Reviewer's report

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

**Version:** 1  **Date:** 27 July 2007

**Reviewer:** Fernando Althabe

**Reviewer's report:**

**General comment**

This manuscript is a modified version of a previous submission to BMC Medical Research Methodology on 2006, with some sections that have been improved. However, the paper still presents some flaws that should be corrected before publication was to be considered. Some of my comments below are very similar to those I made in 2006 to review the first submission.

**General Points**
1. Is the question posed by the authors new and well defined?
   
   It is well defined, but not new.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?

   No

3. Are the data sound and well controlled?

   No

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

   No

5. Are the discussion and conclusions well balanced and adequately supported by the data?

   No

6. Do the title and abstract accurately convey what has been found?

   Yes

7. Is the writing acceptable?

   Yes

**Major Compulsory Revisions**

I will base my comments in that purpose of the study was to test the feasibility of a trial relying solely on routinely collected register data and being based on ordinary health services.
1) Methods

The methods sections describe the design and the procedures for allocation and data collection. However, this section also includes several process measures results that should be included in the results section, as should be the main results of a feasibility study.

1.1) Intervention section

The response rates to the questionnaires should be part of the results of the feasibility study and not part of the methods

1.2) Trial process

The number of women that finally participated and the number of clusters and exclusions (page 9 third pp) should be moved to results.

1.3) Ethical issues

The results include what the Finnish authorities decided on ethical issues. However, there are no description in the methods about what were the designed plans of the protocol regarding human research protection. I suggest to include a paragraph, or delete what it is mentioned in the results section.

1.4) Outcome data

For a feasibility study, the main outcome data should be process data regarding the actual implementation of the trial: clusters and patients recruitment, how the matching procedure resulted, the intervention compliance among the groups, etc. But not the outcomes of the trial itself (Cesarean Section rates).

2) Results

2.1) Permission of the trial

Although important for local Finnish researchers, the description of the steps and the time involved do not seem relevant for other contexts, or generalizable.

The ethical issues however are potentially relevant and interesting if the decisions and recommendations were taken by a well certified research IRB.

2.2) Identification of the study groups and outcome data collection

Following the same reasoning, the time involved in the negotiations and procedures are surely relevant for the local context, but there are not relevant for other settings or trials. I suggest to exclude this part.

2.3) Comparability of the groups.

It is good to provide the data to assess the comparability of the groups. There is no need (and should not be included) the statistical inferences. The differences should be evaluated clinically. If the randomization process was unbiased, the imbalances between the groups are, by definition, caused by chance.
Previous CS rates at each cluster group should correctly be part of the baseline data. For future studies, I suggest to include the rates as a matching variable, as it is the main prognostic factor of CS.

2.4) Effectiveness of the intervention.

This section should not be included, as it is not the purpose of this manuscript. If you include this data, you should change the objectives and the discussion and peer review should follow a different direction.

2.5) the validity of the Helsinki City Customer Register data to correctly include all the women who actually participated in the antenatal classes, at the defined gestational age range, and at one particular maternity center, in not commented. If the study did not perform any validation of this register, the authors should briefly discuss this issue. This is a relevant part of the feasibility objectives.

3) Discussion

All paragraphs related to interpreting the observed effects of the intervention on CS should be excluded.

Outcome data

2.3) Analysis

2.4) First paragraph in page 9 should be moved to the results section

2.5) A sample size paragraph should be included. Even if this was a pilot trial, why 20 maternity centers were selected? Why 1600 women and not less if it was a feasibility study? How this figures were estimated? Was the cesarean section ICC among the clusters taken into account (see below)?

2.6) It seems that the cluster effect have not been considered in the analysis. Unfortunately this is an important issue that should be corrected. The analysis should take into account variability within and among the clusters (intracluster correlation coefficient (ICC)). Not considering this might affect the effect estimation, but without doubt affects the confidence intervals, overestimating the statistical significance of the results (Donner 2000, Murray 1998). The authors should re-analyze the data with the help of an statistician with expertise in cluster RCTs analysis.

2.7) The adjusted analysis by birth weight should not be included. The authors correctly mentioned that birth weight could be an effect of the intervention, and that is the reason to not adjusting by this variable. Only adjustment by baseline variables that are clinically imbalanced (irrespective of the statistical significance) could be done, and this should always be a secondary outcome measure.

Results

3.1) In my opinion, sub-section “1. Mounting the trial” is only of interest to Finish researchers, and thus for a local Finish journal. The contents are not
generalizable. I suggest to delete the sub-section.

3.2) Success of the intervention. This subsection is relevant for the paper only if the piloting of the intervention is one of its main objectives (see comment 1.1). If it is the case, please provide a better quantitative description of the process data, if available. The current description is very unprecise (“Only 40 of the 67 intervention PHNs attended the education; other PHNs had conflicting appointments or were off work; some temporary staff did not attend either”). Interpretation of results should not be placed here; should be moved to the discussion section.

3.3) At the sub-section “3. Identification of the study groups and outcome data collection”, the costs paragraph and table 1, should be excluded from the paper. As the authors well pointed out in the discussion section, the description of the costs of this pragmatic approach without a comparison with the costs of a trial with individual prospective trial data collection are of little value outside Finland. Only the comment at the discussion section may be relevant.

3.4) Effectiveness of the intervention. As I mentioned above (comment 2.6), the analysis should be re-done with appropriate methods. Regarding, the CS rates previous to the intervention that were mentioned in the paragraph just above this sub-section, it is not clear why the authors measured them if there were not used in anyway in the analysis. I suggest to discuss how to use baseline rates to improve the efficiency of the analysis, with an expert statistician.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

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