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Kangaroo mother care for preterm or low birth weight infants: a systematic review and meta-analysis

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ABSTRACT

Importance The Cochrane review (2016) on kangaroo mother care (KMC) demonstrated a significant reduction in the risk of mortality in low birth weight infants. New evidence from large multi-centre randomised trials has been available since its publication.

Objective Our systematic review compared the effects of KMC vs conventional care and early (ie, within 24 hours of birth) vs late initiation of KMC on critical outcomes such as neonatal mortality.

Methods Eight electronic databases, including PubMed®, Embase, and Cochrane CENTRAL, from inception until March 2022, were searched. All randomised trials comparing KMC vs conventional care or early vs late initiation of KMC in low birth weight or preterm infants were included.

Data extraction and synthesis The review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and was registered with PROSPERO.

Main outcomes and measures The primary outcome was mortality during birth hospitalization or 28 days of life. Other outcomes included severe infection, hypothermia, exclusive breastfeeding rates, and neurodevelopmental impairment. Results were pooled using fixed-effect and random-effects meta-analyses in RevMan 5.4 and Stata 15.1 (StataCorp, College Station, TX).

Results In total, 31 trials with 15 559 infants were included in the review; 27 studies compared KMC with conventional care, while four compared early vs late initiation of KMC. Compared with conventional care, KMC reduces the risks of mortality (relative risk (RR) 0.68; 95% confidence interval (CI) 0.53 to 0.86; 11 trials, 10 505 infants; high certainty evidence) during birth hospitalisation or 28 days of age and probably reduces severe infection until the latest follow-up (RR 0.85, 95% CI 0.79 to 0.92; nine trials; moderate certainty evidence). On subgroup analysis, the reduction in mortality was noted irrespective of gestational age or weight at enrolment, time of initiation, and place of initiation of KMC (hospital or community); the mortality benefits were greater when the daily duration of KMC was at least 8 hours per day than with shorter-duration KMC. Studies comparing early vs late-initiated KMC demonstrated a reduction in neonatal mortality (RR 0.77, 95% CI 0.66 to 0.91; three trials, 3693 infants; high certainty evidence) and a probable decrease in clinical sepsis until 28-days (RR 0.85, 95% CI 0.76 to 0.96; two trials; low certainty evidence) following early initiation of KMC.

Conclusions and relevance The review provides updated evidence on the effects of KMC on mortality and other critical outcomes in preterm and low birth weight infants. The findings suggest that KMC should preferably be initiated within 24 hours of birth and provided for at least 8 hours daily.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Kangaroo mother care (KMC) is a simple and cost-effective intervention that decreases neonatal mortality and the risk of infection in low birth weight infants.

⇒ The WHO recommends the initiation of KMC among low birth weight infants after clinical stabilisation.

WHAT THIS STUDY ADDS

⇒ Compared with conventional care, KMC initiated either in the hospital or at home reduces mortality during birth hospitalisation or 28 days of age and probably reduces severe infection until the latest follow-up among preterm and low birth weight infants.

⇒ KMC provided for at least 8 hours a day probably results in greater benefits than a shorter duration of KMC.

⇒ KMC initiated within 24 hours of birth reduces neonatal mortality and may reduce clinical sepsis until 28 days compared with later initiation.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results of this updated review will likely influence health providers to initiate KMC in all low birth weight and preterm infants managed in health facilities and at home. Efforts might be undertaken to initiate KMC within 24 hours of birth and to provide it for at least 8 hours a day.

INTRODUCTION

Prematurity (gestational age <37 weeks) and low birth weight (defined as <2500 g) are important causes of neonatal and infant mortality and long-term neurodevelopmental disability.[1] Low- and middle-income countries (LMIC) have the highest burden of preterm

and low birth weight infants. Kangaroo mother care (KMC) is a simple and cost-effective intervention that has been shown to reduce neonatal mortality and the risk of infection in low birth weight infants.[2] The Cochrane review on KMC, published in 2016, included 21 studies involving 3042 infants and demonstrated a significant reduction in the risks of mortality and severe infection in low birth weight infants.[3]

New evidence from large multi-country and community-based randomised trials became available after the publication of the Cochrane review.[4 5] A few of these trials examined the effect of early KMC, that is, KMC initiated within the first 24 hours of delivery.[5 6] The timing of initiation of KMC is critical because KMC is usually commenced after the infant is stabilised. The WHO guidelines also recommend the initiation of KMC after clinical stabilisation. However, stabilisation of preterm/low birth weight neonates may take anything from hours to days, depending on the gestation, birth weight, and general condition at birth. The median age at initiation of KMC in the facility-based studies included in the Cochrane review varied from 3 to 24 days. KMC initiated after 3 days of life would not naturally reduce the risk of deaths occurring in the first 3 days, which account for about 62% of total neonatal deaths.[7] The efficacy and safety of early initiation of KMC – within 24 hours of life – are unknown.

This systematic review aimed to compare the effects of (a) KMC with conventional care and (b) early initiation, that is, KMC within 24 hours of age, with late initiation of KMC on neonatal and infant mortality and severe morbidities among low birth weight and preterm infants. This review would provide critical evidence for policymakers and other stakeholders and may help to formulate clinical practice guidelines.

METHODS

Inclusion and exclusion criteria

Our review included individually-randomised and cluster-randomised trials that compared KMC with conventional care or early initiation (ie, in the first 24 hours after birth) of KMC with late-initiated KMC among low birth weight and preterm infants, irrespective of the duration of KMC, infant stability at enrolment, study setting, and breastfeeding patterns. Trials reported as only abstracts were included if sufficient information on study methods was available to assess the eligibility and the risk of bias. We excluded quasi-randomised and crossover trials, studies evaluating KMC among term infants or those with birthweight >2500 g, and studies assessing KMC on only physiological parameters, pain scores, maternal mental health, infant colic, or during neonatal transport or as a part of a package of interventions.

Search strategy

We systematically reviewed the relevant publications by searching the electronic databases of MEDLINE (1966 to March 2022) via PubMed® and OVID, Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 1 to March 2022), EMBASE (1988 to March 2022), CINAHL (1981 to March 2022), and the databases PsycINFO, AMED, EMCARE, BNI from inception until March 2022. We used the search terms “kangaroo care,” “kangaroo mother care,” “skin-to-skin care,” and “neonates or infants” in the search strategy. The search was initially conducted until March 2021 (for the presentation of review findings to the WHO Guideline Development Group of the guidelines on the care of low birth weight infants); the search was then updated to March 2022. The search strategy, search results, and the definitions used in the review are provided in online supplemental file 1. We also searched the databases of clinical trials and reference lists of retrieved articles for eligible studies.

Outcomes

The primary outcome was mortality during birth hospitalisation or by day 28 of life. Other outcomes were mortality by 6–12 months of age, severe infections, infant growth, neurodevelopment, hypothermia, length of hospital stay, readmission to hospital, and exclusive breastfeeding at discharge and at one and 6 months of age.

Data extraction

The two review authors (SS and MJS) extracted data using a standardised and pre-tested data abstraction form. The data included study characteristics, sample size, details of KMC initiation, duration, breastfeeding, time of hospital discharge, study setting (hospital or community), outcomes including neonatal mortality, hypothermia, sepsis, rates of exclusive breastfeeding, and weight gain. Discrepancies, if any, were resolved by mutual discussion between the reviewers.

Quality assessment and statistical analysis

The review authors independently evaluated the quality of studies using Cochrane’s Risk of Bias-1 tool, extracted data, and synthesised the effect estimates – relative risks (RR) or mean difference (MD) – using RevMan version 5.4 (The Cochrane Collaboration, 2020) or Stata 15.1 (StataCorp, College Station, TX, USA). The RR and 95% confidence intervals (CI) were calculated based on the extracted frequencies and denominators. Results were pooled using fixed-effect meta-analyses using the Mantel-Haenszel method. The heterogeneity of the pooled studies was assessed using the test of homogeneity of study-specific effect sizes and the I^2 statistic, in addition to visual confirmation from forest plots. If substantial heterogeneity was detected, the reasons for heterogeneity were explored. If there was no critical clinical or methodological heterogeneity among the studies, we pooled their results using the random-effects model. We evaluated the likelihood of potential publication bias using funnel plots.

We used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach[8] to assess the quality of evidence for critical outcomes such as mortality at discharge, severe infection/sepsis at the latest follow-up, weight gain, exclusive breastfeeding, and neurodevelopmental outcomes. Evidence from randomised controlled trials was considered high quality; still, it could be downgraded by one or two levels for serious and very serious limitations, respectively, based on the risk of bias, imprecision, inconsistency, indirectness of study results, and publication bias. The review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and was registered in PROSPERO (CRD42021240336).

Planned subgroup analyses

For the comparison of KMC vs conventional care, we performed subgroup analyses according to different gestational and birth weight categories and by median duration KMC in hours (<8 hours, 8–16 hours, and >16 hours); time of initiation of KMC – early (≤24 hours of life) vs late initiation; stable vs unstable neonates; health facility vs community settings; and countries (high income vs LMIC settings).

Patient and public involvement

The study is a systematic review of the existing literature on the efficacy of KMC in preterm and low birth weight infants. No subjects were enrolled in the review. Therefore, parents, parent advisors, or the public were not involved in developing the research question and outcome measures.

Role of the funding source

The WHO, Geneva, funded the review. The WHO staff helped finalise the protocol and the manuscript; they had no role in the literature search, data extraction, or data analysis. The corresponding author had the final responsibility for the decision to submit for publication.

RESULTS

Of the 3458 records identified from the database and bibliographic searches, 31[4–6 9–35] studies enrolling 15 559 infants were included in the review (figure 1); 25 studies were conducted in LMIC (two from multiple countries[5 14] while seven were conducted in high-income countries[12 20 24 26 29 30 34] (Appendix). Twenty-seven studies compared KMC with conventional care, while four compared early with late initiation of KMC.[5 6 24 25] KMC was initiated in the health facility in 29 studies and at home (community) in two trials.[4 11] While the sample sizes of earlier hospital-based studies ranged from 28 to 777, the most recent facility-based study – WHO iKMC study[5] – had a sample size of 3211. Of the two community-based studies, one trial had enrolled around 8400 infants.[4] Only six studies included infants with birthweight <1500 g.[12 13 19 28 30 34] Figure 2 depicts the risk of bias in the included studies in specific domains. Many studies had an unclear or high risk of selection bias (due to a lack of information on allocation concealment) and detection bias (because the outcomes assessors were not masked to the intervention group).

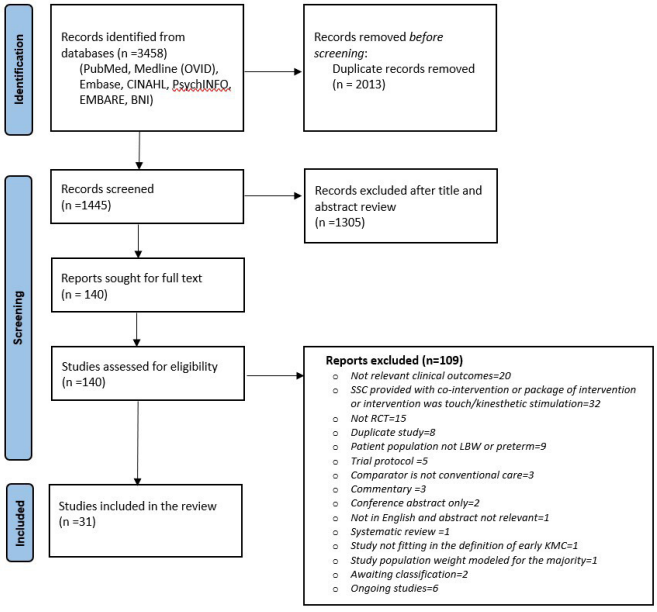

Figure 1 Flow chart of search results (adapted from PRISMA 2009 flow diagram).

KMC versus conventional newborn care

The comparison included 27 studies that enrolled 11 956 infants. The characteristics of included studies are provided in table 1. All but one study enrolled infants after stabilisation (variably defined in different studies as cardiorespiratory stability, off oxygen or any form of respiratory support, or off intravenous fluids). KMC was started within 24 hours after birth in two studies, between 1 and 7 days in 10 studies, and after 7 days in 12 studies (3 studies did not report the time of initiation). The duration of KMC was <8 hours in 9 studies, 8–16 hours in 9 studies, and >16 hours in 4 studies (5 studies did not report the duration).

Pooled analysis revealed a 32% reduction in mortality during birth hospitalisation or by 28 days after birth or 40 weeks of postmenstrual age (risk ratio (RR) 0.68; 95% CI (CI) 0.53 to 0.86; I^2=0%; 12 studies; 10 505 infants; fixed-effect model; high certainty evidence; figure 3). The funnel plot did not show any evidence of a potential publication bias (online supplemental efigure 1). The benefits of KMC in the primary outcome of mortality during birth hospitalisation or by 28 days of age were observed in all subgroup analyses: gestational age category (≤34 weeks vs. >34 weeks), weight at birth/enrolment (≤2000 g vs. >2000 g), setting (health facility vs. community) and time of initiation of KMC (within 24 hours after birth vs later); the benefits were greater when the daily duration of KMC was at least 8 hours per day than with shorter duration (online supplemental efigure 2). Pooled analysis of 4 studies that had reported mortality by 6 months

of age showed a 25% reduction in mortality (RR 0.75; 95% CI 0.62 to 0.92; fixed-effect model; high certainty of evidence).

KMC probably results in a 15% reduction in severe infection/sepsis at the latest follow-up (RR 0.85, 95% CI 0.79 to 0.92; 9 trials, 9847 infants; moderate certainty evidence) and 68% reduction in the risk of hypothermia (RR 0.32, 95% CI 0.19 to 0.53; 11 trials, 1169 infants; moderate-certainty evidence). Infants in the KMC arm had a higher gain in anthropometric parameters, namely weight gain per day and length and head circumference gain per week (table 2). The exclusive breastfeeding rates were higher at discharge/28 days of life (RR 1.48, 95% CI 1.44 to 1.52; 9 trials, 9983 infants, very low certainty evidence), but the evidence was uncertain; also, there was no difference in breastfeeding rates at 1–3 months of age. KMC may result in little to no difference in the Griffith Quotients or the risk of cerebral palsy at 12 months of corrected age[36] or IQ scores at 20 years of age.

Early-initiated versus late-initiated KMC

The evidence was derived from 4 trials that enrolled 3603 infants. One study was done in a high-come country (Sweden), 2 studies were done in low-income countries (Madagascar and The Gambia), and 1 study was multicountry conducted in LMICs (Ghana, India, Malawi, Nigeria, and Tanzania). All trials were conducted in health facilities. Infant stability at enrolment, duration of KMC achieved, and time of initiation of KMC in the included studies are provided in table 3. In two studies (Mörelius *et al*[24] and WHO iKMC)[5] KMC was initiated in the delivery room. Brotherton *et al*[6] enrolled moderately unstable infants in the early KMC arm and stable infants after >24 hour of admission in the control arm. Nagai *et al* began KMC within 24 hours of birth in the early arm and after 24 hours in the late arm.

Early-initiated KMC showed a reduction in the risks of mortality by 28 days of age (RR 0.78, 95% CI 0.66 to 0.92; 3 trials, 3533 infants, high certainty evidence; online supplemental efigure 3) and hypothermia by discharge or at 28 days (RR 0.74, 95% CI 0.61 to 0.90; high certainty evidence). It probably reduces the risk of clinical sepsis until 28-day follow-up (RR 0.85, 95% CI 0.76 to 0.96; table 4; low certainty evidence) and improves exclusive breastfeeding at discharge (RR 1.1.2, 95% CI 1.10 to 1.19; moderate certainty evidence). There was also a decrease in the length of hospital stay (table 4).

On subgroup analysis, there was evidence of a reduction in 28-day mortality for infants with GA ≤34 weeks and BW ≤2000, but there was little data for infants >34 weeks and weighing >2000 g at birth. The mortality reduced with a duration of KMC of at least >16 hours per day, with little data for daily KMC duration of <8 hours or 8–16 hours per day.

Quality of the evidence

For the comparison of KMC vs conventional newborn care, the certainty of the evidence was assessed as high for neonatal mortality and moderate for sepsis/severe infection and hypothermia (table 5). For early vs late-initiated KMC, the certainty of the evidence was high for neonatal mortality and hypothermia, moderate for exclusive breastfeeding at discharge, and low for nosocomial clinical sepsis (table 6). A few outcomes, such as weight gain, breastfeeding, and length of hospital stay, showed a high degree of heterogeneity, partly due to clinical and methodological heterogeneity among the studies (varied definitions of hypothermia and time points of assessment; different methods of breastfeeding assessment, etc.).

DISCUSSION

The systematic review showed that KMC reduces mortality during birth hospitalisation or by 28 days of age and probably reduces severe infection at the latest follow-up in preterm and low birth weight infants in health facilities and at home. KMC may result in a slight increment in growth parameters (weight and length) and exclusive breastfeeding rates at discharge. KMC may result in little to no difference in neurodevelopmental outcomes at 12

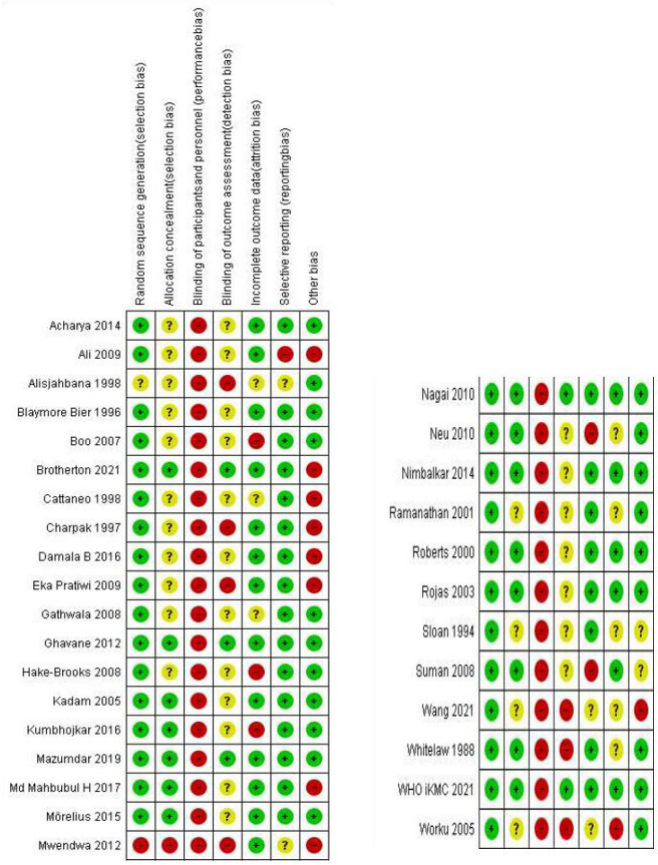

Figure 2 Risk of bias in included studies. Green circle indicates low-risk, red indicates high-risk and yellow, unclear-risk of bias.

Table 1 KMC vs conventional newborn care – characteristics of included studies

S. no	Author, Year	Country	Stabilisation status	Intervention group	Control group	Age at initiation of KMC (days)	KMC duration (hours per day*)	Last follow-up	Schema for follow-up
1.	Ali *et al*[10]	India	Stable	KMC in facility	Conventional warmer or cots	4.7	6.3±1.5 (range 4 to 12)	6 months corrected age	Weekly until 40 weeks' postmenstrual age, fortnightly until 3 months corrected age, and monthly until 6 months corrected age
2.	Alisjahbana *et al*[11]	Indonesia	Stable	KMC in community	Conventional home care	–	–	4 weeks after discharge	Weekly for 4 weeks after discharge
3.	Archarya *et al*[9]	Nepal	Stable	KMC in facility	Conventional warmer or cots	–	6	In-hospital	Not reported
4.	Bier *et al*[12]	USA	Stable	KMC in facility	Conventional clothed	29	–	6 months after hospital discharge	At 1, 3, and 6 months after hospital discharge
5.	Boo *et al*[13]	Malaysia	Stable	KMC in facility	Conventional NICU	25	1	In-hospital	Not reported
6.	Cattaneo *et a*[14]	Ethiopia	Stable	KMC in facility	Conventional open cribs, incubator or warmer	10	20	30 days postnatal age	Four times: at 3, 10, 20, and 30 days, and as usually scheduled at each hospital afterwards
7.	Charpak *et al*[15]	Columbia	Stable	KMC in facility	Conventional incubator	4	24	1 year and 20 years for a subset of enrolled subjected	At least once a week until 40 weeks'postmenstrual age; then monthly up to 3 months' corrected age, every 6 weeks until at least 6 months' corrected age, and every third month until 12 months' corrected age
8.	Bhavana *et al*[16]	India	Stable	KMC in facility	Conventional warmer or cots	–	13–14	Until 2.5 kg weight	After discharge, babies were followed-up twice a week for the first week and weekly until babies reached 2.5 kg
9.	Pratiwi *et al*[17]	Indonesia	Stable	KMC in facility	Conventional warmer or cots	1	10.0±1.8	In-hospital	–
10.	Gathwala *et al*[18]	India	Stable	KMC in facility	Conventional warmer or cots	1.7	10.2±1.5	3 months of age	Weekly until 3 months of age

Continued

Table 1 Continued

S. no	Author, Year	Country	Stabilisation status	Intervention group	Control group	Age at initiation of KMC (days)	KMC duration (hours per day*)	Last follow-up	Schema for follow-up
11.	Ghavane *et al*[19]	India	Stable	KMC in facility	Conventional warmer or cots	14	8	40 weeks postmenstrual age	Weekly until 40 weeks' postmenstrual age
12.	Hake-Brooks *et al*[20]	USA	Stable	KMC in facility	Conventional warmer or cots	1	–		Follow-up done telephonically at 6 weeks and 3 months and by an interview in the clinic at 6, 12, and 18 months
13.	Kadam *et al*[21]	India	Stable	KMC in facility	Conventional warmer or cots	3.2	9.8±3.7	In-hospital	–
14.	Kumbhojkar *et al*[22]	India	Stable	KMC in facility	Conventional warmer or cots	3	11.5	40 weeks' PMA or weight of 2500 g	Weekly until 40 weeks' postmenstrual age in preterm infants, or until a weight of 2500 g was reached
15.	Mazumder *et al*[4]	India	Stable	KMC in community	Conventional home care	32.7 hours	11.5 vs 0.2	28 days postnatal age and 1 year follow-up	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
16.	Md Mahbubul *et al*[23]	Bangladesh	Stable	KMC in facility	Conventional warmer or cots	1.8	–	In-hospital	Outcome measures ended before hospital discharge
17.	Mwendwa 2012	Kenya	Stable	KMC in facility	Conventional warmer or cots	10	8	In-hospital	None. Only in-hospital outcomes reported
18.	Neu and Robinson[26]	USA	Stable	KMC in facility	Conventional	15	1	6 months of age	Twice a week for 2 weeks, followed by weekly visits for 6 months
19.	Nimbalkar *et al*[27]	India	Stable	KMC in facility	Conventional	Immediate	17.0±0.3	In-hospital	–
20.	Ramanathan *et al*[28]2001	India	Stable	KMC in facility	Conventional warmer or cots	11.8	4	In-hospital	–

Continued

Table 1 Continued

S. no	Author, Year	Country	Stabilisation status	Intervention group	Control group	Age at initiation of KMC (days)	KMC duration (hours per day*)	Last follow-up	Schema for follow-up
21.	Roberts *et al*[29]	Australia	Stable	KMC in facility	Conventional clothed	31	1.6±0.9	6 months of age	At 6 weeks after discharge or at 3 months of age, whichever was later, and at 6 months
22.	Rojas *et al*[30]	USA	Stable	KMC in facility	Conventional incubator	19	1.3±0.7	In-hospital	–
23.	Sloan *et al*[31]	Ecuador	Stable	KMC in facility	Conventional incubator or crib	13	–	6 months of age	At 1, 1.5, 2, 3, 4, 5, and 6 months of age
24.	Suman *et al*[32]	India	Stable	KMC in facility	Conventional warmer or cots	3.7	13.5	40 weeks post menstrual age or until weight of 2500 g	Weekly until 40 weeks' postmenstrual age in preterm infants, or until a weight of 2500 g in term SGA infants
25.	Wang *et al*[33]	China	Stable	KMC in facility	Conventional		2.5	6 months corrected age	Follow-up appointments in outpatient setting at 40 weeks, 3 months, and 6 months CA
26.	Whitelaw *et al*[34]	UK	Stable	KMC in facility	Conventional incubator or crib	16	0.6 (0 to 1.5)	12 months of age	At 6, 9, and 12 months of age
27.	Worku *et al*[35]	Ethiopia	Unstable	KMC in facility	Conventional incubator or crib	10	Continuous	Until hospital discharge	–

*mean (± SD) duration of KMC in KMC group
CA, corrected age; KMC, Kangaroo mother care; NICU, give details; SGA, small for gesational age.

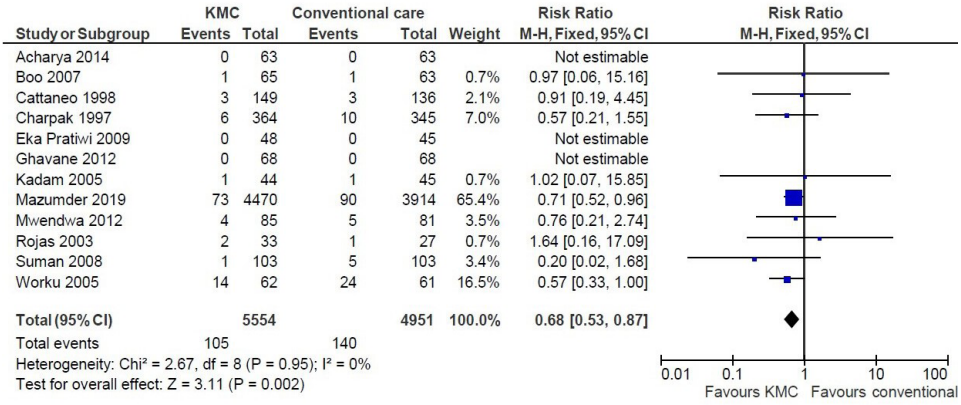

Figure 3 Kangaroo mother care (KMC) vs. conventional care –Risk ratio of mortality during birth hospitalisation or 28 days of life.

months compared with conventional care. Compared with delayed initiation (>24 hours) of KMC, early-initiated KMC (<24 hours) results in a 33% reduction in mortality by 28 days and a slight reduction in clinical sepsis by 28 days.

Three recent systematic reviews examined the effect of KMC compared with conventional care on infant clinical outcomes.[3 37 38] The Cochrane review in 2016 found 21 studies enrolling 3042 low birth weight infants.[3] Our systematic review used a similar search strategy and

Table 2 KMC vs conventional newborn care: key outcomes

Outcome and subgroup	Studies	N	Pooled relative risk (95% CI)
Mortality during birth hospitalisation or by 28 days of age or 40 weeks' PMA	12	10 505	0.68 (0.53 to 0.87)
Health facilities	11	2121	0.62 (0.41 to 0.94)
Community settings	1	8384	0.71 (0.52 to 0.96)
Mortality 6 months follow-up	4	8031	0.75 [(.62 to 0.92)
Health facilities	3	1047	0.74 (0.44 to 1.23)
Community settings	1	6984	0.76 (0.61 to 0.95)
Severe infection/sepsis at latest follow-up*	9	9847	0.85 (0.79, 0.92)
Health facilities	8	1463	0.50 (0.36, 0.69)
Community settings*	1	8384	0.89 (0.82, 0.97)
Hypothermia by discharge or by 40–41 weeks' PMA or 28 days follow-up	*11*	*1169*	0.32 (0.19, 0.53)
Exclusive breastfeeding at discharge or at 28 days of age	9	9983	1.48 (1.44, 1.52)
Health facilities	8	1599	1.18 (1.10, 1.27)
Community settings	*1*	*8384*	1.54 (1.49, 1.59)
Exclusive breastfeeding at 1 to 3 months' follow-up	*7*	*8139*	1.39 (0.99, 1.97)
Weight gain at latest follow-up (g/d)	11	1198	MD 4.08 (2.30, 5.86)
Length gain at latest follow-up (cm/week)	3	377	MD 0.21 (0.03, 0.38)
Head circumference gain at latest follow-up (cm/week)	5	652	MD 0.18 (0.09, 0.27)
Cerebral palsy at 12 months' corrected age	1	588	0.65 (0.21, 2.02)
Severe disability at 20 years	1	264	0.34 (0.09, 1.24)
Neurodevelopmental outcomes at 12 months of age using BSID-III			
Cognitive score	1	516	MD 0.21 (-1.84, 2.26)
Language score	1	516	MD –0.91 (-2.46, 0.64)
Motor score	1	516	MD –0.85 (-2.65, 0.95)

*In community settings, the diagnosis of sepsis or severe infection was based on the WHO definition of possible serious bacterial infection.
BSID-III, Bayley Scales of Infant Development-III; MD, mean difference; PMA, postmenstrual age.

Table 3 Early vs late-initiated KMC – characteristics of included studies

S. no	Author, Year	Inclusion criteria	Exclusion criteria	Intervention: early KMC as planned/ as achieved	Control: late KMC as planned/as achieved
1	WHO iKMC 2021	All infants with birth weight of 1.0 to 1.799 kg, regardless of gestation, type of delivery, or singleton or twin status (irrespective of clinical stability).	Infants who were unable to breathe spontaneously by 1 hour or who had a major congenital malformation	Immediately after birth; **Median initiation time of 1.3 hours after birth**	KMC began after the neonate recovered from preterm birth complications and was at least 24 hours old; Median initiation time 53.6 hours after birth
2	Brotherton 2021	Birth weight <2000 g and age 1–24 hours	Stable and severely unstable neonates were excluded. Triplets, major congenital malformations, severe jaundice, seizures, and lack of study bed were the other exclusion criteria	KMC initiated <24 hours after admission; **Median initiation time 13.6** hours	KMC once stable at >24 hours after admission; Median initiation time 104.5 hours
3	Mörelius 2015[24]	Vaginally born singleton preterm infants (32–35 weeks' gestation)	Infants with congenital malformations and severely unstable infants	Continuous skin-to-skin contact, beginning in the delivery room; **Median initiation time not provided**	KMC began in the NICU; On day 2, both groups were practicing KMC
4	Nagai 2010[25]	Birth weight <2500 g, age <24 hours, no serious malformations, and relatively stable clinical condition	Apnea and intravenous infusion	KMC begun soon as possible, within 24 hours post-birth; **Median initiation time 19 hours (IQR 13.00–23.00**)	KMC began after complete stabilisation (generally after 24 hours post-birth) Median initiation time 28.5 hours (IQR 25–40)

KMC, Kangaroo mother care; NICU, neonatal intensive care unit.

inclusion criteria and included studies until 2022. We found 10 newer studies that provided data on 12 517 additional infants with similar gestation and birth weight range. The Cochrane review reported a similar decrease in mortality at discharge or 40 weeks of postmenstrual age (RR 0.60, 95% CI 0.39 to 0.92; 8 trials, 1736 infants)

Table 4 Early vs late-initiated KMC – critical outcomes

Outcome	Studies	Number of participants	Pooled relative risk (95% CI)
Mortality by 28 days of life	3	3533	0.78 (0.66 to 0.92)
Mortality at 6 months of age	1	72	1.0 (0.15 to 6.72)
Sepsis until 28 days	2	3415	0.85 (0.76 to 0.96)
Exclusive breastfeeding at discharge	3	3464	1.12 (1.07 to 1.16)
Exclusive breastfeeding at 28 days of age	3	2841	1.01 (0.98 to 1.04)
Hypothermia at discharge or by 28 days	3	3553	0.74 (0.61 to 0.90)
Weight gain at 28-day follow-up (g/d)	1	204	MD –2.20 (–5.26 to 0.86)
Nosocomial sepsis			
Clinical sepsis	2	3415	0.85 (0.75 to 0.95)
Culture-positive sepsis	1	279	1.53 (0.44 to 5.31)
Re-admission to hospital at 4 weeks of age	1	73	1.95 (0.18 to 20.5)
Length of hospital stay (days)	3	3498	–0.30 (–0.31 to –0.29)

MD, mean difference.

Table 5 Summary of findings – KMC vs conventional newborn care

Summary of findings table 1. Kangaroo mother care compared with conventional newborn care in preterm or low birth weight infants

Patient or population: *preterm or low birth weight infants*
Setting: *Hospital or community/home*
Intervention: *Kangaroo mother care*
Comparison: *Conventional newborn care*

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with conventional neonatal care	Risk difference with Kangaroo mother care
Mortality during birth hospitalisation or 28 days of age or 40 weeks' PMA	10 505 (*12 RCTs*)	⊕⊕⊕⊕ *HIGH**	***RR 0.68*** (0.53 to 0.87)	*28 per 1000*	nine fewer per 1000 (from 13 fewer to four fewer)
Severe infection or sepsis until latest follow-up	*9847* (*9 RCTs*)	⊕⊕⊕*O* *MODERATE*†	***RR 0.85*** (0.79 to 0.92)	*215 per 1000*	32 fewer per 1000 (45 fewer to 17 fewer)
Hypothermia by discharge or 40 weeks' PMA or 28 days *after birth*	*1169* (*11 RCTs*)	⊕⊕⊕*O* *MODERATE*‡§	***RR 0.32*** (0.19 to 0.53)	*257 per 1000*	*175 fewer per 1000* (*from 208 fewer to 121 fewer*)
Weight gain at latest follow-up (g/d)	*1198* (*11 RCTs*)	⊕⊕*OO* *LOW*§¶	–	*Mean weight gain at latest follow-up was 17* grams/day	MD 4.08 g/day higher (2.3 higher to 5.86 higher)
Exclusive breastfeeding at discharge or at 40 to 41 weeks' PMA or at 28 days of age	*9983* (*9 RCTs*)	⊕*OOO* *VERY LOW* §**	***RR 1.48*** (1.44 to 1.52)	*546 per 1000*	*262 more per 1000* (*from 240 more to 284 more*)
Neurodevelopmental outcome at 12 months' using BSID-III (stable LBW infants)	*516* (*1 RCT*)	⊕⊕*OO* *LOW*††‡‡§§	*Post-hoc equivalence testing using two one-sided tests of equivalence (TOST) demonstrated that composite scores for cognitive, language, and motor domains at 12 months among the study arms were statistically equivalent*		

GRADE Working Group grades of evidence
High certainty: *We are very confident that the true effect lies close to that of the estimate of the effect*
Moderate certainty: *We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different*
Low certainty: *Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect*
Very low certainty: *We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect*

*All 12 studies were at risk of performance bias because the participants/parents/clinical team were not masked to intervention. In all except Mazumder's study (weightage 65.4%), the outcome assessors were also not masked to the intervention. However, mortality being a 'hard' outcome, we did not downgrade for either performance or outcome assessment bias. Six studies, Acharya, Boo, Cattaneo, Charpak, Eka Prawiti, and Worku, contributing to 26.3% weightage in the pooled analysis, are at unclear risk of allocation concealment. Four studies - Boo, Cattaneo, Suman, and Worku - were also at risk of attrition bias due to incomplete outcome data. But they together account for only 22.7% weightage in the pooled analysis. The risk of bias was therefore not downgraded to 'serious' risk. One study Mwendwa 2012 was at high risk of bias for random sequence generation and allocation concealment. It contributed to 3.5% weightage. The total number of neonates enrolled is quite large (~10 500) – therefore, the evidence was not downgraded for imprecision.
†All studies were at moderate or severe risk of bias as participants and outcome assessors were not masked to intervention and outcomes. Only in Mazumder *et al* the assessors were masked to the intervention. Though culture-positive sepsis is a 'hard' outcome, the largest study Mazumder 2019 that accounted for 91% of weightage defined sepsis based on WHO PSBI signs and not on culture positivity; five studies (4.7% weightage; Ali 2009, Eka Prawiti 2009, Kadam 2005, Kumbhojkar 2016, Suman 2008) did not define sepsis in their studies; another study (Rojas 2008; weightage 9.2%) defined it as both clinical and culture-positive sepsis, and only Boo 2007 defined it as culture-positive sepsis. Therefore, the risk of bias was downgraded to 'serious' risk. Allocation concealment was unclear in four studies (Charpak 1997, Ali 2009 Boo, 2007 Eka Pratiwi 2009) that together contribute to 4.8% weightage.
‡All studies were at high risk of outcome ascertainment bias as participants and outcome assessors were not masked to intervention and outcomes. However, weight gain is considered a 'hard' outcome. Therefore, we did not downgrade for the risk of bias. Seven studies (Acharya, Ali, Bier, Boo, Cattaneo, Gathwala, and Ramanathan accounting for 64% weightage) were at risk of allocation concealment bias. Therefore, the evidence was downgraded for 'serious' risk of bias.
§Substantial heterogeneity >50%.
¶All studies were at high risk of outcome ascertainment bias as participants and outcome assessors were not masked to intervention and outcomes. However, weight gain is considered a 'hard' outcome. Therefore, we did not downgrade for the risk of bias. Seven studies (Acharya, Ali, Bier, Boo, Cattaneo, Gathwala, and Ramanathan accounting for 64% weightage) were at risk of allocation concealment bias. Therefore, the evidence was downgraded for 'serious' risk of bias.
**All studies were at high risk of outcome ascertainment bias because the participants and outcome assessors were not masked to the intervention and the outcome was not a 'hard' outcome. Allocation concealment was unclear in six studies that accounted for 82% of weightage.
††95% CI overlap no effect (ie, CI includes RR of 1.0).
‡‡One study Charpak 1997 with moderate risk of bias (unclear allocation concealment; lack of blinding of participants/parents/clinical team and outcome assessors). The follow-up rate at 12–18 months was 80%. The characteristics of infants of KMC and conventional groups who completed follow-up were similar.
§§Single study.
MD, Mean difference; PMA, Postmenstrual age; RR, Risk ratio.

and similar effects on infection, hypothermia, and anthropometry. However, the certainty of the evidence was graded as moderate to very low in the Cochrane review. The addition of information from 12,000-odd infants has improved the precision and certainty of the evidence of the critical outcomes in the current review. In 2020, a systematic review of 416 preterm neonates reported that KMC significantly reduced apneic events in

Table 6 Summary of findings – early initiated KMC vs late-initiated KMC in preterm or low-birth weight infants

Summary of findings table 2. Early initiated KMC compared with late initiated KMC in preterm or low birth weight infants

***Patient or population**: preterm or low birth weight infants*
***Setting**: Hospital or community/home*
***Intervention**: Early initiated KMC (within 24 hours after birth)*
***Comparison**: late initiated KMC (more than 24 hours after birth)*

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with late initiated KMC	Risk difference with early initiated KMC
Mortality by 28 days of age	3693 (3 RCTs)	⨁⨁⨁⨁ HIGH*	RR 0.77 (0.66 to 0.91)	156 per 1000	36 fewer per 1000 (53 fewer to 14 fewer)
Sepsis until 28 days	3694 (2 RCTs)	⨁⨁◯◯ LOW†‡	RR 0.85 (0.76 to 0.96)	249 per 1000	37 fewer per 1000 (from 60 fewer to 10 fewer)
Exclusive breastfeeding - At discharge	3464 (3 RCTs)	⨁⨁⨁◯ MODERATE‡§	RR 1.12 (1.07 to 1.16)	688 per 1000	83 more per 1000 (from 48 more to 110 more)
Exclusive breastfeeding at 28 days of age	2841 (3 RCTs)	⨁⨁⨁◯ MODERATE‡§¶	RR 1.01 (0.98 to 1.04)	855 per 1000	nine more per 1000 (from 17 fewer to 34 more)
Hypothermia at discharge or by 28 days	3713 (4 RCTs)	⨁⨁⨁⨁ HIGH**	RR 0.74 (0.61 to 0.90)	109 per 1000	28 fewer per 1000 (from 42 fewer to 11 fewer)
Weight gain at 28 day follow-up (g/d)	204 (1 RCTs)	⨁⨁◯◯ LOW††‡‡	–	Mean weight gain at 28 day follow-up was 12.5 g/day	MD 2.2 g/day lower (5.26 lower to 0.86 higher)

*Though parents and the clinical team were not masked to the intervention, mortality was considered a 'hard' outcome, so the evidence was not downgraded.
†In both studies, the participants and clinicians were not masked to the intervention. Both diagnosed sepsis based on WHO's PSBI definition and not by culture positivity. Though the outcome assessment was done by an independent team who was unaware of group allocation in the WHO iKMC study (accounting for 95% of weightage), the risk of performance bias by the clinical team and researchers in a subjective outcome like clinical sepsis or PSBI cannot be ruled out.
‡Significant heterogeneity >50%.
§In three studies, participants and the clinical team were masked. Assessment of exclusive or any breastfeeding is prone to bias. However, the outcome assessment in the WHO iKMC study, which contributed to the maximum weightage in the pooled analysis, was done by an independent team not involved in the intervention. The risk of performance bias – by the clinical team or researchers – in breastfeeding outcomes was considered low; hence, the evidence was not downgraded.
¶95% CI overlap no effect (ie, CI includes RR of 1.0), but they also exclude important benefits as well as important harm; so not downgraded.
**All three studies were at low risk of bias. Although parents and clinical team were not masked to the intervention, measurement of temperature is less prone to outcome assessment bias. Hence not downgraded.
††A single study that was prematurely terminated at 75% enrolment. We did not downgrade for lack of masking of caregivers or outcome assessors because weight measurement is an objective outcome.
‡‡95% CI overlaps no effect (ie, CI includes RR of 1.0).
MD, Mean difference; RR, Risk ratio.

preterm neonates.[38] Another review in 2019 concluded that KMC had a significant positive impact on growth and breastfeeding rates in very low birth weight (VLBW) neonates.[37]

We investigated the effect of mean duration KMC in hours and prespecified three categories (<8 hours, 8–16 hours, and >16 hours). The effects on mortality were comparable in the >16 hour and 8–16 hour groups, but there was insufficient data in the <8 hours group. The Cochrane review (2016) explored the effects of the duration of KMC in three different categories; <2 hours and 6–15 hours, and >20 hours per day, and found benefits only when KMC was done for 20 hours or more. We found beneficial effects of KMC in prespecified subgroups of ≤2.0 kg and >2.0 kg and infants with gestational age ≤34 and >34 weeks at birth. T**he two community-**based studies that enrolled infants at home also showed significant benefits on mortality. We found no additional trials – other than the study by Worku *et al* included in the Cochrane review – that compared KMC with conventional care in *unstable* infants.

Only one systematic review – the Cochrane review published in 2016 – has evaluated the effects of early vs late initiation of KMC in low birth weight infants. It also used a cut-off of 24 hours to define early initiation but found only one study of 73 relatively stable low birth weight infants.[25] Our review included three additional studies that recruited 3530 preterm/low birth weight infants and found significant beneficial effects with early initiation of KMC.[5 6 24]

The results of our review have substantial implications for policymaking, particularly in LMIC. First, KMC should be provided to all low birth weight and preterm infants irrespective of the settings – both health facilities and at home. Second, given the probable dose-effect response, KMC should preferably be practiced for at least 8 hours a day for optimal benefits. Third, KMC should be initiated within the first 24 hours of life. Indeed, our findings have helped to make recommendations on KMC in the new WHO guidelines on the care of preterm and low birth weight neonates.[39]

The strengths of the current review include a comprehensive and systematic search of the literature with updated evidence to March 2022. Compared with the existing Cochrane reviews on KMC, our review identified additional studies that had enrolled almost 13 000 low birth weight infants, which resulted in high precision of estimates and improved the certainty of the evidence. The review also had some limitations. The included studies were not blinded, although outcome assessors were blinded in many studies. However, the risk of bias in the included studies was generally low, and the certainty of the evidence for the primary outcomes was moderate to high. Very low birth weight, extremely preterm neonates, and severely unstable neonates were often excluded from studies. More evidence is needed before extrapolating the study results in these high-risk groups.

To conclude, our findings support the practice of KMC for preterm and low birth weight infants as soon as possible after birth and for at least 8 hours a day. Future research should focus on overcoming barriers and facilitators to large-scale implementation of KMC in facility and community settings. Data on long-term neurodevelopmental outcomes are also needed.

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