Reviewer’s report

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

Version: 1 Date: 18 Mar 2017

Reviewer: Jennifer Doering

Reviewer's report:

This is a well designed report of a randomized clinical trial that began April 2016. Being the trial has already begun, the primary focus of this reviewer's comments will be directed towards improving transparency and clarity of the reported design.

- In several places, the words 'fullterms' and 'preterms' are used. It is recommended that adding the word 'infant' or 'neonate' to read 'fullterm infant' or 'preterm neonate' would portray a more humanizing view of the infant study participants.

- In a couple of places, the word 'depression' is used when the paper should read 'depressive symptoms' or 'depression symptoms' as is done in other parts of the paper. I would expect the authors are aware that clinical depression requires a diagnostic interview, which is frequently lacking in research studies. Where screening tools assess depressive symptoms, researchers should refrain from using the term 'depression' to depict a level of symptoms above the screening tool threshold unless there is an accompanying diagnostic interview that validates the presence of a diagnosis. For example, please see page 6, line 2 in addition to other places in the paper. Even researchers themselves have erroneously portrayed their measurement of depression symptoms as 'depression' implying clinical depression (For example, citation 12 does this).

- P6, line 8: Cites study #15 showing lower postpartum depression symptoms - Could the degree to which symptoms were lower be indicated? Was the decrease clinically significant or statistically significant? Including the sample size of this study would also be helpful.

- I have a few questions about the research design that are not clear. If space allows and the authors could include the following information, it would strengthen the paper, but if this is not possible, it is information, then, that could be included in the paper publishing the data.

- Must SSC be done with the mother or could any caregiver provide the 1 hour/day of SSC? Will the researchers assess whether other family members like fathers, grandparents, etc., be assisting the mother to carry out the study protocol? In other words, how will you know it's
only the mother who is engaging in the SSC, or is this an assumption of the study? This could be important feasibility data.

- How will the study differentiate between SSC and breastfeeding contact? The protocol indicates that SSC is the placement of the infant prone between the breasts, but what is the chance that some women will count time breastfeeding during a SSC episode as SSC contact?

- Will the researchers directly ask about any safety events related to spending an hour in SSC? In other words, will the researchers directly ask about whether the mothers fall asleep with the infant prone will delivering SSC? This is a time when infants could be injured if they fall off due to the parent falling asleep. The authors indicate they'll assess for problems with the study protocol, but I would encourage specific questions about any "near-misses" or times when the mother fell asleep unexpectedly. Postpartum fatigue and sleepiness are high in this population of women.

- Does the 1 hour of SSC have to be uninterrupted? Can it be cumulative throughout a 24 hour period to count for the day (30” x 2, 15” x 4)? Also, the authors suggest that the lengthy SSC protocol that wasn't feasible in the cited study gave the current study rationale for decreasing to 1 hour/day and extending the time period to 5 weeks. Do the authors have any actual feasibility data from women who they discussed 1 hour/day x 5 week? I have questions about the feasibility of even this amount of SSC, but perhaps the Netherlands parenting context (e.g., paid leave etc.) makes this amount of SSC over time more feasible. I wondered how the authors would handle the analysis if, say, the sample only adheres to the protocol, say, 60% of the time.

P. 9 line 4: Instead of saying "through different pathways", I suggest further specificity by saying "through direct and indirect pathways".

How will the authors measure and control for SSC done by mothers in the usual care group? SSC has been increasing in popularity both in hospitals at the time of birth and in parenting guidelines and articles online and through social media. I didn't see the authors mention that the use of SSC will be assessed in the usual care group, but that could be a confounding variable.

Will the authors ensure that both study groups are equal on key variables like baseline depression and anxiety symptoms? As well as breastfeeding vs. bottlefeeding?

Will the authors collect data on sleep location? I ask, because bed-sharing could inadvertently introduce increased doses of skin contact above and beyond the 1 hour/day, which also could influence results.
P. 9 provides 3 hypotheses for how SSC may affect health outcomes. As I read, I wondered about one pathway and I share it here for the authors to consider. What about SSC having the effect of increasing breastfeeding (there's good evidence SSC increases breastfeeding initiation, exclusivity, and duration - and I hope all these variables are being collected in the study), and that breastfeeding provides both optimal nutrition to the infant, but also the transfer of bacteria from the infant's oral contact with the breast and hand contact with the breast during breastfeeding, with the infant subsequently sucking on the hand that had extended contact with the mother's skin during breastfeeding. I would think even culturing infant's hands for their bacterial flora would be worth pursuing.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Unable to assess

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