

An Introduction to Pragmatic Trials: A View Into the Rationale and Process of Real-Life Interventions

Plenary Address by Megan Branda, MS

References for Pragmatic Trials

1. NIH Pragmatic and Group Randomized Trials in Public Health and Medicine course (7 parts)
<https://prevention.nih.gov/resources-for-researchers/nih-methods-training/grt>
 - a. This is the online series of courses offered by the NIH. If you have no experience then it could be helpful. A section is on issues other researchers have experienced and what they did to address them.
2. For I., Norrie J. Pragmatic Trials. *N Engl J Med* 2016;375:454-63. DOI: 10.1056/NEJMra1510059
 - a. This is a nice overview of pragmatic trials. It addressed several issues and explained things in an easy to obtain manner.
3. Karanicolas PJ., Montori VM, Devereaux PJ. A new “Mechanistic-Practical” Framework for designing and interpreting randomized trials. *Journal of Clinical Epidemiology* 62 (2009) 479-484. doi: 10.1016/j.jclinepi.2008.02.009
 - a. This is the paper that wants to reframe how we think of pragmatic trials and change terminology.
4. Patsopoulos NA. A pragmatic view on pragmatic trials. *Dialogues in Clinical Neuroscience* - Vol13 . No. 2 . 2011
 - a. This paper explains where pragmatic trials started from and some of the changes and tools to use currently.
5. Godwin M., Ruhland L., Casson I. Pragmatic controlled clinical trials in primary care: the struggle between external and internal validity. *BMC Medical Research Methodology* 2003, 3:28. <http://www.biomedcentral.com/1471-2288/3/28>
 - a. This is two examples of pragmatic trials in primary care and addresses some of the issues.
6. Cook A.J., DeLong E., Murray D. M. Statistical lessons learned for designing cluster randomized pragmatic clinical trials from the NIH Health Care Systems Collaboratory Biostatistics and Design Core. *Clinical Trials*. 2016, Vol. 13(5) 504–512. DOI: 10.1177/1740774516646578
 - a. This paper is more statistically driven but I thought it was a great review of design/planning issues when planning a trial and provides solutions.
7. Sox HC, Lewis RJ. Pragmatic Trials: Practical Answers to “Real World” Questions. *JAMA* September 20, 2016. Volume 316, Number 11.
 - a. This is an explanation of pragmatic trials and gets a little into the argument of why, limitations, and issues.
8. Sugarman J., Califf R. M. Ethics and regulatory complexities for pragmatic clinical trials. *JAMA* June 18, 2014 Volume 311, Number 23
 - a. A look at the ethical implications as well as the regulatory issues that may arise.
9. Weinfurt K.P, Hernandez A.F., Coronado G.D. Pragmatic clinical trials embedded in healthcare systems: generalizable lessons from the NIH Collaboratory. *BMC Medical Research Methodology* (2017) 17:144. DOI 10.1186/s12874-017-0420-7
10. Rachel L Richesson, Beverly B Green, Reesa Laws, Jon Puro, Michael G Kahn, Alan Bauck, Michelle Smerek, Erik G Van Eaton, Meredith Zozus, W Ed Hammond, Kari A Stephens, Greg E Simon, Pragmatic (trial) informatics: a perspective from the NIH Health Care Systems Research Collaboratory, *Journal of the American Medical Informatics Association*, Volume 24, Issue 5, September 2017, Pages 996–1001, <https://doi.org/10.1093/jamia/ocx016>

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11. Emily Pfaff, Adam Lee, Robert Bradford, Jinhee Pae, Clarence Potter, Paul Blue, Patricia Knoepp, Kristie Thompson, Christianne L Roumie, David Crenshaw, Remy Servis, Darren A DeWalt, Recruiting for a pragmatic trial using the electronic health record and patient portal: successes and lessons learned, *Journal of the American Medical Informatics Association*, Volume 26, Issue 1, January 2019, Pages 44–49, <https://doi.org/10.1093/jamia/ocy138>
 - a. This study shows the assessment of different methods for contacting a patient for recruitment.
12. DeBar L, Benes L, Bonifay A, et al. Interdisciplinary team-based care for patients with chronic pain on long-term opioid treatment in primary care (PPACT) - Protocol for a pragmatic cluster randomized trial. *Contemp Clin Trials*. 2018;67:91-99. doi:10.1016/j.cct.2018.02.015
 - a. Example of a pragmatic trial of a complex intervention.
13. Burch T. Patient Commentary: Added Value and Validity to Research Outcomes Through Thoughtful Multifaceted Patient-Oriented Research. *Patient*. 2020
 - a. Strategies on collaborating with patients.

Below are two tools, first to assess bias in a cluster randomized trial and the second to gage 'how pragmatic is your trial'. PRECIS-2 seems to be the current standard (<https://www.precis-2.org>) - PRECIS-2 is coming soon.

14. Caille A, Kerry S, Tavernier E, Leyrat C., Eldridge S, Giraudeau B. Timeline cluster: a graphical tool to identify risk of bias in cluster randomized trials. *BMJ* 2016; 354:i4291.
15. Loudon Kirsty, Treweek Shaun, Sullivan Frank, Donnan Peter, Thorpe Kevin E, Zwarenstein Merrick et al. The PRECIS-2 tool: designing trials that are fit for purpose *BMJ* 2015; 350 :h2147

[Notes]