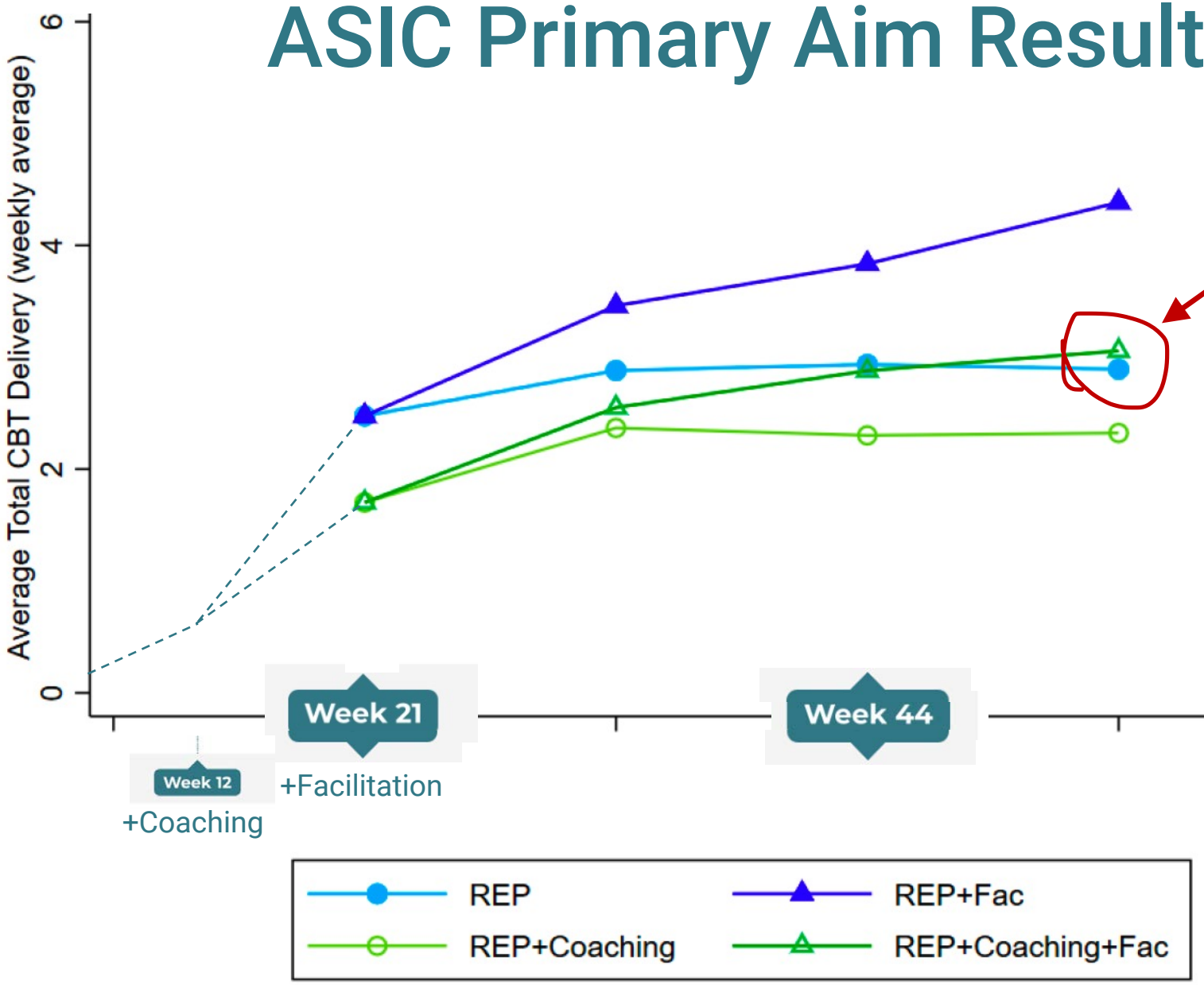


Smith, Almirall, Choi, …Kilbourne (2022), *Impl Sci*

ASIC Primary Aim Results

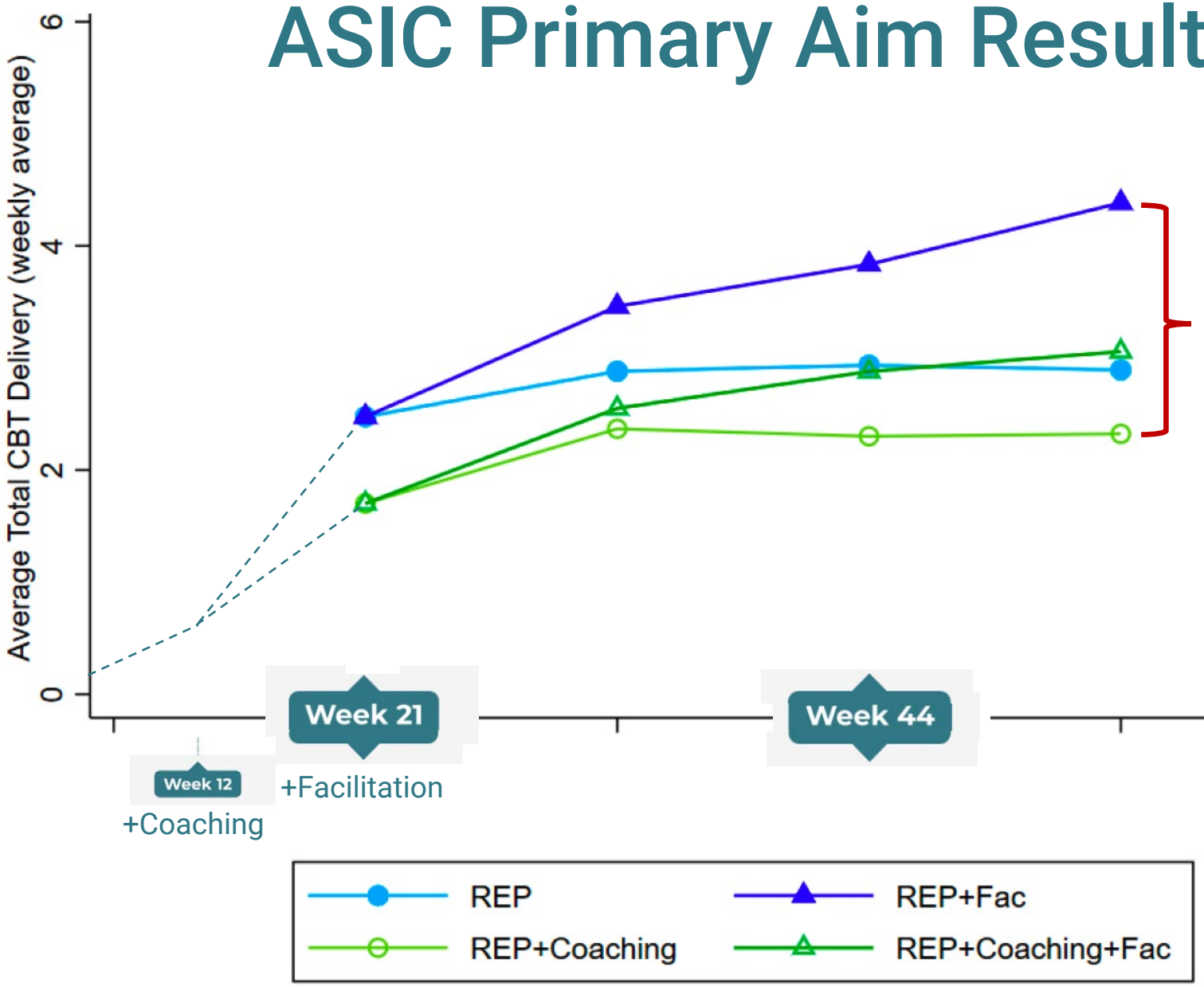


The **first big surprise** was that:

(1) there was no evidence to reject the null that there is no difference between Always REP vs the "cadillac" MAISY.

Smith, Almirall, Choi, …Kilbourne (2022), *Impl Sci*

ASIC Primary Aim Results



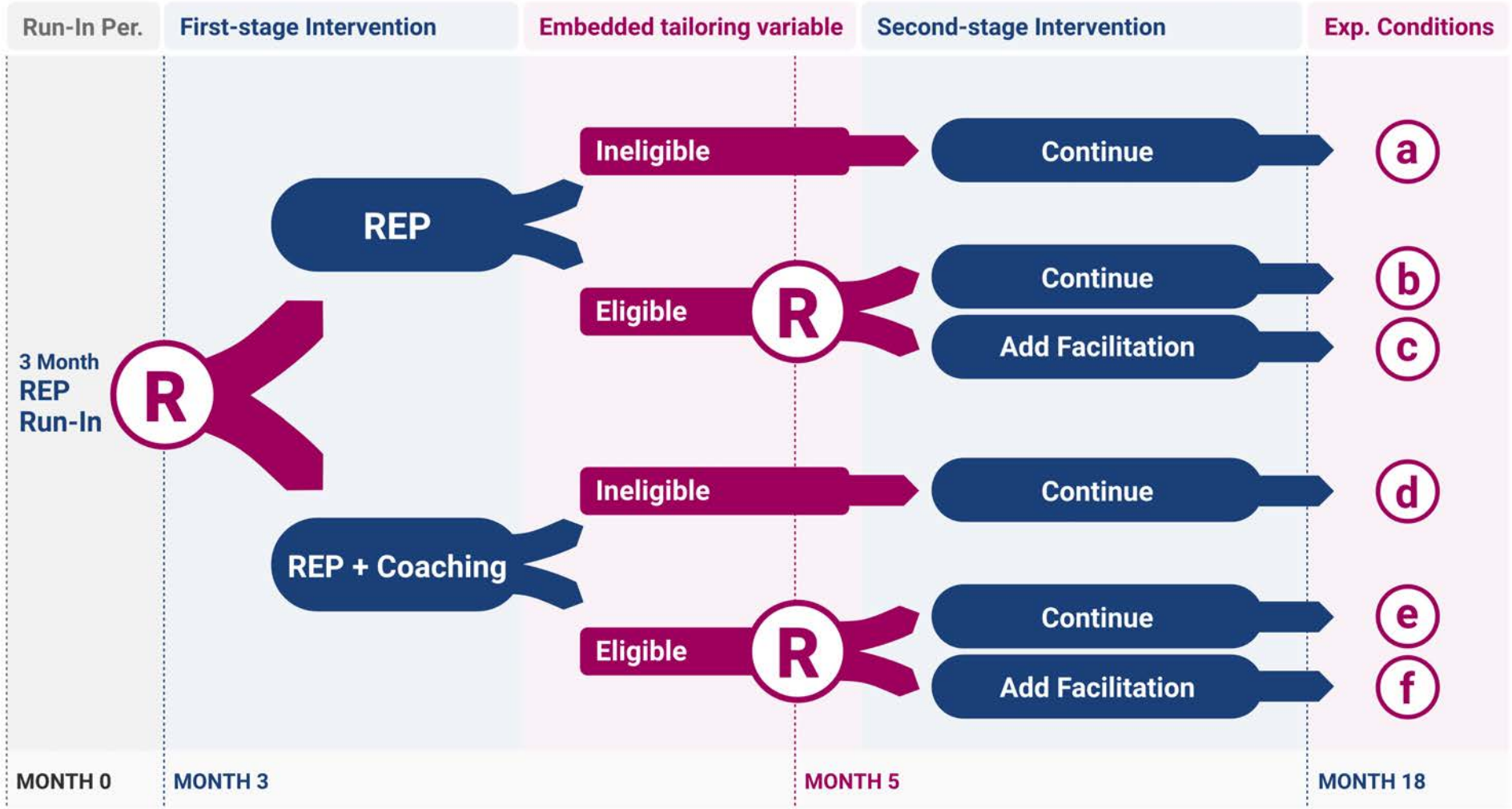
The **second and third big surprises** were that:

(2) the REP+Facilitation MAISY was the <u>most favorable</u> of the 4 implementation strategies; and

(3) Always REP+Coaching was <u>least favorable</u>.

Smith, Almirall, Choi, …Kilbourne (2022), *Impl Sci*

Clustered SMART Example



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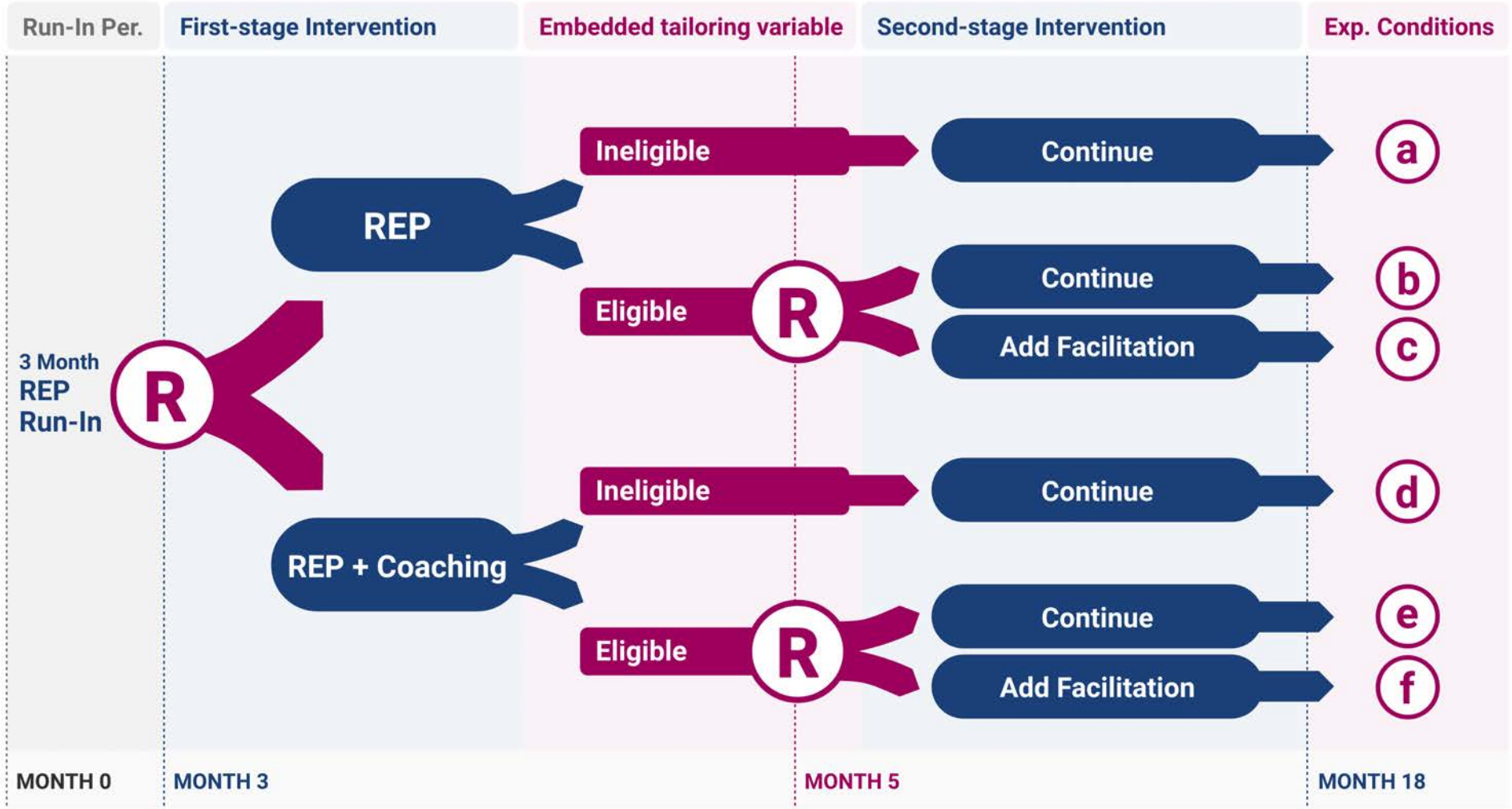
Typical Secondary Aims of a Clustered SMART

Optimization Questions: About tailoring

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

Clustered SMART Example



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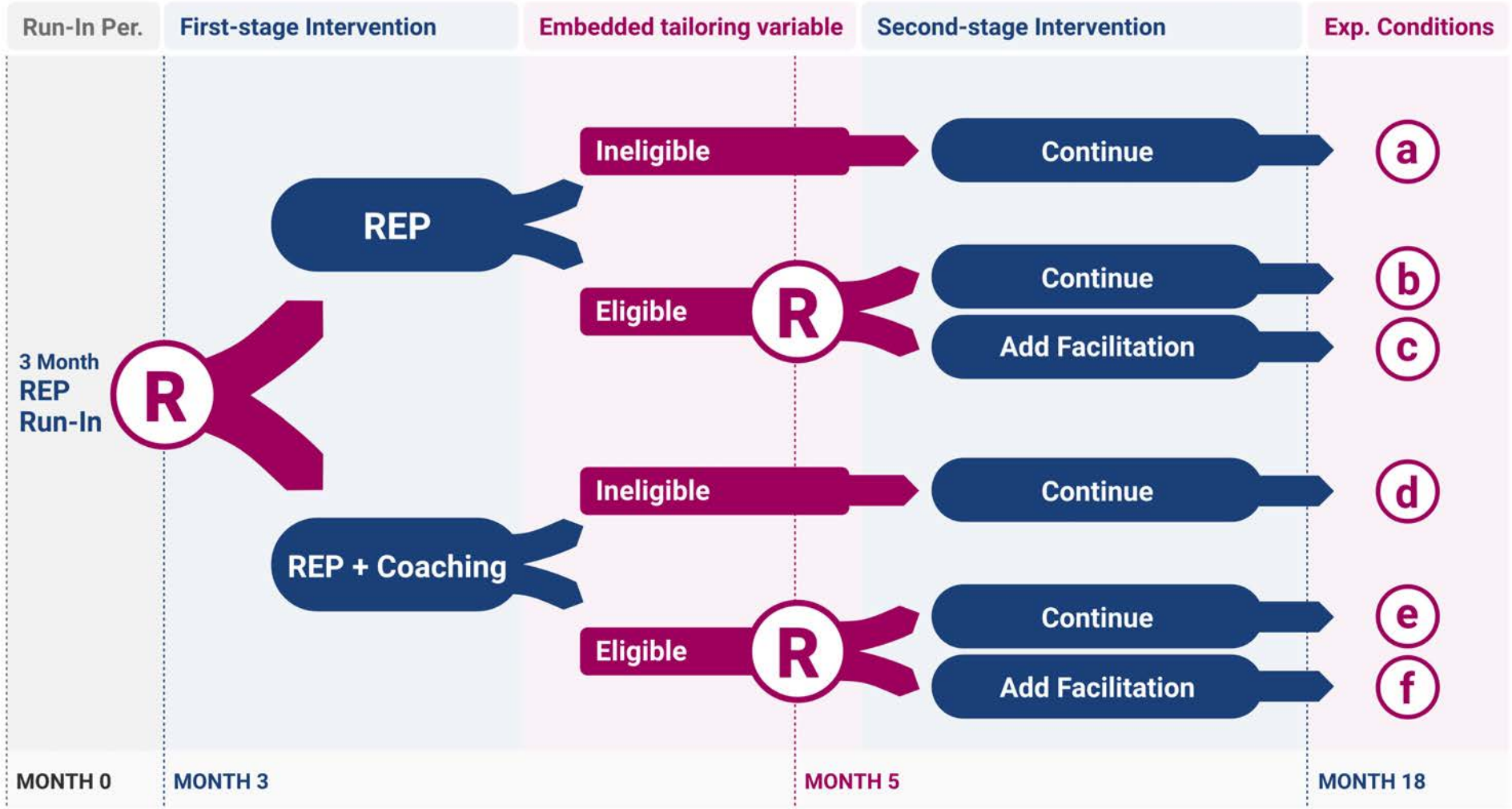
Optimization Questions: More about tailoring

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

Clustered SMART Example



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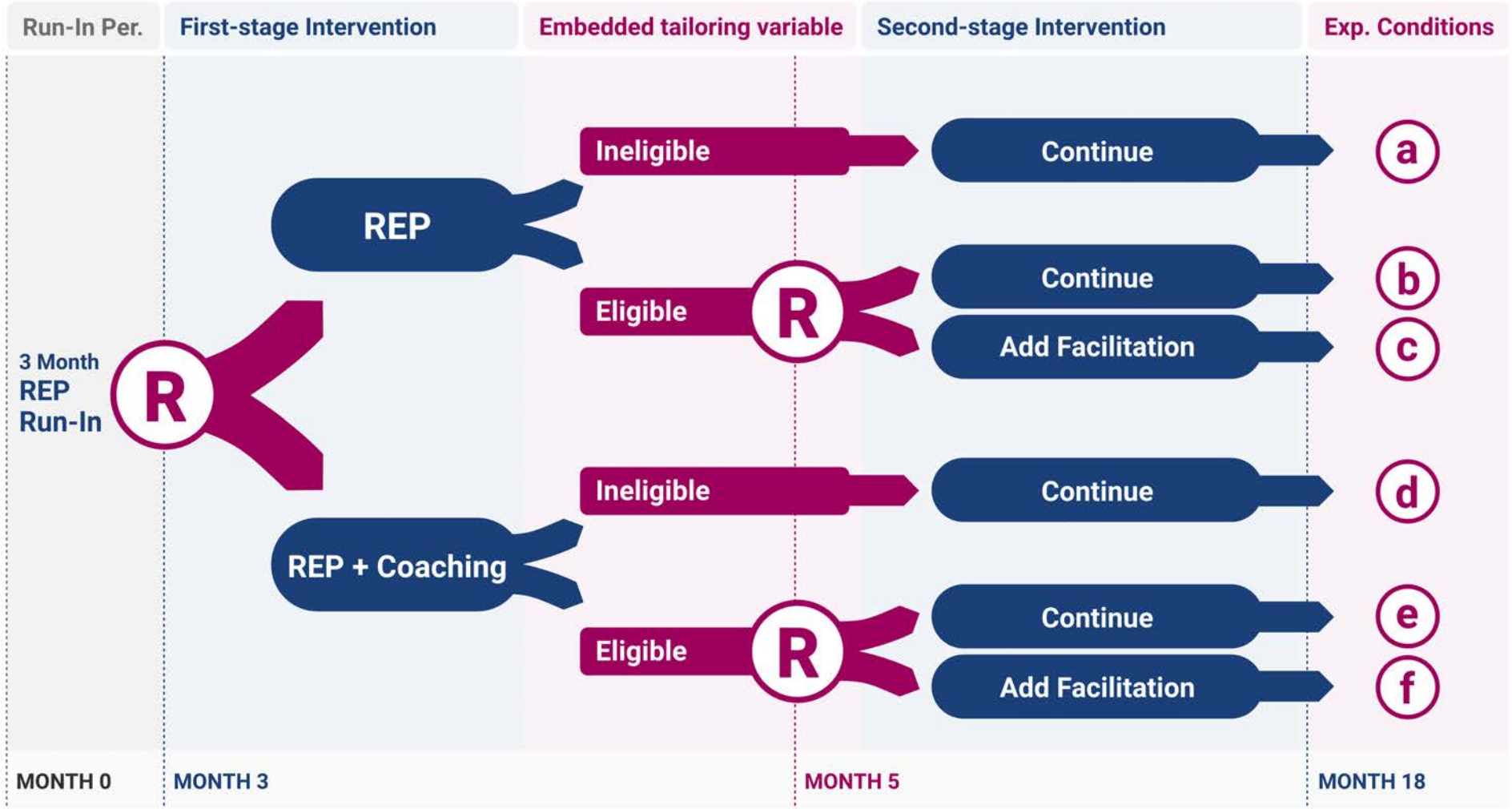
Optimization Questions: Delayed Effects

Type	In the context of ASIC
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?
Prescriptive effects?	Did we learn something from Coaching that can help decide whether to do Facilitation?

Clustered SMART Example



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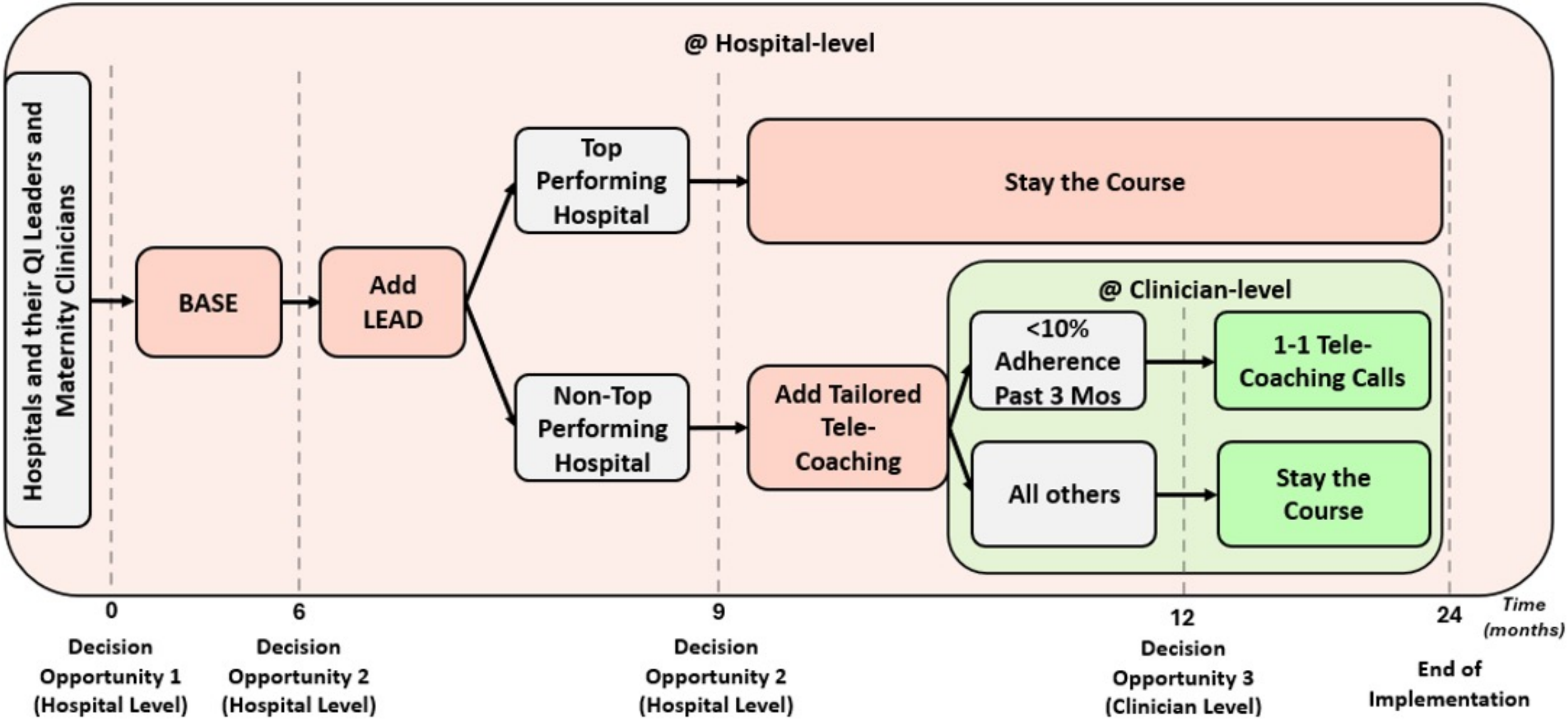
MAISY Example #2

I use this next example to Illustrate distinction between a Clustered SMART and Multilevel SMART

MAISY Example #2(a)

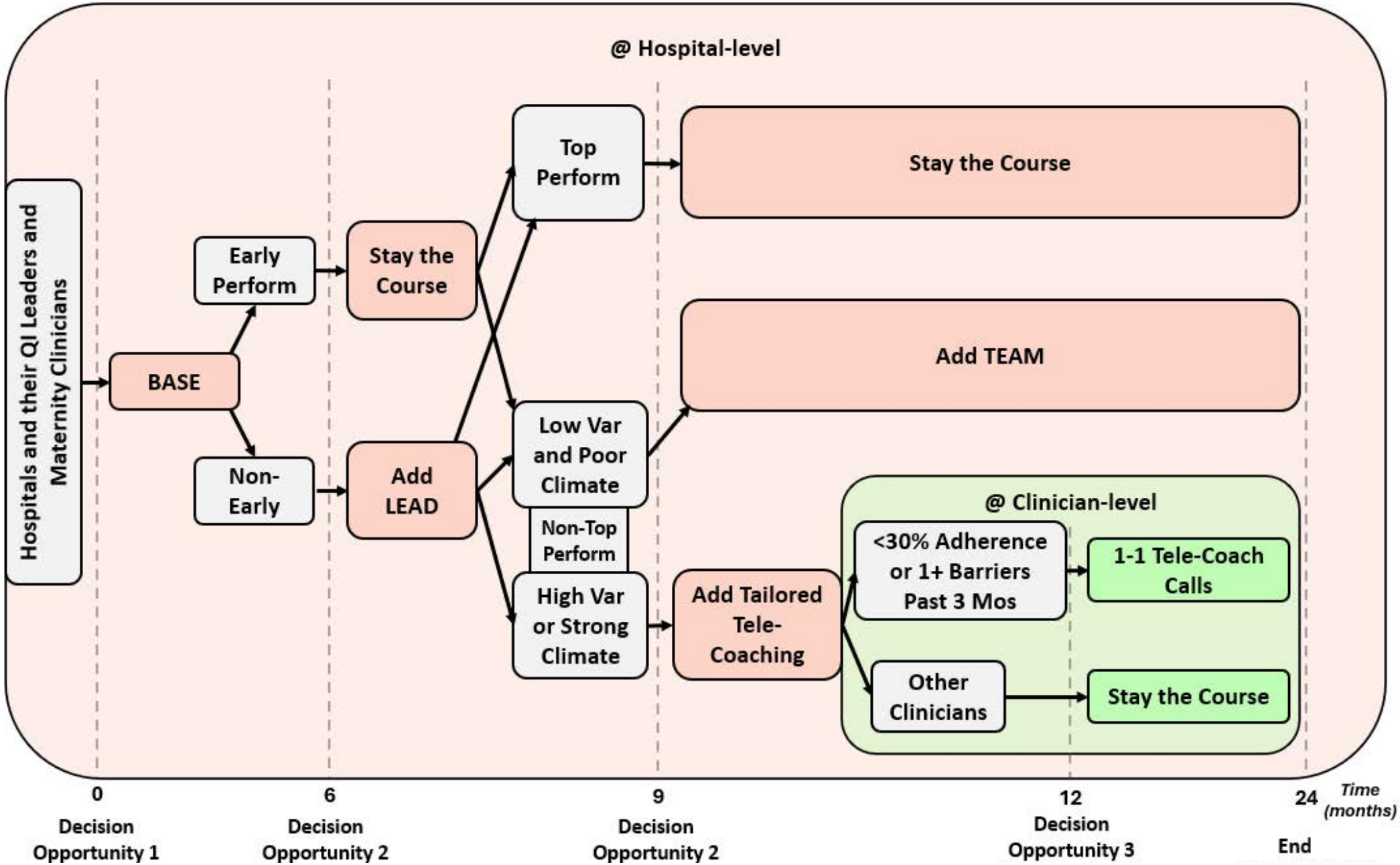
Implementation of EB Induction of Labor
Joint work with: Michelle Moniz, Univ of Michigan



Hypothetical, but inspired by current work in Obstetrics

MAISY Example #2(b)

Implementation of EB Induction of Labor
Joint work with: Michelle Moniz, Univ of Michigan



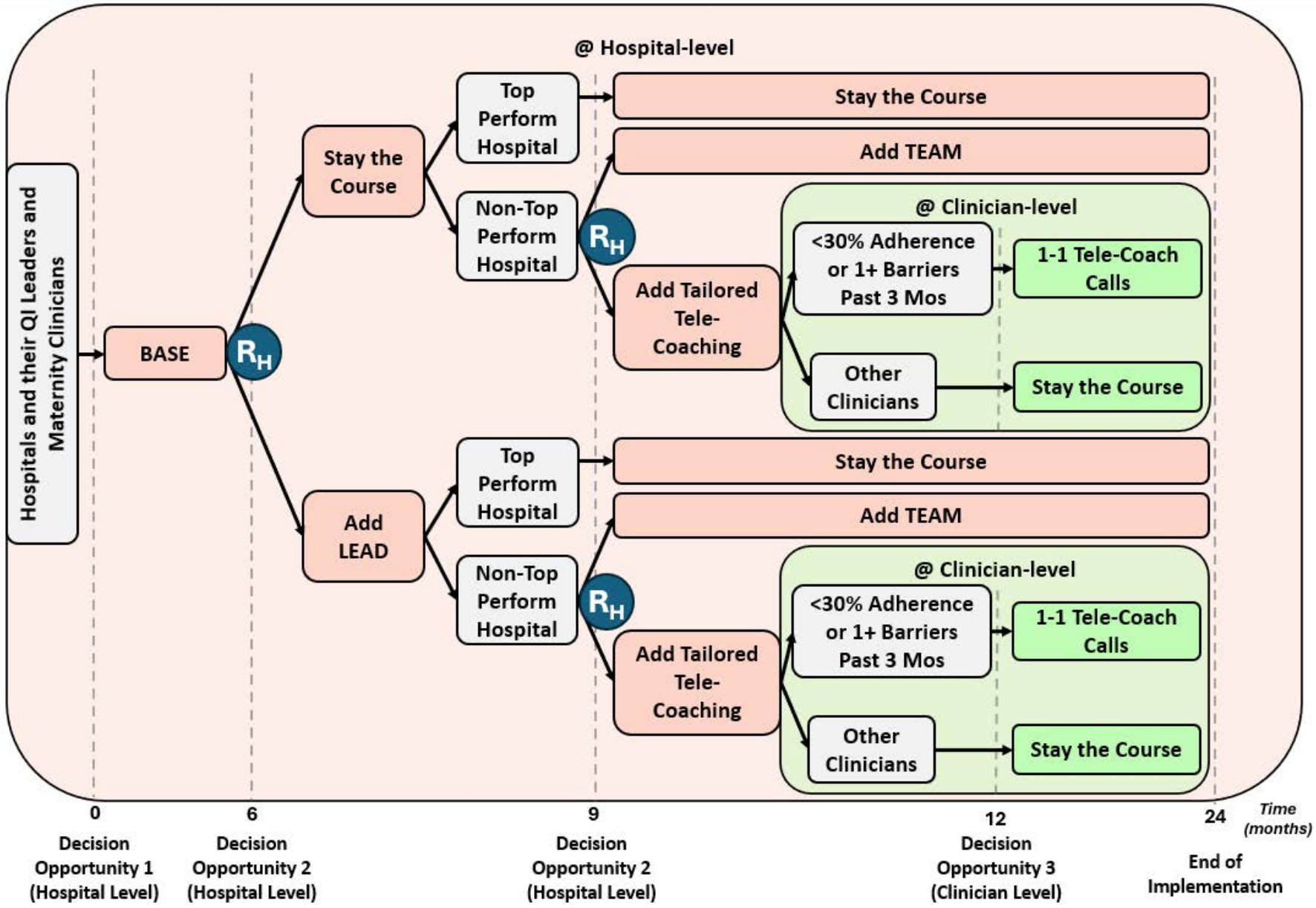
Optimization Questions that Implicate Spillover

Type	In the context of IOL
Earlier stage component effects?	Do all hospitals need LEAD?
Later stage component effects	Among non-Top performing hospitals, what is the relative effect of offering TEAM instead of employing TTC?
Tailoring	Which non-Top performing hospitals ought to be offered TEAM vs TTC?

A Clustered SMART

Domain Area:
Induction of Labor

PI:
Michelle Moniz, Univ of Michigan



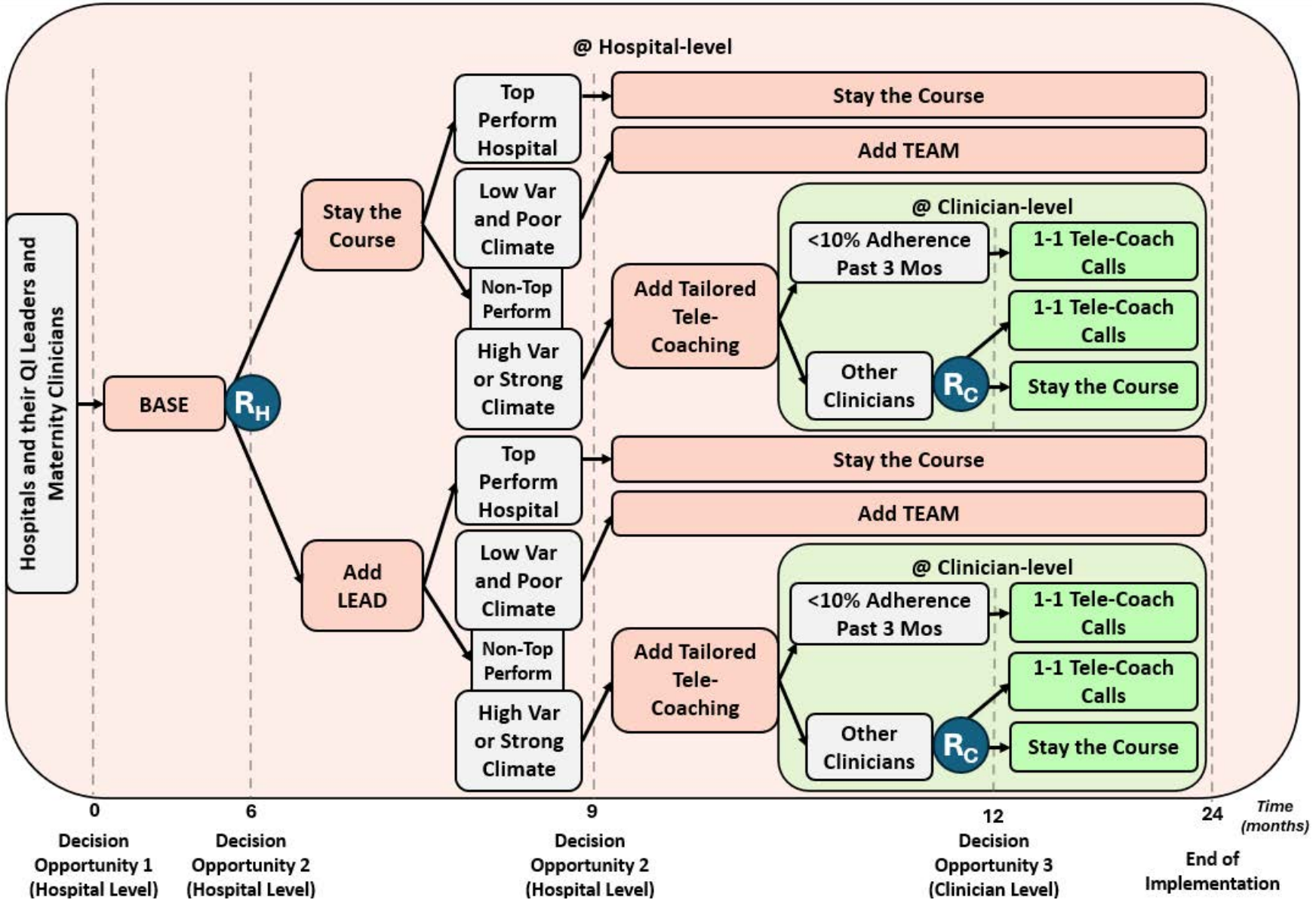
Optimization Questions that Implicate Spillover

Type	In the context of IOL
Earlier stage component effects?	Do all hospitals need LEAD?
Later stage component effects	In non-Top performing hospitals receiving TTC: Among clinicians with 10% adherence, what is the effect of 1-1 Tele-coaching?
Tailoring	Which of these clinicians ought to be offered 1-1 Tele-coaching?

A Multilevel SMART

Domain Area:
Induction of Labor

PI:
Michelle Moniz, Univ of Michigan



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Institutes for Education Sciences

R324B210001 (UMich, d3c);
R305B210004 (UWash, A. Lyon)

Further Reading

Song, Y., Speth, K., Kilbourne, A., Quanbeck, A., Almirall, D., Wang, L. (2025). Q-Learning with Clustered SMART Data (cSMART): Examining Moderators in the Construction of Clustered Adaptive Interventions. arXiv preprint: https://arxiv.org/abs/2505.00822.

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Beyond This:
Extra Slides Just in Case

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Sample
Size
only
$5

SMART Example

Primary Aim

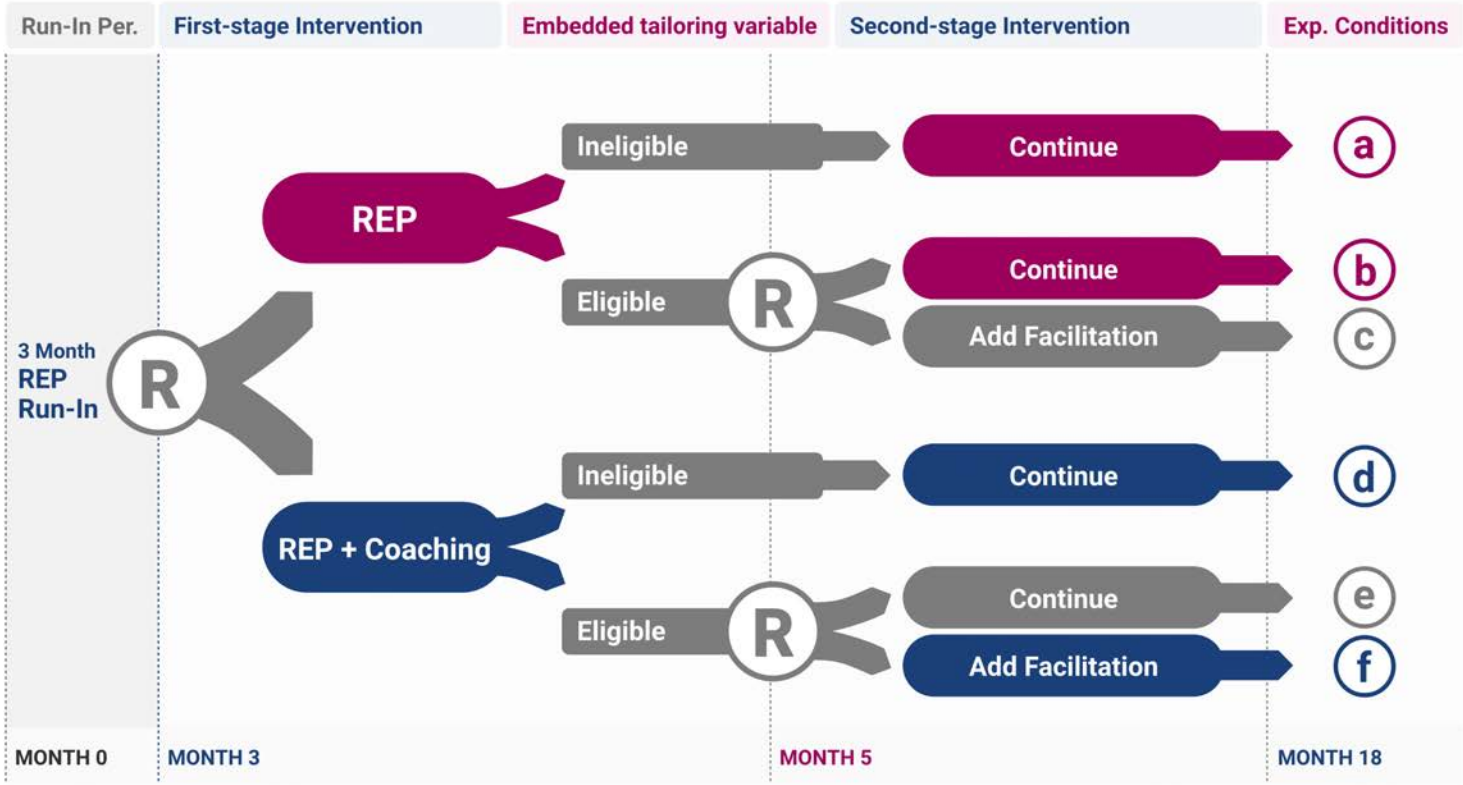
To compare

Always do **REP**

versus

REP + Coaching + Facilitation
MAISY

in terms of the average number of CBT sessions delivered by SPs over 18 months.



Sample Size for a Prototypical Clustered SMART

$$N \geq \frac{4\left(z_{1-\alpha/2}+z_{1-\beta}\right)^2}{m*\delta^2} \times (2-r) \times (1+(m-1)\rho) \times (1-\alpha^2)$$

where

r = response rate after stage 1 impl strategy

m = avg number of SPs at each school

ρ = inter-school correlation in outcome

α = corr(baseline cluster-level covariate, outcome)