

Pragmatic Clinical Trials for Informing Adaptive (Implementation) Interventions

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7-minute Speed Talk

NIH Clinical Trials Collaboratory

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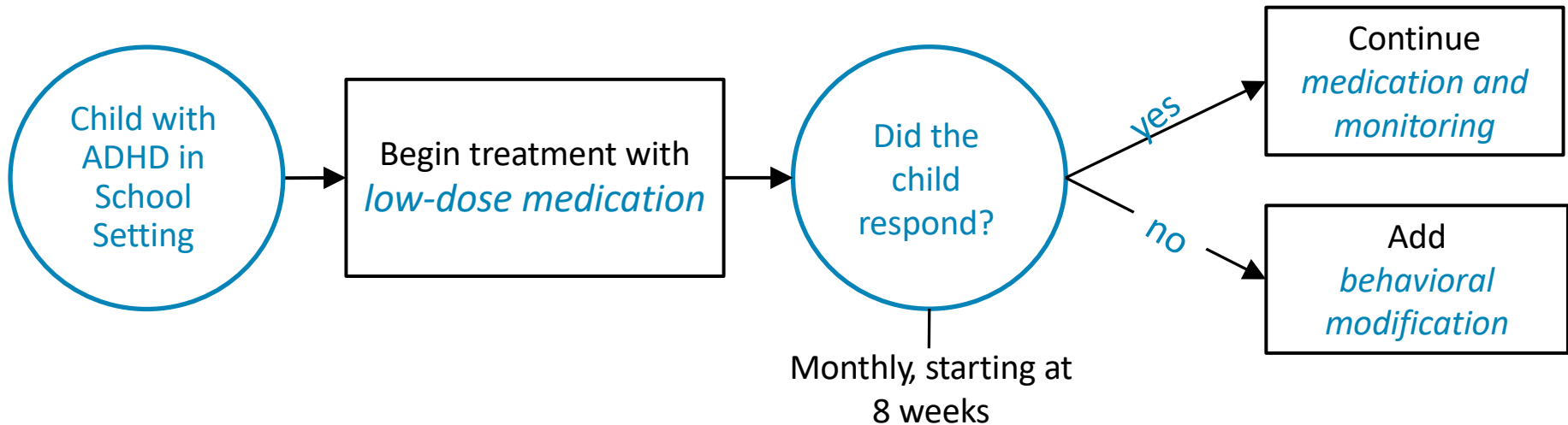


Adaptive Interventions

In real-world settings, intervention is often individualized to accommodate the changing & specific needs of individuals

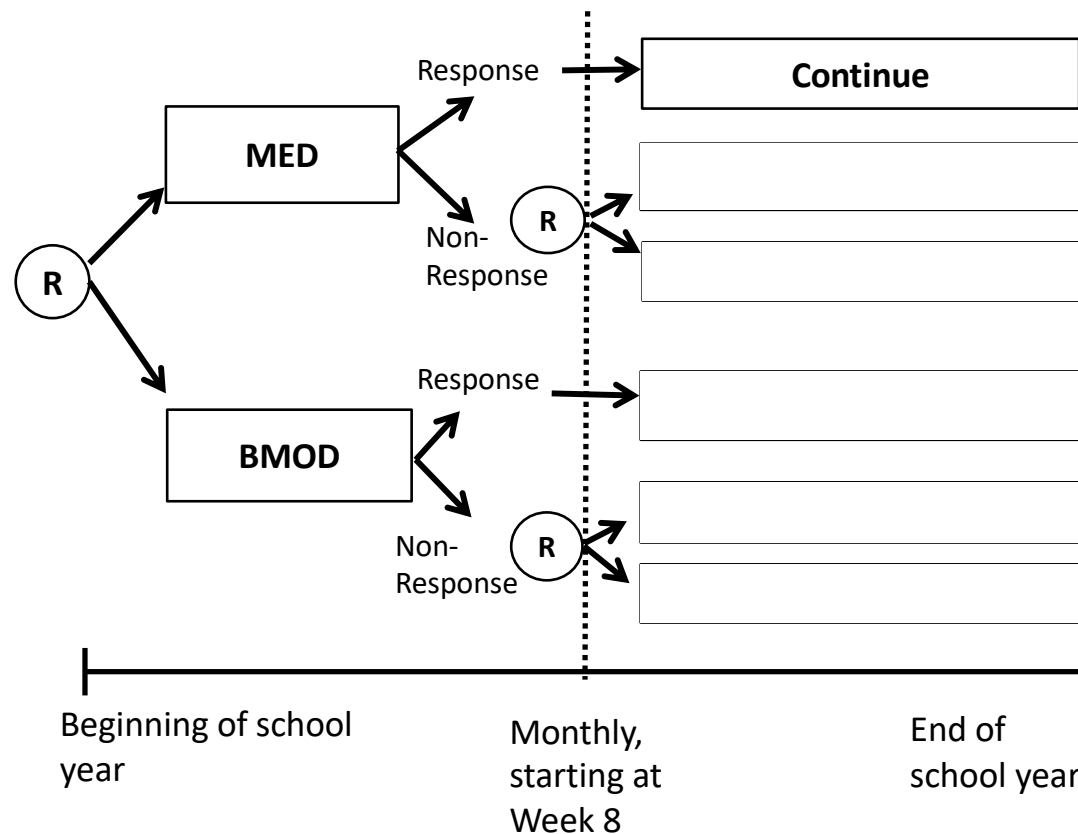
- Chronic disorders
e.g., hypertension, diabetes, obesity
- High levels of non-adherence
e.g., mental health, substance use
- Opposing outcomes
e.g., oncology

In real-world settings, intervention is often individualized to accommodate the changing & specific needs of individuals



This is an example
Adaptive Intervention

But decision-makers may have many pragmatic questions regarding how best to sequence/individualize treatments

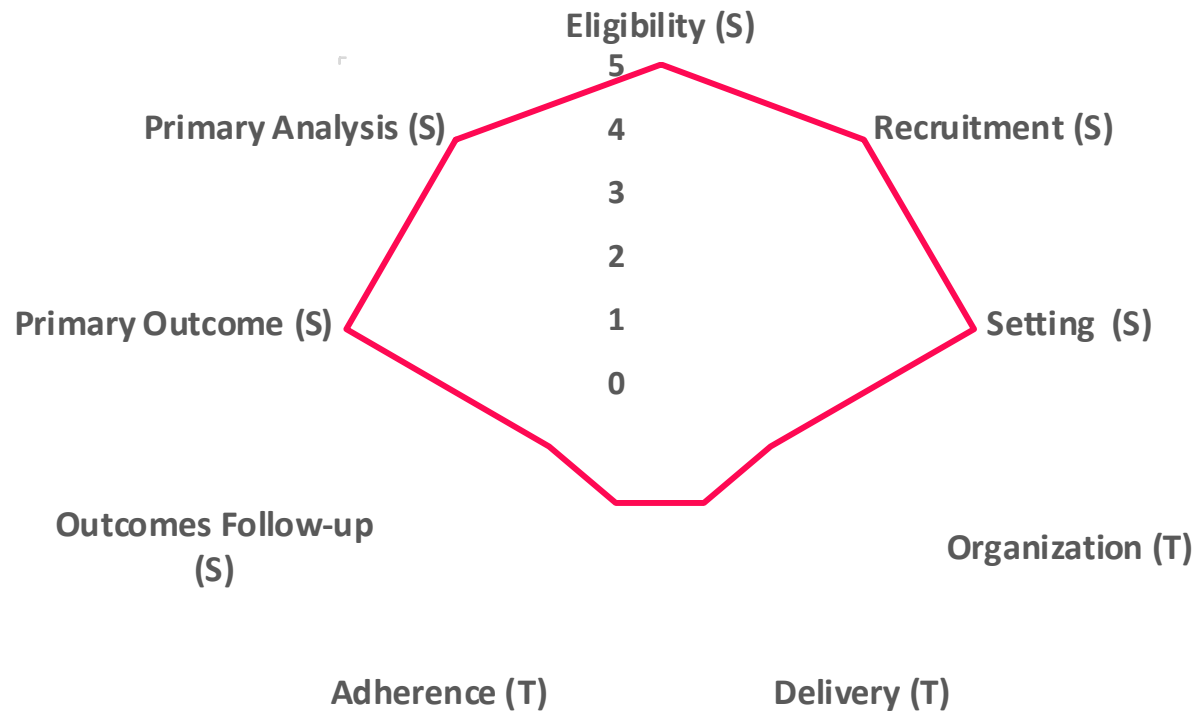


This is an example
Sequentially-randomized Trial

Are these types of trials pragmatic?

“Designed for the **primary purpose of informing decision-makers regarding the comparative balance of benefits, burdens, risks** of a biomedical or behavioral health intervention at the individual or population level” (Califf & Sugarman, 2015)

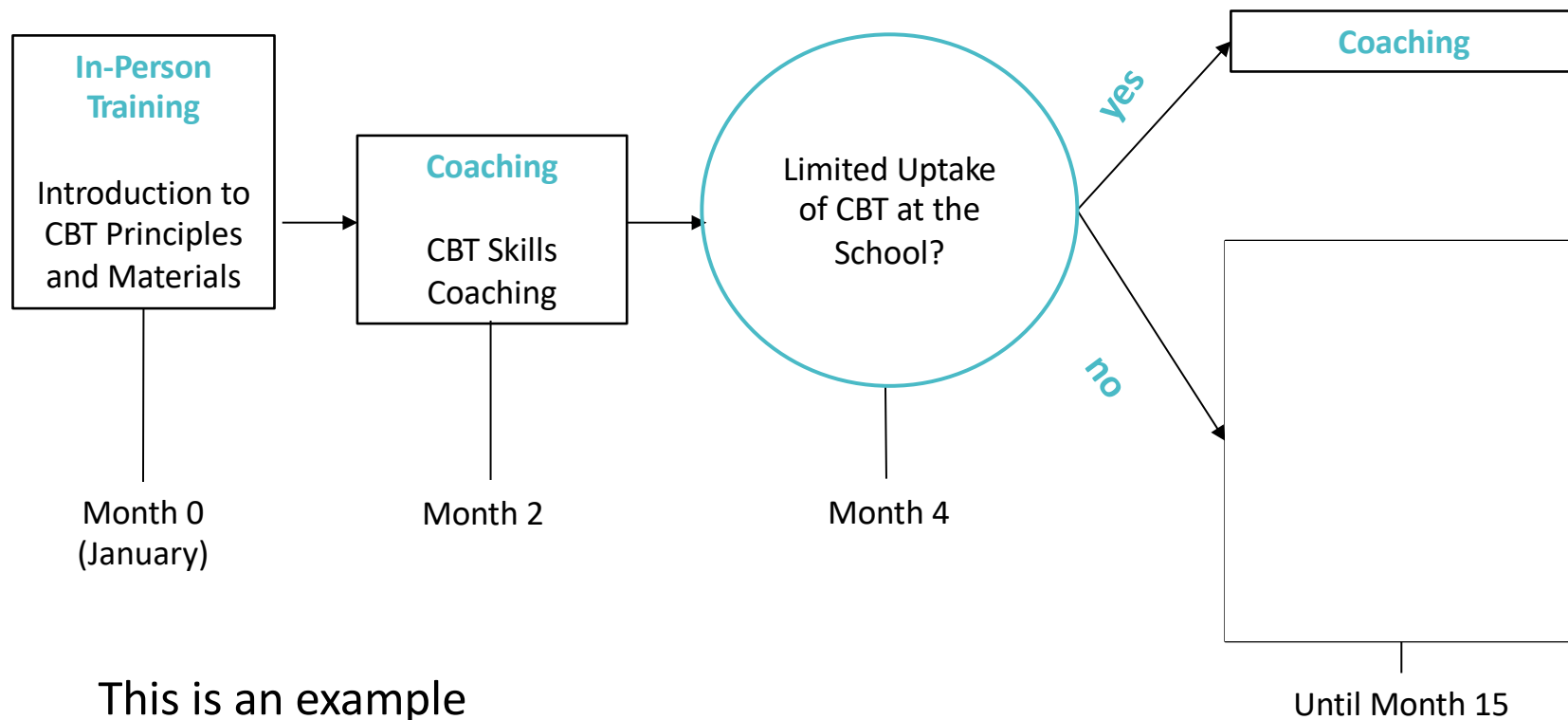
Are these types of trials pragmatic?



Based on my experience, there is room to make these trials more pragmatic.

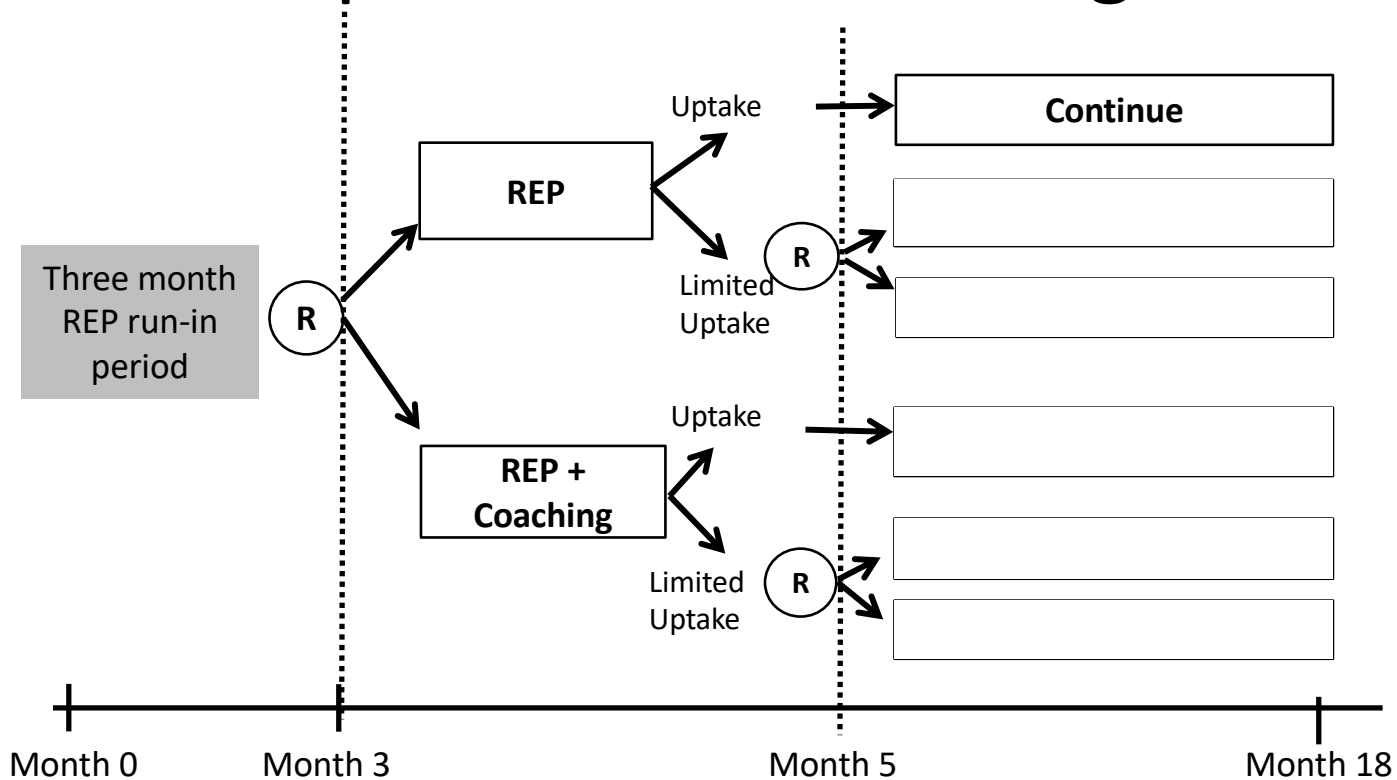
Adaptive Implementation Interventions

Often it is necessary to adapt and re-adapt organizational-level interventions to improve outcomes at the patient level



This is an example
Adaptive Implementation
Intervention

But decision-makers may have many pragmatic questions regarding how best to sequence implementation strategies



This is an example
Clustered, Sequentially-randomized Trial

Are PCT researchers taking advantage of lessons learned?

- Adaptive interventions are meant to guide real-world clinical practice
e.g., tailoring variables are not research assessments – they must be feasible in authentic health settings
- Do you feel that patient outcomes could have been further improved by altering the “fixed intervention” offered your PCT?
e.g., do you have early indicators of long-term failure?
e.g., do you have non-adherence?
- Have you struggled to implement the interventions in your PCT?
e.g., what were the barriers? You might consider embedding/testing implementation interventions in parallel