Author's response to reviews

Title: The use of the cluster randomised crossover design in clinical trials: protocol for a systematic review

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Author's response to reviews: see over
Dear Editor,

Thank you for considering our manuscript “The use of the cluster randomised crossover design in clinical trials: protocol for a systematic review” on behalf of my co-authors Andrew Forbes, Brennan Kahan, Katy Morgan, Steve McDonald and Joanne McKenzie for your consideration in the journal *Systematic Reviews*. We have addressed each of the reviewer and editorial requests below.

Referee requests

1. We agree that the methods used to analyse trial outcomes may differ from those reported in trial manuscripts, and contacting the trialists could provide more insight into the actual methods used in the trial. However our primary interest is to summarise the analysis methods as reported in trial manuscripts, as the trial manuscript is typically how results are communicated to the research community.

The practise of summarising methods as reported has been used by similar reviews, such as “Ivers NM, Taljaard M, Dixon S, Bennett C, McRae A, Taleban J et al. Impact of CONSORT extension for cluster randomised trials on quality of reporting and study methodology: review of random sample of 300 trials, 2000-8 BMJ 2011”, who summarised both reporting aspects and proper methodological conduct in trials following the CONSORT extension to cluster randomised trials. The methodological reviews on handling missing data by “Powney M, Williamson P, Kirkham J, Kolamunnage-Dona R: A review of the handling of missing longitudinal outcome data in clinical trials. Trials 2014, 15(1):237” and “Díaz-Ordaz K, Kenward MG, Cohen A, Coleman CL, Eldridge S: Are missing data adequately handled in cluster randomised trials? A systematic review and guidelines. Clin Trials 2014” also summarise the data as reported in the manuscript, without contacting the trialists.

We have revised the manuscript to make clear we will be summarising the methods as reported in the trial manuscripts.

2. Our search strategy does include “group-randomised(z)ed” trials, along with many other possible indicators of cluster randomisation to provide a sensitive search. Please see the Cluster Allocation Terms in the search strategies in Appendix 1.

Editorial requests

1. Emails for each author have been included on the title page as requested.

2. The review was unable to be registered with PROSPERO as it does not meet the inclusion criteria: “Reviews of methodological issues need to contain at least one outcome of direct patient or clinical relevance in order to be included in PROSPERO. The review may also contain a substantial component of methodological review, but this latter component alone is not sufficient for inclusion.” This was not noted in the Methods section since the review does not fall under the remit of PROSPERO.
We look forward to hearing from you.

Yours sincerely,

Sarah Arnup (on behalf of Andrew Forbes, Brennan Kahan, Katy Morgan, Steve McDonald and Joanne McKenzie)