

Community-based Randomized Controlled Trial Evaluating Effect of Kangaroo Mother Care on Neonatal and Infant Outcomes

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SUMMARY

In this randomized controlled trial, 8402 babies weighing 1500–2250 g at home within 72 h of birth, if not already initiated in kangaroo mother care, irrespective of place of birth, who were stable and feeding were enrolled. Intervention group comprised of 4480 babies initiated on community-initiated kangaroo mother care (KMC) and 3922 were assigned to the control group. Mothers and infants in the intervention group were visited at home to support KMC and breast feeding. The control group received routine care. Primary outcomes were mortality between enrolment and 180 days. 81.4% occurred at a health facility and 36.2% had initiated breastfeeding within 1 h of birth, and infants were enrolled at an average of about 30 hours of age. From enrolment to 28 days, 73 infants died in 4423 periods of 28 days in the intervention group and 90 deaths in 3859 periods of 28 days in the control group (hazard ratio [HR] 0.70, 95% CI 0.51–0.96; $p=0.027$). From enrolment to 180 days, 158 infants died in 3965 periods of 180 days in the intervention group and 184 infants died in 3514 periods of 180 days in the control group (HR 0.75, 0.60–0.93; $p=0.010$). The risk ratios for death were almost the same as the HRs (28-day mortality 0.71, 95% CI 0.52–0.97; $p=0.032$; 180-day mortality 0.76, 0.60–0.95; $p=0.017$). The authors concluded that community-initiated kangaroo mother care substantially improves newborn baby and infant survival.

COMMENTARIES

Evidence-based Medicine Viewpoint

Relevance: In low-income and middle-income countries, whether incorporation of kangaroo mother care for all infants with low birthweight, irrespective of place of birth, could substantially reduce neonatal and infant mortality is an important question to answer. A community-based randomized controlled trial (RCT) was undertaken in Haryana (India) to evaluate the impact of encouraging kangaroo mother care (KMC) initiated at home within 72 hours of birth, among babies weighing 1500-2250g [1].

The trial is summarized in **Table I**.

Critical appraisal: Overall, the trial qualified as having low risk of bias. The random sequence was generated by an off-site statistician using variably sized random permuted blocks. However, the method of generating the sequence was not specified. Although babies were individually randomized, there were certain exceptions. For instance, the second of twins was allocated the same group as the first twin who was randomized. Babies born in households where a previously enrolled infant resided (i.e sibling or member of a joint family) were allocated the intervention arm if the previous infant belonged to the intervention arm. If the previous infant belonged to the comparison arm, then the new infant was randomized to either arm.

Individual allocations were concealed in serially numbered, opaque, sealed envelopes and stored off-site. At enrollment, research staff contacted a central allocator who revealed the allocation. The trial participants and research staff were unblinded. The outcome assessors were intended to be blinded, but the nature of the outcomes to be assessed precluded effective blinding. All randomized participants were included in the primary intention-to-treat analysis. Detailed description of participants who were unavailable for follow-up was mentioned. Most of the clinically relevant outcomes were included. However, it can be argued that parameters reflecting temperature control in the neonatal period could have been included.

This trial has several strengths, notably meticulous pre-trial planning, baseline data acquisition, training of research staff for implementing the trial and data collection, large sample size, use of appropriate definitions for various outcomes measured, standardized tools for data collection, electronic data capture, and close follow-up. These measures reduced the risk of bias and ensure high internal validity. Other refinements included the Data Safety and Monitoring Board, meticulous data storage, appropriate data analysis, etc. Nevertheless, a few issues merit consideration.

TABLE 1 OUTLINE OF THE TRIAL

Clinical question	The research question in the PICOT format could be framed as: “What is the impact of encouraging kangaroo mother care (KMC) initiated at home and sustained through the neonatal period (<i>I=Intervention</i>), among babies with weight 1500-2250g recruited within 72 hours of birth (<i>P=Population</i>), compared to no KMC (<i>C=Comparison</i>), on mortality, anthropometric parameters, and serious childhood illnesses (<i>O=Outcomes</i>), measured at the end of 28 days as well as 6 months of life (<i>T=Time frame</i>)?”
Study design	Randomized controlled trial with allocation of individual participants to the trial arms.
Study setting	Community-based trial in two districts of Haryana state (India) with an estimated pre-trial population of 20 lakhs, birth rate of 26/1000, and neonatal mortality rate of 42 per 1000 live births.
Study duration	August 2015 to October 2018 (39 months).
Inclusion criteria	Newborn babies within 72h of birth, with weight 1500-2250 g, available at home. In this group, those weighing less than 1800 g were referred to hospital, and enrolled within 72 hours of birth, if hospitalization was refused, or hospitalized babies were discharged and sent home.
Exclusion criteria	Babies beyond 72 h, unknown weight, feeding difficulty, breathing difficulty, inadequate movements, or gross congenital malformations. Babies in whom KMC had been initiated already (for example in the delivery facility) were also excluded as also those whose mothers did not intend to stay in the area for 6 months.
Recruitment procedure	Pregnant women in the community were listed through active community-based surveillance carried out every 3 months. Potentially eligible women were approached more frequently closer to the delivery date, and eligible newborn babies identified within 72 hours of birth.
Intervention and Comparison groups	The intervention arm participants received counselling and encouragement for KMC and exclusive breastfeeding, provided by research staff including intervention workers and their supervisors. The mode of providing these was not described. Infants were visited by the research staff on days 1-3, 5, 7, 10, 14, 21, and 28 of life (i.e total 7 visits) for 30-45 minutes each. During these visits, research staff encouraged KMC 24 x 7, observed KMC practice, surveyed KMC and breastfeeding practices, and assisted mothers to resolve difficulties with these. The comparison arm did not receive the above-mentioned intervention. Both groups received standard newborn care delivered by ASHA workers, that comprised 5 visits of unknown duration in the neonatal period. These visits were on days of life 3,7,14,21,28 for babies born in hospital and an additional visit on the day of birth for home-delivered babies. Low birthweight babies were to receive additional ASHA visits at unspecified timepoints. During these visits, the ASHA workers encouraged exclusive breast-feeding, resolved difficulties with breastfeeding, and helped identify (and refer) babies who were ill.
Outcomes	<p>Primary outcome:</p> <ul style="list-style-type: none"> • Mortality within 28 days and 180 days of birth. <p>Secondary outcomes:</p> <ul style="list-style-type: none"> • Proportion of exclusively breastfed infants (at age 28 d, 90 d, 180 d). • Proportion of infants who were not breastfed (at age 28 d, 90 d, 180 d). • Weight for age z score (at age 28 d, 90 d, 180 d). • Length for age z score (at age 28 d, 90 d, 180 d). • Weight for length z score (at age 28 d, 90 d, 180 d). • Proportion with weight for age z score <-3 (at age 28 d, 90 d, 180 d). • Proportion with length for age z score <-3 (at age 28 d, 90 d, 180 d). • Proportion with weight for length z score <-3 (at age 28 d, 90 d, 180 d). • Head circumference (at age 28 d, 90d , 180 d). • Hospitalization for any reason (by age 28 d, 180 d). • Proportion with possible serious bacterial infection, local infection, or diarrhea/dysentery by age 28 d. • Proportion with diarrhea, or pneumonia, or severe pneumonia within a 2-wk window preceding the visit at 90 d of age. • Care seeking behavior for the morbidities described above.

Table 1 continue

Follow-up protocol	Research staff visited enrolled babies on days 28, 90 and 180 to obtain information on the pre-specified outcomes listed above. This was done through interviews (presumably with mothers) and objective measurements of anthropometric parameters.
Sample size	<i>A priori</i> sample size calculation was performed for a superiority trial, to detect a 30% reduction in neonatal mortality from an estimated baseline of 42 per 1000 live births, with alpha error 0.05 and beta error 0.10. Assuming 10% attrition, the estimated sample size was 10500 infants. However, the intended sample size was not reached because a planned Data safety and Monitoring Board (DSMB) review approximately 3 years from the onset of the trial believed that additional recruitment was not required to answer the research question.
Data analysis	Intention-to-treat (ITT) analysis was performed for the primary outcomes, analysing participants in the groups to which they were randomized. Mortality rate was calculated in terms of person-time (i.e until the age of follow-up or death) as well as number enrolled. Thus hazard ratio (HR) as well as relative risk (RR) were presented. Secondary outcomes were measured <i>per protocol</i> . Multiple <i>a priori</i> as well as <i>post hoc</i> subgroup analyses were also performed.
Comparison of groups at baseline	The groups were comparable at baseline with respect to age at enrolment, weight and length at enrolment, gender ratio, birth order, frequency of twin birth, gestation, weight/gestation categorization, timing of initiating breastfeeding, place of delivery, mode of delivery, maternal age, maternal education level, family religion, caste, and income.
Summary of results	Please see Box I .

First, the trial title refers to ‘low birthweight’ infants, traditionally defined as <2500g at birth. Although all the enrolled infants were below this weight (hence low birthweight), not all low birthweight babies were included, as those weighing >2250g were excluded. Thus, strictly speaking, the trial results are valid for infants between 1500 and 2250g only (rather than all low birthweight). The distinction is more than semantic, because it is possible that inclusion of larger weight babies may have minimized the differences between the trial arms. The reason for excluding babies >2250g was that the investigators expected some loss of weight between birth and recruitment. However, it is highly unlikely to be of the magnitude of 250g. The other reason offered is that pre-trial analysis suggested that babies >2250g wriggled out of KMC before the age of 28 days. This reasoning seems implausible given that three quarters of enrolled babies weighed between 2000g and 2250g, hence that many of these would have attained a weight greater than 2250g within the neonatal period (hence wriggled out of KMC). Yet, the trial data showed that the median duration of KMC in the intervention arm was 27-28 days, suggesting that heavier infants did not wriggle out. Fortunately, the issue may not be critical as the authors reported that sub-group analysis showed that heavier weight babies in the intervention arm had outcomes similar to the others.

This trial [1] is not actually a comparison of KMC *versus* no KMC, but rather a trial of implementing a package of interventions (community outreach, motivation of mothers for exclusive breastfeeding and KMC, basic health education, trouble-shooting, practical support, belt binders to facilitate KMC, and close monitoring) to initiate

as well as sustain KMC and breastfeeding in the community within 72 hours of birth for babies weighing 1500-2250g. Viewed in this light, two refinements could have been attempted in this trial [1]. First, the window period of participant recruitment for home-delivered babies could have been narrowed to within 24 (or even 12) hours after birth, rather than 72 hours. This is important because the authors suggested that about only 50% neonatal mortality occurs after the first day of life. Second, outcomes reflecting maternal and family perceptions of KMC, its feasibility at home, impact on other household activities, impact (positive or negative) on the care of other infants/children at home, socio-economic implications, etc could also have been considered.

Another extremely important issue is how much KMC contributed to the beneficial outcomes observed at various time points in this trial [1]. The investigators attributed mortality reduction to KMC, offering biologically plausible explanations in terms of better infant care, higher breastfeeding rates, closer maternal bonding, etc. However, it is important to note that the intervention was not merely the administration of KMC, but a package comprising motivation for KMC, encouraging exclusive breastfeeding, ensuring KMC and breastfeeding, resolving difficulties in these practices, close monitoring, etc- all of which were delivered through seven dedicated visits by an exclusive research team. These visits were over and above the routine five visits to be made by ASHA workers in both trial groups. Thus, the two arms of the trial differed in more ways than just KMC. This point is especially important as the data showed that over one-third infants (in both trials arms) were not visited even once by ASHA workers during

BOX I SUMMARY OF RESULTS (INTERVENTION VS COMPARISON GROUPS)*Primary outcome*

- Mortality within 28d: 73 per 4423, 28d periods vs 90 per 3859, 28d periods; HR 0.70 (CI 0.51, 0.96)*
- Mortality within 28d: 73/4470 vs 90/3914; RR 0.71 (CI 0.52, 0.97)*
- Mortality within 180d: 158 per 3965, 180d periods vs 184 per 3514, 180d periods; HR 0.75 (CI 0.60, 0.93)*
- Mortality within 180 d: 138/3653 vs 166/3331; RR 0.76 (CI 0.60, 0.95)*

*Secondary outcomes**Breastfeeding*

- Exclusively breastfed at 28d: 3739/4470 vs 2125/3914; RR 1.54 (CI 1.49, 1.59)*
- Exclusively breastfed at 90d: 2239/3961 vs 1091/3521; RR 1.82 (CI 1.72, 1.93)*
- Exclusively breastfed at 180d: 127/3539 vs 13/3199; RR 8.83 (CI 5.0, 15.6)*
- Not breastfed at 28d: 116/4470 vs 160/3914; RR 0.63 (CI 0.50, 0.81)*
- Not breastfed at 90d: 123/3961 vs 175/3521; RR 0.62 (CI 0.50, 0.79)*
- Not breastfed at 180d: 254/3539 vs 343/3199; RR 0.67 (CI 0.57, 0.78)*

Anthropometric parameters, mean (SD) z scores

- Weight for age at 28d: -2.64 (0.92) vs -2.77 (0.91); MD 0.12 (CI 0.08, 0.16)*
- Weight for age at 90d: -2.43 (1.04) vs -2.50 (1.06); MD 0.07 (CI 0.02, 0.12)*
- Weight for age at 180d: -2.24 (1.10) vs -2.23 (1.13); MD -0.02 (CI -0.07, 0.04)
- Length for age at 28d: -2.43 (0.99) vs -2.49 (0.99); MD 0.06 (CI 0.01, 0.10)*
- Length for age at 90d: -2.08 (1.04) vs -2.12 (1.06); MD 0.04 (CI -0.01, 0.09)
- Length for age z score at 180d: -1.91 (1.06) vs -1.86 (1.07); MD -0.05 (CI -0.10, 0.00)
- Weight for length at 28d: -1.02 (1.06) vs -1.16 (1.10); MD 0.14 (CI 0.09, 0.19)*
- Weight for length at 90d: -0.96 (1.13) vs -1.02 (1.17); MD 0.06 (CI 0.01, 0.12)*
- Weight for length at 180d: -1.30 (1.11) vs -1.32 (1.14); MD 0.03 (CI -0.03, 0.08)

Anthropometric parameters

- Weight for age z score <-3 at 28d: 1329/4380 vs 1363/3813; RR 0.85 (CI 0.80, 0.90)*
- Weight for age z score <-3 at 90d: 945/3772 vs 938/3340; RR 0.89 (CI 0.82, 0.97)*
- Weight for age z score <-3 at 180d: 763/3499 vs 718/3142; RR 0.95 (CI 0.87, 1.05)
- Length for age z score <-3 at 28d: 1092/4379 vs 1023/3812; RR 0.93 (CI 0.86, 1.00)
- Length for age z score <-3 at 90d: 630/3772 vs 598/3340; RR 0.93 (CI 0.84, 1.03)
- Length for age z score <-3 at 180d: 487/3499 vs 415/3143; RR 1.05 (CI 0.93, 1.19)
- Weight for length z score <-3 at 28d: 175/4275 vs 210/3725; RR 0.73 (CI 0.60, 0.89)*
- Weight for length z score <-3 at 90d: 149/3771 vs 158/3339; RR 0.84 (CI 0.67, 1.04)
- Weight for length z score <-3 at 180d: 216/3499 vs 232/3142; RR 0.84 (CI 0.70, 1.00)
- Mean (SD) head circumference at 28d: 34.0 (1.2) vs 33.9 (1.2); MD 0.07 (CI 0.01, 0.13)*
- Mean (SD) head circumference at 90d: 37.2 (1.3) vs 37.2 (1.2); MD 0.03 (CI -0.03, 0.10)
- Mean (SD) head circumference at 180d: 40.0 (1.3) vs 39.9 (1.4); MD 0.03 (CI -0.04, 0.10)

Hospitalization

- For any reason by 28d: 580/4470 vs 460/3914; RR 1.10 (CI 0.98, 1.24)
- For any reason by 180d: 852/3653 vs 793/3331; RR 0.98 (CI 0.90, 1.07)

Morbidity

- Possible serious bacterial infection by 28d: 919/4470 vs 904/3914; RR 0.89 (CI 0.82, 0.97)*
- Local infection by 28d: 390/4470 vs 300/3914; RR 1.14 (CI 0.98, 1.32)
- Diarrhea or dysentery by 28d: 235/4470 vs 334/3914; RR 0.62 (CI 0.52, 0.72)*
- Diarrhea in 2 wk preceding 90d visit: 640/4042 vs 609/3612; RR 0.94 (CI 0.85, 1.04)
- Diarrhea with dehydration or dysentery in 2 wk preceding 90d visit: 9/4042 vs 26/3612; RR 0.31 (CI 0.15, 0.66)*
- Pneumonia in 2 wk preceding 90d visit: 53/4042 vs 81/3612; RR 0.58 (CI 0.41, 0.82)*
- Severe pneumonia in 2 wk preceding 90d visit: 39/4042 vs 60/3612; RR 0.58 (CI 0.39, 0.87)*

Care seeking behavior

- Care sought from an appropriate provider for possible serious bacterial infection by 28d: 385/919 vs 297/904; RR 1.28 (CI 1.13, 1.44)*
- Care sought within 24h of identifying illness by 28d: 349/919 vs 261/904; RR 1.32 (CI 1.15, 1.50)*
- Care sought from an appropriate provider for local infection by 28d: 104/390 vs 37/300; RR 2.16 (CI 1.53, 3.05)*
- Care sought within 24h of identifying illness by 28d: 77/390 vs 29/300; RR 2.04 (CI 1.37, 3.05)*
- Care sought from an appropriate provider for diarrhea in 2 wk preceding 90d visit: 65/640 vs 53/609; RR 1.17 (CI 0.82, 1.65)
- Care sought within 24h of identifying illness in 2 wk preceding 90d visit: 46/640 vs 39/609; RR 1.12 (CI 0.74, 1.69)
- Care sought from an appropriate provider for pneumonia in 2 wk preceding 90d visit: 13/53 vs 21/81; RR 0.95 (CI 0.52, 1.73)
- Care sought within 24h of identifying illness in 2 wk preceding 90d visit: 11/53 vs 18/81; RR 0.93 (CI 0.48, 1.82)

*Statistically significant at $P < 0.05$.

the first seven days of life. While this would not matter for babies in the intervention arm (who would have received 3 visits by research staff within that period), it would severely impact breastfeeding initiation and maintenance in the comparison arm. Even beyond seven days, only about one-third to half the infants received scheduled ASHA visits. Could this be the reason for the stark differences observed in the trial groups for breastfeeding as well as outcomes positively affected by breastfeeding (such as immediate and longer-term mortality, sustained breastfeeding, reduced infections, etc)? This perception is further strengthened by the fact that most anthropometric parameters (except weight) did not show clinically significant differences between the trial groups. Thus, the higher proportions of exclusively breastfed babies in the intervention arm, could be the cause rather than the effect, of the findings in this trial.

The trial [1] showed some interesting findings that were not highlighted by the authors. First, the quantity of ASHA worker visits appears to be well below the scheduled plan as per government norms. ASHA worker visits are designed to promote exclusive breastfeeding and ensure compliance through practical assistance, counselling, and problem resolution. Second, the quality of these visits appears questionable considering that only half the babies in the comparison arm were exclusively breastfed during the neonatal period, with declining proportions over time. Other indicators are that less than 10% babies received breastfeeding within an hour of birth, and the mean time of initiation was over 4 hours. Even more worrisome is that all this happened in a setting wherein a highly controlled RCT was in progress. Since ASHA workers are the frontline health force for universal health care coverage in the community, this does not augur well for the community or the healthcare system. In addition, it has two implications for the trial [1] itself. The issue of compromised care of babies in the comparison arm (and imbalance *vis-à-vis* the intervention arm) has already been highlighted. The second issue is that replication and scale-up of the trial findings [1] in the real-world scenario would ultimately devolve to ASHA workers, in order to achieve the investigators' optimistic projection of thousands of lives saved. The experience from this trial [1] suggests that this is unlikely to happen given the current scenario. This view is strengthened by the fact that the number needed to treat (NNT) to prevent a single additional death was fairly high, suggesting that intensive efforts would be required on the part of ASHA workers.

CONCLUSION

This well-designed and well-executed RCT showed that home initiation and maintenance of KMC and

breastfeeding, ensured by a dedicated team of trained workers, through 7 additional home visits (3.5 to 5.3 hours duration), in babies weighing 1500-2250g, reduced neonatal and early infant mortality by about 30%. There were additional benefits for outcomes influenced by better newborn care and exclusive breastfeeding viz reduced infection, less severe diarrhea & pneumonia, and better care-seeking behaviour in the community. The trial also indirectly highlighted the challenges to be overcome if a bundle of interventions (including KMC) were to be implemented in the real-world scenario.

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Neonatologist's Viewpoint

Kangaroo mother care (KMC) is one of the most cost-effective interventions in preventing deaths of low birthweight (LBW) neonates [1]. A recent Cochrane review (21 studies, 3042 infants) showed that facility-initiated KMC can result in decrease in risk of mortality, serious infection, hypothermia, improved exclusive breastfeeding and improved early weight gain as compared to conventional care [2]. Despite this fact, the global uptake of KMC among eligible babies is low, with estimated coverage being less than 5% [3]. The situation is even worse in the community.

Even though, both WHO as well as the Government of India (GOI) [4,5] have recommended uninterrupted and early KMC for all stable LBW infants in health facilities, no clear-cut guideline is available for community-initiated KMC. In lower-middle-income-countries including India, nearly half of all child births happen at home. In many cases LBW neonates are discharged early (within 24 hours of birth) from facility-care, before KMC can be initiated. In remaining, even if KMC is initiated in hospital, it is never sustained beyond discharge due to lack of awareness and involvement of family members at home. In a systematic review by Seidman, *et al.* [6], lack of a conducive environment and support from family members were two of the top five barriers to the practice of KMC. However, in the community, both these barriers can be alleviated. Mothers in a community are more likely to get support

from other family members, friends and relatives (listed as one of the top enablers of KMC).

(Hence, the authors need to be congratulated for conducting this rigorous randomized controlled trial on community initiated KMC (ciKMC) in rural India [7], which has important public health implications. In this first-of-its-kind RCT, the authors showed improved survival of enrolled LBW infants in both neonatal period (till 28 d, Number needed to treat 83) as well as early infancy (up to six months, 180 d, NNT 150) by 30% following initiation of KMC within 72 hours of life as compared to control group in rural Haryana. Some other noteworthy benefits of community initiated KMC (ciKMC) as proven from the study were decrease in incidence of severe infection, improved rates of exclusive breast feeding, improved growth parameters and increase in health seeking behavior for illness by parents of enrolled infants.

The results of this large RCT call the policy makers in India to incorporate ciKMC as part of national guidelines for home-based care of low birthweight babies. However, there are few issues in translation of this evidence in to practice. ciKMC requires active participation of community health workers (Accredited social health activists, Anganwadi workers and Auxiliary nurse midwives) as well as family members. Prior counselling of antenatal mothers and her family members by community health workers is also essential. Similar to rigorous training of intervention workers of the current trial, there is a need of strong capacity building of community health workers in basic essential newborn skills like skin-to-skin contact and exclusive breastfeeding through regular training (by neonatologists/pediatricians). Providing ciKMC can be challenging in settings where mother starts doing household chores soon after delivery. To avoid this, the entire family needs to be counselled about providing uninterrupted KMC in mother's absence. A recent quality improvement study [8] showed that duration of facility-based KMC can be improved by active participation of other family members (father, grandparents etc.), and ciKMC is not an exception. Simultaneously, the role of hygiene (daily bath and hand washing) needs to be underscored. The role of the neonatologist in community-initiated KMC; although minimal, nevertheless is vital, since many eligible LBW infants are discharged from hospital early (before KMC is initiated). It is the prime responsibility of treating neonatologist to utilize this vital window period for initiating KMC (in hospital) and also to teach the family about appropriate technique of skin-to-skin contact as well as explaining the monitoring

parameters like neck position, breathing pattern and color of the baby during ciKMC. CiKMC should be advised to continue at home as long as possible. It is the primary responsibility of the neonatologist to ensure that none of these infants get discharged before initiation of KMC at facility.

With the combined efforts of administrators and healthcare providers, we expect ciKMC to get incorporated into national guidelines on care of LBW babies and imbibed in the community for improved survival of LBW infants in near future.

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