WASHINGTON UNIVERSITY IN ST.LOUIS
Institute of Clinical and Translational Sciences

DIRC Dissemination and Implementation Research Designs Toolkits

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Overview

Dissemination and Implementation (D&I) research examines the use of strategies to increase the use and quality of evidence-based interventions in real-world settings[1]. As a result, particular attention is paid to contextual factors that may influence external validity, which includes decision-making related to the existence and level of randomization, grouping plans, and level of analysis.

Objective

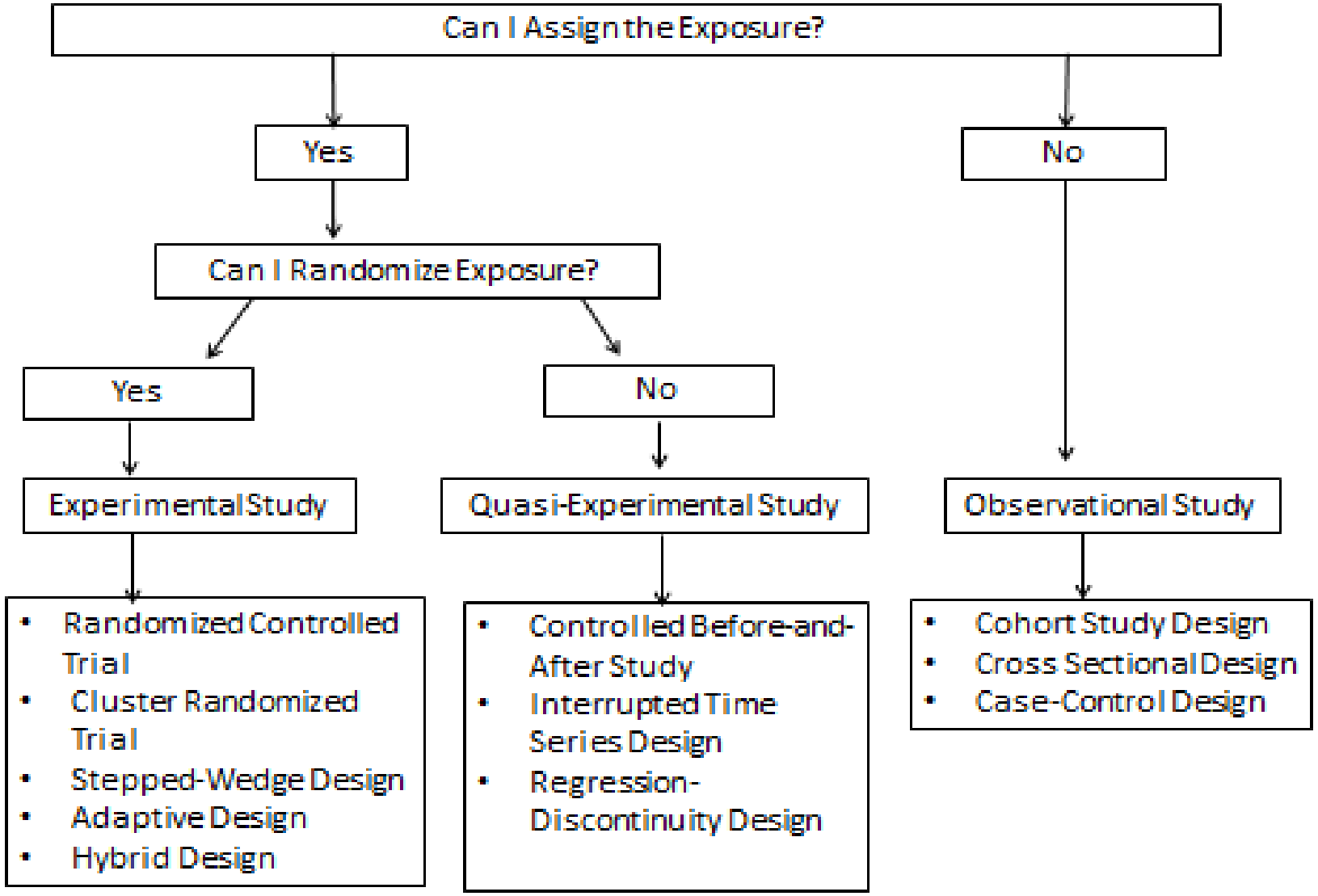
- Provide a brief introduction and review of research designs for experimental, quasi-experimental, and observational D&I studies
- Assist researchers in identifying the most appropriate design(s) to addresses the contextual nuances within their D&I study.

What's Inside?

Inside this toolkit, you will find a decision tree, definitions, and supplemental resources related to D&I research designs.

[1] Definition adapted from the National Institutes of Health's Office of Behavioral and Social Sciences Research (https://obssr.od.nih.gov/scientific_areas/translation/dissemination_and_implementation/index.aspx)

Revised 7/27/17



D&I Research Design Decision Tree (Part I)

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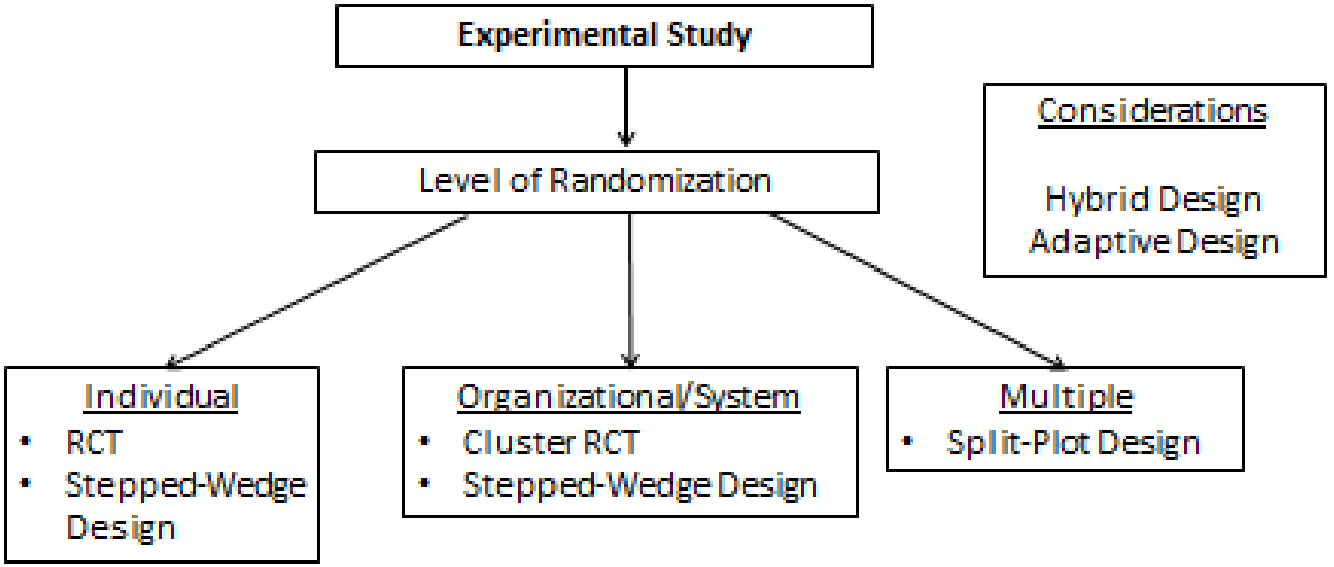

Randomization Plan

Randomized by Intervention	Randomized by Time
RCT	Stepped-Wedge Design
Cluster RCT	

D&I Research Design Decision Tree (Part II)

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Quasi-Experimental Study

Group by Appropriate Control Site	Group by Specific Qualifying Characteristics	Group by Time
Controlled Before-and- After Study Design	Regression-Discontinuity Design	Interrupted Time Series Design

D&I Research Design Decision Tree (Part III)

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Research Design	Definition	Example Articles & Supplemental Resources
EXPERIMENTAL STUDY		
Randomized Controlled Trial (RCT)	• Participants are assigned to control group OR an alternative group(s) • Examples of groupings include alternative evidence-based interventions or implementation strategies • Requires random assignment • Random assignment occurs at the ***individual level***	• Brown, C. H., Curran, G., Palinkas, L. A., Aarons, G. A., Wells, K. B., Jones, L., ... & Tabak, R. G. (2017). An overview of research and evaluation designs for dissemination and implementation. *Annual Review of Public Health*, *38*(1). • Landsverk,I. J., Brown,C. H., Chamberlain, P., Palinkas, L., Ogihara, M., Czaja, S., ... & Horowitz, S. M. (2012). 12 Design and Analysis in Dissemination and Implementation Research. *Dissemination and implementation research in health: Translating science to practice*, 1225.
Cluster Randomized Trial	• Random assignment takes place at the ***organizational level*** • Examples of organizational-level assignment includes hospitals, schools, or agencies	• Donner, A., & Klar, N. (2004). Pitfalls of and controversies in cluster randomization trials. *American Journal of Public Health*, *94*(3), 416-422. • Eccles M, Grimshaw J, Campbell M, Ramsay C. Research designs for studies evaluating the effectiveness of change and improvement strategies. *Quality and Safety in Health Care* 2003; 12: 47-52. • Fox, Chester H., et al. "Improving evidence-based primary care for chronic kidney disease: study protocol for a cluster randomized control trial for translating evidence into practice (TRANSLATE CKD)." *Implement Sci* 8 (2013): 88.
Stepped Wedge Design **Subtypes** Dynamic Wait-List Design Rollout Design	• Sequential roll-out of an intervention or implementation strategy to individuals/clusters over multiple time periods • Requires the order of the roll-out to be ***random*** • All individuals/clusters will receive the intervention or strategy • Data must be collected each time a new group receives the intervention/strategy (i.e., step)	• Brown, C. A., & Lilford, R. J. (2006). The stepped wedge trial design: a systematic review. BMC medical research methodology, 6(1), 54. • Liddy, C., Hogg, W., Russell, G., Wells, G., Armstrong, C. D., Akbari, A., ... & Cornett, A. (2011). Improved delivery of cardiovascular care (IDOCC) through outreach facilitation: study protocol and implementation details of a cluster randomized controlled trial in primary care. *Implement Sci*, *6*, 110.

Adaptive Design **<u>Subtypes</u>** Adaptive Designs of Trials Adaptive Sequencing of Trials Enrollment Design Sequential Multiple Assignment Trial (SMART)	• Sequential roll-out of an intervention or implementation strategy to individuals/clusters over multiple time periods • Study characteristics change during the study • Changes in the process are in response to data being collected in "real time" • Examples of study characteristics include assignment of individuals/clusters to intervention or control groups	• Almirall, D., Compton, S. N., Gunlicks-Stoessel, M., Duan, N., & Murphy, S. A. (2012). Designing a pilot sequential multiple assignment randomized trial for developing an adaptive treatment strategy. *Statistics in medicine*, *31*(17), 1887-1902. • Brown, C.H., Ten Have, T.R., Jo, B., Dagne, G., Wyman, P.A., … R.D. Gibbons (2009). Adaptive designs for randomized trials in public health. *Annual Review of Public Health, 30,*1-26. • Howard, M. C., and Jacobs, R. R. (2016) The multiphase optimization strategy (MOST) and the sequential multiple assignment randomized trial (SMART): two novel evaluation methods for developing optimal training programs. J. Organiz. Behav., doi: 10.1002/job.2102. • Smith, J. D. (2012). Single-case experimental designs: A systematic review of published research and current standards. *Psychological Methods*, *17*(4), 510-550. doi:10.1037/a0029312 **<u>Power Point Slides</u>** • Sequential Multiple Assignment Randomized Trials (SMART) & Adaptive Designs for Implementation Studies (Kilbourne, 2015) Smart Designs
Hybrid Design **<u>Subtypes</u>** Hybrid Trial Type 1 Hybrid Trial Type 2 Hybrid Trial Type 3	• Combines assessment of efficacy or effectiveness of intervention ***<u>and</u>*** implementation processes • Level of assessment is dependent on design type **<u>Hybrid Type 1</u>** • Primary Focus= assessing clinical intervention • Secondary Focus= collecting information on implementation process is a secondary focus **<u>Hybrid Type 2</u>** • Dual Focus=assessing clinical intervention effectiveness and testing implementation strategies **<u>Hybrid Type 3</u>** • Primary Focus= testing implementation strategies	• Cully, J. A., Armento, M. E., Mott, J., Nadorff, M. R., Naik, A. D., Stanley, M. A., ... & Kauth, M. R. (2012). Brief cognitive behavioral therapy in primary care: a hybrid type 2 patient-randomized effectiveness implementation design. *Implement Sci*, *7*(1), 64. • Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Medical care, 50(3), 217. • Damschroder, L. J., Moin, T., Datta, S. K., Reardon, C. M., Steinle, N.,… & Richardson, C. R.. (2015). Implementation and evaluation of the VA DPP clinical demonstration: protocol for a multi-site non-randomized hybrid effectiveness-implementation type III trial. *Implement Sci, 10(1), 68.* **<u>Power Point Slides</u>** • Designs that Are Used, or Should be Used, for Dissemination and Implementation Research (Brown, 2009) Hybrid Designs

	• Secondary Focus= assessing clinical intervention	
QUASI-EXPERIMENTAL STUDY		
Controlled Before-and-After Study (CBA) Design	• Participants are assigned to control group OR an alternative group(s) • ***No random assignment*** • Requires data collection at baseline • Study and control sites are comparable • Pre and post intervention periods are the same across study and control sites	• Cochrane EPOC (2002). Data Collection Checklist. Retrieved from http://epoc.cochrane.org/sites/epoc.cochrane.org/files/uploads/datacollectionchecklist.pdf • Fraser, K. D., Sales, A. E., O'Rourke, H. M., & Schalm, C. (2012). Data for improvement and clinical excellence: protocol for an audit with feedback intervention in home care and supportive living. *Implementation Science*, *7*(1), 4.
Interrupted Time Series (ITS) Design **Subtypes** Delayed Treatment Design Multiple Baseline Design	• Design detects whether the intervention or strategy was effective, based on time trend comparison • Data is collected at multiple time points before and after the intervention or strategy • Requires data collection at least 3 data points before and 3 data points after the intervention or strategy • Intervention/Strategy time points should be identified and clearly defined	• Bartlem, K., Bowman, J., Freund, M., Wye, P., McElwaine, K., Knight, J., ... & Wiggers, J. (2013). Evaluating the effectiveness of a clinical practice change intervention in increasing clinician provision of preventive care in a network of community-based mental health services: a study protocol of a non-randomized, multiple baseline trial. *Implementation Science*, *8*(1), 85. • Cochrane EPOC (2002). Data Collection Checklist. Retrieved from http://epoc.cochrane.org/sites/epoc.cochrane.org/files/uploads/datacollectionchecklist.pdf • Team, O. N. (2013). Evaluation of a multisite educational intervention to improve mobilization of older patients in hospital: protocol for mobilization of vulnerable elders in Ontario (MOVE ON).
Regression-Discontinuity Design	• Participants are assigned to a particular intervention or strategy based on ***specific and measurable qualifying conditions*** • Examples of qualifying conditions include symptom severity, needs assessment, etc., • Dichotomizing qualifying conditions allows for groups to act as a control for "model selection effects"	• Glasgow, R.E., Magid, D.J., Beck, A., Ritzwoller, D., & Eastabrooks, P.A. (2005). Practical clinical trials for translating research to practice: Design and measurement recommendations. *Medical Care, 43* (6), 551-557. • Linden, A., Adams, J. L., & Roberts, N. (2006). Evaluating disease management programme effectiveness: an introduction to the regression discontinuity design. *Journal Of Evaluation In Clinical Practice*, *12*(2), 124-131. doi:10.1111/j.1365-2753.2005.00573.x • Moscoe, E., Bor, J., & Bärnighausen, T. (2015). Regression discontinuity designs are underutilized in medicine, epidemiology, and public health: a review of current and best practice. *Journal of clinical epidemiology*, *68*(2), 132-143.

OBSERVATIONAL STUDY		
Cohort Study Design	• Describes incidence or natural history • Enables calculation of relative risk; • Provides support for casual inferences • Allows for analyses of retrospective or prospective data • Intervention or strategies and outcomes must be measured in temporal sequence	• Elliot, D. L., Kerry, K. S., Moe, E. L., DeFrancesco, C. A., Goldberg, L., MacKinnon, D. P., ... & Favorite, K. C. (2010). The IGNITE (investigation to guide new insight into translational effectiveness) trial: Protocol for a translational study of an evidenced-based wellness program in fire departments. *Implement Sci*, *5*(73.10), 1186.
Cross Sectional Design	• Determines prevalence • Does ***not*** differentiate between cause and effect or the sequence of event • Exposure and outcome are determined simultaneously for each participant	• Moreno, L. A., De Henauw, S., Gonzalez-Gross, M., Kersting, M., Molnar, D., Gottrand, F., ... & Marcos, A. (2008). Design and implementation of the healthy lifestyle in Europe by nutrition in adolescence cross-sectional study. *International Journal of Obesity*, *32*, S4-S11.
Case-Control Design	• Retrospective comparison of two groups • Aims to identify predictors of an outcome • permit assessment of the influence of predictors on outcome via calculation of an odds ratio • Does not allow for assessment of multiple outcomes at once • Compares individuals who have the outcome ("cases") to individuals who do not have the outcome ("controls")	• Fulop, N., Boaden, R., Hunter, R., McKevitt, C., Morris, S., Pursani, N.. ... & Wolfe, C. D. (2013). Innovations in major system reconfiguration in England: a study of the effectiveness, acceptability and processes of implementation of two models of stroke care. *Implement Sci*, *8*(5), 19.
SYSTEMS SCIENCE APPROACHES		
System Dynamics	• Utilizes models and computer simulations to understand complex system behavior	
Network Analysis	• Studies the relationships and flows among social actors • Examples of social actors includes people and organizations	
Agent-Based Modeling	• Utilizes computer simulations to examine how elements of a system behave as a function of their interactions with each other and their environment	**Webinars** • Advanced Topics for Implementation Science Research: Agent-Based Models