



One day work shop: Research and reporting methods for the stepped wedge cluster randomised controlled trial

Background

The stepped-wedge cluster randomised trial (SW-CRT) is a novel research study design that is increasingly being used in the evaluation of service delivery type interventions. Recent systematic reviews have demonstrated that use of this study design is clearly on the increase. In the early history of cluster randomised trials it was not unusual to see trial results which were published without allowing for the clustering, and so results which were overly precise. Because the SW-CRT is a new study design, it is possible that the analysis and reporting of these trials are not adequately reported. Reporting guidelines specific to SW-CRTs do not exist, but here we recommend some minor additions or modifications that can be made to the cluster consort guidelines until specific guidelines for SW-CRTs are formalised.

Aims

The workshop will cover:

- Overview of what a SW-CRT is, including typical design features and its similarities and dissimilarities to the conventional parallel cluster trial and the parallel cluster trial with baseline observations.
- Two case studies to illustrate this design, including the EPOCH SW-CRT which is a large multi-centre stepped wedge study across 90 UK hospitals.
- How a generic framework can be used to determine power and sample size for a SW-CRT and compare the comparative efficiency of the parallel cluster trial and the SW-CRT. Examples and a practical focus will be used throughout.
- Guidelines on how a SW-CRT should be analysed, with particular emphasis on temporal confounding, and introduce initial reporting guidelines for this design.

Target audience: Those with experience in running or designing parallel cluster trials and who want to better understand the methodological and statistical principles behind conducting stepped wedge cluster trials. We will cover statistical topics but the workshop targeted at statisticians and applied methodologists. A significant part of the workshop will be devoted to practical examples, illustrating real world stepped wedge studies.

Faculty:

Richard Lilford, Professor of clinical epidemiology, University of Warwick, UK
Alan Girling, Reader in biostatistics, University of Birmingham, UK
Karla Hemming, Senior lecturer in medical statistics, University of Birmingham, UK

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