Reviewer's report

Title: Effectiveness of score card-based antenatal risk selection, care pathways, and multidisciplinary consultation (the Healthy Pregnancy 4 All study): study protocol for a cluster randomized controlled trial

Version: 2 Date: 7 November 2014

Reviewer: Audrey Prost

Reviewer's report:

I commend the authors on this important trial. Minor suggested revisions are outlined below:

1. Will the study design adequately test the hypothesis?

The study design should adequately test the hypothesis that a new antenatal risk screening approach guided by a score card will improve perinatal outcomes in Dutch municipalities.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?

Considerable detail is provided, but it would be most helpful for the authors to clarify the following:

a. Municipality selection: How were the 14 participating municipalities selected? In line 120, authors refer us to another publication. However given that this is the main study protocol, it would be helpful to briefly summarise the municipality selection process in line 120.

b. Intervention feasibility: Do the authors have data to support the feasibility and acceptability of 28 or more care pathways resulting from the use of the R4U card? This seems like a very complex system. It would be helpful to summarise the results of any prior pilot study for this approach.

c. Implementation in control areas: on line 168, the authors suggest that they will implement the intervention in previous control municipality two thirds of the way through the study. In the subsequent sentence, the authors discuss implementing the intervention in all control clusters at the end of the study. This raises two questions:

(i) Which approach is actually being taken? Is this a stepped-wedge trial with phased implementation, or is it a parallel trial with implementation in the control group at the end of the study?

(ii) Why do the authors commit to implementing the intervention in the control area at the end of the study. Surely this simply depends on whether the intervention is successful at improving perinatal outcomes or not?
d. Randomisation according to numbers at risk: Could the authors clarify how this was done in practice, i.e. how this number was calculated?

. e. Outcome recording: Who will provide data on the two primary perinatal outcomes (gestational age, preterm birth? The mothers or health professionals? Who completes the case record form? This would be useful to clarify.

3. Is the planned statistical analysis appropriate?

More details could be provided on statistical analyses for the two primary perinatal outcomes (logistic regression with random effects)?

4. Do the figures appear to be genuine, i.e. without evidence of manipulation?

Yes, the figures appear to be genuine.

5. Is the writing acceptable?

It would be helpful to carefully edit the manuscript for grammar and syntax, perhaps with the help of a native speaker.

Some phrases could be misinterpreted, for example:

Line 68: “immigrants who are poorly integrated in society’ has slightly pejorative connotations.

Line 87: “These risk factors remain highly underexposed in the current risk selection.” I would suggest ‘these factors are usually not considered in current risk screening practices’.