Reviewer’s report

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

Version: 0 Date: 02 Sep 2018

Reviewer: Patrick McElduff

Reviewer's report:

This is a well written manuscript by authors with expertise in stepped wedged cluster randomised trials (SW-CRT). 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? 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.

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.

Minor comments

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

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."
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?
If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal