

HOW TO APPLY THE MULTIPHASE OPTIMIZATION STRATEGY (MOST) IN YOUR INTERVENTION DEVELOPMENT RESEARCH

Module 3 Introduction to the optimization trial

Lesson 8: Different interventions, different optimization trial designs



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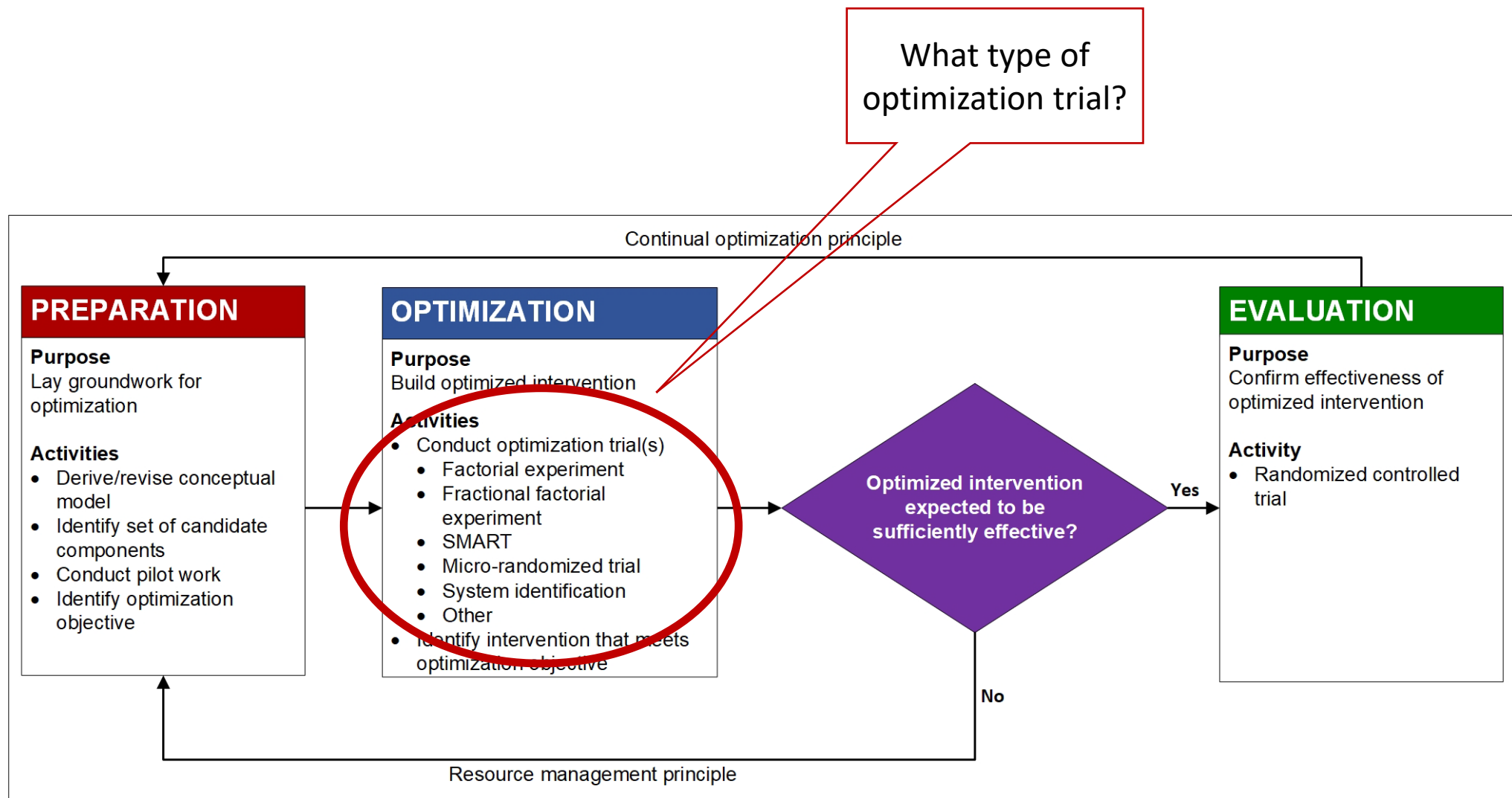
In the previous lesson you learned how to:

- Distinguish (1) between fixed and adaptive interventions; (2) among adaptive interventions with different intensities of adaptation



In this lesson you will learn how to:

- Recognize that optimization of different types of interventions may require different types of optimization trials



Flow chart of the three phases of the multiphase optimization strategy (MOST). Rectangle = action. Diamond = decision.

Figure adapted from Collins, L.M. (2018)

Choice of design for optimization trial is critical

- Any experimental design is a possibility BUT...
- **...must be selected based on Resource Management Principle!!!**

Review: Resource management principle

- In Module 1 you learned:
 - An investigator using MOST must strive to make the best and most efficient use of available resources when obtaining scientific information
- ANY experimental design is OK as long as it is the most efficient one

The most efficient design for an optimization trial is the one that...

- ...best manages research resources
 - We discussed this in a previous lesson
- ...most directly addresses the primary research questions
 - This depends partly on the type of intervention to be optimized – we will discuss this now

An adaptive intervention to encourage adherence to HIV treatment

Some aspects that could be considered intervention components:

Text messaging
Behavioral skills training
Peer mentoring
Motivational interviewing
The tailoring variable: Adherence
The decision point: Day 45
The decision rules

If >1 decision point, the interval between decision points (review interval)

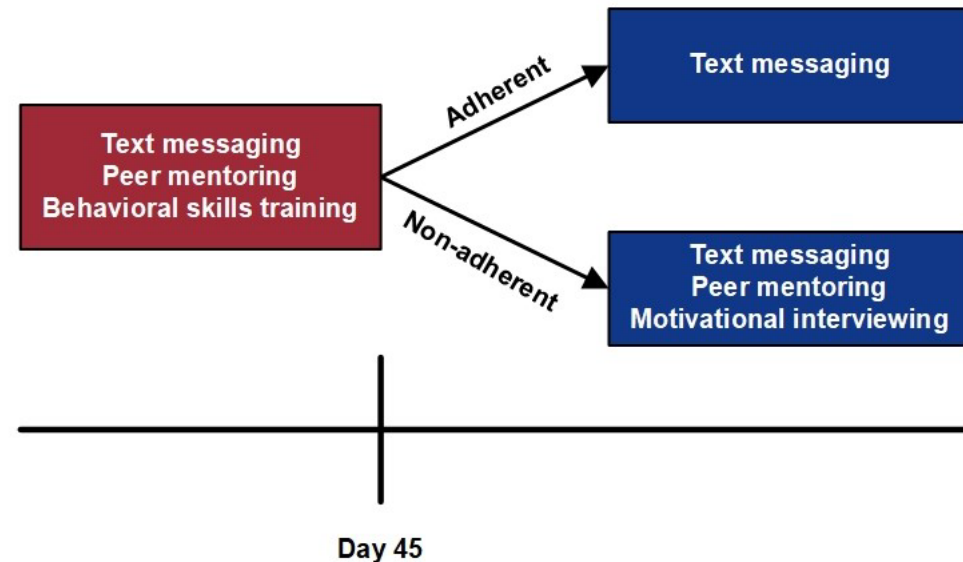
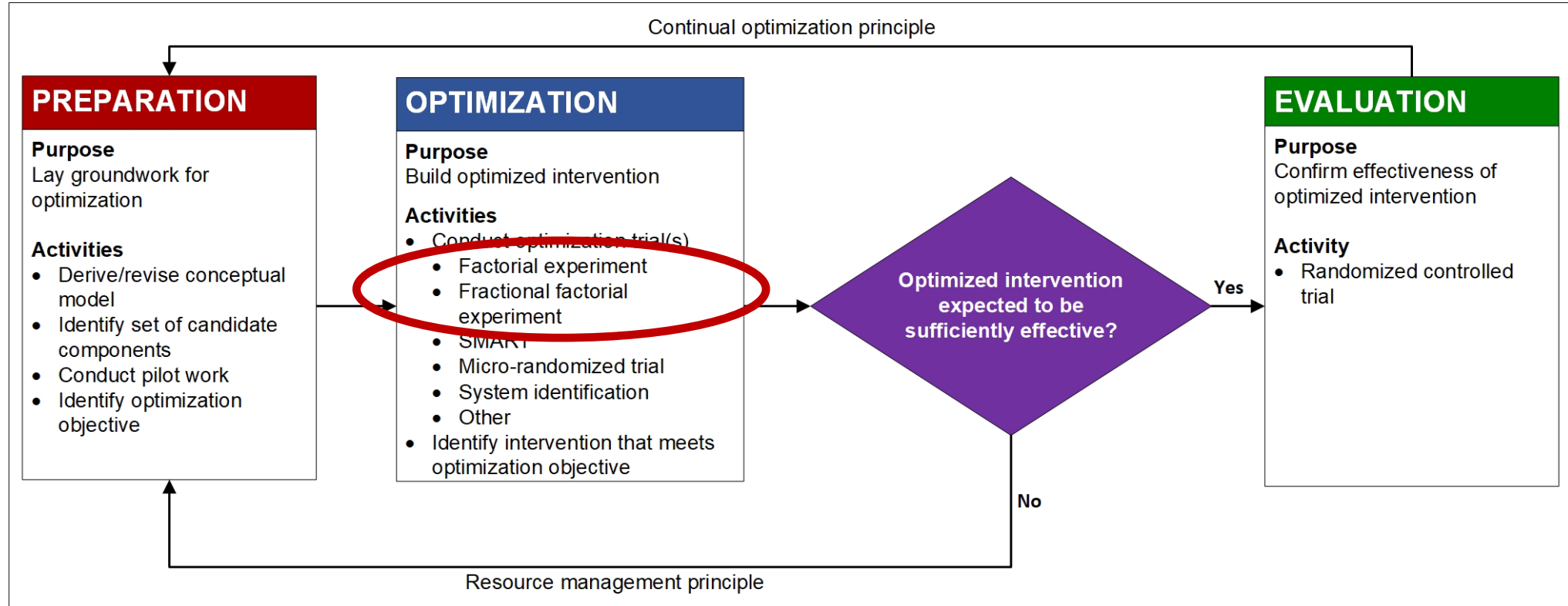


Figure reprinted from Collins (2018)

How type of intervention design impacts choice of experimental design

- For a fixed intervention, the question is usually “How well does this component perform?” or “Is the high dose better than the low dose of this component?”



Flow chart of the three phases of the multiphase optimization strategy (MOST). Rectangle = action. Diamond = decision.

Figure adapted from Collins, L.M. (2018)

How type of intervention design impacts choice of experimental design

- For an adaptive intervention, there may be different questions
- Suppose you are to develop and optimize an adaptive intervention similar to the one we've been discussing.

How type of intervention design impacts choice of experimental design

- QUESTION 1: Is the initial treatment (i.e. text messaging, peer mentoring, and behavioral skills training) effective overall? Does it outperform a comparison or control treatment?

How type of intervention design impacts choice of experimental design

- Addressing Question 1 requires randomly assigning participants *at the outset* to:
 - The initial treatment or
 - A control

How type of intervention design impacts choice of experimental design

- QUESTION 2: For participants who are **adherent** after 45 days, which is a better second-line treatment:
 - (a) continue with text messaging only; or
 - (b) continue with text messaging + peer mentoring?

How type of intervention design impacts choice of experimental design

- Addressing Question 2 requires:
 - Waiting until Day 45
 - Assessing adherence and identifying **adherent** participants
 - Randomizing **only adherent** participants to:
 - Continue to receive text messaging only or
 - Continue with text messaging and add peer mentoring

How type of intervention design impacts choice of experimental design

- QUESTION 3: For participants who are **non-adherent** after 45 days, which is a better second-line treatment:
 - (a) continue with text messaging + peer mentoring only; or
 - (b) continue with these treatments and add motivational interviewing?

How type of intervention design impacts choice of experimental design

- Question 3 requires:
 - Waiting until Day 45
 - Assessing adherence and identifying **non-adherent** participants
 - Randomizing **only non-adherent** participants to:
 - Continue to receive text messaging + peer mentoring only or
 - Continue to receive text messaging + peer mentoring and add motivational interviewing

How type of intervention design impacts choice of experimental design

- Sets of questions like these can be addressed using a sequential multiple-assignment randomized trial (SMART)
- You can learn more about the SMART in Almirall, Nahum-Shani, Wang, & Kasari (2018)

How type of intervention design impacts choice of experimental design

- SMARTs are useful when the adaptive intervention being optimized has low intensity of adaptation
- For adaptive interventions with high intensity of adaptation, a good choice is often the micro-randomized trial (MRT; Klasnja et al., 2015), or a system identification experiment (Rivera et al., 2018)

In this course we are emphasizing the factorial optimization trial because

1. It's the most widely applicable optimization trial
2. Many other optimization trial designs are rooted in the factorial experiment
 - Fractional factorial
 - Sequential multiple-assignment randomized trial (SMART)
 - Micro-randomized trial (MRT)

When selecting an experimental design for the optimization trial, remember:

- Optimization of different types of interventions can generate different types of scientific questions.
- For different types of scientific questions, the resource management principle may suggest different experimental designs

When selecting an experimental design for the optimization trial, remember:

- SMARTs and MRTs are often good choices for optimization of adaptive interventions.
- However, factorial and fractional factorial experiments are sometimes the appropriate choice for optimization of adaptive interventions!

When selecting an experimental design for the optimization trial, remember:

- Start with the scientific questions. Then use the resource management principle to select the most appropriate and efficient experimental design
- If the scientific questions are sufficiently clearly and explicitly stated, selection of the appropriate experimental design is usually not difficult

In this lesson you learned how to:

- Recognize that optimization of different types of interventions may require different types of optimization trials



In the next lesson you will:

- Review what you have learned in Module 3



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