

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

Module 5

**Rigorous and responsible conduct of
intervention optimization research**

Lesson 7: How to avoid contamination



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In the previous lesson you learned how to:

- Generalize the concept of clinical equipoise to an optimization trial



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In this lesson you will learn how to:

- Avoid accidental contamination between experimental conditions



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What is contamination?

- Contamination occurs when uncontrolled contact between participants results in some participants being exposed to treatment that
 - Is not a part of the treatment in their randomly assigned condition but...
 - Is a part of the treatment in other randomly assigned conditions
- Contamination can occur in BOTH optimization AND evaluation trials

Examples where contamination may occur

- Participants become acquainted and have time to interact
 - e.g. participants sometimes have to spend an extended period in a waiting room, where they have a chance to interact

Examples where contamination may occur

- Participants are nested in clusters, e.g.
 - One candidate component is delivered in a group setting, and the random assignment procedure allows participants from different experimental conditions to be in the same group
 - Participants are students in the same school

Contamination

- In any of these situations, the participants may share information about treatments they are receiving
- They may even share the treatment! e.g.
 - “Take some of these nicotine lozenges, I think you will find them helpful.”
 - “When I get the daily encouraging text message I will forward it to you.”

The effect of contamination

- Take this to its logical extreme. If there is a lot of contamination, essentially all participants receive the same treatment
- Thus, contamination tends to obscure any effects and reduce statistical power

Some measures you can take to avoid contamination

- Keep unstructured contact between participants to an absolute minimum
- If one or more components are delivered in a group setting, it is a good idea to keep all group members in the same experimental condition
- Never allow more than one individual from the same household to participate in an experiment
 - Same for close friends, but harder to detect

Some measures you can take to avoid contamination

- If the participants are nested in clusters, between-cluster randomization may be necessary to avoid contamination
- If everyone within a cluster is in the same experimental condition, their sharing information will not cause contamination

Some measures you can take to avoid contamination

- Remember (Module 4) clustering is an important motivation for using between-cluster randomization
- There is a trade-off here. Contamination reduces power, but so does between-cluster randomization

In this lesson you learned how to:

- Avoid accidental contamination between experimental conditions



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In the next lesson you will learn how to:

- Prevent protocol deviations



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