

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

Module 2

**The preparation phase: Laying the foundation for successful
optimization**

Lesson 6: The pilot study



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Intervention Optimization Initiative

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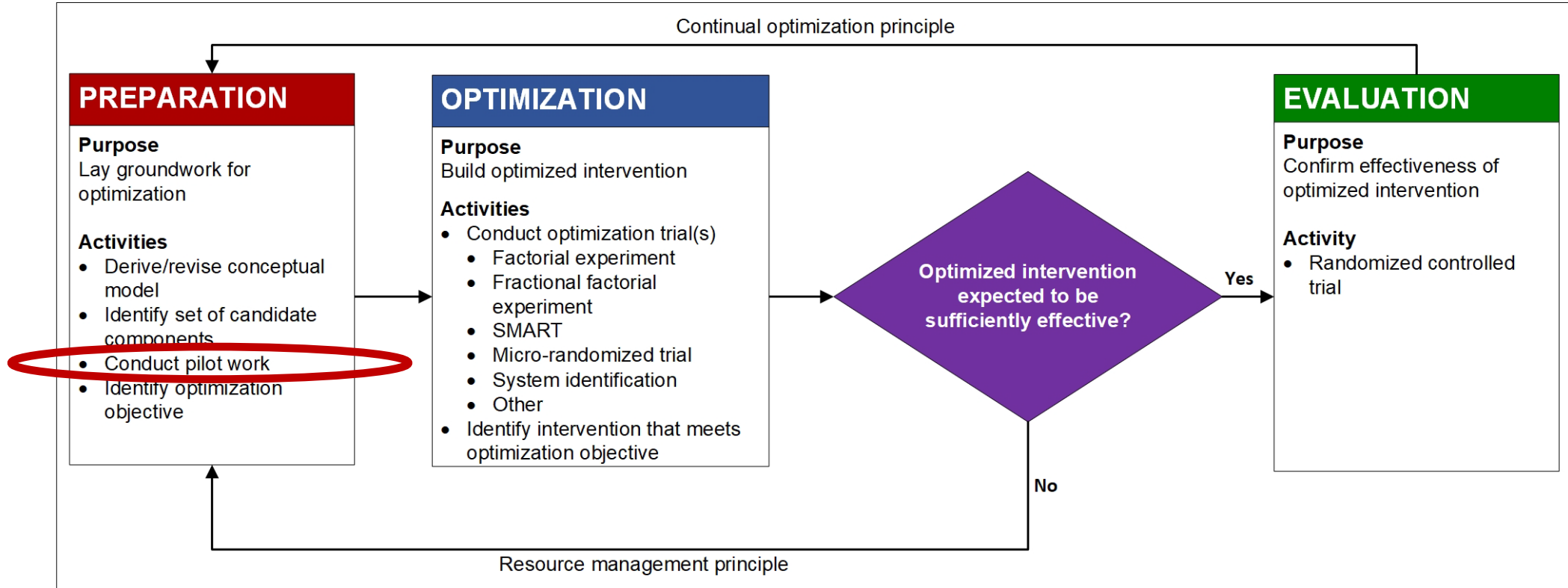
Intervention Optimization Initiative

In the previous lesson you learned how to:

- Express moderation in conceptual models

In this lesson you will learn how to:

- Define the term pilot study
- Distinguish pilot studies from optimization trials



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

Figure adapted from Collins (2018)

Pilot studies

- There are different views on what constitutes a pilot study
- We will take our view from this article:



Pilot studies

- Leon et al. (2011) say:
 - “The fundamental purpose of conducting a pilot study is to examine the feasibility of an approach that is intended to be used in a larger scale study.” (p. 626)

Pilot studies

- Leon et al. (2011) say:
 - “A pilot study is not a hypothesis testing study. Therefore no inferential statistical tests should be proposed in a pilot study protocol.” (p. 627)

Pilot studies

- Leon et al. (2011) say:
 - “Power analyses should not be presented... A pilot sample size is instead based on the pragmatics of recruitment and the necessities for examining feasibility.” (p. 627)

Pilot studies

- The purpose of pilot studies is NOT to
 - Support classical hypothesis testing
 - Support decision-making, except concerning study procedures and feasibility for the larger study

Pilot studies

- In other words, the purpose of pilot studies is to try out study procedures and establish feasibility

Pilot studies

- By the Leon et al. definition, optimization trials are NOT pilot studies

Pilot studies

- Designed with no regard for statistical power
- No need for experimental control
- Primary purpose is to prepare for a subsequent trial that will support statistical inference/decision-making

Optimization trials

- Designed to be adequately powered
- Carefully controlled
- Primary purpose is to support statistical inference/decision-making

Optimization trials should be pilot tested!

- It's a good idea to pilot the entire optimization trial as designed, i.e., run all of the experimental conditions
 - This will double-check that all conditions are feasible
 - If you are junior, will help establish that you have pilot tested all procedures and can handle a complex experiment

In this lesson you learned how to:

- Define the term pilot study
- Distinguish pilot studies from optimization trials

In the next lesson you will learn how to:

- Specify an optimization objective to express what is meant by intervention EASE in a particular study

References cited

- Collins, L.M. (2018). Optimization of Behavioral, Biobehavioral, and Biomedical Interventions: The Multiphase Optimization Strategy (MOST). New York: Springer.
- Leon, A.C., Davis, L.L., & Kraemer, H.C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research*, 45, 626-629.

