Author's response to reviews

Title: Designing a stepped wedge trial: three main designs, carry-over effects and randomisation approaches

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Response to Reviewers

We thank Dr Kanaan for her thoughtful review and now list our responses to each of her comments.

Reviewer's report:
This manuscript is one of a series of articles under review looking at issues related to the stepped wedge trial (SWT) design. It identifies three main designs; however, its main focus is on closed and open cohorts designs. It also discusses potential carry-over effects and randomisation approaches. This manuscript extends the recent attempt of Hemming et al (2015) to establish a framework for SWT designs.

Major Compulsory Revisions

1. The paper focuses mainly on the published SWTs post the systematic review of Mdege et al (2011). However, given that the manuscript attempts to add to the general framework of reporting of SWTs, it would be of interest to include those as well in the results.

Response
We carefully considered this suggestion but we feel that our article is primarily a methodological article that sets out design principles for SWTs, rather than a review article. Whilst we do report the number of trials that follow each of 3 main designs on the basis of a recent review (see response to next comment), we do not feel that this quantification is central to the paper, and we are also aware that the relative frequency with which each design is used may change over time. In the future there may be further designs used but we feel our article sets a framework that can be extended naturally. For these reasons rather than extend the allocation of published trials to particular designs further into the past we have now changed the abstract and main text in other instances to be clear that
the any statements we make about the relative of frequency of designs are based on recent trials.

2. On Page 3 under Background the authors mention that most “SWT described in the literature do not follow this particular design”, this most probably depends on the time frame the authors investigate. They cite one of the other articles in this series of under review articles but it would be beneficial if further details are also given here. Also, it would be valuable to provide the distribution of the type of SWT designs of all the studies included in the previous two systematic reviews and the systematic review that is currently under review.

Response

Please see response to comment 1. The reason we are able to make the assertion that most SWT described recently in the literature do not follow this particular design is because, in the terminology we later develop, the continuous recruitment short exposure design and closed cohort design are distinct from that particular design and these together represent most recent trials. Specifically the continuous recruitment short exposure design involves data collection in continuous time and the closed cohort design involves repeated observation of the same individuals. Open cohort trials may or may not follow the particular design we describe on page 3 depending on the measurement scheme. In our article we do report the number of trials that follow each design (13 continuous recruitment short exposure, 11 closed cohort, 11 open cohort, 2 ‘other) and have now added to page 5 that the review article examined 37 trials. On page 7 we refer back to the introduction and state that: “In the introduction we mentioned that the design literature has focussed mainly on designs where measurements are obtained cross-sectionally at pre-defined discrete time points [2-5]. Now that we have outlined a range of possible SWT designs, we see that amongst recent trials the design literature mainly addresses two special cases: the open cohort design with only a very small proportion of participants sampled at each time point (so that participants are measured at most once), and the repeated closed cohort design of Williams and colleagues [12].”

3. Figure 1 does not seem to add further value to the text and it’s also hard to follow why the different labels are where they are. For example, the duration of the step, (c), does it refer to the whole period after the introduction of the intervention? Would this notation also apply to the continuous recruitment with short exposure design? Also, it’s not clear why (a) is placed in that particular cell.

Response

We would prefer to retain the figure as we feel it has some value, particularly in clarifying that some trials involve data collection either whilst all clusters are in the control condition and/or when all clusters are in the intervention condition. However we thank the reviewer for alerting us that the figure is unclear. We have heavily revised the figure, and feel the figure now also helps the reader understand our terminology, which has changed slightly from the previous version.

4. On Page 5 under “Continuous recruitment with short exposure”, the authors
mention thirteen trials that use this design. It would be interesting to quantify the total number of trials that were included in the review; the review article needs to be cited here as well. As mentioned above, it would be interesting to report how many trials in total across the three systematic reviews that have used this design and how many have used the other two designs, possibly, using the typology detailed on Page 8. Also, how many SWTs will not fit the proposed typology?

Response

Please see response to comments 1 & 2. Two of the recent trials considered did not follow any of the three main designs, but they can still be described using the typology in terms of how individuals start exposure, exposure duration and measurement.

Minor Revisions

5. The numbering of the figures does not match the results section.

Response:

Sorry for this error, we hope we will be able to control the Figure numbers displayed on resubmission.

6. Page 8, last sentence replace “measurement” with “measurements”.

Response:

This text has been modified.

7. Page 10, define BHOMA on first appearance.

Response:

Corrected