Author’s response to reviews

Title: Effectiveness of skin-to-skin contact versus care-as-usual in mothers and their full-term infants: Study protocol for a parallel-group randomized controlled trial

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Dr. Nawsheen Boodhun, Executive Editor
BMC Pediatrics
Floor 6, 236 Gray's Inn Road
London
WC1X 8HB
United Kingdom
Dear Dr. Boodhun,

We would like to thank for your consideration of our manuscript entitled “Effectiveness of skin-to-skin contact versus care-as-usual in mothers and their full-term infants: Study protocol for a parallel-group randomized controlled trial” (BPED-D-16-00331).

We carefully considered your comments and addressed the editorial requests. We formatted the manuscript to adhere to the journal guidelines. The modifications in the revised manuscript are marked in yellow. Below we offer detailed responses to the editorial comments and requests.

We hope our responses adequately meet the expectations.

Most sincerely,

Kelly Cooijmans, MSc.

(also on behalf of the co-authors)

Responses to the editor’s comments:

Comment 1: Ethical and Funding Approval Documentation

Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system. If your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution. Please also include the original documents. Can you please confirm in your cover letter that you have forwarded the requested documentation to BMCSeriesEditorial@biomedcentral.com.

Response 1: We have sent the requested original Ethical and Funding Approval Documentation to BMCSeriesEditorial@biomedcentral.com.

Comment 2: Funding
A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the ‘competing interests’ section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board. Can you please confirm whether your study protocol has undergone peer-review by the funding body.

Response 2: The study is financially supported for four years by the Radboud University, (Nijmegen, The Netherlands), and by the Behavioural Science Institute (Nijmegen, The Netherlands). The study protocol has undergone two peer-review processes by the funding bodies:

1) The Ethics Committee of Social Sciences of the Radboud University
2) The Science Committee of the Behavioural Science Institute of the Radboud University

Information about the Ethics Committee of Social Sciences (ECSS):

The ECSS inform the faculty board on the ethical conduct of research projects. The committee maintains a review process by all members of the ethics committee. They examine the level of scrutiny in proportion to the risk of harm or adverse effects. The committee includes six independent researchers:

- Prof. dr. Gilles van Luijteralaar (chair)
- Prof. dr. Ton Coenen (chair)
- Dr. Tineke van Rijn
- Dr. Maaike Cima
- Dr. Anouk Scheres
- Dr. Femke Takes

Information about the Science Committee:

The Science Committee advises the Behavioural Science Institute director on scientific policy with respect to the quality of content as well as quality of strategy of submitted research proposals. The committee includes seven independent researchers from different disciplines:
The committee assesses proposals based on the following criteria:

1. Scientific Relevance & Quality
   • What is the scientific relevance and theoretical background of the proposal?
   • Is the proposed research ‘innovative’ in its field?
   • Does the proposal build on existing knowledge and research?

2. Research Design and Methods
   • Can the problem be analysed?
   • What is the quality of the research methods?
   • Are these methods suitable (and optimal)?
   • Is the sample size based on adequate power calculations?
   • Are the data-analyses feasible?
   • Are these sources apt to meet the research questions?

3. Feasibility
   • Is the research problem evident and feasible?
• Good description of the work plan (time plan)?
• Is the budget adequate to conduct the research?
• What is the expected scientific output?
• What's the quality of the research environment (research group and collaborations)?

4. Societal relevance
• If applicable: how can results be applied in other scientific disciplines?
• If applicable: how can results be applied in society, business, or other non-scientific environments?

Comment 3: Study status

The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.

Response 3: We confirm that this project is an ‘ongoing’ study. In April 2016 we started to include the first pregnant women. Currently, twenty women are participating in the study. Detailed information regarding the start date and the planned closing date is also available in the online Dutch Trial Registration (NTR): http://wwwtrialregisternl/trialreg/admin/rctviewasp?TC=5697

Comment 4: Related Articles

Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles.

Response 4: In April 2016, the study started to include the first participants. As the results are not available yet, no publications have been published or submitted to any journal.

Comment 5: Thank for including the trial registration number. Please provide also the trial registration date in the Abstract of the manuscript, and update this information in the submission system.
Response 5: We now included the trial registration date in the Abstract of the revised manuscript. The modification is marked in yellow on page 3 line 7.

Comment 6: Sample size. Please clarify whether the statement “A 5% significance level and a power of 80% was used for the analysis” is correct. Also please provide the references you refer to in Page 18 line 14 “Based on prior studies in similar populations…”.

Response 6:

1) We added statements to the protocol to better clarify and define the statement “A 5% significance level and a power of 80% was used for the analysis” (see page 13 line 11-17) in the revised manuscript.

2) We now included a reference in the revised manuscript regarding the sentence “Based on prior studies in similar populations…” We included a paper of the BIBO study (Beijers et al., 2013)). The BIBO study is an ongoing, prospective longitudinal project designed to understand child development of behavioural and physiological regulatory capacities. BIBO stands for the Dutch ‘Basale Invloeden op de Baby Ontwikkeling’, which translates as ‘Basal Influences on the Baby’s Development’. The study began in 2006 with 193 pregnant women from Nijmegen and surrounding areas, in The Netherlands. The modification is marked in yellow on page 13 line 17 and line 20.

Comment 7: Please move the ‘List of Abbreviations’ and the rest of Declarations sections to the end of the manuscript, after the Discussion/Conclusions.

Response 7: The “List of Abbreviations” (see page 23) and the rest of the Declaration sections are now moved to the end of the manuscript, after the Discussion/ Conclusions (see page 24 and page 25). The modifications are marked in yellow.

Comment 8: Please move the pertinent information included in the manuscript to the Declarations (see point below).

Response 8: We now moved the pertinent information to the Declaration sections (see page 24 and page 25).

Comment 9: Also ensure you provide the heading and all sections listed under Declarations in our Submission guidelines:
http://bmcpediatr.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol. Please note also that any Declarations sections which are not applicable to your manuscript should still be included with the statement "Not applicable".

Response 9: We now included the headings of all sections listed under Declarations in the submission guidelines. We included the statement “Not applicable” to the sections that are not applicable to our manuscript. Modifications are marked in yellow (see page 24 and page 25).

Comment 10: Please move the Administrative Information summary of the trial provided in pages 2-3 to the supplementary files, and provide a section 'Supplementary files' after the References where you list the following information: Name of the file (e.g. Supplementary file 1), title (e.g. Table 1) and description of the file.

Response 10: We now moved the Administrative Information summary of the trial of the manuscript to a supplementary file: “Supplementary File 2”. Also, we included a section “Supplementary files” after the References with a list of the three supplementary files, including the (1) name of the file, (2) file format, (3) title of the file, (4) description of the file (see page 36).