Effect of community-initiated kangaroo mother care on survival of infants with low birthweight: a randomised controlled trial

Sarmila Mazumder, Sunita Taneja, Brinda Dube, Kiran Bhatia, Runa Ghosh, Medha Shekhar, Bireshwar Sinha, Rajiv Bahl, Jose Martines, Maharaj Kishan Bhan, Halvor Sommerfelt, Nita Bhandari

Summary

Background Coverage of kangaroo mother care remains very low despite WHO recommendations for its use for babies with low birthweight in health facilities for over a decade. Initiating kangaroo mother care at the community level is a promising strategy to increase coverage. However, knowledge of the efficacy of community-initiated kangaroo mother care is still lacking. We aimed to assess the effect of community-initiated kangaroo mother care provided to babies weighing 1500–2250 g on neonatal and infant survival.

Methods In this randomised controlled, superiority trial, undertaken in Haryana, India, we enrolled 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 (ie, home or health facility) and who were stable and feeding. The first eligible infants in households were randomly assigned (1:1) to the intervention (community-initiated kangaroo mother care) or control group by block randomisation using permuted blocks of variable size. Twins were allocated to the same group. For second eligible infants in the same household as an enrolled infant, if the first infant was assigned to the intervention group the second infant was also assigned to this group, whereas if the first infant was assigned to the control group the second infant was randomly assigned (1:1) to the intervention or control group. Mothers and infants in the intervention group were visited at home (days 1–3, 5, 7, 10, 14, 21, and 28) to support kangaroo mother care (ie, skin-to-skin contact and exclusive breastfeeding). The control group received routine care. The two primary outcomes were mortality between enrolment and 28 days and between enrolment and 180 days. Analysis was by intention to treat and adjusted for clustering within households. The effect of the intervention on mortality was assessed with person-time in the denominator using Cox proportional hazards model. This study is registered with ClinicalTrials.gov, NCT02653534 and NCT02631343, and is now closed to new participants.

Findings Between July 30, 2015, and Oct 31, 2018, 8402 babies were enrolled, of whom 4480 were assigned to the intervention group and 3922 to the control group. Most births (6837 [81·4%]) occurred at a health facility, 36·2% (n=3045) had initiated breastfeeding within 1 h of birth, and infants were enrolled at an average of about 30 h (SD 17) of age. Vital status was known for 4470 infants in the intervention group and 3914 in the control group at age 28 days, and for 3653 in the intervention group and 3331 in the control group at age 180 days. Between enrolment and 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). Between enrolment and 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).

Interpretation Community-initiated kangaroo mother care substantially improves newborn baby and infant survival. In low-income and middle-income countries, incorporation of kangaroo mother care for all infants with low birthweight, irrespective of place of birth, could substantially reduce neonatal and infant mortality.

Funding Research Council of Norway and University of Bergen.

Published Online
October 4, 2019
https://doi.org/10.1016/S0140-6736(19)32223-8

See Online/Comment
https://doi.org/10.1016/S0140-6736(19)32257-3

Centre for Health Research and Development, Society for Applied Studies, New Delhi, India (S Mazumder PhD, S Taneja PhD, B Dube MSc, K Bhatia MCA, R Ghosh MSc, M Shekhar BA, B Sinha MD, N Bhandari PhD); **Department of Maternal, Newborn, Child and Adolescent Health, World Health Organization, Geneva, Switzerland** (R Bahl PhD); **Centre for Intervention Science in Maternal and Child Health, Centre for International Health** (J Martines PhD, Prof H Sommerfelt PhD), **University of Bergen, Bergen, Norway** (N Bhandari); **and Indian Institute of Technology, New Delhi, India** (Prof M K Bhan MD)

Correspondence to:
Dr Nita Bhandari, Centre for Health Research and Development, Society for Applied Studies, New Delhi 110016, India
nita.bhandari@sas.org.in

Introduction

Globally, over 20 million babies have low birthweight (weight less than 2500 g at birth) each year and approximately 70% of neonatal deaths occur in these infants.[1,2] About 97% of the world's babies with low birthweight are born in developing countries.[2] Of these births, 40% are in India alone.[3] Babies with low birthweight are not only at high risk of death, but they also have impaired growth and development.[1] High coverage of effective interventions to prevent and manage low birthweight is required to improve newborn baby and infant survival, growth, and development.

Since 1990, mortality among children younger than 5 years has substantially decreased, but this decrease has

Research in context

Evidence before this study

Before undertaking this study, we reviewed the published evidence on the effect of kangaroo mother care that was summarised in a Cochrane review, published at the time of our protocol development in 2014. The Cochrane review was subsequently updated to include publications up to June 30, 2016. The review indicated that kangaroo mother care was associated with 40% reduction in risk of death and 65% reduction in nosocomial infection or sepsis at time of hospital discharge or 40–41 weeks' postmenstrual age compared with conventional neonatal care for newborn babies. We also did a PubMed search for publications in English between the last Cochrane update (June 30, 2016) and Dec 5, 2018, including combinations of the search terms "kangaroo mother care", "kangaroo mother method", "kangaroo care", "skin-to-skin contact", and "skin-to-skin care" and MeSH terms "infant", "low birth weight", "infant mortality", "breast feeding", "morbidity", "randomized controlled trials", "systematic reviews", "commmunity trials", and "home-initiated". We identified only one randomised controlled trial that examined the effect of community-initiated kangaroo mother care on mortality, and its findings were inconclusive. Current WHO and national guidelines recommend that kangaroo mother care be initiated in health facilities for stable babies with low birthweight. However, in rural settings and for poorer populations, close to half of births still happen outside of health facilities. Added to the rarity of facilities that assist initiation of kangaroo mother care and the common discharge of mothers and babies on the first day after birth, coverage of babies in need with this life-saving intervention is lacking. Research on the benefits of community-initiated kangaroo mother care has been identified among the global research priorities for the health of newborn babies.

Added value of this study

This is the first study to show the survival benefits of kangaroo mother care in babies with low birthweight, including those weighing 2000–2250 g. We found that, compared with routine care for newborn babies, the intervention substantially improves neonatal survival (ie, until age 28 days) and infant survival to age 180 days and reduces severe infection. The intervention also improves exclusive breastfeeding in the neonatal period and during the first 6 months of life, and appropriate care-seeking behaviour for illness in newborn babies. In addition to its unique insights on community-initiated kangaroo mother care, the number of infants enrolled in the study was almost three times higher than the number included in the last Cochrane review, thereby improving the precision of estimates for the assessment of kangaroo mother care effect on mortality.

Implications of all the available evidence

Kangaroo mother care should be started in the community for babies with low birthweight if it has not yet been started in hospital. This change from current policy will be particularly important in settings where a substantial proportion of babies with low birthweight are born at home or discharged early from hospitals without kangaroo mother care. The strengthened evidence on benefits of kangaroo mother care should add impetus for adequate initiation of kangaroo mother care in health facilities, where an increasing number of babies with low birthweight are being born globally. To maximise benefits, kangaroo mother care should be continued beyond facility discharge for as long as possible during the day and for as many days as possible. Community-initiated kangaroo mother care could provide a strong platform for the establishment of programmes for the promotion of health and survival of babies with low birthweight.

been slower for neonatal mortality.[4] Kangaroo mother care has been identified as one of the most effective interventions for improving neonatal survival.[5] This approach encompasses continuous skin-to-skin contact and exclusive breastfeeding. A 2016 Cochrane review[6] showed that kangaroo mother care initiated in health facilities after stabilisation of babies with a birthweight of less than 2000 g results in a 40% relative reduction in the risk of death by the time of discharge or 40–41 weeks postmenstrual age, and a 33% reduction in risk of death by the latest follow-up for which data were available compared with conventional neonatal care. Kangaroo mother care also reduced the risk of severe infection or sepsis and improved breastfeeding.[6] The review provided some evidence that kangaroo mother care might improve growth in the initial weeks of life.[6] Based on this evidence, WHO recommends kangaroo mother care for babies with a birthweight of less than 2000 g. It should be initiated in health facilities after the infant's clinical condition is stable.[2] The current WHO policy states that kangaroo mother care should be initiated in hospitals and continued at home after discharge across the facility community care continuum. However, community-initiated kangaroo mother care is currently not a part of WHO or India's National policy because its efficacy and safety have not been evaluated.

Global data on coverage of kangaroo mother care are not available but the estimated coverage is less than 5% for eligible infants with low birthweight.[7] A recent review found a lack of endorsement of kangaroo mother care by health-care providers and managers who might consider it useful but not critical.[8] The review found that time constraints, lack of appropriate training of health-care providers, medical concerns, inadequate social support and empowerment, and unsupportive cultural norms were major barriers for scaling-up kangaroo mother care.[8] Although close to 80% of babies in India are now born in health facilities, kangaroo mother care is rarely initiated, and even newborn babies with low birthweight are often discharged too early, many on the

first day of life.[9] Coverage of this highly effective child survival intervention remains very low. Two of the top global research priorities identified by WHO for newborn baby health for 2015–25 were how to scale up facility-initiated kangaroo mother care and continuing it at home after discharge and assessing the efficacy of community-initiated kangaroo mother care.[10]

Initiating kangaroo mother care at the community level for babies with low birthweight who are born at home or discharged from health facilities without kangaroo mother care initiation is a promising strategy to increase coverage of kangaroo mother care and the duration for which it is provided. However, knowledge of the efficacy of community-initiated kangaroo mother care is still lacking. We identified only a single study that investigated the feasibility of community-initiated kangaroo mother care,[11] which had inconclusive results with respect to feasibility and effect, and the evidence was insufficient to support the formulation of a public health recommendation.[11] No evidence exists to support increasing the birthweight criterion for recommending kangaroo mother care to more than the currently recommended 2000 g", but if kangaroo mother care was found to be effective in babies who weigh 2000 g or more, it would increase the overall survival effect of the intervention.

We did a randomised controlled trial to assess the efficacy of promoting community-initiated kangaroo mother care on the mortality of babies with low birthweight from enrolment to age 28 days, and from enrolment to age 180 days (ie, 6 months). We undertook the trial in two districts in Haryana, India, which have a total population of approximately 2 million and a birth rate of approximately 26 per 1000 population. About 40% of deliveries occur at home and 25% of all babies have low birthweight. The median duration of schooling for women was 5 years (IQR 0–8) and for men was 8 years (IQR 5–11).[12,13]

Methods

Study design and participants

This randomised, controlled, superiority trial, was undertaken in rural and semi-urban areas in two districts in Haryana, India: Faridabad and Palwal. The details of study methods have been published previously,[14] and are briefly summarised here. Before trial initiation, we undertook formative research to ascertain practices around birth and understand the feasibility and acceptability of community-initiated kangaroo mother care in the study population.[15] Our findings guided the development of the intervention package and delivery strategy for this trial.

Pregnant women were identified via door-to-door surveillance every 3 months. The pregnancy follow-up, screening, and enrolment (PSE) team followed up these women regularly and with increasing frequency as the expected date of delivery approached. Newborn babies were identified using a pregnancy surveillance and early birth identification system and visited at home. If they weighed 1500–2250 g at home, they were enrolled as soon as possible after birth but not later than 72 h after birth. Babies were excluded if they had not been weighed within 72 h of birth, were unable to feed, had difficulty in breathing, had less than normal movements, had major congenital malformations, kangaroo mother care was initiated in hospital, and whose mothers did not intend to stay in the study area for the next 6 months or did not consent to participate in the study. Infants weighing 1500–1800 g were referred for hospital care following Government of India guidelines,[16] but they were invited to participate in the trial 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 they became 72 h old. The cutoff of 2250 g was chosen because we expected some weight loss between birth and screening for enrolment. Furthermore, our formative research suggested that many infants with a birthweight greater than 2250 g wriggle out of the kangaroo mother care position before the end of the neonatal period (ie, first 28 days of life). We excluded infants weighing less than 1500 g and referred them to a hospital for management because most of them were likely to be unstable and have feeding and breathing problems.

The study protocol has been published.[14] We obtained ethical approval for this trial from the ethics committees of the Society for Applied Studies and Regional Committee for Medical and Health Research Ethics in Norway. Additionally, approval for the initial part of the trial (NCT02631343) was obtained from WHO. Written informed consent was obtained by the PSE team from the caregivers of eligible newborn babies.

Randomisation and masking

Low birthweight babies were randomly assigned 1:1 to either the intervention group (community-initiated kangaroo mother care) or the control group. The randomisation sequence was prepared by a WHO statistician who was not involved with other trial activities using random permuted blocks of variable size. The WHO statistician concealed the allocation in serially numbered opaque sealed envelopes that were shipped to the off-site randomisation coordinator in India.

Once written informed consent had been obtained, the members of the PSE team contacted the off-site randomisation coordinator who opened the opaque envelopes. The randomisation coordinator communicated the infant's unique identification number to the PSE team members and to the intervention delivery team if the baby was to receive the intervention. Twins were assigned to the same group, with the first twin randomly assigned to a group, and the second twin then assigned to the same group.

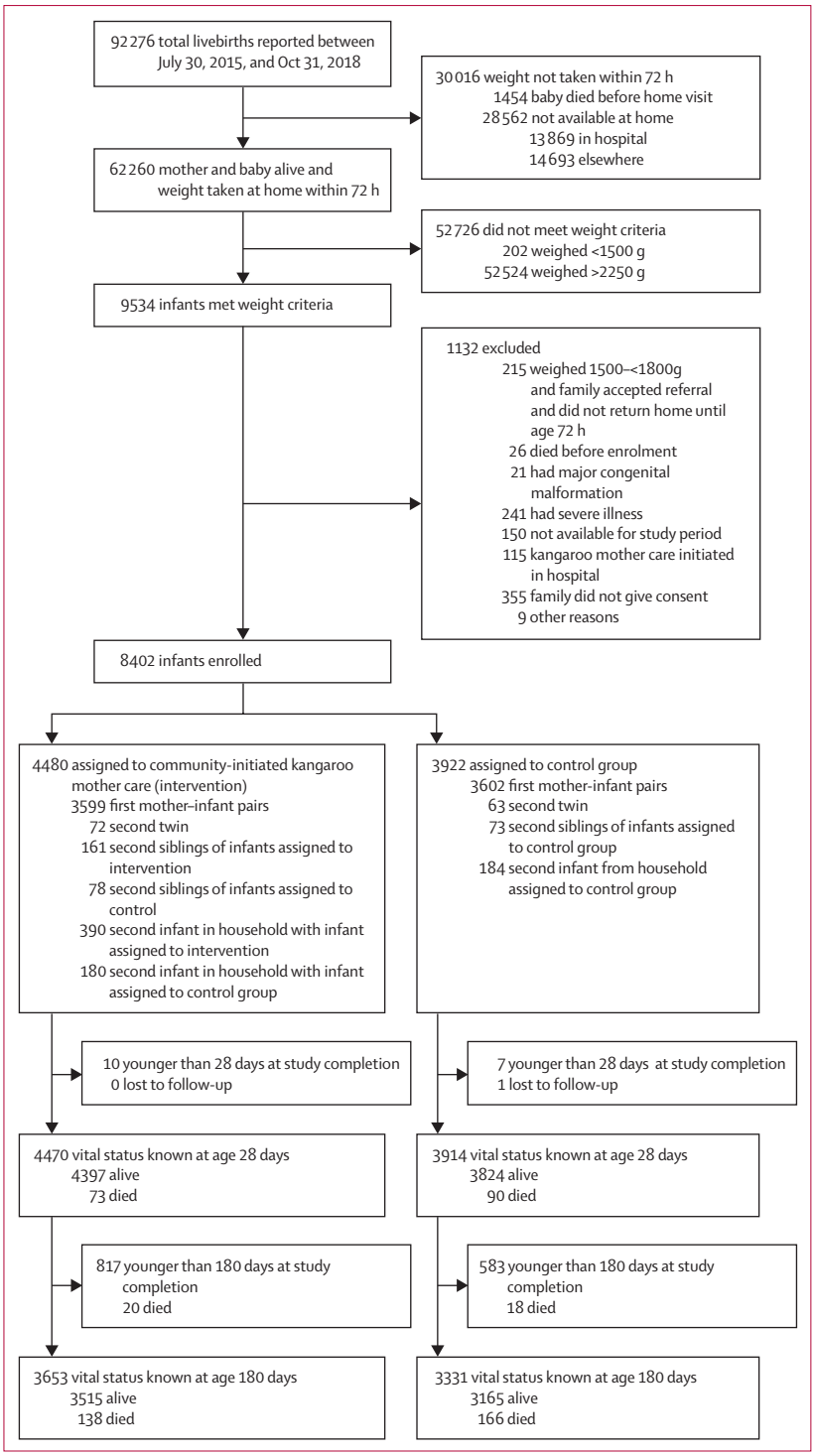

Figure 1: **Trial profile**

To reduce contamination between trial groups, we allocated infants who were born into a household in which a previously enrolled infant (whether a sibling or another infant) had been randomly assigned to the intervention group to also receive the intervention. If a household had a previously enrolled infant allocated to the control group, the second infant was randomly assigned (1:1) using the original randomisation method to the intervention or control group. This strategy was used to give the new infant from the same household a chance of receiving the intervention.

Due to the nature of the intervention, mothers and members of the PSE team were not masked to allocation; however, an attempt was made to keep the independent assessors unaware of the intervention allocation.

Procedures

The intervention comprised promotion and support of skin-to-skin contact and exclusive breastfeeding by intervention workers and supervisors. They counselled that skin-to-skin contact be done for as long as possible during the day and night, preferably for 24 h a day, with the assistance of other family members. During home visits, the worker observed the mother practising kangaroo mother care, enquired about skin-to-skin contact and breastfeeding in the preceding 24-h period, and supported the mother and family to solve any problems or overcome barriers to effective kangaroo mother care.

The intervention delivery workers had 10–12 years of school education, but no previous training in health care. Their educational background was similar to community health workers in India.[17] Their supervisors were college graduates with no previous training in health care, similar to Accredited Social Health Activist (ASHA) supervisors (ie, government community health workers).[17] These workers are hereafter referred to as intervention workers and intervention supervisors. The intervention delivery team was intensively trained in supporting skin-to-skin contact and lactation management and counselling skills and had hands-on practice in kangaroo mother care wards in hospitals.

The home visit schedule of the intervention delivery team was similar to that of the schedule in the national programme for babies with low birthweight.[18] Infants allocated to the intervention group were visited on days 1–3, 5, 7, 10, 14, 21, and 28 of life. The average time spent by an intervention worker at each home visit was 30-45 min. The team supported the mother and family to initiate and sustain kangaroo mother care until age 28 days, or earlier if the infant wriggled out indicating they no longer needed kangaroo mother care.[15]

Infants allocated to the control group did not receive any intervention from the study team. They continued to receive home-based care from government ASHA workers. ASHA workers are trained by the government to provide essential care to all newborn infants through four rounds of training of 5 days each (modules 6 and 7) over a period of 1 year.[17] They do home visits (on days 1, 3, 7, 14, 21, 28, and 42 for homebirths and days 3, 7, 14, 21, 28, and 42 for hospital births) and examine every newborn baby for prematurity and low birthweight.

	Intervention group (n=4480)	Control group (n=3922)
Age at enrolment, h	29·7 (17·2)	30·1 (17·2)
Weight at enrolment, kg	2·1 (1·7)	2·1 (1·7)
1·50–1·79	335 (7·5%)	277 (7·1%)
1·80–1·99	870 (19·4%)	757 (19·3%)
2·00–2·25	3275 (73·1%)	2888 (73·6%)
Length at enrolment, cm*	44·6 (1·6)	44·6 (1·6)
Sex		
Male	1907 (42·6%)	1741 (44·4%)
Female	2573 (57·4%)	2181 (55·6%)
Twins pairs enrolled	72 (1·6%)	63 (1·6%)
Household birth order		
First baby	1728 (38·6%)	1543 (39·3%)
Second, third, or fourth baby	2361 (52·8%)	2077 (53·0%)
Fifth baby or later	386 (8·6%)	302 (7·7%)
Gestational age, weeks †	36·1 (1·8)	36·1 (1·8)
Weight and gestational age category‡		
Term and small-for-gestational age	1386 (41·6)	1628 (42·3)
Term and appropriate-for-gestational age	NA	NA
Preterm and small-for-gestational age	857 (19·4)	746 (19·4)
Preterm and appropriate-for-gestational age	1726 (39·1)	1476 (38·3)
Time of breastfeed initiation, h§	4·4 (9·7)	4·4 (9·6)
Breastfeeding initiated within 1 h of birth	1628 (36·3%)	1417 (36·1%)
Place of birth		
Home birth	828 (18·5%)	737 (18·8%)
Hospital birth	3652 (81·5%)	3185 (81·2%)
Birth attendant doctor, nurse, midwife, or auxiliary nurse midwife	4382 (97·8%)	3849 (98·2%)
Caesarean section	80 (1·8%)	70 (1·8%)
Age of mother, years¶	23·3 (3·7)	23·4 (3·8)
Mother's duration of schooling, years¶	6·0 (5·2)	6·2 (5·2)
Mother never been to school¶	1625 (36·3%)	1341 (34·2%)
Mother working outside of home¶	226 (5·0%)	223 (5·7%)
Family below poverty line ¶	909 (20·3%)	796 (20·3%)
Family religion¶		
Hindu	3653 (81·6%)	3195 (81·5%)
Other	827 (18·5%)	727 (18·5%)
Family scheduled caste or tribe¶	1573 (35·2%)	1305 (33·3%)
Family wealth quintile§¶		
Least poor	891 (19·9%)	794 (20·2%)
Less poor	917 (20·5%)	766 (19·5%)
Poor	891 (19·9%)	783 (20·0%)
Very poor	904 (20·2%)	768 (19·6%)
Most poor	871 (19·5%)	811 (20·7%)

(Table 1 continues in next column)

(Continued from previous column)

Data are mean (SD) or n (%). NA=not applicable. *Length not measured for 19 infants in intervention group and 18 infants in control group. †As reported by the mothers. ‡Categories defined as term: gestational age ≥37 weeks; preterm: gestational age <37 weeks; small-for-gestational age: birthweight <10th percentile for gestational age according to INTERGROWTH-21st standards; appropriate-for-gestational age: ≥10th percentile for gestational age according to INTERGROWTH-21 standards. Small-for-gestational age not calculated for 61 infants in intervention group and 72 in control group. §Breastfeeding never initiated for one infant in control group. ¶Information on mother not available for five infants in intervention group.

Table 1: **Baseline characteristics of enrolled newborn babies and their families, by treatment group**

For more on **INTERGROWTH-21** see https://intergrowth21.tghn.org/

Additional home visits are made for babies who are born preterm and with low birthweight. The workers support exclusive breastfeeding by teaching the mother proper positioning and attachment for initiating and maintaining breastfeeding, and diagnosis and counselling in case of problems with breastfeeding. They also aid in early identification of illnesses in newborn babies and provision of appropriate care and referral, and support the family in healthy practice.

An independent team ascertained outcomes during home visits at age 28 days, 90 days, and 180 days. Outcome measurement procedures were identical in both intervention and control groups. The team asked questions about the primary outcomes before those on skin-to-skin contact and other factors and they were closely supervised to prevent ascertainment bias. At the time of enrolment, information on socioeconomic and demographic characteristics was collected and newborn baby's weight, length, and head circumference were measured. At the outcome measurement visits, information on feeding in the preceding 24 h, illness, and details of treatment-seeking and hospitalisation (ie, admission to and treatment in hospital were obtained, and weight, length, and head circumference were measured. All anthropometric measurements were taken twice using a digital hanging weighing scale (AWS-SR-20; American Weigh Scales, Cumming, GA, USA; 10 g sensitivity), an infantometer (model 417; Seca, Chino, CA, USA; sensitivity 0·1 cm); and a head circumference measuring tape (model 212; Seca, Chino, CA, USA; sensitivity 0·1 cm). Information on skin-to-skin contact (number of days, and h per day) was ascertained only at the 28-day follow-up visit. At this visit, the team also documented home visits made by the study team and government workers (ASHAs or auxiliary nurse midwives [community health workers who supervise the work of ASHAs]) for all enrolled neonates.[18]

All study teams underwent intensive training in study procedures and good clinical practice.[19] Study activities were monitored and supervised by the study coordinators. All data were captured electronically on smartphones or tablets with built-in range and consistency checks. Queries generated by the data management team were

	Intervention group (n=4470)	Control group (n=3914)
Information from outcome measurement team		
Skin-to-skin contact		
Any from enrolment to 28 days	4438 (99·3%)	174 (4·5%)
Duration per day, h		
Mean	11·5 (4·0)	0·2 (1·3)
Median	12 (9–14)	0 (0–0)
Days with skin-to-skin contact		
Mean	26·8 (4·7)	1·1 (5·0)
Median	28 (28–28)	0 (0–0)
Visited by ASHA (mother's report)		
At least once from enrolment to 28 days	3666 (82·0%)	3223 (82·3%)
In the first week	2739 (61·3%)	2438 (62·3%)
In the second week	2393 (53·5%)	1906 (48·7%)
In the third week	1435 (32·1%)	1168 (29·8%)
In the fourth week	1444 (32·3%)	1200 (30·7%)
Information from intervention workers		
Age of infant at initiation of skin-to-skin contact, h		
Mean	32·7 (18·3)	NA
Median	31·0 (19·5–43·9)	NA
Days of skin-to-skin contact		
Mean	25·0 (5·0)	NA
Median	27 (25–28)	NA
Duration of skin-to-skin contact per day, h		
Mean	10·7 (4·4)	NA
Median	10·8 (7·6–13·8)	NA
Number of visits from intervention team		
Mean	8·5 (1·1)	NA
Median	9 (8–9)	NA

Data are n (%), mean (SD), and median (IQR). ASHA=Accredited Social Health Activists. NA=not applicable.

Table 2: **Intervention compliance and home visits for enrolled infants**

resolved within 7 days of data collection. After de-identifying the study participants, data were transferred monthly to WHO for off-site data quality checks. Technical staff from WHO assessed monthly reports from the study team and interacted through regular conference calls and site monitoring visits.

Outcomes

The two primary outcomes were death from enrolment to age 28 days and early infant deaths from enrolment to age 180 days. The secondary outcomes were exclusive breastfeeding at 28 days and 90 days; weight, length, and anthropometric status (ie, stunting, wasting, and underweight) at age 28 days, 90 days, and 180 days; possible serious bacterial infection[20] or localised infection, and diarrhoea with or without dehydration or dysentery in the neonatal period (ie, from enrolment to age 28 days); diarrhoea, with or without symptoms of dysentery or dehydration, pneumonia, or severe pneumonia in the 2 weeks preceding the 90-day visit and 180-day visit; hospitalisation; and care seeking for these illnesses.

Pneumonia was defined as history of cough (as reported by the mother) or difficulty breathing and reported fast breathing or chest indrawing.[21] Severe pneumonia was defined as pneumonia with one or more of the following general danger signs: not able to breastfeed, feed, or drink; lethargy or unconsciousness; convulsions; or stridor. Diarrhoea was as reported by the mother or caregiver, and symptoms of dehydration were not able to drink, lethargy or unconsciousness, restlessness or irritability, and sunken eyes. Possible serious bacterial infection was defined as one of the following: not able to breastfeed or feed, fever, cold to touch, lethargy or unconsciousness, or fast or difficult breathing or pneumonia (local term).

Statistical analysis

We estimated the study sample size assuming a background mortality risk of 42 deaths per 1000 infants between ages 1 and 28 days.[13] A total of 10 500 infants would need to be enrolled to detect a 30% or larger relative risk reduction, with 95% confidence level and 90% power, and accounting for 10% attrition. This sample size would enable us to detect an even lower reduction in mortality from enrolment until 180 days of age.

A data safety and monitoring committee (DSMC) undertook two interim analyses pre-planned to occur when about half of infants has been enrolled (Sept 18–19, 2017) and when almost three-quarters of infants had been enrolled (June 29–30, 2018). After the second interim analysis, the DSMC concluded that a sufficient number of infants would be enrolled by the end of September, 2018, to clearly answer the study question and recommended that data collection be completed by the end of October, 2018.

After data cleaning and before analysis, the databases were locked at data cutoff (Nov 15, 2018). Means or proportions of the prespecified baseline characteristics were compared between the study groups to examine whether they were similar, indicating successful randomisation and to describe the study participants.

Our analysis included all participants who were enrolled and assigned to the two trial groups. We first assessed the effect of the intervention on mortality with person-time as the denominator using a Cox proportional hazards model to estimate hazard ratios (HRs). In this analysis, we calculated the days of follow-up for each infant as the date of enrolment subtracted from the date of last follow-up or death using a person-time analysis—ie, the 28-day and 180-day periods were computed for each infant by dividing the actual follow-up days by either 28 or 180. We also calculated the risk ratios (RRs) and absolute risk differences for deaths between the two study groups for infants with complete follow-up using generalised linear models of the binomial family with a log-link function for the RRs and identity-link

function for the absolute risk difference. Both these models accounted for clustering of deaths in households with multiple births and we adjusted both analyses for infants enrolled from the same household. We calculated efficacy against death as (1−HR)×100 and (1−RR)×100, while the number needed to treat—ie, the number of babies that would need to receive community-initiated kangaroo mother care to prevent one death—as 1/absolute risk difference.

We analysed the effects of the intervention on secondary outcomes using the risk-based approach in infants with complete follow-up. The growth data were analysed as mean weight-for-length, weight-for-age, and length-for-age Z scores between the two groups and proportion severely stunted (length-for-age Z scores <−3), wasted (weight-for-length Z score <−3), and underweight (weight-for-age Z score <−3). We used mean difference for comparison of the two means and RRs for comparison of proportions.

We did prespecified subgroup analyses of the primary outcomes by sex, weight category at enrolment, and infant age at enrolment, and assessed heterogeneity of effects by including interaction terms in the regression models. We also did post-hoc subgroup analyses of the primary outcomes by reported gestation at birth (<35 weeks or ≥35 weeks, as reported by the mother), gestational age at birth and birthweight categories (preterm [<37 weeks] and birthweight small-for-gestational age, preterm [<37 weeks] and birthweight appropriate-for-gestational age, and term [≥37 weeks] and birthweight small-for-gestational age), duration of skin-to-skin contacts (in h), and weight and length gain.

For all analyses, p values of less than 0·05 were considered to be significant. We used Stata software version 15.1 for analyses. This study is registered with ClinicalTrials.gov, NCT02653534 and NCT02631343.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between July 30, 2015, and Oct 31, 2018, of 92 276 reported livebirths, we screened 62 260 newborn babies, of whom 9534 weighed 1500–2250 g. 1132 were excluded because they did not meet eligibility criteria or the family did not give consent to participate, and 8402 were enrolled. These newborn babies were randomly assigned to either the intervention (n=4480) or control (n=3922) group (figure 1). The number of infants enrolled in each of the groups was unequal because of the enrolment strategy.

Table 1 shows the baseline characteristics of the newborn babies, their mothers, and their families. Sociodemographic characteristics between study groups were very similar. The study population characteristics were similar to those of the population in large parts of India, with few years of education for women, most births (6837 [81·4%]) occurring at a health facility, and only 36·2% (n=3045) of infants having initiated breastfeeding within 1 h of birth. Infants were enrolled at a mean age of 30 h (SD 17).

	Intervention group (n=4470)	Control group (n=3914)	Adjusted effect size* (95% CI; p value)
From enrolment to age 28 days			
Person-time analysis			
28-day periods (infants)†	4423 (4470)	3859 (3914)	..
Deaths	73	90	HR 0·70 (0·51–0·96; p=0·027)
Risk-based analysis			
Infants	4470	3914	..
Deaths	73 (1·6%)	90 (2·3%)	RR 0·71 (0·52– 0·97; p=0·032)
From enrolment to age 180 days			
Person-time analysis			
180-day periods (infants)†	3965 (4470)	3514 (3914)	..
Deaths	158	184	HR 0·75 (0·60–0·93; p=0·010)
Risk-based analysis			
Infants	3653	3331	..
Deaths	138 (3·8%)	166 (5·0%)	RR 0·76 (0·60–0·95; p=0·017)

HR=hazard ratio. RR=risk ratio. *HRs and RRs are adjusted for children enrolled in the same household. †Twins were counted and adjusted for clustering.

Table 3: **Effect of community-initiated kangaroo mother care on deaths from enrolment to 28 days, ane enrolment to 180 days of age**

Vital status was known for 4470 infants in the intervention group and 3914 in the control group at age 28 days, and for 3653 in the intervention group and 3331 in the control group at age 180 days (figure 1).

In the intervention group, kangaroo mother care was initiated at a median age of 31·0 h (IQR 19·5–43·9). Mothers reported that they gave kangaroo mother care for a median of 27 days (25–28) with a median duration of 10·8 h (7·6–13·8) per day. Almost all mothers in the intervention group (4438 [99·3%] of 4470) reported giving kangaroo mother care compared with 174 [4·5%] of 3914 in the control group (table 2). In the intervention group, the median duration of skin-to-skin contact per day was 9·9 h (IQR 6·5–13·2) in infants weighing less than 1800 g and 10·8 h (7·7–13·8) in those weighing 2000 g or more at enrolment (appendix p 1). The number of infant visits at home by ASHAs was similar between kangaroo mother care and control groups throughout the neonatal period (table 2).

See Online for appendix

73 deaths occurred in 4423 periods of 28 days in the intervention group, compared with 90 deaths in 3859 periods of 28 days in the control group (table 3). The Cox proportional hazards model with adjustment for multiple infants in a household yielded an HR of 0·70 (95% CI 0·51 to 0·96; p=0·027) and an efficacy of 30%. 158 deaths occurred in 3965 periods of 180 days in the intervention group compared with 184 deaths in

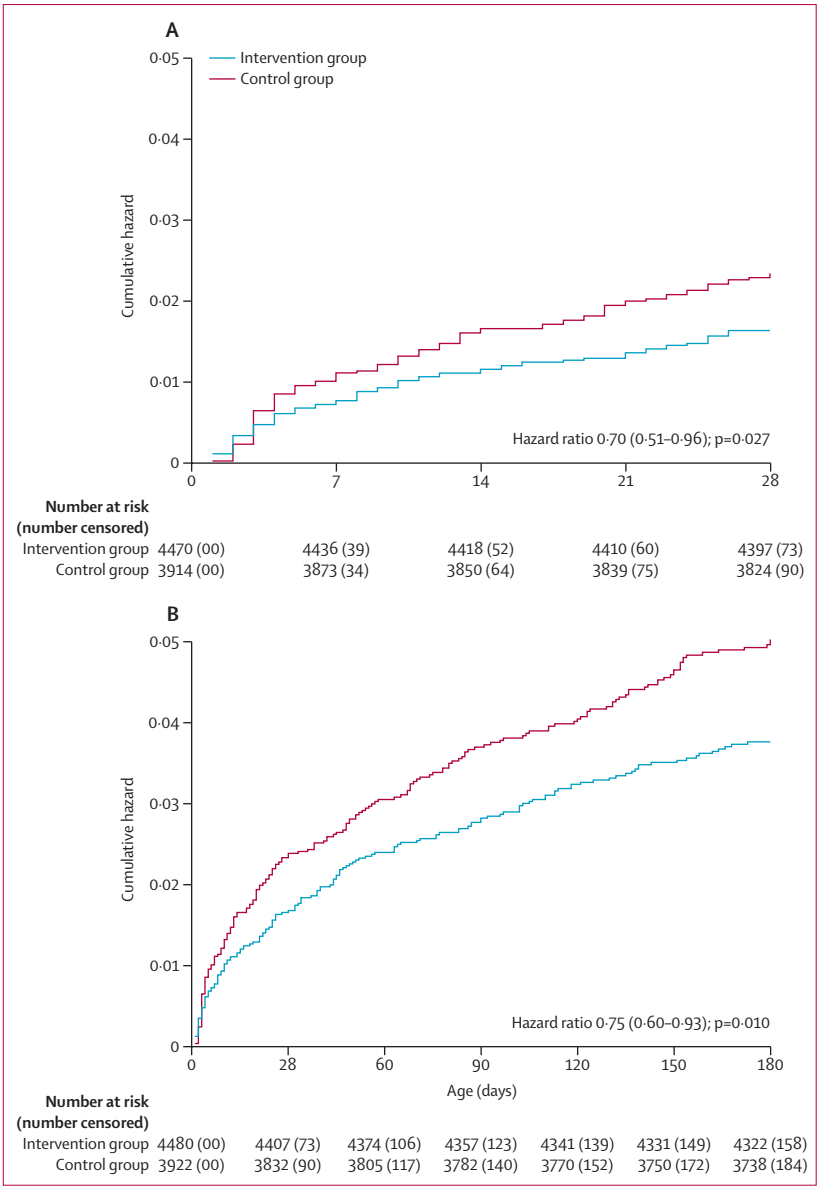

Figure 2: **Cumulative hazard of death from enrolment to age 28 days (A) and from enrolment to age 180 days (B)**

3514 periods of 180 days in the control group (HR 0·75, 95% CI 0·60 to 0·93; p=0·010). The relative risks of death were almost identical to the HRs for each outcome (table 3). The absolute risk difference was –0·7% (95% CI –1·3 to –0·1) for death between enrolment and 28 days of age, and –1·2% (–2·2 to –0·2) for death between enrolment and 180 days of age. 83 babies with low birthweight would need to be given community-initiated kangaroo mother care to prevent one early infant death (ie, within 180 days of enrolment); and 150 babies with low birthweight would need to be given the intervention to prevent one neonatal death (ie, within 28 days of enrolment).

Figure 2 shows the cumulative mortality hazard curves from enrolment to 28 days of age and the same from enrolment to 180 days of age. The hazards curves for the two groups began to separate within days of randomisation and this separation continued to increase over the follow-up period.

Table 4 shows the effect of the intervention on breastfeeding and growth. Exclusive breastfeeding was substantially more common in the intervention group than in the control group during the first 6 months of life (56·5% *vs* 31·0% at age 3 months; RR 1·82, 95% CI 1·72–1·93; p<0·0001; and 3·6% *vs* 0·4% at age 6 months; RR 8·83, 95% CI 5·0–15·6; p<0·0001). A lower proportion of mothers was not breastfeeding in the intervention group than in the control group at age 6 months (7·2% *vs* 10·7%; RR 0·67, 95% CI 0·57–0·78; p<0·0001).

Infants in the intervention group had higher weight-for-age Z scores than the control group at age 28 days (adjusted mean difference 0·12, 95% CI 0·08–0·16; p<0·0001) and age 90 days (0·07, 0·02–0·12; p=0·006). Similarly, weight-for-length Z scores were higher in the intervention group than in the control group at age 28 days (adjusted mean difference 0·14, 0·09–0·19; p<0·0001) and at age 90 days (0·06, 0·01–0·12; p=0·025). A small beneficial effect of the intervention on length-for-age Z score was seen, but only at age 28 days (adjusted mean difference 0·06, 95% CI 0·01–0·10; p=0·011). The proportion of infants who were severely wasted was significantly lower in the intervention group than in the control group at age 28 days (RR 0·73, 95% CI 0·60–0·89; p=0·002), and no difference was seen between groups at ages 90 days and 180 days. Furthermore, head circumference was slightly larger at age 28 days in the intervention group than in the control group (adjusted mean difference 0·07, 95% CI 0·01–0·13; p=0·016), with no difference seen between groups at 90 days and 180 days. Except for a lower prevalence of severe wasting (RR 0·84, 95% CI 0·70–1·00; p=0·052), growth effects were not seen at age 180 days (table 4).

Table 5 shows the effect of the intervention on hospitalisation, morbidities, and care seeking for illness. No significant difference was seen in the proportion of infants hospitalised between enrolment and age 28 days or between enrolment and age 180 days between the intervention and control groups. A lower proportion of infants in the intervention group than in the control group had signs of possible serious bacterial infection (RR 0·89, 95% CI 0·82–0·97; p=0·005) and diarrhoea or dysentery (0·62, 0·52–0·72; p<0·0001) between enrolment and age 28 days, whereas no difference was seen between the groups in the proportions of infants who had a local infection. The proportion of infants with pneumonia in the 2 weeks preceding the 90-day visit was lower in the intervention group than in the control group (0·58, 0·41–0·82; p=0·002) and the effect was similar for severe pneumonia (0·58, 0·39–0·87; p=0·008). No effect on diarrhoea was seen at age 90 days, but the proportion of infants with diarrhoea with symptoms of dehydration or dysentery was lower in the intervention group than in

	Intervention group (n=4470)		Control group (n=3914)		Adjusted risk ratio or adjusted mean difference* (95% CI; p value)
	Number followed up	Measure	Number followed up	Measure	
Breastfeeding					
Exclusively breastfed					
At age 28 days	4470	3739 (83·7%)	3914	2125 (54·3%)	1·54 (1·49 to 1·59; p<0·0001)
At age 90 days	3961	2239 (56·5%)	3521	1091 (31·0%)	1·82 (1·72 to 1·93; p<0·0001)
At age 180 days	3539	127 (3·6%)	3199	13 (0·4%)	8·83 (5·0 to 15·6; p<0·0001)
Not breastfed					
At age 28 days	4470	116 (2·6%)	3914	160 (4·1%)	0·63 (0·50 to 0·81; p=0·0002)
At age 90 day	3961	123 (3·1%)	3521	175 (5·0%)	0·62 (0·50 to 0·79; p=0·0001)
At age 180 days	3539	254 (7·2%)	3199	343 (10·7%)	0·67 (0·57 to 0·78; p<0·0001)
Growth					
WAZ					
At age 28 days	4380	−2·64 (0·92)	3813	−2·77 (0·91)	0·12 (0·08 to 0·16; p<0·0001)
At age 90 days	3772	−2·43 (1·04)	3340	−2·50 (1·06)	0·07 (0·02 to 0·12; p=0·006)
At age 180 days	3499	−2·24 (1·10)	3142	−2·23 (1·13)	−0·02 (−0·07 to 0·04; p=0·545)
LAZ					
At age 28 days	4379	−2·43 (0·99)	3812	−2·49 (0·99)	0·06 (0·01 to 0·10; p=0·011)
At age 90 days	3772	−2·08 (1·04)	3340	−2·12 (1·06)	0·04 (−0·01 to 0·09; p=0·147)
At age 180 days	3499	−1·91 (1·06)	3143	−1·86 (1·07)	−0·05 (−0·10 to 0·00; p=0·074)
WLZ					
At age 28 days	4275	−1·02 (1·06)	3725	−1·16 (1·10)	0·14 (0·09 to 0·19; p<0·0001)
At age 90 days	3771	−0·96 (1·13)	3339	−1·02 (1·17)	0·06 (0·01 to 0·12; p=0·025)
At age 180 days	3499	−1·30 (1·11)	3142	−1·32 (1·14)	0·03 (−0·03 to 0·08; p=0·354)
Severely underweight (WAZ <−3)					
At age 28 days	4380	1329 (30·3%)	3813	1363 (35·8%)	0·85 (0·80 to 0·90; p<0·0001)
At age 90 days	3772	945 (25·1%)	3340	938 (28·1%)	0·89 (0·82 to 0·97; p=0·005)
At age 180 days	3499	763 (21·8%)	3142	718 (22·9%)	0·95 (0·87 to 1·05; p=0·316)
Severely stunted (LAZ <−3)					
At age 28 days	4379	1092 (24·9%)	3812	1023 (26·8%)	0·93 (0·86 to 0·00; p=0·054)
At age 90 days	3772	630 (16·7%)	3340	598 (17·9%)	0·93 (0·84 to 1·03; p=0·189)
At age 180 days	3499	487 (13·9%)	3143	415 (13·2%)	1·05 (0·93 to 1·19; p=0·402)
Severely wasted (WLZ <−3)					
At age 28 days	4275	175 (4·1%)	3725	210 (5·6%)	0·73 (0·60 to 0·89; p=0·002)
At age 90 days	3771	149 (4·0%)	3339	158 (4·7%)	0·84 (0·67 to 1·04; p=0·113)
At age 180 days	3499	216 (6·2%)	3142	232 (7·4%)	0·84 (0·70 to 1·00; p=0·052)
Head circumference, cm					
At age 28 days	3686	34·0 (1·2)	3124	33·9 (1·2)	0·07 (0·01 to 0·13; p=0·016)
At age 90 days	3209	37·2 (1·3)	2776	37·2 (1·2)	0·03 (−0·03 to 0·10; p=0·342)
At age 180 days	3135	40·0 (1·3)	2783	39·9 (1·4)	0·03 (−0·04 to 0·10; p=0·385)

Data are n, n (%), and mean (SD), with outcome measures of adjusted risk ratio for breastfeeding outcomes and adjusted mean difference or adjusted risk ratio for growth outcomes. WAZ=weight for age Z score. LAZ=length for age Z score. WLZ=weight for length Z score. *Risk ratio and mean are adjusted for children enrolled within the same household.

Table 4: **Effect of community-initiated kangaroo mother care on breastfeeding and growth (secondary outcomes)**

the control group (0·31, 0·15–0·66; p=0·002). Care seeking from an appropriate provider within 24 h of onset of symptoms for possible serious bacterial infection (1·32, 1·15–1·50; p=0·0001) and for local infection (2·04, 1·37–3·05; p=0·0005) occurred more significantly in the intervention group than in the control group between enrolment and age 28 days, but no such effect was seen for diarrhoea or pneumonia at age 90 days (table 5).

In our prespecified subgroup analyses of the primary outcomes, we found no evidence of modification of the survival effect of community-initiated kangaroo mother care (appendix p 2). The tests for heterogeneity of HR across subgroups defined by sex, weight category at enrolment, and age at enrolment all had p values greater than 0·05. In our post-hoc subgroup analyses, no difference was seen in the survival effect of

	Intervention group	Control group	Adjusted risk ratio*
Infants hospitalised			
Between enrolment and age 28 days	580/4470 (13·0%)	460/3914 (11·8%)	1·10 (0·98–1·24; p=0·094)
Between enrolment and age 180 days	852/3653 (23·3%)	793/3331 (23·8%)	0·98 (0·90–1·07; p=0·637)
Morbidities			
Between enrolment and age 28 days			
Possible serious bacterial infection	919/4470 (20·6%)	904/3914 (23·1%)	0·89 (0·82–0·97; p=0·005)
Local infection	390/4470 (8·7%)	300/3914 (7·7%)	1·14 (0·98–1·32; p=0·080)
Diarrhoea or dysentery	235/4470 (5·3%)	334/3914 (8·5%)	0·62 (0·52–0·72; p<0·0001)
In the 2 weeks preceding 90-day visit			
Diarrhoea	640/4042 (15·8%)	609/3612 (16·9%)	0·94 (0·85–1·04; p=0·229)
Diarrhoea with symptoms of dehydration or dysentery	9/4042 (0·2%)	26/3612 (0·7%)	0·31 (0·15–0·66; p=0·002)
Pneumonia	53/4042 (1·3%)	81/3612 (2·2%)	0·58 (0·41–0·82; p=0·002)
Severe pneumonia	39/4042 (1·0%)	60/3612 (1·7%)	0·58 (0·39–0·87; p=0·008)
Care seeking for morbidity			
Between enrolment and age 28 days			
Possible serious bacterial infection			
Care sought from an appropriate provider	385/919 (41·9%)	297/904 (32·9%)	1·28 (1·13–1·44; p=0·0001)
Care sought within 24 h of identification of illness	349/919 (38·0%)	261/904 (28·9%)	1·32 (1·15–1·50; p=0·0001)
Local infection			
Care sought from an appropriate provider	104/390 (26·7%)	37/300 (12·3%)	2·16 (1·53–3·05; p<0·0001)
Care sought within 24 h of identification of illness	77/390 (19·7%)	29/300 (9·7%)	2·04 (1·37–3·05; p=0·0005)
In the 2 weeks preceding the 90-day visit			
Diarrhoea			
Care sought from an appropriate provider	65/640 (10·2%)	53/609 (8·7%)	1·17 (0·82–1·65; p=0·386)
Care sought within 24 h of identification of illness	46/640 (7·2%)	39/609 (6·4%)	1·12 (0·74–1·69; p=0·583)
Pneumonia			
Care sought from an appropriate provider	13/53 (24·5%)	21/81 (25·9%)	0·95 (0·52–1·73; p=0·857)
Care sought within 24 h of identification of illness	11/53 (20·8%)	18/81 (22·2%)	0·93 (0·48–1·82; p=0·841)

Data are n/N (%) or adjusted risk ratio with 95% CIs and p value in parentheses. Hospitalisations are admissions to and treatment in hosptial. *Adjusted for children enrolled within the same household.

Table 5: **Effect of community-initiated kangaroo mother care on morbidity, care seeking, and hospitalisations (secondary outcomes)**

community-initiated kangaroo mother care by gestation at birth in the neonatal period and from enrolment to 180 days (appendix p 3). Similarly, no difference was seen in the survival effect of the intervention by weight and gestational age categories in the neonatal period (appendix p 4). For the period from enrolment to 180 days, the effect of the intervention was similar among preterm appropriate-for-gestational age and term small-for-gestational age subgroups from enrolment to 180 days; however, no benefit from the intervention was seen in the preterm small-for-gestational age subgroup (for survival at age 180 days, $p_{interaction}$=0·0176; appendix p 4). The number of deaths reduced with increase in duration of skin-to-skin contact per day (appendix p 5). Notably, the intervention substantially reduced mortality even in infants weighing more than 2000 g to 2250 g at enrolment (deaths between enrolment and age 28 days: RR 0·60, 95% CI 0·37–0·97; deaths between enrolment and 180 days of age: RR 0·64, 0·46–0·89; appendix p 2). The effect of community-initiated kangaroo mother care on the primary outcomes by weight and length gain, and moderate malnutrition are shown in the appendix (p 6). Infants in the intervention group gained 50 g additional weight during the neonatal period compared with those in the control group.

Discussion

We found that community-initiated kangaroo mother care in babies with low birthweight (1500–2250 g) who did not have substantial comorbidities and were able to feed properly, enrolled within 72 h of birth, substantially improved survival compared with usual care. Our findings suggest that 83 babies with low birthweight would need to be given community-initiated kangaroo mother care to prevent one early infant death (ie, within 180 days of birth); and to 150 babies with low birthweight to prevent one neonatal death (ie, within 28 days of birth). The global estimates assume that approximately 70% of 2·5 million neonatal deaths occur in infants with low birthweight[2] and about half of these deaths occur after the first day of life.[22] Therefore, the 30% efficacy of the community-initiated kangaroo mother care intervention to prevent death between birth and age

28 days implies that it has the potential to prevent about 236 250 neonatal deaths every year if 90% coverage can be achieved. The potential number of lives saved would be even larger if the efficacy of the intervention in preventing deaths beyond age 28 days is taken into consideration.

The substantial reduction in mortality observed in the intervention group might have been mediated by the higher prevalence of exclusive breastfeeding and lower proportion of babies who were not breastfed in the intervention group compared with the control group and the reduced risk of possible serious bacterial infection, diarrhoea, and pneumonia; reduced risk of wasting; and improved care-seeking behaviour compared with the control group. Interventions to increase exclusive breastfeeding rates and reduce the proportion of babies who are not breastfed have been shown to be highly effective in reducing newborn baby and infant deaths.[23] Although reduced exposure to pathogens might have played a role in the benefits of kangaroo mother care, other pathways that we did not measure in this trial might have contributed to a reduction in morbidity (eg, breastmilk quality and quantity, gut inflammation, gut microbiome, infant skin integrity, and maternal mental health). Severe wasting is known to increase morbidity and mortality. The possibility of long-term developmental consequences in babies who are born small in whom severe wasting occurs in infancy is not well established.[24] Infants in the community-initiated kangaroo mother care group gained 50 g additional weight during the neonatal period compared with those in the control group. A pooled estimate from a Cochrane Review of kangaroo mother care showed a 4 g per day additional weight gain compared with conventional neonatal care, equivalent to 112 g over a 28-day period. A possible reason for lower benefit in weight gain in our study might be because kangaroo mother care was not given 24 h a day every day. The differences in growth were not sustained to age 6 months because other factors might have diluted the effect of the intervention during the course of follow-up (eg, asymptomatic infections, issues associated with gut enteropathies in resource-poor settings, no intervention beyond 28 days of age, non-exclusive breastfeeding). However, an effect was evident on severe wasting at age 6 months.

The improved care-seeking behaviour observed in the intervention group compared with the control group might have resulted from the intimacy fostered by prolonged periods of skin-to-skin contact, frequent breastfeeding, and focus of the mother on the wellbeing of the vulnerable newborn baby. Increased attention and care from the mother and family is likely to promote early recognition of signs of illness and timely response.

The only other study to our knowledge that has assessed the effect of community-initiated kangaroo mother care on mortality of newborn babies and infants, although large in population size (4165 babies and infants) had substantial challenges in the implementation of the intervention and major data gaps made its findings inconclusive.[11] This study, by Sloan and colleagues, was a cluster randomised trial in which pregnant women and their families in the intervention clusters were taught kangaroo mother care during pregnancy and post-partum. The intervention was delivered to all babies with no exclusion criteria regarding birthweight or whether they were stable. Furthermore, about 40% of all neonates and 65% of neonates who died did not have any weight measurement within 7 days of birth, making it difficult to assess the effect of the intervention on the target population of infants with low birthweight. Also, the duration of skin-to-skin contact (in h) offered by mothers to their infants was very low (eg, 4·5 h [SD 4·8] in the first 2 days of life, 2·7 h [SD 3·4] in the next 5 days of life, 1·2 h [SD 2·4] in the second week of life, and 0·5 h [SD 1·4] for the remainder of the first month of life). Sloan and colleagues, acknowledging the problems, recommended that more rigorously implemented trials be undertaken to clarify the intervention effects.[11] The intervention in our study was designed and delivered only to infants with low birthweight (1500–2250 g). All babies with signs of illness and birthweight below 1500 g were referred to hospital as per government guidelines. To ensure long duration of skin-to-skin contact, the timing of visits was strategically planned, the quality of counselling was high, and practical support was provided to the mothers. Deep engagement was sought from the families for high compliance of the intervention. In India, for 4-6 weeks after delivery, women are kept in isolation and do not do household chores, which helped in increasing the duration and number of days of skin-to-skin care. Additionally, belt binders were provided to mothers to enable them to securely fasten the baby in the position for kangaroo mother care while doing household chores, if required. Finally, encouraging mothers to provide kangaroo mother care for 24 h a day, rather than providing kangaroo mother care for a few h a day, emphasising that the baby needs this kind of care all the time, helped in leading to a greater duration of kangaroo mother care per day.

Our findings are consistent with the results of intervention trials assessing kangaroo mother care initiated in hospitals.[6] A Cochrane review of kangaroo mother care in hospitals identified 21 studies with data for 3042 infants.[6] The review shows substantial reduction in mortality, severe infection, risk of hypothermia, and respiratory diseases, and improved early weight gain compared with conventional neonatal care. Our study, given its large size and quality, adds substantial weight to the evidence of the benefits of kangaroo mother care irrespective of the setting of initiation, and uniquely shows the efficacy of kangaroo mother care when started at home.

Our study has several strengths and limitations that merit consideration. The study size of 8402 infants is

more than double the number of infants included in the Cochrane review, which makes this the largest study to assess the effect of kangaroo mother care on newborn baby and infant survival. Randomisation resulted in similar baseline demographic characteristics between the intervention and control groups. The high follow-up, and the quality and completeness of ascertainment of all outcomes make selection bias highly unlikely. During the formative research, we identified barriers to implementing the intervention and found effective and pragmatic solutions in consultation with families and intervention workers. This formative research contributed to the high rates of adoption of community-initiated kangaroo mother care by caregivers.

Even though this trial was unmasked because of the nature of the intervention, measurement bias in assessment of primary outcomes is unlikely because the primary outcome was death and follow-up was almost complete. Furthermore, an independent team measured outcomes after the end of the 28-day intervention period. This team was kept unaware the infants' group allocations; however, because the team asked questions about skin-to-skin contact, it would have been possible to guess the group allocation.

The findings are generalisable to most infants with low birthweight, except those with very low birthweight (<1500 g) or who have substantial comorbidities. Vigilant tracking for pregnancy enabled early identification of births in the community, including those that were low birthweight. Over 80% of babies enrolled in the study were born in hospitals but were not given kangaroo mother care before discharge. Only 2·3% (215 of 9534) of potentially eligible babies, all below 1800 g, could not be enrolled in the trial because they did not return home within 72 h from the health facilities they were referred to. We did not enrol babies with weight under 1500 g or above 2250 g. According to Indian guidelines, babies weighing under 1500 g should be managed in health facilities and those weighing 2250 g at the time of enrolment were likely to have weighed more at birth given the physiological weight loss between birth and within 72 h of birth.

Given that this was an efficacy trial, intervention delivery was largely in the hands of the intervention workers. The study workers' focus on community-initiated kangaroo mother care strengthened the quality of delivery of the intervention. However, the delivery system was realistic and compatible with current government guidelines for community health workers' provision of home care for babies with low birthweight, which involves multiple contacts at home from the first day of birth until age 6 months. The additional home visits to support kangaroo mother care, which are an integral part of the intervention package, might have contributed to improved care of babies.

This study has important public health implications. Our findings together with those from facility-initiated kangaroo mother care trials provide conclusive evidence that kangaroo mother care, irrespective of the setting where it is initiated, has major benefits for the survival and growth of babies and infants with low birthweight. This finding implies that kangaroo mother care should be initiated for stable babies with low birthweight as soon as possible and should be given right through the neonatal period for as long as possible every day, as feasible. However, providing kangaroo mother care at home might be challenging in settings where women do household chores or start work outside home soon after delivery. Implementation research studies in other low-income and middle-income country settings are needed to help assess the feasibility of delivering this intervention effectively.

Integrating kangaroo mother care into essential newborn baby care programmes that are currently operational in most countries should be a high priority. Attention to careful intervention design and delivery is crucial to achieve high coverage and quality. Identifying relevant local barriers, monitoring quality and equity in coverage, community mobilisation for generating awareness, and demand are important as this programme is scaled up. The findings of this study provide an opportunity for policy makers and managers to review and improve current design and architecture of programmes for the care of infants with low birthweight and babies who have the highest risk of death, poor physical growth, and impaired development.

Contributors

All authors contributed substantially to the conception or design of the study or to the data acquisition, analysis, or interpretation. They also contributed to the drafting of the manuscript or to revising it critically for important content. SM, ST, BD, KB, RG, MS, and BS were responsible for the day-to-day implementation of the study, data management, and analysis. NB, RB, JM, MKB, and HS provided technical support, monitoring, and coordination for the trial. The manuscript was prepared during a workshop with the participation of SM, ST, BD, KB, NB, RB, JM, MKB, and HS. The manuscript was reviewed and has final approval from all authors.

Declaration of interests

We declare no competing interests.

Data sharing

The dataset pertaining to the results reported in the manuscript will be made available to others only for health and medical research, subject to constraints of the consent under which the data was collected. De-identified individual participant data will be made available along with the data dictionary, study protocol, and informed consent form. Data will be available beginning 6 months and ending 5 years after publication of this Article. Requests for data should be made to Dr Nita Bhandari (nita.bhandari@sas.org.in) and Dr Halvor Sommerfelt (halvor.sommerfelt@uib.no). The requester should provide a methodologically sound secondary research proposal, approved by an independent review committee. The requester must be able to show their ability to carry out the proposed use of the requested dataset through their peer review publications and declare conflicts of interest in relation to the requested dataset and their funding sources. The authors reserve the right to refuse sharing of data in the face of potential adversarial conflicts of interest. A Data Sharing Agreement that meets the data sharing requirements of the Society for Applied Studies (New Delhi, India) and Centre for International Health, University of Bergen (Norway) will be signed with the data requester. Data must only

be used for the purpose described in the secondary research proposal as further stipulated in the Data Sharing Agreement. Data will be transferred only to requesters named in the original proposal and as specified in the relevant Data Sharing Agreement.

Acknowledgments

We acknowledge the contribution and support of the mothers and families of participating babies and infants and others in the community who supported this work. We thank the government of Haryana for the active participation and cooperation. We thank Vinod K Paul and Ramesh Agarwal (All India Institute of Medical Sciences, New Delhi, India); M L Jaipal and S S Bisht (Swami Dayanand Hospital, Shahdara, New Delhi, India); and Zelee Hill (Institute of Global Health and University College of London, London, UK) for their technical input. We thank the Department of Child and Adolescent Health and Development at WHO for technical support. We also acknowledge the support extended by the Knowledge Integration and Technology Platform of the Biotechnology Industry Research Assistance Council of the Department of Biotechnology, Government of India. We also thank Manju Bagdwal (Society for Applied Studies [SAS], New Delhi, India) for administrative support, and Girish Pant, Dinesh Dhingra, Manisha Gupta (SAS) for their contribution to data management. We also thank Sachiyo Yoshida (WHO) for her contributions to the randomisation and data management assistance. We thank the members of the data safety and monitoring committee: Betty Kirkwood (Chair), R M Pandey, Harish Chellani, and Vishwajeet Kumar for their outstanding contributions to the trial. This trial was supported by the Research Council of Norway through its Centers of Excellence Scheme (223269) and by the University of Bergen through funding to the Centre for Intervention Science in Maternal and Child Health.

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