Author's response to reviews

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

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Reviewer's response to reviews:

Reviewer 1
Dear Ronna Chan, thank you for your compliments and the effort you put forth in extensively reviewing our manuscript and the revised version of the manuscript. Below you will find the responses to you additional two comments.

(1) Under comment #9, I asked the authors to provide details on how missed clinic visits, non-response for questionnaire assessments, and participant lost-to-follow-up are handled in this study during the data collection phase, and the authors indicated missing data will be addressed using linear mixed analysis (as detailed on page 22). The choice in using linear mixed model analysis is a sound method for addressing these concerns statistically; however, I would like the authors to comment and provide further details whether a study protocol is in place to handle missed visits and non-response during data collection (e.g. follow-up reminder calls from midwives and/or trained study personnel).

In order to provide more information about the study protocol regarding non-response during data collection, we added to page 16: “Participants receive the questionnaires by postal mail or internet according to the woman’s personal choice. If a woman does not respond within one week, a researcher of the study team (CB), will call her to inform whether she received the questionnaire and check her email or postal address if this was not the case. After checking the contact information, the women will receive a reminder email (or reminder call). If a woman does not respond – despite having received a written informed consent – she is regarded as lost to follow-up. If obstetric data that are collected by questionnaires during pregnancy are missing (parity, previous abortion e.g.) these data will be collected from the parturition record form which contains all
relevant obstetric data.”

At page 17 we added: “If collection of an additional tube of blood fails, these data (thyroid parameters and HCG) will be regarded as missing, because the study protocol does not allow to perform an additional venipuncture.”

(2) Methods/Designs, Recruitment and Sample Size Calculation: In the revised manuscript, the authors provided additional details (page 14, lines 23-24) to indicate that recruitment of study participants was completed in between the submissions of the original manuscript and the revised manuscript. In light of this development, I would like to recommend that the language in Recruitment and Sample Size Calculations sections be modified to reflect work completed.

Furthermore, lines 3-4 (page 16) can be omitted and I think it will be of great interest to the readers to know the total number of women who were recruited and included in the study (instead of saying n≥2500).

As we included 2,200 women at the first of July 2014, the inclusion is previewed to be finished at the end of September 2014. In the manuscript (page 14) we changed the expected end of the inclusion from July into September 2014.