



Co-Chairs:

- Patrick Heagerty, PhD
- Elizabeth L. Turner, PhD



Biostatistics and Study Design Core

Mission

- Provide expertise in novel designs and methods for ePCTs
- Document new statistical issues and share knowledge
- Develop methods to address challenges

Meeting Schedule

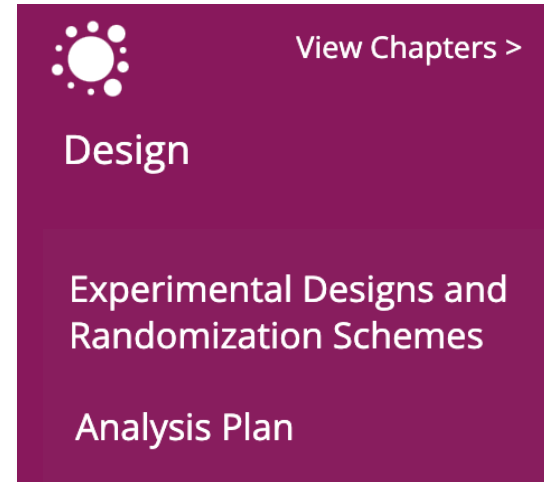
Monthly

First Wednesday

Biostatistics and Study Design Core: Key Resources



- Living Textbook chapters on study designs and analysis plans
- Study Design eLearning and video modules
- Intraclass Correlation Coefficient Cheat Sheet
- Design and Analysis of ePCTs workshop (recording available)
- Substantial literature on design and analysis of group-randomized trials



Review Article

Mixed-effects models for the design and analysis of stepped wedge cluster randomized trials: An overview

Fan Li^{1,2}, James P Hughes³, Karla Hemming⁴, Monica Taljaard⁵, Edward R. Melnick⁶ and Patrick J Heagerty³



Contemporary Clinical Trials

Volume 114, March 2022, 106702



Two weights make a wrong: Cluster randomized trials with variable cluster sizes and heterogeneous treatment effects

Xueqi Wang^a, Elizabeth L. Turner^a, Fan Li^b, Rui Wang^{c,d}, Jonathan Moyer^e, Andrea J. Cook^{f,g}, David M. Murray^e, Patrick J. Heagerty^g

Biostatistics and Study Design Core: Contributions to Trials



- Direct impact on many trials, resulting in revised:
 - Statistical analysis plans
 - Sample sizes
 - Trial designs
- Expertise in:
 - Cluster randomization
 - Stepped-wedge designs
 - Handling missing data
 - Heterogenous treatment effects
 - Power and sample size
- Collaborated with trials on lessons learned and methods publications

Consultation
in first
3 months

“Take the Biostats Core Working Group advice seriously—get it early and act on it early.”

—*Ted Melnick, PI of EMBED*

“They helped with our early problems, and we got quite a bit of help towards the end for the publication in *JAMA Internal Medicine*, which was very productive.”

—*Bev Green, Co-PI of STOP CRC*

“Originally...the statistical analysis we used had the effect of overcorrecting our data.”

—*Gloria Coronado, Co-PI of STOP CRC*