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

Module 5

Responsible conduct of intervention optimization research

Lesson 5: How to enter an optimization trial in a trial registry

NYU SCHOOL OF GLOBAL PUBLIC HEALTH

Intervention Optimization Initiative

This course was developed by

Linda M. Collins

School of Global Public Health

New York University

Kate Guastaferro

College of Health and Human Development

The Pennsylvania State University

(narrator)

In the previous lesson you learned how to:

- Develop appropriate informed consent procedures for a factorial optimization trial

In this lesson you will learn how to:

- Enter an optimization trial into a clinical trials registry (such as ClinicalTrials.gov in the US)

Clinical Trial Definition

- National Institutes of Health (U.S.):
  - “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.”
    - https://grants.nih.gov/policy/clinical-trials/definition.htm

A factorial experiment is considered a clinical trial

- This means you will likely need to register it with a national, publicly available registry
  - For example, ClinicalTrials.Gov (US)

- This registry may be accessed by:
  - Patients and families
  - Researchers
  - Study record managers

Registering a factorial experiment

- Definitions

ClinicalTrials.Gov	Factorial Optimization Trial
Arm	Experimental condition
Intervention	Combination of factors for each experimental condition

- There is a factorial study design example with results to follow
- Errors will be pointed out by system

Clinical Trial Registry Example: itMatters

- R01 AA022931; PI Collins
- Two optimization trials using a 2^5 factorial experiment
  - Wyrick et al., 2020
- RCT evaluation study
  - Tanner et al., 2021

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Clinical Trial Registry Example: itMatters

Study Design

Study Type:	Interventional
Primary Purpose:	Prevention
Study Phase:	N/A
Interventional Study Model:	Factorial Assignment
Number of Arms:	32
Masking:	None (Open Label)
Allocation:	Randomized
Enrollment:	3997 [Actual]

NCT02897804

Clinical Trial Registry Example: itMatters

Arms and Interventions

Arms	Assigned Interventions
Experimental: Knowledge alone Participants will have access to the knowledge module for a period up to 3 weeks.	Behavioral: Knowledge alone Increase knowledge related STIs, STI risk, alcohol impairment, condom use skills, alcohol use behavior tracking skills, testing & treatment services.
Experimental: Self-efficacy alone Participants will have access to the knowledge module plus the self-efficacy module for a period up to 3 weeks.	Behavioral: Self-efficacy alone Increase self-efficacy to use protective behavioral strategies (e.g., condom negotiation skills) to reduce unprotected sex.
Experimental: Perceived benefits alone Participants will have access to the knowledge module plus the perceived benefits module for a period up to 3 weeks.	Behavioral: Perceived benefits alone Increase perceived benefits to use protective behavioral strategies to reduce the negative consequences of engaging in sexual behaviors under the influence of alcohol.

Clinical Trial Registry Example: itMatters

Experimental: Descriptive norms and injunctive norms Participants will have access to the knowledge module plus the descriptive norms and injunctive norms modules for a period up to 3 weeks.	Behavioral: Descriptive and injunctive norms Correct misperceptions of prevalence of alcohol-induced sexual risk behaviors, alcohol use/misuse, and sexual risk behaviors and correct misperceptions regarding approval of alcohol misuse & sexual risk taking.
Experimental: Descriptive norms, injunctive norms,self-efficacy Participants will have access to the knowledge module plus the descriptive norms, injunctive norms, and self-efficacy modules for a period up to 3 weeks.	Behavioral: Descriptive norms, injunctive norms,self-efficacy Correct misperceptions of prevalence of alcohol-induced sexual risk behaviors, alcohol use/misuse, and sexual risk behaviors; correct misperceptions regarding approval of alcohol misuse & sexual risk taking; and increase self-efficacy to use protective behavioral strategies (e.g., condom negotiation skills) to reduce unprotected sex.

Clinical Trial Registry

- You will be required to input results at the end of the trial
  - By experimental condition
- Other resources available for other optimization trial designs
  - SMART, MRT

- Can be time consuming, especially the first time you do it so plan accordingly!

In this lesson you learned how to:

- Enter an optimization trial into a clinical trials registry (such as ClinicalTrials.gov in the US)

In the next lesson you will learn how to:

- Generalize the concept of clinical equipoise to an optimization trial

References Cited

- Wyrick, D.L., Tanner, A.E., Milroy, J.J., Guastaferro, K., Bhandari, S., Kugler, K.C., Thorpe, S., Ware, S., *Miller, A.M., & Collins, L.M. (2020). *itMatters*: Optimization of an online intervention to prevent sexually transmitted infections in college students. *Journal of American College Health,* 1-11.
- Tanner, A.E., Guastaferro, K., Wyrick, D.L., Milroy, J.J., Rulison, K., Bhandari, S., Thorpe, S., Ware, S., Miller, A.M., & Collins, L.M. (2021). A hybrid evaluation-optimization trial to evaluate an intervention targeting the intersection of alcohol and sex in college students and simultaneously test an additional component aimed at preventing sexual violence. *Annals of Behavioral Medicine, 55*(12), 1184-187.