

Methods in Epidemiologic Research
Sample Problems
Chapter 11 - Controlled Studies

Background

Before accepting the reported results of research studies, each study should undergo a critical assessment. In turn, the completion of that assessment depends on the author's reporting clearly and completely and details of their research. The main items to be reported in randomized controlled trials have been listed and discussed in CONSORT (www.consort-statement.org) (also printed on pages 266-7 of the text).

Questions

Below we have listed a few example controlled studies that you can use to practice your assessment of study design and research reporting. Given that there is some subjectivity in the assessment of studies, we do not provide “solutions” to the following questions. Where possible, it will be worthwhile to discuss your views with colleagues and mentors. For one or more of the studies listed below, consider the following

1. Use the CONSORT checklist to determine how well the study has been reported.
2. It is difficult to think about forward projection (described on page 159 of the text) once you have already seen the results of the study. Nevertheless, use this approach to project a set of results that are different from those observed. Does this exercise help to identify any issues of concern with the study design?

Papers

- Beran J, Peeters M, Dewe W, Raupachova J, Hobzova L, Devaster JM. Immunogenicity and safety of quadrivalent versus trivalent inactivated influenza vaccine: a randomized, controlled trial in adults. *BMC Infect Dis.* 2013;13:224.
- Cormie P, Pumpa K, Galvao DA, Turner E, Spry N, Saunders C, et al. Is it safe and efficacious for women with lymphedema secondary to breast cancer to lift heavy weights during exercise: a randomised controlled trial. *Journal of cancer survivorship : research and practice.* 2013;7(3):413-24.
- Holmberg L, Bill-Axelsson A, Steineck G, Garmo H, Palmgren J, Johansson E, et al. Results from the Scandinavian Prostate Cancer Group Trial Number 4: a randomized controlled trial of radical prostatectomy versus watchful waiting. *J Natl Cancer Inst Monogr.* 2012;2012(45):230-3.
- Meerovitch K, Torkildsen G, Lonsdale J, Goldfarb H, Lama T, Cumberlandidge G, et al. Safety and efficacy of MIM-D3 ophthalmic solutions in a randomized, placebo-controlled Phase 2 clinical trial in patients with dry eye. *Clinical ophthalmology.* 2013;7:1275-85.