


COMMENTARY

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# A website for cluster randomised trials including stepped wedge: facilitating quality trials and methodological research

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## Abstract

**Background** A cluster randomised trial is a randomised controlled trial in which groups of individuals (clusters) are randomised to treatment arms. Stepped wedge cluster randomised trials are a type of cluster randomised trial where clusters are randomised to sequences. These trial designs are important for impacting decision-making, and it is therefore important that they be well-conducted and reported.

**Main body** In November 2018, we created a new website dedicated to cluster randomised trials, including stepped wedge designs: <https://clusterrandomisedtrials.qmul.ac.uk/>. The idea for the website emerged from the conference on Current Developments in Cluster Randomised Trials and Stepped Wedge Designs held in November 2016 at Queen Mary University of London, with the aim to provide an online resource to facilitate quality trials and methodological research on these types of trial. The website is divided into sections covering Design, Analysis and Reporting for traditional (i.e. parallel two-arm) cluster randomised trials and stepped wedge designs and contains resources in the form of hyperlinks to relevant papers along with brief explanations. A noticeboard page provides details on announcements, events, and past events.

**Conclusion** We aim to keep the site updated with the latest publications and events related to cluster randomised trials, and welcome suggestions from the research community on further resources or events to add. We hope that the site will facilitate high-quality traditional and stepped wedge cluster randomised trials.

**Keywords** Cluster randomised trial, Group randomised trial, Stepped wedge, Website

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## Background

### What are cluster randomised trials?

In a cluster randomised trial (CRT), groups of individuals, or clusters, are the unit of randomisation. Examples of clusters include schools, hospitals and communities, and the individuals of interest within these clusters might be pupils, patients, and residents. In a traditional CRT (the parallel two-arm design), clusters are randomised to one of two treatment arms and outcomes are then measured in individuals in all clusters at the same follow-up time(s) (i.e. durations from baseline).

An alternative to the parallel two-arm design is the stepped wedge CRT (SW-CRT), where clusters are randomised to a treatment sequence. All or most clusters start by receiving the control condition and eventually end by receiving the treatment condition, moving from control to intervention at different time points depending on the treatment sequence randomised to. The time between these time points is referred to as periods, and outcomes are measured in each time period. A related design is the cluster crossover trial, for example, where clusters are randomised to two sequences; in one sequence clusters start with the control condition followed by the intervention, and in the other sequence clusters start with the intervention condition followed by the control. On the website, we focus on parallel CRTs and SW-CRTs and include some references to cluster crossover trials.

CRTs and SW-CRTs are a more complex design choice than used by most trials. In both designs outcomes between members of the same cluster are correlated, that is, outcomes from individuals in the same cluster tend to be more similar to each other than a random sample for the whole group. In SW-CRTs (and parallel CRTs with multiple follow-up time points) observations in the same period are, in general, more similar than observations in different periods, making the correlation structure more complex. The correlation of outcomes of members of the same cluster leads to a lower power than would be expected were the same number of individuals enrolled in a regular randomised controlled trial with individual-level randomisation and no clustering.

These correlations must be accounted for in the design and analysis of CRTs and SW-CRTs and be appropriately reported. These study designs are also at a higher risk of bias [1, 2].

### Why perform cluster randomised trials?

Despite the complexities described above, CRTs are sometimes the most practical choice of design. For example, the intervention may be at the cluster level, such as a new appointment system in a general practice, or there

may be reasons not to randomise at the individual level due to issues of contamination. For example, if the intervention consists of educational sessions to staff in a care home then it would be difficult for staff to use the education they have had to support some residents and not others. Stepped wedge designs have become increasingly popular in recent years. They can be a useful design when an intervention is scheduled to be rolled out to all clusters as part of routine implementation: the stepped wedge design then provides an opportunity to perform a randomised evaluation [3]. They also have power advantages in some circumstances [4]. However, delivering the intervention to all clusters towards the end of the trial may increase the implementation burden of a SW-CRT compared to a traditional parallel-arm CRT. Moreover, more traditional cluster designs allow investigators to incorporate design features often erroneously thought of only as advantages of a stepped wedge design. For example, it is possible to include a sequential roll-out of the intervention or use a wait-list control in a traditional parallel-arm CRT so that all control arm clusters receive the intervention after the trial has ended. The choice between CRT and SW-CRT requires careful consideration.

### What is the current state of conduct and reporting?

CRTs are often the design of choice for complex, multi-component interventions and thus they impact decision-making regarding adoption of health interventions. It is important therefore that they are reported well and follow the CONSORT extensions for CRTs and SW-CRTs [5, 6]. There are also many papers describing how to design and conduct them well [7–11]. Nevertheless, their increasing popularity has meant that despite all of this information accessible to researchers, the conduct and reporting of these trials could often be improved.

A recent review showed that in CRTs with binary primary outcomes, most trials did not comply with reporting guidelines with regards to the outcome measure [12]. Another review of stratified CRTs highlighted that the additional complexities due to stratification were often overlooked when analysing and reporting the results [13]. Similarly, for pilot CRTs, a review showed suboptimal reporting in many areas, including sample size rationales and sample characteristics [14].

Reviews of SW-CRTs have shown inadequate reporting in several areas too. One review showed reporting of research ethics review and informed consent is suboptimal [15]. Another study showed SW-CRTs are not adequately detailing why clustered allocation was used in their trial or why a SW-CRT design was chosen [16]. Furthermore, a recent review showed major deficiencies in the methodology and reporting of sample size calculations for SW-CRTs [17].

### Aim of this article

The ongoing need for good conduct and reporting of CRTs and SW-CRTs led to discussions about the utility of a website to gather useful information for investigators together in one place. These discussions took place at the 2016 conference on Current Developments in Cluster Randomised Trials and Stepped Wedge Designs. This is an annual conference hosted by Queen Mary University of London, consisting of a series of submitted and invited presentations and discussions on recent developments in the design, conduct, analysis and reporting of cluster randomised and stepped wedge trials [18]. From discussions at the November 2016 conference led by Sandra Eldridge, the idea emerged to design a website where all the research on CRTs could be brought together and collated to provide an easily accessible resource for those conducting or considering the implementation of such studies.

The purpose of this commentary is to describe and draw attention to the website and its contents, and discuss plans for maintenance of the website and how the research community can contribute.

### The website

The website is hosted by Queen Mary University of London and can be viewed at <https://clusterrandomisedtrials.qmul.ac.uk/>. The website is aimed at anyone conducting CRTs and SW-CRTs or carrying out methodological research on these studies, such as trialists, health professionals, and researchers.

Draft outlines for the structure of the website began in March 2017. Once the structure of the website was agreed, sections of the website were populated by Claire Chan, Sandra Eldridge, Karla Hemming, Clémence Leyrat, James Martin, Mélanie Prague, Jennifer Thompson, and Elizabeth Turner. Further helpful comments were received during the development and/or review of the site before it went live from Prof. Agnès Caille (University of Tours), Prof. Bruno Giraudeau (University of Tours), Prof. Richard Hooper (Queen Mary University of London), Sally Kerry (Queen Mary University of London), and Dr. Michael Grayling (University of Cambridge). In April 2018, an external web designer began creating the website in parallel with another website on pilot and feasibility studies that some of the groups above were also involved in [19]. Queen Mary University of London had a Docker Containers Environment to host small websites and provided the domain name and an empty container with WordPress pre-installed. The website went live in November 2018.

The website follows a similar structure to the pilot and feasibility studies site designed in parallel [19]; it

comprises six pages: homepage, introduction page, resources page, noticeboard, who we are, and a contact page. The introduction page and resources pages are divided into separate sections for CRTs and SW-CRTs. The introduction page for CRTs lists some well-known textbooks on CRTs, provides some example CRTs, reasons to perform such a study, and information on correlation in CRTs and different types of designs. The introduction page for SW-CRTs follows a similar format. Each of the resources pages is subdivided into sections on design, analysis, and reporting, where hyperlinks are provided to relevant papers and some explanations are provided. Finally, the noticeboard page displays announcements and details on events and past events.

We aim to keep the site updated as new publications and guidelines emerge. We encourage the research community to contribute any material they feel would be well-placed on the site using the 'Contact us' page on the website, or sending an email to: [clusterrandomisedtrials@qmul.ac.uk](mailto:clusterrandomisedtrials@qmul.ac.uk). Individuals can also contact us with news items or events to add to our noticeboard.

### Conclusion

CRTs and SW-CRTs are a relatively complex design choice but can often be the most practical option. They are important for impacting decision-making related to health interventions, yet their conduct and reporting still require improvement. We therefore developed a website providing resources to help researchers perform these studies well and to aid methodologists as they look to improve the efficiency and conduct of such trials. As far as we were aware, there was no other similar online resource at the time. Additional resources can now be found for example on a website devoted to stepped wedge trials [20], which has blog posts related to stepped wedge trials and some resources in the form of hyperlinks to relevant papers, but does not cover traditional parallel two-arm CRTs in the same depth. The London School of Hygiene and Tropical Medicine (LSHTM) website has a page devoted to CRTs where a short summary is given of the book by Hayes and Moulton on cluster randomised trials [21], and another page devoted to SW-CRTs where an overview of stepped wedge trials is provided highlighting a series of papers by researchers at LSHTM [22, 23], but these pages do not have the same breadth as our website. Finally, the National Institutes of Health (NIH) website provides some resources to help researchers design their studies, including specific information for CRTs and stepped wedge designs [24]. The site does not advertise any events or announcements in the same way as our website here. We aim to keep our site updated with the latest resources and events related to CRTs and SW-CRTs, and welcome suggestions from the

research community on additional resources and notices to include. We hope that the site will prove to be a helpful aid for improving conduct and reporting within the field.

#### Abbreviations

CRT	Cluster randomised trial
NIH	National Institutes of Health
SW-CRT	Stepped wedge cluster randomised trial

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#### Authors' contributions

CC wrote the first draft of this commentary. All authors contributed to subsequent drafts, and read and approved the final manuscript.

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#### Data availability

Not applicable.

#### Declarations

##### Ethics approval and consent to participate

Not applicable.

##### Consent for publication

Not applicable.

##### Competing interests

The authors declare the following competing interests: All authors are contributors to the cluster randomised trials and stepped wedge website. The website was funded through SE's NIHR Senior Investigator Award.

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