Author's response to reviews

Title: The stepped wedge trial design: literature review

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The Stepped Wedge Trial Design: Literature Review
Response to reviewers’ comments

General
We would like to thank the reviewers for their positive response to this paper and for their helpful comments. We have acknowledged the reviewers at the end of the paper.

Reviewer: Rebecca Turner

Major revisions
1. We have re-worded the section in the background to make the motivations for using a stepped wedge design clearer and more distinct from a cross-over design.
2. We have expanded our review of the studies to include a brief quality assessment of methods of randomisation and blinding. Given the heterogeneity in methods of statistical analysis (and lack of reported detail in some papers), it is difficult to provide a critical analysis of these methods in a concise manner. However we refer to the recent paper by Hussey and Hughes in the conclusion, and thank the reviewer for drawing this paper to our attention.
3. We have included a section on the disadvantages of the stepped wedge design, including the complex nature of the statistical analysis in both the introduction and conclusion.

Minor revisions
1. We have added a note to Table 1c to explain the column headings ‘Intervention’ and ‘Control’.
2. We have noted that the design presented in Figure 1 has 5 steps.

Reviewer: Jim Hughes

Discretionary revisions
1. We have noted the disadvantages of using the stepped wedge design in the background section and the conclusion. However, we leave the possibilities for a reduced number of communities and the need to consider time effects between communities for our subsequent modelling paper.

Reviewer: George Borm

Minor revisions
1. We have added some examples to help illustrate the motivations for using a stepped wedge design in the background section.
2. We have re-worded the sentence on page 10 to make the meaning clearer: the papers in question used the stepped wedge design as they deemed it unethical to withhold the intervention from participants.
3. This sentence was unclear due to a typing error and it should read “the authors reported a desire to use an RCT for evaluation in four studies”.

Discretionary revisions
1. Within participant correlations and time trends will be dealt with in detail in our modelling paper.
2. All areas receiving the Sure Start intervention (or acting as controls in the initial phases) are deprived: we have amended the sentence to make this point clearer.
3. We have re-worded the sentence to describe how Priestly et al. analyse the effects of time to make the explanation clearer (although the method is rather complicated!).

4. We have highlighted two possible pitfalls of statistical analysis in the conclusion: modelling the effects of time and controlling for within-participant correlations.

5. We have highlighted one problem with only including two steps, in that such a design does not allow generalisation as to the impact of time on effectiveness to be made.