Letter to the editor commenting on the paper:


By Karla Hemming July 2015

The stepped wedge cluster randomised trial does not always need fewer clusters

Hooper and Bourke introduce and illustrate the sample size calculations in a novel type of cluster randomised design, the so called dog-leg design (the incomplete cross-forward design) [1]. This design is related, but has distinct features to the stepped wedge cluster randomised design.

Whether a simple parallel cluster trial, or some alternative design, will be the preferable design depends on many considerations, of which efficiency is just one. In cluster trials, comparisons of efficiency, can consider minimising the number of clusters or the number of participants (or preferably both). There has been much debate and confusion in the literature over the relative efficiencies of different designs. Hooper and Bourke make the following two claims:

1. “Stepped wedge designs need fewer clusters than parallel group designs with a single follow-up, simply because they assess the same clusters repeatedly.”
2. “A dog leg design run over two repeated cross sections, for example, needs fewer clusters and fewer participants in total than a trial with a single cross section.”

Both of these claims are debatable and potentially miss-leading.

Firstly, it is not true that the cross-sectional stepped wedge design always requires a fewer number of clusters than the simple parallel design [2]. Whether or not this statement holds depends on whether the cluster sizes are fixed across the designs. If the cluster size is fixed (i.e. the recruitment rate and duration of the study is fixed) then the design choice comes down to a decision of, in which clusters and when, to intervene. In this case the stepped wedge design might need more clusters than the parallel designs (for low intra-cluster correlations). An alternative comparison is to compare a simple parallel design with a smaller cluster size, to a stepped wedge study that is allowed to run for a longer duration and so have a larger total cluster size. It is only when the cluster sizes are not fixed across the designs that the stepped wedge design always requires fewer clusters than the parallel design [3]. We illustrate this below by way of a counter example:

<table>
<thead>
<tr>
<th>Design constraints</th>
<th>CRT</th>
<th>SW-CRT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total cluster size</strong></td>
<td>ICC</td>
<td>Number steps</td>
</tr>
<tr>
<td>30</td>
<td>0.01</td>
<td>2</td>
</tr>
<tr>
<td>30</td>
<td>0.25</td>
<td>2</td>
</tr>
</tbody>
</table>

TSS: Total sample size; ICC: Intra-cluster correlation; DE: Design effect (multiplication over sample size needed under individual randomisation). Study designed to detect a moderate standardised effect size (0.2) at 80% power and 5% significance.
Secondly, whilst Hopper and Bourke have shown previously that the dog-leg design does indeed require fewer clusters and fewer participants than the conventional parallel design [4], it is important to note that the commonly used parallel design with a baseline period can offer an even more efficient design than the dog-leg design. And whilst this didn’t hold in the example presented in their paper, this is because efficiency depends on the correlations (e.g. the ICC), a point which deserves recognition. The parallel cluster design with a baseline isn’t necessarily the most efficient design amongst all competing designs, but as a well-used and known design it should be considered a contender.

References


