

## BOOK REVIEW

## Rethinking randomized controlled trials

**Randomized Controlled Trials: Questions, Answers and Musings, second edition**

Alejandro R. Jadad, Murray W. Enkin  
 BMJ Books/Blackwell Publishing; 2007  
 160 pp \$35.95 ISBN 978-1-4051-3266-4

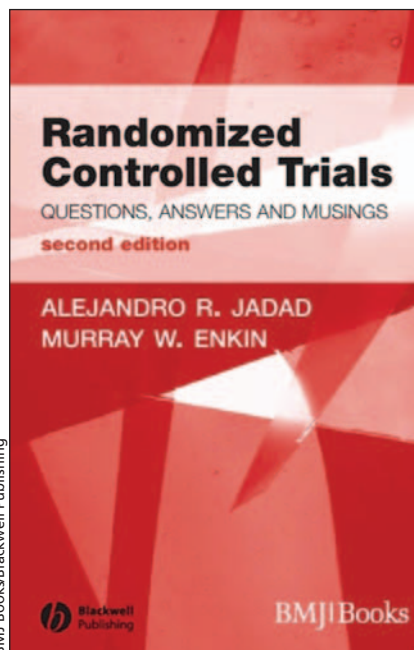
When *Randomized Controlled Trials* was first published in 1998, it was hailed in a *BMJ* review as a complete, concise and clearly written guide. Almost a decade later, the disappointing results of efforts to improve the reporting and conduct of clinical trials<sup>1</sup> suggest that a succinct description of the randomized controlled trial that is free from unnecessary jargon remains useful.

The updated edition surpasses the first edition as a lucid and readable description of randomized controlled trials in several ways. For example, the table of contents fits neatly onto a page, compared to the unnecessarily complex 3-page table of contents in the first edition, while the discussion of bias is better organized.

The new edition, however, is much more than a tidied-up version of the original. The new book is co-authored by Murray Enkin (who played a major editorial role in the first edition), a long-standing colleague and collaborator of Alejandro Jadad. The latest edition also dedicates a chapter to the ethics of clinical trials.

The most important innovation, however, is that the new book endorses a new *attitude* toward randomized controlled trials. Although the authors “were, and are, strong and enthusiastic proponents of RCTs” (p. 44), they caution against the uncritical view that randomized controlled trials provide the best answers to all medical problems. The authors’ revised views are expounded mostly in new sections entitled “Musings” at the end of each chapter.

Jadad and Enkin’s new outlook on randomized controlled trials stems partly from their argument that since there is a “practically infinite” number of possible biases, no randomized controlled trial



will deliver results that are absolutely bias-free. They admonish us to stop worshipping the randomized controlled trial as if it were a talisman that would guarantee objectivity. Yet one could object that this problem could be overcome to a large extent if we were much better at *conducting* randomized controlled trials, for example, if we blinded all of the groups involved in a trial. Jadad and Enkin, however, contend that there is a deeper problem. Although (they argue) the randomized controlled trial is useful for simple problems (how to treat pneumococcal pneumonia), as well as *complicated* problems (how to anesthetize a patient for chest surgery), it has limited use for the increasingly complex problems faced by the medical community today. Factors that add complexity range from the effects of patient preference on outcomes and the effects of being enrolled in a trial to the qualitative aspects of health care.

They advocate a more critical stance and a multidisciplinary approach to solving complex problems. More specifically, Jadad and Enkin recommend nontraditional randomized controlled trials (such as the patient preference design), qualitative re-

search, increased democratization of the research process, evaluation of research by independent bodies and even investigation of the rhetorical aspects of trials.

However, the authors’ claim that complex problems cannot be solved by randomized controlled trials, although intuitively plausible, lacks sufficient motivation. The authors’ cite 2 examples of complex problems — raising a child and treating dementia — where randomized controlled trials have limited use. Yet raising a child is not a medical problem, while it would seem that randomized controlled trials would be a good way to evaluate a pharmacological intervention for dementia. One looks forward to a third edition, or indeed a separate book, where the authors bring their expertise and clear expository style to bear on a description of the alternatives to randomized controlled trials and more extensive justifications for why we need these other methods.

Lastly, the short section on “equivalence” trials might be expanded to explain the often-confused difference between noninferiority, superiority and equivalence trials. These distinctions bear on the practical and ethical problems (that the authors mention in their chapter on ethics) surrounding the use of placebo-controlled trials where there is an established treatment.

Overall, this book succeeds in providing a remarkably clear and readable description of the randomized trial. Anyone interested in a highly accessible description of randomized trials, whilst enjoying a good read, will acquire their personal copy.

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## REFERENCE

1. Plint AC, Moher D, Morrison A, et al. Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review. *Med J Aust* 2006;185:263-7.