A Practical Guide to Cluster Randomised Trials in Health Services Research

Sandra Eldridge and Sally Kerry

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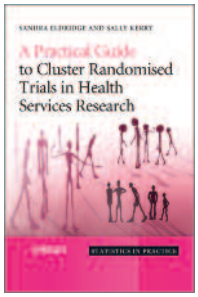

In this book, Sandra Eldridge and Sally Kerry have provided an informative and readable resource for conducting cluster randomised trials. Clustered trials first occurred in schools in the 1940s and by the 1970s they were used for medical research; however it was not until the 1990s that a text book was first written on the subject. Due to the relative newness of this medical research tool, many methodological developments have occurred in the last 10 years. This practical guide provides well-referenced information on many of the recent developments in this area, as well as a comprehensive general overview.

Cluster-based trials have specific strengths that are useful in modern healthcare. There is an increasing emphasis on prevention in medicine, and psychiatry is no exception. In recent years, there has been a significant financial investment in educational and population-based interventions aimed at prevention. This is seen in campaigns such as 'drink responsibly' and 'see change'. In addition to this, there is growing pressure to improve the provision of services and to restructure organisations more efficiently. Interventions in these two areas, prevention and organisational management, have two elements in common that make cluster based trials an efficient tool for evaluating change. Firstly, these interventions do not occur at an individual level and secondly, such interventions are often complex in nature. One of the strengths of cluster-based trials is that they are able to investigate interventions on these levels. These trials can help answer questions such as: Are the leaflets and information posters we see in GPs, pharmacies and hospitals an effective use of resources, and do administrative changes improve the attendance at a clinic?

As we can see from the above, cluster randomised trials are important and this book serves as an excellent introduction to conducting them. This book covers every aspect of embarking on trials of this nature: from initial planning, through ethics, design and analysis, to reporting.

The first five chapters begin by looking at the basic principals of cluster based trials. The introduction is very informative and gives some useful background. Recruitment and ethics are discussed next which give guidance in the complex area of consent in cluster trials. The third chapter, on design of intervention, is very helpful in providing an approach to creating an intervention and may be the most useful section in the book. Study design including pilot and feasibility studies are discussed in these early chapters. These chapters also cover such questions as: Who consents in a cluster, is information gathered on all members of a cluster, does not doing this introduce bias, and how is a complex intervention developed?

While this is not a book that will be enjoyed by the arithmophobic, should they survive the first five chapters they may well want to take a well-deserved break of a few chapters, and skim through to chapter nine. These three chapters cover analysis, sample size calculation and inter-cluster correlation coefficient, and are well laid out and very approachable, however they are unavoidably mathematically dense. The chapter dealing with analysis is comprehensive and provides illustrations for different types of outcome and design: while the 37 pages dedicated to this require full concentration they are surprisingly manageable. This chapter discusses, amongst other things, the important influence of cluster size, number and variability.

Chaper seven covers sample size calculation. This chapter does a good job of alleviating much of the fear and paralysis which is often often associated with power calculations. This chapter is as compelling a read as the title; Sample size calculation would lead you to believe. It does, however, carefully talk through some important considerations and address many of the questions concerning power calculation in a straight-forward manner. Chapter eight, on calculation of intra-cluster correlation coefficient, gives information on an area which researchers unfamiliar with cluster based trials will find essential.

The final two chapters cover topics including systematic reviews, cost-effective analysis, process evaluation and trial reporting. The information on trial reporting discusses the CONSORT statement section by section and gives information on improving trial reporting.

One of the main strengths of this book is the breadth of topics considered. This book, also, walks the fine line between providing too much basic epidemiological information and not providing enough. From the start this book gives lots of examples of cluster trials to flesh out theoretical points, which helps hold the readers interest and promotes thinking about practical issues. Each chapter is well referenced allowing a reader to easily gain a deeper understanding of the topic should they so wish. This is essential reading for anyone considering conducting a cluster based intervention and a useful reference book for people evaluating the results of such trials.

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