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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Author's response to reviews: see over
Dear Editor,

Please find enclosed the manuscript of our study protocol entitled: “The HAPPY study (Holistic Approach to Pregnancy and the first Postpartum Year): design of a large prospective cohort study”, which we would like to submit for publication.

In this large prospective longitudinal cohort study, about 2,500 pregnant women will be followed during the entire pregnancy and the whole first year postpartum. The HAPPY study will collect a substantial amount of physiological and psychological data investigating all kinds of determinants that might interfere with general well-being during pregnancy and postpartum, with special attention to the effect of maternal mood, thyroid function, human chorionic gonadotropin (HCG), and pregnancy related somatic symptoms (including nausea and vomiting (NVP) and carpal tunnel syndrome (CTS)), on pregnancy outcome of mother and fetus. The HAPPY study with its holistic multidimensional approach is among the first to investigate within one design physiological and psychological aspects of NVP and CTS symptoms during pregnancy. Also, the concept of anhedonia and depressed mood as two distinct aspects of the concept depression and its possible relation on obstetric outcome, breastfeeding, and postpartum well-being will be studied.

The study was approved by the Psychological Ethical Committee of Tilburg University, The Netherlands on November 16th, 2012, and approved by the Medical Ethical Committee of the Maxima Medical Centre Veldhoven, The Netherlands on December 4th, 2012.

All authors have fulfilled the conditions required for authorship. None of the authors has any conflict of interest. We confirm that this study protocol has not been published elsewhere and is not under consideration by another journal. All authors have approved the manuscript and agree with its submission to BMC Pregnancy & Childbirth.

The questions we received from the journal editorial are answered below.

1. Ethical and Funding approval
The original Dutch documents and the English translations of the ethical approval have just been sent to you by e-mail (BMCSeriesEditorial@biomedcentral.com).

2. Funding
Authors have not been awarded a grant for this study. The study has not been peer-reviewed by a major funding body.

3. Study status
This study is ongoing. At the moment, pregnant women are included to participate in the study.

4. Related articles
No results of this study have yet been published or submitted to any journal.
Hopefully, we fully answered your questions, so that the manuscript is now ready to be reviewed. If you need further answers please do not hesitate to contact us.

Looking forward to your answer, on behalf of all the authors.

Sincerely yours,

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