Reviewer's report

Title: Special features of health services and register based trials - experiences from a randomized trial of childbirth classes

Version: 2 Date: 2 March 2008

Reviewer: Fernando Althabe

Reviewer's report:

Special features of health services and register based trials - experiences from a randomized trial of childbirth classes

Reviewer: Fernando Althabe

General comment

This version of the manuscript is much better than the previous one in my view, and it can be of interest for BMC readers. I have only a few methodological comments that, although relevant, would probably be easy to correct by the authors.

Minor Essential Revisions

1) Comparability of the groups (page 11)

1.1 It would be good (but not compulsory) if you could provide some baseline information at the cluster level (characteristics of the MCHs and of the PHNs working at each MCH) besides those already provided at the maternal individual level. This would provide more data to evaluate how well the randomization resulted. Another reason is that the intervention was targeted to the health provider level, and no there are no data regarding the comparability of the groups regarding those health providers. Potential differences in the characteristics of the PHNs or MCHs could have been determinants of the results and help to interpret them. This point is specifically recommended in the CONSORT statement for cluster trials (reference at the end).

1.2 Again I strongly suggest not including p values in the baseline comparison of the groups. The differences should be evaluated only clinically and it is not appropriate to base on statistical inferences the decision on which variables to select for adjustment. If the randomization process was unbiased, the imbalances between the groups are, by definition, caused by chance. This recommendation is also specifically stated in the CONSORT statement.

2) Effectiveness of the intervention (page 12 and table 2)

2.1 The statistical analysis does not consider the cluster effect and this is acknowledged by the authors. Considering that this is a feasibility study and the main objective was not to interpret the results of the intervention, I suggest
eliminating statistical inferences including Ors and 95%CI. It is enough to see the CS rates for a cautious comment about your perception on the weakness of the intervention. Nevertheless, I would be in favor of including them, but using the correct statistical approach that takes account of the cluster effect. The intracluster correlation coefficient for the primary outcome might be large, and CIs much more wide than you expect, perhaps preventing you to exclude potential beneficial or harmful effects.

2.2 If you include the correct statistical analysis, please also include the CS ICCs. It will be valuable information for the research community working in CS issues.

3) Discussion
As the discussion about the weakness of the intervention is not sustained by good statistical inferences, I suggest being more cautious regarding the definitive interpretation about its weakness. Unless this is supported by the appropriate analysis, of course.

**What next?:** Accept after minor essential revisions

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

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
'I declare that I have no competing interests'