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 Apr 2017

**Reviewer:** Ann E. Bigelow

**Reviewer's report:**

This randomized control trial has a primary goal of examining the effect of skin-to-skin contact (SSC) on maternal depression in a low-risk sample of mothers. The study also will investigate the effect of SSC on a number of maternal and infant health and development variables, and explore potential underlying mechanisms that may account for the effectiveness of SSC. The strengths of the study are many: the length of the longitudinal follow-up, the number of measures taken, the number of contacts with participants that may assure retention and compliance, and the plan to include the data in an open access database.

The planned statistical analyses appear appropriate. The writing is clear. The methods and controls are appropriate, although below I have a few questions and suggestions, plus two cautions.

1. The demographics do not include maternal age or education. Both of these maternal variables have been shown to be correlates with maternal depression in previous studies, so they ideally should be added to the demographics collected. As the study has just started and enrolled mothers have not yet completed the protocol, these demographics could easily be added.

2. On Page 4, the authors imply that SSC and Kangaroo Mother Care (KMC) are the same, but they are not. SSC is a component of KMC, which also includes breastfeeding. The researchers plan to measure breastfeeding frequency and duration but it does not appear that breastfeeding is a necessary choice for inclusion in the study. If breastfeeding is a condition for inclusion, this should be made clear.

3. Is the Experiences in Close Relationships (ECR) questionnaire assessing the mother's attachment to her partner, her own parents, or someone else? How will the cultural conceptions of parenting be used in the data analyses?

4. What will constitute cortisol synchrony between mother and infant during the infant bathing in week 5? Is synchrony the only cortisol outcome assessed?

5. The SSC log asks the mothers to log SSC or holding the infant. These are not the same; holding the infant may or may not be in SSC. Will the log of SSC be separate from the log
of simply holding the infant? This would be important if the research is to track the effects of SSC per se.

6. With the exception of a measure of maternal sensitivity during infant bathing in week 5, all of the data collected will be through questionnaires, logbooks, or physiological assessments. Although it may be too late to add more measures, it would be beneficial to have more behavioral assessments, e.g., attachment security at one year via the Strange Situation.

Two Cautions:

1. The maternal oxytocin measure is from saliva. Although some reputable researchers have used measures of oxytocin from saliva, the measure has been criticized as unreliable (e.g., see Horvat-Gordon et al., 2005, Physiology & Behavior 84, 445-448; McCullough et al., 2013, Neuroscience and Biobehavioral Reviews, 37, 1485-1492). Salimetrics, a noted lab that supports salivary research studies in North America, does not currently have a reliable detection method for oxytocin in saliva.

2. If SSC is shown to reduce maternal depression in this low-risk sample, the researchers note that developing a program to use SSC as a preventative measure with high-risk mothers may be considered. Caution should be used here, as some mothers with histories of sexual abuse may find SSC with their infants to be a trigger. SSC may be of benefit to many high-risk mothers but they should be screened and monitored so that the intervention does not make their condition worse.

**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.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

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