Reviewer's report

Title: Community initiated kangaroo mother care and early child development in low birth weight infants in India-A randomized controlled trial

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Reviewer: Nils Bergman

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Community initiated kangaroo mother care and early child development in low birth weight infants in India-A randomized controlled trial

This manuscript describes developmental outcomes following a community initiated kangaroo mother care intervention on 552 infants, a major, original and very valuable contribution. That KMC initiated in health facilities has benefit is well established, almost nothing is known about whether benefits follow if initiated at home. Indeed, these very authors are the first to show a survival benefit, which is a profound finding, such is usually last on a list of evidence based benefits. However, in this paper this fact is buried in the substance of the manuscript, and rather down-played. The abstract presents this as a ‘stand-alone’ study, rather than a sub-analysis of a bigger study.

That bigger study is indeed reported and referenced, and shows a survival benefit from over 8000 subjects. It is in that context that the question about developmental outcome is usually asked: if survival is improved, is it at the cost of poorer development? The authors have laudably registered this sub-sample as a separate study, aiming to show a benefit from the intervention. That is fails to do so can be explained in many ways, including the TRUE possibility that KMC does not influence neurodevelopment. But would this not be a valuable study in providing support for the contention that KMC does not to do harm in terms of neurodevelopment? There are separate statistical methods for 'equivalence', perhaps it would be valuable to examine these?

I feel the abstract should clarify that this is a subsample from a larger study.

The sample size is commendably large compared to many publications using Bayley. Authors reference and discuss the study by Bera (7) with a very similar sample size, but using a locally adapted Indian version of the Bayley. Whether to mention in the methodology or discussion, perhaps the locally modified DASII would have given a result more like that of Bera?
The trail registry (https://clinicaltrials.gov/ct2/show/study/NCT02631343) provides a different set of primary and secondary outcomes than those reported. It would be adequate to acknowledge that as grist for another paper.

A six week visit is mentioned, but results consigned to a supplement. I do feel these add value, (even for inclusion in future meta-analyses) and could be included in the body of the paper.

The sub-sample approach I do think was/is appropriate (given Bera), but given these results and with perfect hindsight: would the whole sample have been helpful? In discussing Bera, you suggest they could have adjusted for birth weight and gestational age: given their design, would not such adjustment make an even greater difference in outcome?

The discussion's citing of the Cochrane review in support of no benefit are slightly misleading/inflating in that it is a single study by Charpak, with a specific population. Interestingly, that larger study was late KMC and initiated on discharge for home (community) KMC, making it similar to this study.

It may also be interesting to know whether the pooled results (Interventions and controls together) have developmental scores that are very low compared to other studies? (Or perhaps same or better?) Given the poor community described, perhaps the overall adversity smothers any benefit that has been found elsewhere?

The main study on 8402 babies reports an earlier initiation time (30 vs 48h) and a higher daily dose (11.5 vs 8.7h). For any intervention, (and for KMC in particular, Conde-Agudelo 2014 review) the dose-response is relevant, and here also initiation time. Perhaps in your future, a subsample from the last 500 cases (with likely a higher dose) would be interesting? This could be mentioned in your discussion, along with any other plans for future feedback.

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?
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Yes
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I recommend additional statistical review

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