Author’s response to reviews

Title: The current use of feasibility studies in the assessment of feasibility for stepped-wedge cluster randomised trials: a systematic review

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Author’s response to reviews:

Editor Comments:

1. We would like to ask for you to provide more justification for the contributions of SE, as currently they do not automatically qualify for authorship. Contribution to one aspect of the study, alone, does not usually justify authorship.

An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study. According to the ICMJE guidelines, to qualify as an author one should have:

a) made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; AND

b) been involved in drafting the manuscript or revising it critically for important intellectual content; AND

c) given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; AND

d) agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
Anyone who contributed towards the article who does not meet the criteria for authorship can be acknowledged in the ‘Acknowledgements’ section.

Response to Editor Comments:

We thank you for making us aware of this oversight, SE has been added to the list of authors that were involved in refining the design of the study. A line has also been added highlighting the contribution of SE towards the interpretation of the results (Lines 361-365). We believe this is sufficient for authorship. We would also like to thank you for your consideration of our manuscript. The comments we have received have allowed us to improve the quality and clarity of our paper.

Reviewer reports:

Patrick McElduff (Reviewer 1):
Reviewer:
This is a well written manuscript by authors with expertise in stepped wedged cluster randomised trials (SW-CRT).
Response:
We thank you for taking the time to review our manuscript and for complementing the writing of the paper. Your comments have helped us to improve the clarity and comprehensibility of the paper.

Reviewer:
However I am left wondering what purpose the manuscript serves. Assuming that feasibilities studies should be conducted for any trial, what does this paper add to the current literature?
Response:
Although it is recommended that feasibility studies should be conducted for any trial, our review shows that only a small number are being conducted and published for SW-CRTs. Our manuscript therefore highlights the need for increased awareness of the importance of feasibility studies, as well as highlighting the importance of publishing feasibility studies for SW-CRTs. In addition, since few studies investigated issues specifically relating to the trial procedures and in particular those relating to the stepped-wedge design, our manuscript highlights the need not
only for feasibility studies for SW-CRTs, but for feasibility studies investigating the feasibility of using this specific design of trial. It is our intention that as a result of the publication of this manuscript, more feasibility studies will be conducted and published for SW-CRTs and these studies will be investigating, among other things, the feasibility of using this specific design of trial. We have amended the Conclusions of the manuscript to emphasise these points (lines 37-38 and lines 329-334).

Reviewer:
After being involved in six SW-CRT, it is my view that the unique challenge to the SW-CRT is ensuring consistency in patient recruitment over time. Not just the number of patients but the type of patient. In an individual level randomised trial or a cluster randomised trial, blocking allows patients or clusters of patients to be matched over time. This is not the case for SW-CRTs. If enthusiasm wanes as the trial progress, or there is staff turnover within trial sites, there is the real likelihood that the type of patient changes and therefore confounders are introduced. This review would benefit from a real discussion about this issue to highlight its importance. The issues raised by the authors, "Known challenges include delays in the start of the trial, poor recruitment and limited quantity and quality of data" are not problems that are specific to SW-CRT. Although delays in the start of the trial at specific sites is an important problem.

Response:
We thank you for your suggestion, we agree that it is indeed a challenge for SW-CRTs to ensure consistency in its participants over time. We have therefore included a discussion of this point in the Background (lines 66-71), along with further examples of issues faced by SW-CRTs (lines 59-66). Although not all of these issues are specific to SW-CRTs, these issues do have potentially more serious consequences for SW-CRTs than for other designs as the staggered nature of the introduction of the intervention can be rather inflexible to changes.

Reviewer:
The other main issue I have with the manuscript is an incorrect inference being made by the authors. The first couple of sentences in the discussion, and similar information in the introduction, are misleading. It is wrong to assume that all feasibility studies are published. And it is wrong to assume that all published feasibility studies are identifiable using the search terms used in this review. Therefore the inference, "feasibility studies are rarely being conducted in of running a definitive SW-CRT" is not supported. Pilot studies often need a different angle to get published.

Response:
We thank you for bringing this to our attention. We acknowledge that the conclusions drawn from the data are more complicated than originally stated and have adjusted them accordingly to reflect that unpublished feasibility studies are not represented. These changes can be seen in line 105, lines 251-254, line 294, lines 324-325, and lines 330-332. That some published feasibility studies will not be identifiable using our search terms and other limitations of this review are discussed in the Strengths and Limitations section (302-322).

Minor comments

Reviewer:

When referring to the design as novel, the authors should consider reference the first use of the design.

Response:

We have added a reference to the Gambia Hepatitis Study in line 43 where we refer to the design as novel.

Reviewer:

Sites have to be randomised to the intervention so it is a bit misleading to claim, "The implementation of interventions under evaluation can often proceed as it would have had the evaluation not been taking place."

Response:

We have added clarification to this point in lines 48-50, which now highlights that randomisation does have an effect on how the implementation of the intervention is altered by the evaluation.

Reviewer 2 (Reviewer 2):

REVIEWER COMMENTS FROM REPORT:

The overall impression of the study is positive. Systematic reviews are very helpful in understanding where a field is moving in its progress, and this one was done well. The systematic review methods were used clearly, cited clearly, and applied correctly. It certainly
meets best practice for systematic reviews and is a creative way to gain an understanding of the field.

Response:

Thank you for your complimentary comments towards the way in which we conducted our study.

REQUESTED REVISIONS:

The interpretation of the data reviewed is more complicated than the authors have identified. They reviewed the existence and content of published feasibility studies for stepped wedge cluster randomized trials. However, they did not and could not review non published feasibility studies. The conclusions should be that there are few feasibility studies published, not that there are few feasibility studies conducted.

Response:

We acknowledge that the conclusions drawn from the data are more complicated that originally stated and have adjusted them accordingly to reflect that unpublished feasibility studies are not represented. These changes can be seen in lines 105, 251-254, 294, 324-325 and 330-332 and reflect what is discussed in the Strengths and Limitations section (lines 302-322).

Reviewer:

The conclusions about the lack of stepped wedge content and issues in these feasibility studies seems to be true, however.

Response:

Thank you for acknowledging this. We have kept this conclusion as it was in the original manuscript.

ADDITIONAL REQUESTS/SUGGESTIONS:

The title has imbedded in it the findings and this should not be the case. The title should focus on the mission of the systematic review, not the outcome of the systematic review.

Response:

We have changed the title to focus on the aim of our review, rather than the findings (lines 1-2).
Reviewer:
Also the definition of stepped wedge cluster design deserves another sentence to clarify exactly what is meant.

Response:
We have added another sentence to clarify exactly what is meant by a stepped-wedge cluster randomised trial. (Lines 45-47).

Reviewer:
The feasibility issues at the end of the introduction are not really unique to stepped wedge cluster designs. Can the authors provide clearer issues that would be? If not, this review should be a review of feasibility studies in general.

Response:
We thank you for your observation. We have included additional issues to the Background (lines 59-71) which are particular problems for SW-CRTs. Although they may not be specific only to SW-CRTs, they do have potentially more serious consequences for SW-CRTs compared to other designs of trial due to the inflexibility of the design brought about by the staggered implementation of the intervention.

Reviewer:
Pilot and feasibility studies are not defined.

Response:
The description of feasibility studies in the Background has been expanded upon to give a clearer description of pilot and feasibility studies. (Lines 75-76 and 86-90).

Reviewer:
The authors did not cite systematic review guidelines. Were they used to conduct this systematic review?

Response:
PRISMA guidelines were used and the PRISMA checklist was provided with the original submission. A statement has been added (lines 167-168) to highlight this and includes a reference to the PRISMA statement.

Reviewer:

An appendix should be provided listing study by study included, and the characteristics that are summarized in the existing table.

Response:

The characteristics summarised in Table 2 have been provided by study and can be found in the new Additional File 3. The information summarised in Table 3 has been provided by study and can be found in the new Additional File 4. The manuscript has been updated with descriptions of these files provided in the last few lines of the manuscript (lines 475-479).