Reviewer's report

Title: Changing cluster composition in cluster RCTs: design and analysis considerations

Version: 1 Date: 15 December 2013

Reviewer: Clare Rutterford

Reviewer's report:

Major compulsory revisions
1. This is a topic that I have not seen covered before however there were only 1/211 (0.5%) reported incidences of cluster merging and 1/27 (4%) unreported instances, which implies this problem occurs with relatively low frequency. I would have liked to have seen more emphasis about the importance of addressing this at the design stage. The authors recommend that additional clusters be recruited to anticipate cluster merging, however I wonder how realistic this is in practice given the potentially high costs associated with the recruitment of an extra cluster in comparison to the relatively low occurrence of cluster merging, and the fact that the clusters may merge on purely an administrative level only.

2. For those who may not be as familiar with cluster randomised trials I think it would be helpful to explicitly describe what is meant by cluster size in this paper. Are the authors assuming that cluster size is the entire cluster, or just the subset from the cluster who are being analysed? I think the authors are assuming the former. The ICC is related to the size of the entire cluster, so as clusters merge the natural cluster size is increasing and this affects the ICC. The underlying value of the ICC does not change as the numbers sampled from a cluster increase, it is just estimated with greater precision. I think this relationship needed to be more explicitly described.

3. This paper started from the assumption of fixed cluster size, so again it is not clear whether the authors are talking about sampling a fixed number or if this refers to the entire cluster. How reasonable is this assumption given the background to the paper is primary care where cluster sizes are large and variable? If variable cluster size is accounted for in the design does cluster merging have much of an effect?

4. In my mind this topic seems to be connected to the sample size issues of variable cluster sizes and cluster drop out, which have been discussed by others. It would be useful if the authors could make the distinction or similarity between these issues and cluster merging more explicit.

Minor essential revisions
5. In figure 2, at 0 merges in each treatment group should the blue line not be at 80% power?

Discretionary revisions
6. From a practical perspective I wonder how easy it is for researchers to find or choose appropriate ICC estimates that reflect cluster size as recommended by the authors.

7. It would be helpful to state in the introduction that this paper excludes scenarios where a cluster may merge with one which is not already participating in the trial.

8. On page 5 the design effect method of sample size calculation is only one approach, albeit the most common, rather than the only approach.

9. On page 8 equation 7 has also been shown by Eldridge, Kang and Manatunga. 

10. On figure 1 it would also be useful to include 5 on the x axis for ease in seeing the relationship as k tends to c/2.

11. Figure 4 should appear prior to the discussion.

12. Page 19, remind the reader what is meant by the pragmatic analysis.

**Level of interest:** An article whose findings are important to those with closely related research interests

**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.