Author's response to reviews

Title: Cluster randomised trials in the medical literature

Authors:

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Author's response to reviews:

I have extended the title as suggested in the authors' checklist.

The reviewers' comments were all helpful and I have acted on them as follows.

Reviewer: Michael Campbell

Main points

1) The author states that his own statistics notes had been cited 121 times. It would be easy to find out which papers cited his work, and I wondered whether these had been included in the survey, although if they were they are likely to be well written!

Only one of the papers in the BMJ survey cited the Statistics Notes. This has been added to the results.

2) The BMJ has fairly rigorous statistical refereeing, which may mean that the quality is better than in other journals, so generalisation about quality may be premature.

I have strengthend the comment in the second paragraph of the discussion.

3) P5 l -2 Not strictly true that summary statistic cannot be adjusted for covariates - can adjust using ordinary methods and then use summary statistic of adjusted values.

I have deleted this sentence.

4) Fig 1 seems to show more than 0 for BMJ papers in 1998, in contrast to Table 2

These papers are not reports of trials, but methodological articles by Kerry and Bland. A comment has been added to this effect in the text.

In places the English is rather casual.

Mea culpa. I have accepted all these suggestions.

Reviewer: Judy M Simpson

1. First paragraph of Methods (page 5): 'artical'

Corrected.

2. Page 8: line 3 of 2nd paragraph: 'that' should be 'than'

Corrected.

3. Page 9: first sentence of first whole paragraph does not make sense, and should probably read: 'The trials in which I regarded ignoring the clustering as important were as follows.'

Corrected, but slightly differently, as I did not think it was important in one case, which I discuss.
4. Page 11: 'others aspects'
Corrected.

5. Page 12: 'authorhas'
Corrected.

6. Table 2: the title should specify that this was a hand search; also the heading of column 5 would be better as 'Ignoring clustering judged important' without the '?' which is confusing, given the footnote.
Corrected.

Discretionary Revisions (which the author can choose to ignore)

1. Towards the end of the Background (bottom of page 4), the author admits to having ignored clustering in the analysis of clustered designs. I think this should be qualified, e.g. 'when I was young and ignorant', lest readers think he is condoning this practice under some (unspecified) circumstances.
Amended.

2. One of the main reasons for the dramatic increase found by the Web of Science search is likely to be simply increased acceptance and adoption of the term 'cluster randomised', which apparently originated with Donner. There is implicit recognition of this, e.g. reference to 'older terminology', but it would be better to make it explicit. It seems, in fact, that Murray and colleagues are sticking with 'group-randomized' (see reference 13) against this trend. It would be interesting to know whether this reflects different jargon being adopted in the educational and medical fields.

The term "cluster" appears to antedate Donner, being used by Cornfield in 1979. I think that a proper investigation of this is beyond the scope of this paper. I have not pursued this point.

3. In the Discussion Bland comments on the improvement in the analysis of cluster randomised trials published in the BMJ, and refers to their series of articles on the correct analysis and reporting of such trials, and to the 'relatively high methodological standard' of the BMJ. There is no explicit mention here of peer review, and I think it would be helpful to have a description of that journal's policy with respect to statistical review of articles.

I have given some references and added a comment about their checklist.