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: Nathalie Charpak

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Manuscript Number: BPED-D-19-01418

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

General Comment to Authors

I believe that the results found in this study are really difficult to interpret because of the selection bias of the sample: low risk LBW infants, small for gestational age term infants mainly or near term infants without any difficulty at birth which forbid any generalization for mortality or for early child development during the first year of corrected age. It seems that KMC do not impact the psychomotor development of these infants nor the behaviour of the family but one year is probably too short to evaluate these impacts in this population. Taking into account that it was demonstrated at 20 years that adults born small for gestational age at term had lower performances in subtests assessing attention and executive functions with lower volumes in the associated brain structures (Suffren, S., Angulo, D., Ding, Y., Reyes, P., Marin, J., Hernandez, J. T., ... & Lodygensky, G. A. (2017). Long-term attention deficits combined with subcortical and cortical structural central nervous system alterations in young adults born small for gestational age. Early human development, 110, 44-49.), authors could try to follow this cohort for more time and try to evaluate the attention performance.

Personally, I believe that all the low birth weight infants and premature must have access to a medical examination at birth and to a KMC program with a high risk follow up to allow early and opportune intervention when any deviation in the normal neuro-psychomotor and sensorial development is detected. Community KMC could be used for transferring the infant to the hospital where the KMC candidate will be evaluated and sent back home if found appropriated with a follow up in an ambulatory program. KMC programs are cost effective but routine home follow up as it is performed in this study would be too expensive in many countries.
Only if the authors make explicit in the abstract and in the manuscript the complete details on the selection of the sample, this paper could be interesting for the medical community.

Specific comments to authors

Abstract:

Line 33

552 infants weighing 1500 to 2250 gms.

Authors must write Stable Infants weighting 1800 - 2250g.

Infants weighing between 1500g and 1800g were referred for hospital care following Government of India guidelines. Nevertheless, they were enrolled in the study if the families refused to take the baby to the hospital, or if the baby was taken to hospital but was either not admitted, or admitted and discharged before s/he became 72 hours old. Between 1800g and 2250g all infants unable to feed, with difficulty in breathing, with less than normal movements or gross congenital malformations, those for whom KMC was initiated in hospitals, and those whose mothers did not intend to stay in the study area for the next 6 months or did not consent to participate were excluded. The sample used in this study is a specific and selected sample, the details of the selection must be made explicit and very clear in both the abstract and the manuscript.

Line 45:

"Our study was not able to capture any effect of ciKMC on neurodevelopment during infancy."

Authors must add at the end of the sentence "in this selected sample of stable near term or term infant small for gestational age:

What this paper adds

Authors wrote: Probably the first trial to document the effect of KMC initiated at home (community initiated KMC; ciKMC) on neurodevelopmental outcomes in low birth weight infants"

They must add at the end of the sentence "in a selected sample of stable low birth weight infant."
Manuscript

Line 112

Authors must clarify that this cohort is a very selected cohort and that the inclusion weight was not 1500g-2250g but 1800g-2250g as the less than 1800g were remitted to hospital according to Indian guidelines. Only if the families refused to take the baby to the hospital, or if the baby was taken to hospital but was either not admitted, or admitted and discharged before s/he became 72 hours old, the less than 1800g was included. For this reason, only 7% of the cohort had a weight between 1500g-1800g. All infants with respiratory or hypotonia or feeding problems between 1500g to 2250g were also remitted to the hospital, for this reason the sample is composed of stable near term infants, term infants small for gestational age without any problems at birth who did not need admission in the hospital.

This selection process and the sample selection details must be made very clear and need to be explicit.

Line 115-117

The underlying rationale was that ciKMC could improve neurodevelopmental outcomes through ensuring optimal nutrition, reducing severe infections, promoting child stimulation and improving maternal responsiveness and mother-infant interaction.

Can the author clarify who is teaching to the mother the appropriate nutrition? Who is teaching the early stimulation to the mother and to the family? Where the different tests were performed? At home or in a special center? By who?

Line 122-127

Authors must clarified that that the cohort is a very selected cohort and that the inclusion weight was not 1500g-2250g but 1800g-2250g as the less than 1800g were remitted to hospital according to Indian guidelines. Only if the families refused to take the baby to the hospital, or if the baby was taken to hospital but was either not admitted, or admitted and discharged before s/he became 72 hours old, the less than 1800g was included. For this reason, only 7% of the cohort had a weight between 1500g-1800g. All infants with respiratory or hypotonia or feeding problems between 1500g to 2250g were also remitted to the hospital. For these reasons, the sample is composed by stable near term infants o term infants small for gestational age without any problems at birth who did not need admission in the hospital.

This selection process and the sample selection details must be made very clear and need to be explicit.
LBW babies (with birth weight between 1500 g to 2250 g)"
Authors must write "stable LBW babies (with birth weight between 1800g to 2250g)"

Conclusion
Line 325
The present study found no statistically significant effect of ciKMC on cognitive, language, motor, socio-emotional development as assessed by BSID-III and temperament during infancy.

Authors must add at the end of the sentence "in this selected sample of stable late preterm or term small for gestational age"

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.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics
Quality of written English
Please indicate the quality of language in the manuscript:

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