

Research Designs: Choosing and Fine-tuning a Design for Your Study

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Sportscience 12, 12-21, 2008 (sportsci.org/2008/wghdesign.htm)

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Researchers can design a study to characterize a single instance of a phenomenon or to make an inference about a phenomenon in a population via a sample. Single-subject (or case) studies are justifiable when sampling is difficult or inappropriate. Psychosocial cases aimed at solving a specific problem usually require qualitative methods. Clinical cases are reports of diagnosis or treatment of injury or illness and are usually based on quantitative assessments and qualitative analysis. Non-clinical quantitative cases involve repeated sampling on a single subject and a quantitative inference about the subject generally. Sample-based designs are either observational or interventional, and most are aimed at quantifying a causal effect, in which changes in a predictor variable on average cause changes in a dependent variable. Establishing such causality in observational designs is problematic, owing to difficulties in adjusting for bias in the effect arising from confounders (variables that cause changes in the predictor and dependent). This problem is eliminated in interventions, but the necessary inclusion of a control treatment introduces bias mediated by differences between the groups in administration of treatments, compliance with study requirements, or imbalance in subject characteristics. Use of blinding and randomization at the design stage and inclusion of covariates in the analysis generally lead to trustworthy outcomes by reducing bias in interventions, but observational studies are sometimes the only ethically or logistically possible choice. In both types of study the role of a potential mechanism (or mediator) variable can be investigated by including it in the analysis as a covariate. The observational studies in approximate ascending order of the quality of evidence they provide for causality are case series, cross-sectional studies, case-control studies, and cohort studies. The corresponding approximate order for interventions is pre-post single group, post-only crossover, pre-post crossover, pre-post parallel groups, and post-only parallel groups. Methodological designs are also of interest to researchers; these are special kinds of cross-sectional study aimed at characterizing the validity, diagnostic accuracy, reliability or factor structure of a measure. Finally, reviews are another kind of cross-sectional study in which the “subjects” are study-estimates of an effect and in which the analyst estimates the effect of different settings on the outcome. Each design has particular strengths that offset its weaknesses and make it the most appropriate for a research question. **KEYWORDS:** analysis, bias, case study, confounding, control, intervention, mediators, moderators, modulators, observational, randomized controlled trial, RCT, single subject.

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Update 2 May 2017: The scatterplots for moderator and mediator analyses are now in the slideshow on Linear Models and Effect Magnitudes.

Update to 2011: Slides on the different kinds of controlled trial copied from slideshow in the article on Controlled-trial Decision Tree.

Update 6 Aug 2008: A slide on mechanisms in interventions has been added to clarify how to es-

timate the contribution of a mechanism variable.

My [article on research design](#) (Hopkins, 2000) is one of the most popular pages at this site, netting 3000-4000 unique visitors per month, possibly because it is the third or fourth hit in a Google search for “research design”. The article is sound but needed an update. The present article meets that need, in the form of a

slideshow on research design. (Related resources at this site, especially for undergraduate or novice researchers: [Finding Out What's Known](#) and [Dimensions of Research](#).)

Some material in the slideshow is based on sections of the first draft of an article on statistical guidelines (Hopkins et al., 2009) that Steve Marshall, Alan Batterham and Juri Hanin co-authored with me. We subsequently deleted the sections on design from the article to make the length acceptable for the intended journal. The sections in question were themselves based mainly on my earlier article, but I acknowledge here the contribution of these colleagues. Some material comes from [an article](#) about the different kinds of controlled trial (Batterham and Hopkins, 2005). Estimates of sample size for each design come from my [article and spreadsheet](#) on sample size for magnitude-based inferences (Hopkins, 2006). I can point to no other published articles or books that I used to support the assertions in the first draft of this slideshow or in the earlier article. The assertions are either common knowledge amongst researchers and statisticians or are based on my own experience or introspections. I have sometimes checked that my use of jargon and understanding of concepts concur with what other apparent experts state at Wikipedia and other sites. The assertions are also now consistent with references that the reviewer brought to my attention (see below).

The diagrams I have used to explain confounding and mediation in observational studies are simple versions of the so-called directed acyclic graphs (DAGs) that have been used to facilitate understanding of confounding in epidemiology. What appears to be a definitive reference on this topic (Greenland et al., 1999) is probably too difficult for the average researcher (including me) to understand without an unreasonable investment of time. The simpler treatment I have presented here should provide researchers with sufficient understanding to be meticulous about design and analysis of their own observational studies and wary of the confounding that inevitably biases the effects in published observational studies. For a classic reference on such biases, see Taubes (1995).

I devised a similar set of DAG-like diagrams to explain bias in interventions. A figure with imaginary data explaining what happens when

you adjust for a covariate in an intervention is similarly original and has certainly helped me to understand the issues.

The [PDF reprint version](#) of this article contains the images of the slides, preceded by this text. The [slideshow in Powerpoint format](#) is a better learning resource, because the slides build up point by point in full-screen view.

The reviewer (Ian Shrier) identified several minor problems and made comments that led to the following improvements in the slides on inferences about causation: customary use of the term *moderator* (and its synonym, *modifier*); a note that some kinds of covariate can create bias (Hernan et al., 2004; Shrier, 2007); and a note that unknown confounders can bias estimates of effects and their mechanisms (Cole and Hernan, 2002). He queried the use of *time series*, which Batterham and I used for the simplest type of intervention, so I now refer to such designs as *pre-post single-group*. He also noted that “you have made some over-simplifications for pedagogical purposes, and people should [be advised to] seek help if they are not familiar with the nuances of any particular design.” I agree and have added such advice.

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