Reviewer's report

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

Version: 1  Date: 12 April 2015

Reviewer: Raphael Porcher

Reviewer's report:

General comments
The paper belongs to a series of articles on stepped wedge trials (SWT) all considered together for publication in Trials (references 1, 13, 14 and 15). Overall, the reviewer found it sometimes difficult to follow the many references to these other manuscripts (that were not available). Perhaps fewer references to these works would make this paper more self-contained and easier to read.

Major Compulsory Revisions
1. After reading the paper, it appears that it contains useful information. Nonetheless, it is very narrative, and it is difficult to have a clear idea of the aims and methods. For instance, it is unclear whether it is a result of a systematic review, a non-systematic review, or simply a collection of topics covered by the experience of the authors. It is also not so clear whether the paper primarily aims at helping the design or the reporting of SWT. This should be clarified, and the paper revised accordingly.

2. The different topics covered are all useful, but their succession lacks a clear progression or transitions. We are left without knowing if all these topics are the most important ones when designing a SWT (but then the issue on incomplete and unbalanced designs is too short to be really helpful), or just some topics the authors develop among others.

3. Related to my previous point, the issue of incomplete designs should be covered more in-depth, with pros and cons. We even learn more in the discussion, which is strange.

4. The case studies are only briefly described in terms of main design, and then quickly referred to when tackling different issues such as carry-over. A more in-depth analysis of the case studies may help illustrating the authors' take-home message on the different points they cover.

5. The issues concerning analysis of SWT are described in another paper of the series. But this manuscript refers to analyses several times (e.g. page 10, end of the first paragraph; pages 11-12 on mixed-effects models ...) A short introduction on how SWT are analysed would therefore be helpful.

6. The manuscript would be improved if the authors could make a table with the three main designs, the other issues, and summarize the advantages and disadvantages of each.
Minor Essential Revisions
1. Many statements lack precision. For instance, page 11, “[the gain in efficiency] is probably greater when the baseline and subsequent values are taken from the same individuals”. Does the “probably” mean the authors are unsure of their statement? It would be better to be more specific or to give a reference.
2. The numbering of figures in the text does not fit the numbered figures at the end of the manuscript.
3. Page 6, 3 lines from the bottom, isn’t a “time point” missing?
4. The paragraph on the need to check for balance throughout the trial is either too short (and then the point would deserve more details) or too long (and thus can be omitted, since the issue is covered in reference 15).

Discretionary Revisions
1. The issues raised by data collection in case study no. 3 (in particular during the 21 months after rollout) may be further developed to better show why this would not be advisable.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests