

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

Module 5

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

**Lesson 2: Ensuring that all participants are
provided with at least the standard of care**



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This course was developed by

Linda M. Collins

School of Global Public
Health

New York University
(narrator)

Kate Guastaferro

College of Health and
Human Development

The Pennsylvania State
University



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In the previous lesson you learned how to:

- Recognize the critical importance of selecting experimental factors that can be manipulated independently



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In this lesson you will learn how to:

- Ensure that all participants are provided at least the standard of care by including a constant component in a factorial experiment



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Participants should never be denied the standard of care

- Sometimes participants
 - Have already had the standard of care or
 - Can be provided with the standard of care after the experiment is over
- But often whatever is the standard of care can be incorporated into an optimization trial

Review: Each factor has its own control

- Remember: In a factorial experiment each factor has its own control
- This control could be whatever is standard of care for that factor
- This assumes that participants not in the control level are being offered something that exceeds standard of care, or will be provided standard of care later

Experimental conditions in a factorial experiment with four factors, each using its respective standard of care as a control

Experimental condition	<i>Factor A</i>	<i>Factor B</i>	<i>Factor C</i>	<i>Factor D</i>	<i>Outcome</i>
1	SOC-A	SOC-B	SOC-C	SOC-D	\bar{Y}_1
2	SOC-A	SOC-B	SOC-C	Yes	\bar{Y}_2
3	SOC-A	SOC-B	Yes	SOC-D	\bar{Y}_3
4	SOC-A	SOC-B	Yes	Yes	\bar{Y}_4
5	SOC-A	Yes	SOC-C	SOC-D	\bar{Y}_5
6	SOC-A	Yes	SOC-C	Yes	\bar{Y}_6
7	SOC-A	Yes	Yes	SOC-D	\bar{Y}_7
8	SOC-A	Yes	Yes	Yes	\bar{Y}_8
9	Yes	SOC-B	SOC-C	SOC-D	\bar{Y}_9
10	Yes	SOC-B	SOC-C	Yes	\bar{Y}_{10}
11	Yes	SOC-B	Yes	SOC-D	\bar{Y}_{11}
12	Yes	SOC-B	Yes	Yes	\bar{Y}_{12}
13	Yes	Yes	SOC-C	SOC-D	\bar{Y}_{13}
14	Yes	Yes	SOC-C	Yes	\bar{Y}_{14}
15	Yes	Yes	Yes	SOC-D	\bar{Y}_{15}
16	Yes	Yes	Yes	Yes	\bar{Y}_{16}

Another approach: Add a constant component

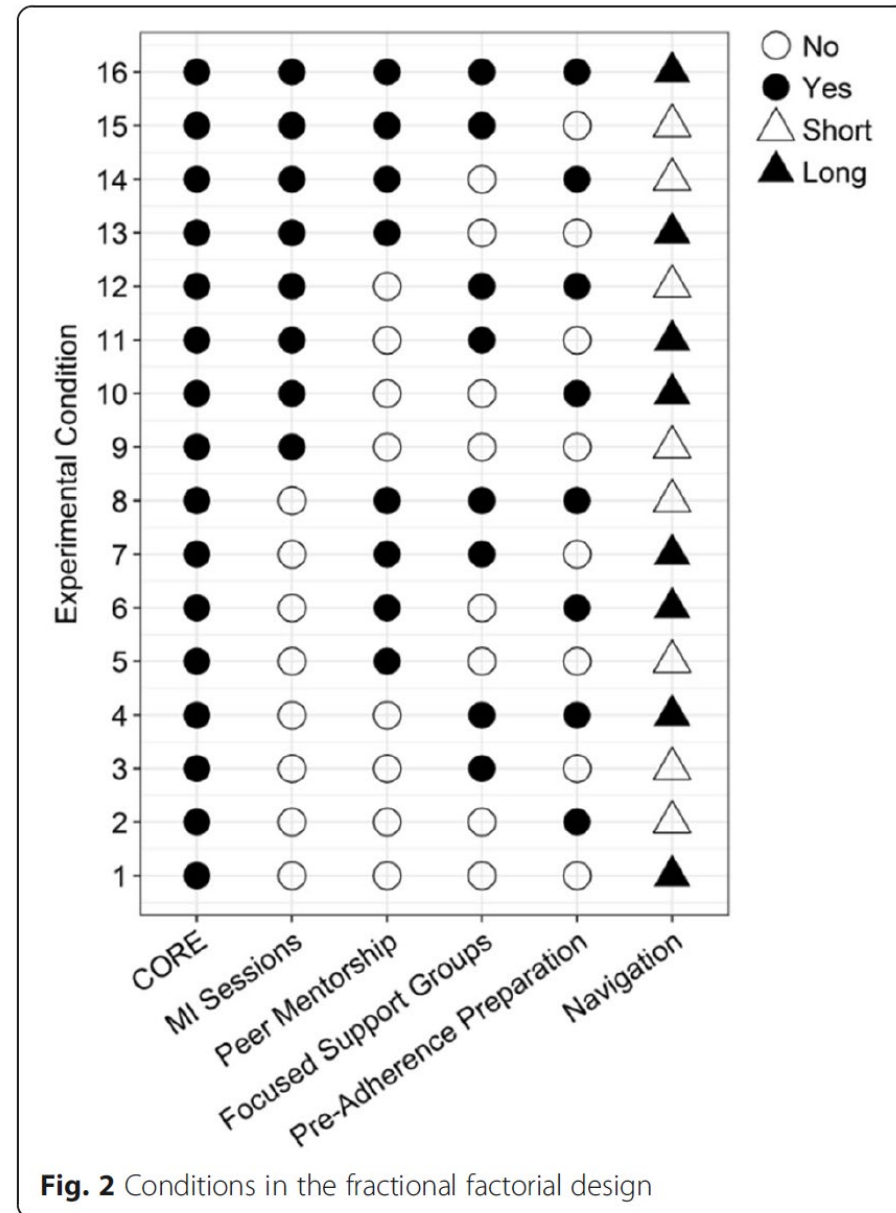
- This is a component that is not experimentally manipulated
- Instead, all participants are offered this component
- Suppose in our example, standard of care for HIV patients is to provide a prescription for ART along with basic education in HIV and how to take ART

This illustrates
how a
constant
component
could be
incorporated

Experimental condition	SOC	MI	PEER	TEXT	MIND	Outcome
1	Yes	No	No	No	No	\bar{Y}_1
2	Yes	No	No	No	Yes	\bar{Y}_2
3	Yes	No	No	Yes	No	\bar{Y}_3
4	Yes	No	No	Yes	Yes	\bar{Y}_4
5	Yes	No	Yes	No	No	\bar{Y}_5
6	Yes	No	Yes	No	Yes	\bar{Y}_6
7	Yes	No	Yes	Yes	No	\bar{Y}_7
8	Yes	No	Yes	Yes	Yes	\bar{Y}_8
9	Yes	Yes	No	No	No	\bar{Y}_9
10	Yes	Yes	No	No	Yes	\bar{Y}_{10}
11	Yes	Yes	No	Yes	No	\bar{Y}_{11}
12	Yes	Yes	No	Yes	Yes	\bar{Y}_{12}
13	Yes	Yes	Yes	No	No	\bar{Y}_{13}
14	Yes	Yes	Yes	No	Yes	\bar{Y}_{14}
15	Yes	Yes	Yes	Yes	No	\bar{Y}_{15}
16	Yes	Yes	Yes	Yes	Yes	\bar{Y}_{16}

In describing an experimental design in a publication or funding application, it is necessary to describe any constant component along with the rest of the treatment, but including the constant component in a table or figure representing the design is optional.

This example of one way to include the constant component is from Gwadz et al. (2017).



More about the constant component

- The constant component is not experimentally manipulated
- You will not be able to determine whether the constant component
 - Has a main effect
 - Interacts with the candidate components

More about the constant component

- Thus, any results cannot be generalized to a setting in which the constant component is not provided

This illustrates how behavioral skills training (BST) could be included as a constant component

Experimental condition	BST	<i>MI</i>	<i>PEER</i>	<i>TEXT</i>	<i>MIND</i>	<i>Outcome</i>
1	Yes	No	No	No	No	\bar{Y}_1
2	Yes	No	No	No	Yes	\bar{Y}_2
3	Yes	No	No	Yes	No	\bar{Y}_3
4	Yes	No	No	Yes	Yes	\bar{Y}_4
5	Yes	No	Yes	No	No	\bar{Y}_5
6	Yes	No	Yes	No	Yes	\bar{Y}_6
7	Yes	No	Yes	Yes	No	\bar{Y}_7
8	Yes	No	Yes	Yes	Yes	\bar{Y}_8
9	Yes	Yes	No	No	No	\bar{Y}_9
10	Yes	Yes	No	No	Yes	\bar{Y}_{10}
11	Yes	Yes	No	Yes	No	\bar{Y}_{11}
12	Yes	Yes	No	Yes	Yes	\bar{Y}_{12}
13	Yes	Yes	Yes	No	No	\bar{Y}_{13}
14	Yes	Yes	Yes	No	Yes	\bar{Y}_{14}
15	Yes	Yes	Yes	Yes	No	\bar{Y}_{15}
16	Yes	Yes	Yes	Yes	Yes	\bar{Y}_{16}

More about the constant component

- Thus, any results cannot be generalized to a setting in which the constant component is not provided
- Include a constant component only when it is a given that the constant component will be in the optimized intervention

In this lesson you learned how to:

- Ensure that all participants are provided at least the standard of care by including a constant component in a factorial experiment



In the next lesson you will learn how to:

- Plan an optimization trial when the outcome of interest is far in the future



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References Cited

- Gwadz, M. V., Collins, L. M., Cleland, C. M., Leonard, N. R., Wilton, L., Gandhi, M., Braithwaite, R.S., Perlman, D.C., Kutnick, A., & Ritchie, A. S. (2017). Using the multiphase optimization strategy (MOST) to optimize an HIV care continuum intervention for vulnerable populations: a study protocol. *BMC Public Health*, 17, 1-20.



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