

NIH Pragmatic Trials Collaboratory: Then, Now, and Future

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Biostatistics, Design and Analysis: **Then...**

- > **New cooperative group process!**
- > **Development of support and review mechanisms**
 - Share best practice information; literature
 - Evidence-based statistical practice
- > **Scholarship**
 - Gaps; collaboration in methods development
- > **Education and training**



Biostatistics, Design and Analysis: Then...

Research Article

Statistics
in Medicine

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An evaluation of constrained randomization for the design and analysis of group-randomized trials

Fan Li,^a Yuliya Lokhnygina,^{a,b} David M. Murray,^c Patrick J. Heagerty^d and Elizabeth R. DeLong^{a,b,*†}

PCORI in the Literature

swCRTdesign: An RPackage for Stepped Wedge Trial Design and Analysis

COMPUTER METHODS AND PROGRAMS IN BIOMEDICINE

May 2020

[View Journal Publication](#)

AJPH METHODS

Review of Recent Methodological Developments in Group-Randomized Trials: Part 1—Design

In 2004, Murray et al. reviewed methodological developments

Elizabeth L. Turner, PhD, Fan Li, MSc, John A. Golis, ScM, Melanie Pragne, PhD, and David M. Murray, PhD



Biostatistics, Design and Analysis: Now...

> Process contagion!

- VA/DoD Pain Management Collaboratory
- NIA IMPACT Collaboratory
- NCATS CTSA Program
- NHLBI DECIPHeR Program

> Scholarship

- ePCT: Embedded leads to complexity

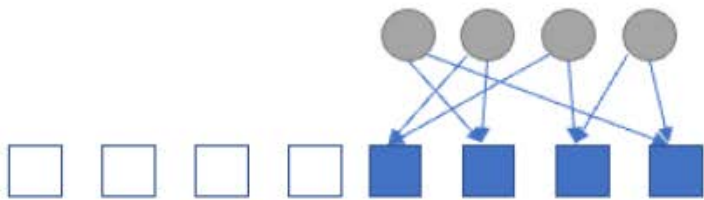
> Education and training

- Textbook; workshops



Biostatistics, Design and Analysis: Now...

Multiple Membership



- Multiple membership IRGT trial.

- Agent
- Intervention Participant
- Control Participant



New Methods for Planning Cluster
Randomized Trials to Detect Treatment Effect
Heterogeneity



Contents lists available at [ScienceDirect](#)

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

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, Design and Analysis: **Future...**

> **Scholarship**

- **Design: Rigorous, flexible and fluid (platform)**
- **Analysis: Robust methods**
- **Evidence-based statistical practice**

> **Education and training**

- **Future scholars: Integration of pre- and post-doc opportunities within our cores / networks**



Conclusions

- > **Evidence-based statistical practice requires foundation in methodologic scholarship**
- > **ePCT Methodology / Clinical Trial Conduct --
apprentice opportunities are key to future leadership**