Reviewer’s report

Title: The HAPPY study (Holistic Approach to Pregnancy and the first Postpartum Year): design of a large prospective cohort study.

Version: 2  Date: 9 May 2014

Reviewer: Ronna L Chan

Reviewer’s report:

Comments to Authors:

Major Compulsory Revisions
The author must respond to these before a decision on publication can be reached.

(1) Abstract, Methods, Discussion: This manuscript details a study that is already ongoing. The language of the text throughout the manuscript should reflect that work on this study already has begun and that more work will continue.

(2) Introduction, Maternal and foetal thyroid functioning during pregnancy: The authors stated, “However, up until now, most studies looking at foetal outcome and maternal thyroid function did not use intra-uterine foetal parameters to evaluate the CNS development, such as ultrasound data.” Please provide references to support this statement.

(3) Introduction, Breastfeeding: The authors also indicated that, “Determinants that predict start and continuation of breastfeeding are of multifactorial origin including education level, … Also, absence of facilities at work to breastfeed or to express milk might result in quitting breastfeeding.” Please provide references to support this statement.

(4) Introduction, Breastfeeding: “It is important to detect women at risk for early cessation of breastfeeding because simple antenatal intervention techniques (including involvement of the partner in decision making) can increase the likelihood to breastfeed.” While I agree with the authors that antenatal intervention can increase the likelihood of breastfeeding initiation and duration of breastfeeding, I believe this statement oversimplifies the challenges some mothers face with breastfeeding (e.g. low milk production, infant weight loss while being exclusively breastfed, etc.) despite their willingness and continuous efforts to try to breastfeed their infants.

(5) Introduction, Breastfeeding: “A recent study from Spain showed an odds ratio…” Please include confidence intervals to help determine the precision of estimates on the odds of withdrawing breastfeeding in this research.

(6) Methods/design, Design and setting: “Furthermore, the two obstetric departments of two large hospitals in the area will collaborate.” Please elaborate
the role(s) of the OB departments (presumably to collect infant and OB data).

(7) Methods/design, Recruitment: Please provide recruitment timeframe.

(8) Methods/design, Recruitment: This study excludes women with gemelli pregnancy. Please verify and indicate on the manuscript that women with other higher ordered pregnancies (triplets, quadruplets, etc.) are also excluded.

(9) Methods/design, Data collection: Please provide details on how missed clinic visits, non-response for questionnaire assessments (entire questionnaire, not selected items within a questionnaire), and participant lost-to-follow-up are handled in this study.

(10) Methods/design, Materials/Measures: The authors indicated in the Introduction section that a subset of maternal-fetal pairs will be chosen for the analysis on the relationship between maternal and fetal thyroid data. Please describe selection methodology (n and how. E.g. Simple random sample?) on how the pairs will be chosen.

(11) Methods/design, Statistical analyses: Given CTS is one of the primary study outcomes, the authors should describe analytical techniques that will be used to answer research questions pertaining to CTS.

(12) Methods/design, Statistical analyses: How or what criteria will be used by the authors to determine which confounders will be included into each final multivariable models?

Minor Essential Revisions
The author can be trusted to make these. For example, missing labels on figures, the wrong use of a term, spelling mistakes.

(1) Table 1: Define each abbreviation in footnote of table.

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

Quality of written English: Needs some language corrections before being published

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.