All-cause mortality and infection-related outcomes of hospital-initiated kangaroo care versus conventional neonatal care for low-birthweight infants: a systematic review and meta-analysis

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Summary

Background Kangaroo care has a well-established role in preterm infant stabilisation and in protecting low-birthweight newborns from mortality. Yet kangaroo care is far from fully embedded in conventional inpatient neonatal care practice. The evidence on infection outcomes of hospital-initiated kangaroo care is unclear. We aimed to evaluate the existing evidence to understand the role of hospital-initiated kangaroo care in preventing mortality, sepsis, and invasive infection in low-birthweight infants.

Methods In this systematic review and meta-analysis, we searched Embase, MEDLINE, Cochrane Library, and Web of Science databases for literature published between Jan 1, 2013, and Feb 26, 2025. At least two authors independently undertook study selection, data extraction, and quality assessment. Reports of randomised controlled trials presenting data on at least one of our set primary outcomes (all-cause mortality and/or sepsis and/or invasive infection) comparing kangaroo care with conventional neonatal care in low-birthweight infants (<2500 g) were eligible for inclusion. The primary outcomes were all-cause mortality, sepsis, and invasive infection (composite of necrotising enterocolitis, pneumonia, meningitis, and other severe infections). Hypothermia and apnoea were assessed as adverse events. A random effects model was used to estimate the pooled overall effect sizes for each outcome, presented as odds ratios (OR [95% CI]), with between-study heterogeneity assessed by Cochran's Q test and sources of heterogeneity investigated using univariable random effects meta-regression analyses. This study is registered with PROSPERO, CRD42024501546.

Findings We synthesised data from 29 studies, mainly from lower-middle income countries, including 17 513 low-birthweight infants. Most studies were moderate-to-high quality. 25 (86%) of 29 studies reporting all-cause mortality were included in the meta-analysis of hospital-initiated kangaroo care, which showed that hospital-initiated kangaroo care reduced all-cause mortality (pooled OR 0·77 [95% CI 0·67–0·89]; high-quality evidence, with I^2=0%). 17 (59%) of 29 trials reported sepsis as an outcome, and the pooled results showed that kangaroo care reduced the odds of sepsis (OR 0·55 [95% CI 0·37–0·82]; moderate-quality evidence, with I^2=53%). Similarly, among the 11 (38%) of 29 studies reporting invasive infection, the pooled results showed that kangaroo care reduced the odds of invasive infection (OR 0·49 [95% CI 0·33–0·74]; moderate-quality evidence, with I^2=0%). Kangaroo care was associated with a significant reduction in the odds of sepsis-related or invasive infection-related mortality (OR 0·63 [95% CI 0·47–0·84], I^2=0%, high-quality evidence), hypothermia (0·28 [0·16–0·46], I^2=72%, moderate-quality evidence), and apnoea (0·46 [0·25–0·85], I^2=45%, moderate-quality evidence). Meta-regression showed that between-study heterogeneity was due to variation in level of kangaroo care offered as part of conventional neonatal care.

Interpretation The joint protective effect of hospital-initiated kangaroo care against all-cause mortality and infection in low-birthweight infants reinforces its importance in routine neonatal care across settings, in line with WHO recommendations. The extent of the protective effects in low-birthweight infants through averted infections suggests that kangaroo care should be integrated into standard infection prevention and control practice globally.

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Introduction

High-quality maternal and neonatal care is crucial to achieving low neonatal mortality rates.[1,2] Preterm birth, birth complications, infections, and congenital anomalies are leading causes of neonatal death, accounting for 47% of deaths in children under 5 years of age.[3,4] Low-birthweight infants (<2500 g), who might be both preterm and small-for-gestational-age, accounted for 15% of births in 2020 worldwide, with a greater prevalence in low-resource countries. Low-birthweight is a major risk factor for neonatal morbidity and mortality, as well as for lifelong disability.[5] Consequently, neonatal

Research in context

Evidence before this study

A 2016 Cochrane review supports the use of kangaroo care in low-birthweight infants as an alternative to conventional neonatal care, mainly in resource-limited settings, with a significant reduction in mortality and severe infection. A 2023 systematic review and meta-analysis confirmed the mortality risk reduction with kangaroo care compared with conventional care in low-birthweight or preterm newborns, but the evidence on infection outcomes is unclear, and outcomes such as infection-related or sepsis-related mortality or bacterial colonisation were not addressed. For an up to date evaluation of hospital-initiated kangaroo care and its role in all-cause mortality, sepsis, invasive infection, sepsis-related or infection-related mortality, bacterial colonisation, hypothermia, and apnoea in low-birthweight infants, we searched Embase, MEDLINE, Cochrane Library, and Web of Science databases for literature published between Jan 1, 2013, and Feb 26, 2025, using the terms "infant, newborn" AND "kangaroo care" AND "randomised controlled trial" and no language restrictions. Considering only reports of randomised controlled trials presenting data on at least one outcome among all-cause mortality, sepsis, or invasive infection and comparing any kind of kangaroo care with conventional neonatal care in stabilised or non-stabilised low-birthweight infants, we extracted information about study setting, cohort, and kangaroo care and comparator characteristics, and outcomes.

Added value of this study

30 reports, providing data on 29 trials and 17 513 low-birthweight infants, demonstrate moderate-to-high quality of evidence of a beneficial effect of kangaroo care on neonatal outcomes. Many of the contributing trials, however, were small and underpowered for some of our selected outcomes, with few reported endpoints. Nevertheless, our meta-analysis confirms the role of in-hospital kangaroo care in reducing all-cause mortality, particularly for resource-limited settings, and lends support to kangaroo care's protective role against hospital-acquired sepsis, invasive infections, and infection-related mortality. Furthermore, kangaroo care appears protective against hypothermia and apnoea. Although bacterial colonisation was only reported in one trial, kangaroo care was protective against colonisation from meticillin-resistant staphylococci.

Implications of all the available evidence

Family-centred kangaroo care has clear and well-established benefits in infant stabilisation and in protecting low-birthweight newborns from adverse outcomes. Yet gaps in implementation of kangaroo care as part of standard neonatal care, in line with WHO recommendations, exist across all settings, with neonatal infection prevention and control (IPC) practice having sometimes been a barrier to kangaroo care. Although an important limitation of the current systematic review and meta-analysis lies in the heterogeneous nature of conventional neonatal care practices, which often encompass some level of kangaroo care, the results of our meta-analysis show not only that fear of neonatal infection should not preclude kangaroo care but that kangaroo care ought to be integrated into IPC practice across all settings. Future work should derive shared definitions for kangaroo care as an intervention, and larger randomised controlled trials powered on sepsis, invasive infection, and especially considering regular colonisation assessments are necessary.

care strategies prioritising low-birthweight infants managed in neonatal units with high risk of exposure to hospital pathogens and of nosocomial infections are key to reduce neonatal and childhood adverse outcomes.[6–8]

Kangaroo care is an evidence-based intervention to improve survival of low-birthweight neonates. According to WHO, it includes early, continuous, and prolonged skin-to-skin contact between infants, even if not yet medically stable, and the caregiver, with support for exclusive breastfeeding or breastmilk feeding and early discharge.[9] Skin-to-skin contact implies the action of holding the infant generally only wearing a nappy against the skin of the caregiver.

The implementation of kangaroo care to facilitate early discharge, minimising exposure to the hospital environment and maximising physiological care, might considerably reduce the risk of neonatal infections, alongside the well-established mortality benefits.[9] Kangaroo care is variably included in conventional care practices in inpatient neonatal settings of low-income, middle-income, and high-income countries.

Immediate or early kangaroo care is increasingly considered an effective intervention to prevent neonatal sepsis and sepsis-related mortality.[10,11] However, kangaroo care has not been extensively studied as a specific infection prevention and control (IPC) measure in neonatal units, regardless of setting, and its potential role in preventing bacterial colonisation and subsequent invasive infection and related mortality has not yet been fully established. Evidence from a 2016 Cochrane review supports the use of kangaroo care in low-birthweight infants as an alternative to conventional neonatal care, mainly in resource–limited settings, with a significant reduction in mortality and severe infection.[12] A recent systematic review and meta-analysis confirmed the mortality risk reduction with kangaroo care compared with conventional care in low-birthweight or preterm newborns, but the evidence on infection outcomes was less clear.[13] To our knowledge, outcomes such as infection-related or sepsis-related mortality or bacterial colonisation have not been addressed before. In this systematic review and meta-analysis, we compared the

effects of kangaroo care versus conventional neonatal care for low-birthweight infants on all-cause mortality, sepsis, invasive infection, sepsis-related or invasive infection-related mortality, and bacterial colonisation, considering hypothermia and apnoea as adverse events.

Methods

Search strategy and selection criteria

See Online for appendix

This systematic review and meta-analysis was conducted in line with PRISMA guidelines[14] (appendix p 3) and was prospectively registered with PROSPERO (CRD42024501546). MEDLINE, Embase, the Cochrane Library Central Register of Controlled Trials, and Web of Science were searched on Feb 26, 2025, with no language restrictions, for literature published since Jan 1, 2013. The full search strategy is described in the appendix (p 2); in brief, Medical Subject Heading and free-text terms for "infant, newborn" AND "kangaroo care" AND "randomised controlled trial" were combined. We further evaluated for inclusion the 21 studies from the 2016 Cochrane review[12] as well as records identified from citation searching. Reports of randomised controlled trials (RCTs) comparing kangaroo care with conventional neonatal care (potentially including some level of kangaroo care) in low-birthweight infants (weighing less than 2500 g at birth) were considered eligible for full-text review if presenting data on at least one of our set primary outcomes. Studies not reporting outcomes for low-birthweight infants, investigating interventions other than kangaroo care, or not providing granular data on the set primary outcomes were excluded. Duplicates were identified automatically, then checked manually and removed accordingly.

The types of kangaroo care described in the included reports could be delivered continuously or intermittently, by any caregiver, and either immediately (initiated within 2 h of birth[10]), early (initiated within the first 24 h of life[13]), or late (initiated after 24 h of life). Continuous and prolonged kangaroo care is inconsistently defined as long, uninterrupted sessions providing as many continuous hours as possible, or up to 20–24 h per day.[15] Most guidelines recommend at least 1 h of uninterrupted kangaroo care (shorter sessions might lead to exhaustion for the infant for the transfer to and from the caregiver), and WHO recommends target durations of 8–24 h kangaroo care per day.[16]

Two investigators (CM and KJ) independently screened records retrieved from the electronic database search for inclusion, assessing titles and abstracts before assessing full texts; they remained masked to each other's decisions, and disagreements were resolved by discussion with a third reviewer (JB). The Cohen's kappa score was used to evaluate inter-reviewer reliability.

A standardised predefined form was used for data extraction, which included information about the publication, study setting (including World Bank country classifications by income level[17,18]), study population, intervention, comparator, and outcomes, as well as descriptions of study cohort and intervention characteristics (birthweight, gestational age, median time to initiation of skin-to-skin contact, and kangaroo care daily duration). One reviewer (CM) extracted data, and another reviewer (KJ) checked the extracted data. Disagreements were resolved by discussion with a third reviewer (JB).

Data analysis

The primary outcomes were all-cause mortality, sepsis, and invasive infection (a composite outcome of necrotising enterocolitis, severe pneumonia, meningitis, and other severe health-care-associated infections, as separately reported by the included studies) within 28 days of birth or before discharge from hospital. For sepsis and invasive infection, we considered proven or suspected infection in any combination (including antibiotic administration for suggestive signs), as defined in individual studies. The secondary outcomes were mortality from sepsis or nosocomial bacterial invasive infection and bacterial colonisation (including resistant bacteria), as defined in individual studies. Hypothermia and apnoea were assessed as adverse events.

Measure of effect for both primary and secondary outcomes are presented as odds ratio (OR) with 95% CI. Risk of bias evaluation was done independently by two investigators (CM and KJ) using the Cochrane risk of bias 2.0 tool for RCTs, version Aug 22, 2019.[19] The quality of the evidence was assessed using the Grading of Recommendations Assessment Development and Evaluation (GRADE) approach (appendix p 3).[20] Disagreements were resolved by discussion. The quality rating of each study did not affect the inclusion in this review but was considered in the evidence synthesis.[19]

The effect sizes of kangaroo care and conventional care for each primary and secondary outcome, including adverse events, were compared by meta-analysis. The rarity of some outcome events necessitated methods suitable for the rare events settings[21,22] and treatment group continuity correction for handling studies with zero events.[22–24] To account for potential large between-study heterogeneity, a random effects model was used to estimate the pooled overall effects, with pooled OR calculated with the Mantel–Haenszel weighting approach. The DerSimonian–Laird estimator was used to assess the between-study variance (τ^2).[25] Relative risk ratios and p values were directly extracted from the only study reporting bacterial colonisation.

We used Cochran's Q test to assess and I^2 statistics to quantify between-study heterogeneity (I^2 <25% was considered low heterogeneity, 25-75% moderate heterogeneity, and >75% high heterogeneity). Sources of between-study heterogeneity were investigated using univariable random effects meta-regression analyses, including the following variables: population including extremely low-birthweight (<1000 g) infants; population

with mean gestational age younger than 32 weeks; immediate kangaroo care as intervention; intermittent kangaroo care as intervention; and conventional care including kangaroo care. Funnel plots were used to assess potential publication bias and small-study effects.[26]

Having considered the rarity of events and the low number of studies included in some of the meta-analyses, we quantified statistical heterogeneity in a common effect model as a sensitivity analysis using the Mantel–Haenszel weighting method.[27–29] The metabin function of the meta package in R 3.6.1 was used for all analyses.[30] Informed consent or approval by the local Ethics Committee was not required for this study.

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.

Results

The database search yielded 2275 records, from which 2265 records were excluded as they were duplicates or ineligible (figure 1). The Cohen's kappa score of

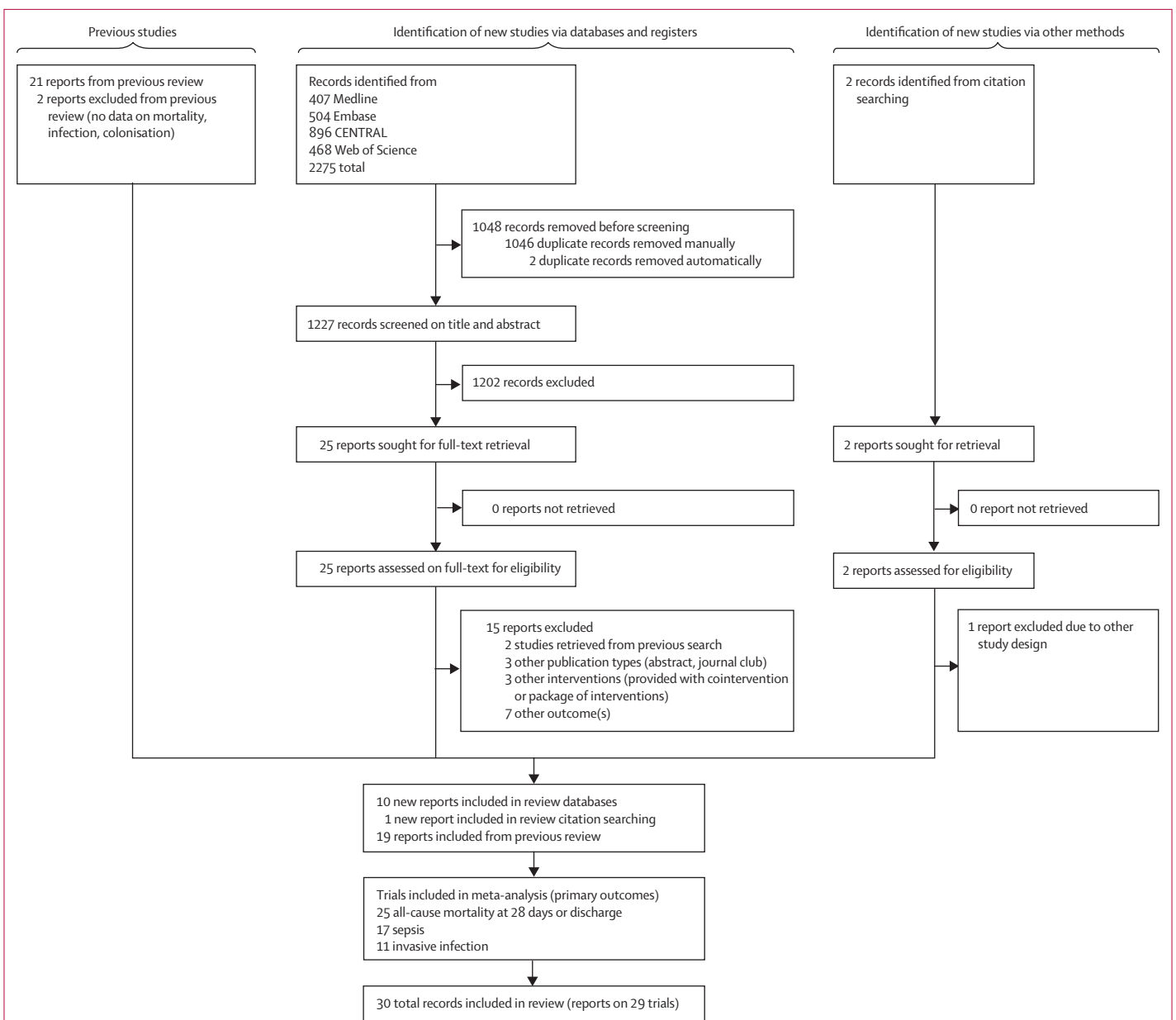

Figure 1: **Characteristics of studies included in systematic review**

	Country	Hospital or community setting	World Bank Classification	Human Development Index	Intervention description	Control description	Study population size	Birth weight category	Intervention group birthweight, g	Control group birthweight, g	Intervention group gestational age, weeks	Control group gestational age, weeks	Stabilised	Received non-invasive respiratory support	Received invasive respiratory support
Acharya, 2014[31]	Nepal	Hospital	Low-income	Medium	KC	Conventional care (no KC)	126	<2000 g	1385·9 (234·1)	1458·6 (172·7)	32·2 (2·4)	32·5 (1·9)	Yes	No	No
Ali, 2009[32]	India	Hospital	Lower-middle income	Medium	KMC	Conventional care	114	1200–1800 g	1607·0 (211·0)	1615·0 (179·0)	33·1 (2·3)	33·6 (2·3)	Yes	..	..
Arya, 2023[10]	Ghana, India, Malawi, Nigeria, Tanzania	Hospital	Lower-middle income	Medium (Ghana, India)/Low	Immediate KMC	Conventional care (including KMC after stabilisation)	3211	1000–1800 g	1500·0 (200·0)	1500·0 (200·0)	32·6 (3·0)	32·6 (2·8)	No	Yes	..
WHO Immediate KMC Study Group, 2021[58]	Ghana, India, Malawi, Nigeria, Tanzania	Hospital	Lower-middle income	Medium (Ghana, India)/Low	Immediate KMC	Conventional care (including KC after stabilisation)	3211	1000–1800 g	1500·0 (200·0)	1500·0 (200·0)	32·6 (3·0)	32·6 (2·8)	No	Yes	..
Bier, 1996[33]	USA	Hospital	High-income	Very high	KMC	Conventional care (no KC)	50	VLBW and ELBW	993·0 (275·0)	942·0 (322·0)	28·0 (2·0)	27·0 (2·0)	Yes	No	No
Boo, 2007[34]	Malaysia	Hospital	Upper-middle income	Very high	KC	Conventional care	126	VLBW	1515·0 (120·0)	1492·0 (128·0)	..	..	Yes	Yes	No
Brotherton, 2021[35]	The Gambia	Hospital	Low-income	Low	Early, continuous KC before stabilisation	Conventional care (including intermittent KMC)	279	<2000 g	1459·0 (1204·0–1650·0)	1436·0 (1180·0–1660·0)	33·0 (31·0–34·0)	32·0 (31·0–34·0)	No	Yes	..
Cattaneo, 1998[36]	Ethiopia, Indonesia, and Mexico	Hospital	Low-income and upper-middle income	High	Continuous KC	Conventional care (no KC)	285	1000–1999 g	1622·0 (239·0)	1638·0 (247·0)	33·7 (2·5)	34·0 (2·2)	Yes	No	No
Charpak, 1997[37]	Colombia	Hospital	Lower-middle income	High	Continuous KMC	Conventional care	746	≤2000 g	1705·0 (261·0)	1735·0 (256·0)	33·6 (2·5)	33·9 (2·7)	Yes	..	No
Chi Luong, 2016[38]	Viet Nam	Hospital	Lower-middle income	High	Early KMC	Conventional care (no KMC)	100	LBW	2060·0 (291·9)	2081·0 (259·3)	33·6 (1·8)	33·9 (1·8)	No	Yes	Yes
de Ocampo, 2021[39]	Philippines	Hospital	Lower-middle income	High	KMC	Conventional care	52	VLBW	1166·1 (190·0)	1210·0 (230·0)	32·5 (2·8)	32·1 (2·5)	Yes	No	No
Gathwala, 2008[40]	India	Hospital	Lower-middle income	Medium	KMC	Conventional care (no KC)	100	<1800 g	1690·0 (110·0)	1690·0 (112·0)	35·5 (1·2)	35·0 (1·1)	Yes	..	..
Ghavane, 2012[41]	India	Hospital	Lower-middle income	Medium	KMC	Conventional care	140	VLBW	1170·0 (191·0)	1198·0 (194·0)	30·8 (2·1)	30·7 (2·1)	Yes	No	No
Jayaraman, 2017[42]	India	Hospital	Lower-middle income	Medium	Early delayed KMC within the first 4 days of life	Late-delayed KMC after 4 days of life	160	1000–1800 g	1376·0 (203·0)	1369·0 (230·0)	32·7 (2·2)	32·3 (2·4)	Yes	Yes	No

(Table 1 continues on next page)

	Country	Hospital or community setting	World Bank Classification	Human Development Index	Intervention description	Control description	Study population size	Birth weight category	Intervention group birthweight, g	Control group birthweight, g	Intervention group gestational age, weeks	Control group gestational age, weeks	Stabilised	Received non-invasive respiratory support	Received invasive respiratory support
(Continued from previous page)															
Kadam, 2005[43]	India	Hospital	Low-income	Medium	KMC	Conventional care	89	<1800 g	1467·0 (228·0)	1461·0 (217·0)	33·3 (2·1)	34 (1·7)	Yes	No	No
Kumbhojkar, 2016[44]	India	Hospital	Lower-middle income	Medium	KMC	Conventional care	120	<2000 g	1677·2 (201·3)	1699·0 (199·3)	32·4 (1·8)	32·4 (1·9)	Yes	No	No
Lamy Filho, 2015[45]	Brazil	Hospital	Upper-middle income	High	KMC	Conventional care	102	1300–1800 g	1524·1 (157·4)	1509·1 (172·8)	32·0 (2·4)	32·2 (2·3)	Yes	..	..
Logronio, 2021[46]	Philippines	Hospital	Lower-middle income	High	Continuous KMC	Intermittent KMC	46	1800–2200 g	2066·1 (120·5)	2003·9 (133·2)	36·1 (1·2)	35·8 (0·9)	Yes	No	No
Mazumder, 2019[47]	India	Community	Lower-middle income	Medium	Continuous KMC	Conventional care (including KC)	8402	1500–2250 g	2100·0 (170·0)	2100·0 (170·0)	36·1 (1·8)	36·1 (1·8)	Yes	No	No
Nagai, 2010[48]	Madagascar	Hospital	Low-income	Low	Early, continuous KMC	Late, continuous KC	73	LBW	2075·2 (272·4)	2077·5 (291·6)	36·6 (2·2)	36·0 (2·1)	Yes	No	No
Nimbalkar, 2014[49]	India	Hospital	Lower-middle income	Medium	Immediate KMC	Conventional care	45	≥1800 g	..	..	..	..	No	..	..
Pratiwi, 2009[50]	Indonesia	Hospital	Lower-middle income	High	Early KMC	Conventional care	93	1500–2250 g	2033·8 (159·3)	1987·8 (176·1)	35·6 (2·3)	35·5 (2·3)	Yes	No	No
Ramanathan, 2001[51]	India	Hospital	Low-income	Medium	KMC	Conventional care	28	VLBW	1219·0 (186·4)	1270·9 (170·4)	30·4 (28·8–34·1)	30·9 (29·0–33·3)	Yes	Yes	..
Ricero-Luistro, 2021[52]	Philippines	Hospital	Lower-middle income	High	KMC	Conventional care (no KMC)	70	1000–2000 g	1559·4 (330·2)	1551·3 (287·8)	32·7 (2·6)	32·3 (2·2)	No	Yes	No
Rojas, 2003[53]	USA	Hospital	High-income	Very high	KC	Conventional care (no KC)	60	VLBW and ELBW	906·0 (245·0)	939·0 (230·0)	26·6 (2·3)	27·2 (2·3)	Yes	Yes	No
Sloan, 1994[54]	Ecuador	Hospital	Lower-middle income	High	Continuous KMC	Conventional care	275	<2000 g	1704·0 (243·0)	1704·0 (248·0)	34·5 (2·5)	34·1 (2·4)	Yes	No	No
Suman, 2008[55]	India	Hospital	Lower-middle income	Medium	KMC	Conventional care (no KC)	206	<2000 g	1683·4 (235·0)	1723·6 (242·0)	35·3 (2·3)	35·9 (2·1)	Yes	No	No

(Table 1 continues on next page)

	Country	Hospital or community setting	World Bank Classification	Human Development Index	Intervention description	Control description	Study population size	Birth weight category	Intervention group birthweight, g	Control group birthweight, g	Intervention group gestational age, weeks	Control group gestational age, weeks	Stabilised	Received non-invasive respiratory support	Received invasive respiratory support
(Continued from previous page)															
Tumukunde, 2024[58]	Uganda	Hospital	Low-income	Medium	Early KMC	Conventional care (KC possible after stabilisation)	2221	700–2000 g (LBW, VLBW, and ELBW)	1500·0 (300·0)	1500·0 (300·0)	32·3 (2·4)	32·3 (2·2)	No	Yes	..
Whitelaw, 1988[57]	UK	Hospital	High-income	Very high	KMC	Conventional care (no KMC)	71	VLBW	1152·0 (220·0)	1135·0 (263·0)	29·1 (2·3)	29·5 (2·3)	Yes	No	No
Worku, 2005[59]	Ethiopia	Hospital	Low-income	Low	Early, continuous KMC	Conventional care	123	<2000 g (LBW, VLBW, ELBW)	1514·8	1471·8*	32·4*	31·6*	No	Yes	..

All trials were individually randomised. Birthweight and gestational age at birth are shown as mean (SD) or median (IQR). Conventional care=not clearly stated in the study whether conventional care also included some degree of KC. Conventional care (no KC)=specified in the study that conventional care did not include the provision of KC. ELBW=extremely low birth weight (<1000 g). KC=kangaroo care. KMC=kangaroo (mother) care. LBW=low-birthweight (<2500 g). VLBW=very low birth weight (<1500 g). *SD not available.

Table 1: **Characteristics of the included studies**

inter-reviewer reliability was 0·83. The 2298 reviewed records included 21 studies from the 2016 Cochrane review and two from citation searching. 30 reports of 29 trials were deemed eligible for inclusion in the systematic review,[10,31–59], with data on 17 513 low-birthweight infants, 9055 of whom received kangaroo care.[60] Characteristics of the included studies are shown in table 1. Notably, only one study (3%) was conducted in the community; the rest (n=28 [97%]) were conducted in hospitals. Two studies (7%) were led across multiple countries (Ethiopia, Indonesia, and Mexico; Ghana, India, Malawi, Nigeria, and Tanzania). Most studies (n=16 [55%]) took place in lower-middle income countries, and one (3%) study included both low-income and upper-middle income countries (appendix p 4).

Five (17%) of the 29 trials investigated continuous kangaroo care,[36,37,46,47,55] three (10%) investigated early kangaroo care,[38,50,56] three (10%) investigated early and continuous kangaroo care,[35,48,59] and two (7%) investigated immediate kangaroo care (table 1).[10,49,58] One trial (3%) compared early continuous kangaroo care with late kangaroo care.[48] One study (3%)[46] compared continuous kangaroo care with intermittent kangaroo care. The control was conventional neonatal care, including the offer of some kangaroo care, in seven (24%) trials.[35,42,46–48,56,58] Additional study population features, further characteristics of kangaroo care, and length of hospital stay are summarised in the appendix (pp 5–6).

Of 25 studies reporting all-cause mortality data for hospital-initiated kangaroo care, seven[35,38,49,52,56,58,59] included unstable infants. Three RCTs[53,56,59] included extremely low-birthweight infants, and one[38] included infants on mechanical ventilation.

Of 17 studies reporting sepsis data, seven included infants on non-invasive respiratory support.[10,34,35,38,52,53] Five included unstable infants.[10,35,38,52,56] Three included extremely low-birthweight infants.[33,53,56] Three included infants with a mean gestational age younger than 32 weeks.[33,41,53] One study enrolled infants on mechanical ventilation.[38]

None of the included studies used masking. Risk of bias ratings are listed in the appendix (pp 7–8). An evidence table along with details on the primary and secondary outcomes for each study are provided in the appendix (pp 9–15). Effect sizes for the primary and secondary outcomes (derived in random effect models) and quality of the evidence are summarised in table 2. Overall, the quality of evidence was moderate-to-high.[20,61] Despite a mild asymmetry in the funnel plots for sepsis, hypothermia, and apnoea, publication bias was not statistically significant (appendix pp 17–19).

25 (86%) of 29 studies reporting all-cause mortality were included in the meta-analysis of hospital-initiated kangaroo care (figure 2A). The trial by Mazumder and colleagues, which showed statistically significant lower mortality in the intervention group (appendix p 12), was not included in the meta-analysis as it was conducted

	Effect size (95% CI)	Number of participants (number of studies)	Quality of the evidence (GRADE[20])*	Heterogeneity
Primary outcomes				
All-cause mortality	OR 0·77 (0·67–0·89)	8717 (25 studies)	High	I^2=0%
Sepsis	OR 0·55 (0·37–0·82)	7611 (17 studies)	Moderate	I^2=53%
Invasive infection	OR 0·49 (0·33–0·74)	4080 (11 studies)	Moderate	I^2=0%
Secondary outcomes				
Sepsis-related or invasive infection-related mortality	OR 0·63 (0·47–0·84)	4326 (10 studies)	High	I^2=0%
Bacterial colonisation	RR 2·30 (1·30–4·06), p=0·004	102 (1 study)	Low	Evidence from one study; no meta-analysis.
Hypothermia	OR 0·28 (0·16–0·46)	7252 (18 studies)	Moderate	I^2=72%
Apnoea	OR 0·46 (0·25–0·85)	3435 (11 studies)	Moderate	I^2=45%

Effect size estimates were derived in random effect models. For details of how the GRADE approach was used to consider the quality of the evidence, see appendix (p 16). I^2=0% means heterogeneity not quantifiable. OR=odds ratio. RR=risk ratio. *High quality of evidence suggests further research is very unlikely to change our confidence in the estimate of effect. Moderate quality of evidence suggests further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality of evidence suggests further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Table 2: **Effect sizes and quality of the evidence**

in the community.[47] Meta-analysis shows that hospital-initiated kangaroo care is associated with a significant reduction in mortality by 28 days or discharge (OR 0·77 [95% CI 0·67–0·89]; 95% prediction interval excluding the null effect; I^2=0% [not quantifiable]; high-quality evidence).

Hospital-acquired sepsis was reported by 17 (59%) of 29 trials, with pooled results showing a significant effect of kangaroo care in reducing the odds of sepsis (OR 0·55 [95% CI 0·37–0·82]); however, with heterogeneity of 53% and the 95% prediction interval containing the null effect, the evidence was deemed moderate quality (figure 2B).

Similarly, the meta-analysis of 11 (38%) of 29 studies reporting invasive infection showed a statistically significant beneficial effect of kangaroo care, with a reduction in the odds of invasive infection (OR 0·49 [95% CI 0·33–0·74]. With heterogeneity not quantifiable (I^2=0%) and a 95% prediction interval containing the null effect, the evidence was deemed moderate quality (figure 2C). Of note, the only study yielding results in favour of the control group was also one of the largest RCTs and offered kangaroo care after stabilisation in the control group.[56] It was conducted in level 2 care facilities in sub-Saharan Africa and enrolled unstable extremely low-birthweight infants and infants requiring non-invasive respiratory support. Three studies[54,36,37] were responsible for most of the pooled effect favouring kangaroo care, with incubator care in the control group.

Kangaroo care was associated with a significant reduction in the odds of sepsis-related or invasive infection-related mortality (OR 0·63 [95% CI 0·47–0·84], I^2=0% [not quantifiable], high-quality evidence), hypothermia (0·28 [0·16–0·46], I^2=72%, moderate-quality evidence), and apnoea (0·46 [0·25–0·85], I^2=45%, moderate-quality evidence; figure 3).

Lamy Filho and colleagues[45] were the only investigators to report bacterial colonisation data, showing that kangaroo care was associated with a greater decolonisation of preterm infants' nostrils from meticillin-resistant *Staphylococcus Aureus* (MRSA) and *Staphylococcus epidermidis* (MRSE). None of the studies reported the risk of acquiring (resistant) bacterial colonisation.

A meta-regression was conducted for sepsis, hypothermia, and apnoea, showing that variation in the characteristics of conventional care in the control groups was contributing substantially to heterogeneity, with the intervention effect being smaller in trials where the control groups also received some level of kangaroo care. No association was identified for the remaining variables (population including extremely low-birthweight infants, population with mean gestational age younger than 32 weeks, immediate kangaroo care as intervention, and intermittent kangaroo care as intervention).

Discussion

The results of this systematic review and meta-analysis confirm the important effect of kangaroo care compared with conventional neonatal care on reducing all-cause mortality in low-birthweight infants. Our analysis further indicates moderate-to-high quality evidence favouring kangaroo care in reducing the odds of sepsis, invasive infection, and sepsis-related or invasive infection-related mortality in low-birthweight infants, mainly from resource-limited settings. Kangaroo care was further associated with lower odds of hypothermia and apnoea. Our meta-analysis was hampered by substantial heterogeneity mainly due to variation in conventional care characteristics in the control groups, which sometimes included some kangaroo care, especially in more recent trials conducted on the

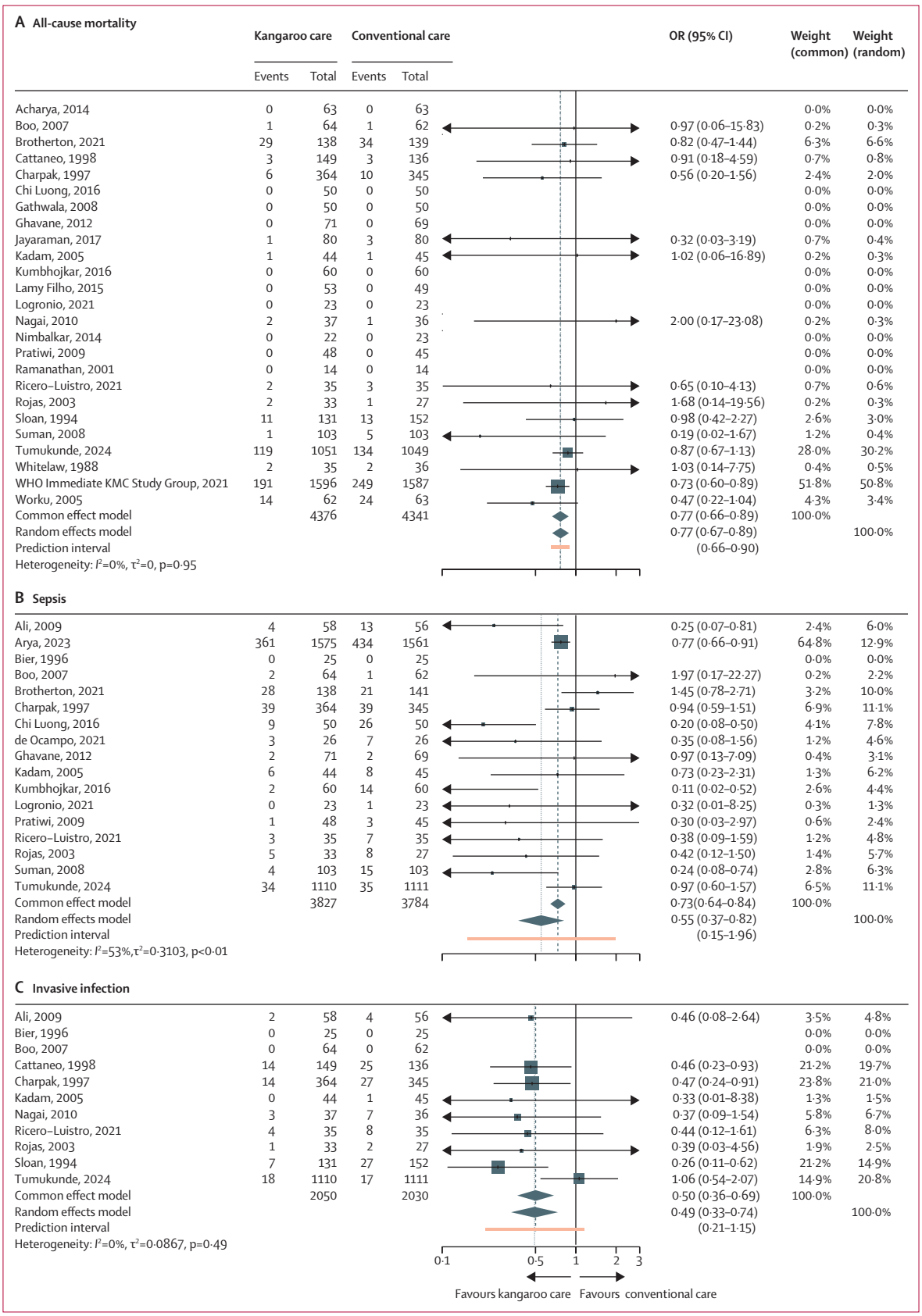

Figure 2: **Effect of hospital-initiated kangaroo care versus conventional care on all-cause mortality (A), sepsis (B), and invasive infection (C) within 28 days of birth or by hospital discharge**
Invasive infection was the composite of necrotising enterocolitis, severe pneumonia, meningitis, and other severe health-care-associated infections. OR=odds ratio. Arrowheads indicate that a line extends beyond the scale in the direction of the arrow.

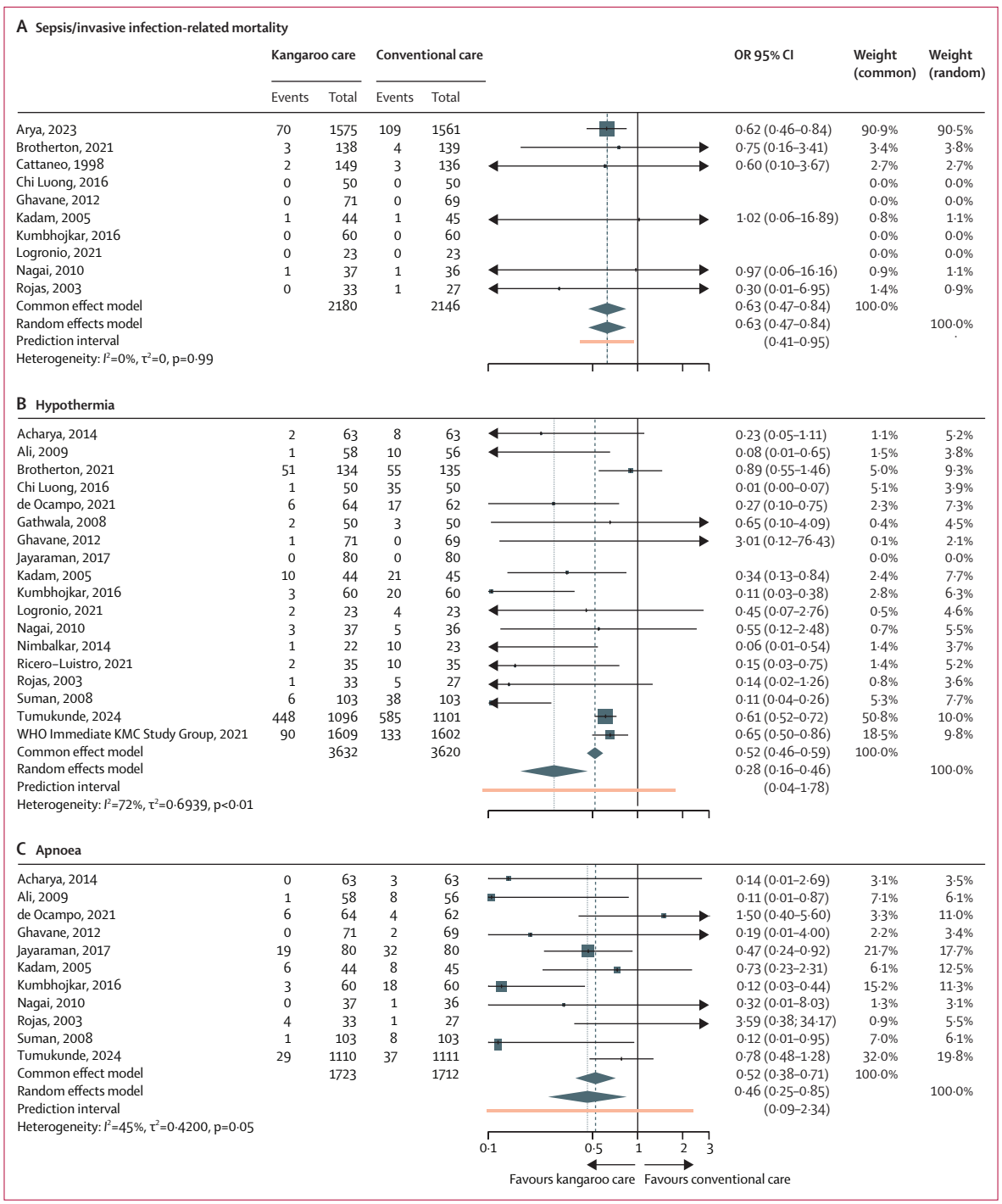

***Figure 3*: Effect of hospital-initiated kangaroo care versus conventional care on sepsis-related or invasive infection-related mortality (A), hypothermia (B), and apnoea (C)**

OR=odds ratio. Arrowheads indicate that a line extends beyond the scale in the direction of the arrow.

background of best practice recommendations. For this reason, an even higher benefit of kangaroo care might be expected compared with no kangaroo care.

Our findings align with previous systematic reviews,[12,13,62] showing kangaroo care as being protective against neonatal mortality, sepsis or severe infection, and hypothermia in low-birthweight infants.[12,13] Our systematic review added further RCTs, corroborating the significant beneficial effect of kangaroo care with enhanced precision and increased certainty. Moreover, we

found compelling evidence of significantly decreased odds of hospital-acquired sepsis and other invasive infections, and sepsis-related or invasive infection-related mortality. Undoubtedly, mortality is the most patient-relevant and clinician-relevant outcome. However, understanding the effect of kangaroo care on our co-primary outcomes together is crucial for understanding the use of kangaroo care as an IPC intervention. If positive effects on mortality are not mediated through reductions in neonatal sepsis or invasive infection, kangaroo care could lead to improvements in mortality but paradoxical increases in morbidity (eg, because of neurodevelopmental impairment associated with neonatal sepsis).[63] Furthermore, based on our findings, a concurrent protective effect of kangaroo care against mortality and infection is an important counterargument to any restrictions on kangaroo care imposed to improve IPC, for example in the context of maternal or infant carriage of resistant bacteria.

Among our secondary outcomes, evidence on bacterial colonisation was only reported by one trial, showing benefits of kangaroo care in decolonising infants' nostrils from MRSA and MRSE.[45] This identifies a key research gap. To date, RCTs providing data on the potential role of skin-to-skin contact for newborn decolonisation in neonatal units are lacking, with previous studies focusing on other methods, such as skin antiseptics.[64–66] Compared with body washing with antiseptics, skin-to-skin contact physiologically facilitates early breastfeeding and might help infants acquire a protective microbiome against colonisation by resistant and difficult-to-treat bacteria. Thus, kangaroo care is likely to not only reduce infection indirectly due to maternal antibodies from breastmilk, but also directly through microbiome transfer with skin-to-skin contact. In term infants, breastmilk microbiota are an important source of infant microbiota[67] and conversely the modality of breastfeeding influences the microbiome of the breastmilk.[68] In addition, such contact might reduce the handling of the infant by health-care workers and others, thereby decreasing the risk of cross-transmission of resistant bacteria from the hospital environment.

Conducting a meta-analysis around a behavioural intervention such as kangaroo care is challenging. The approach adopted in this meta-analysis was deliberately conservative and yet showed significant benefits of kangaroo care on mortality and severe health-care-associated infections, providing compelling evidence in support of kangaroo care as a neonatal IPC intervention in neonatal intensive care units of all settings.

A limitation of our study lies in the fact that evidence from the included RCTs is mostly representative of the Global South; in line with this we did not perform a subgroup analysis stratified by country income category. Specific race and ethnicity or sex data were not collected, as they were inconsistently or not reported by the included studies. We can only speculate on the extent of the applicability of our findings to high-resource countries. In high-income countries with low neonatal mortality, the key question could indeed be the impact of kangaroo care on sepsis and invasive infection which are common. In many high-technology units, despite a strong focus on family-centred care, rigorous and extensive kangaroo care practice is still highly variable and would benefit from tailored implementation strategies. Among the few recent RCTs on kangaroo care in high-income countries is the IPISTOSS trial, which focused on cardiorespiratory stabilisation and normal thermoregulation as well as infant-carer interaction at 4 months of corrected age.[69–71]

We were also unable to fully address the specific effects of immediate, early, or continuous kangaroo care practice, as kangaroo care was poorly defined in most studies. Moreover, immediate kangaroo care has not yet been widely studied with RCTs in the most fragile subgroups of infants, with a consequent gap for extremely preterm or extremely low-birthweight infants in high-income settings.[72] However, recent evidence from the Swedish Neonatal Quality Register does not report an increased risk of sepsis or intraventricular haemorrhage for extremely and very preterm infants exposed to early skin-to-skin contact.[73]

Many of the evaluated RCTs had small sample sizes, resulting in a small study effect, and were underpowered for some outcomes or observed no events in either group. Furthermore, the definition of invasive infection applied in individual studies was heterogeneous. We also identified an absence of a consistent definition for kangaroo care with variable implementation in the intervention and control groups. This contributes to heterogeneity in the meta-analysis of some outcomes and would likely result in underestimations of kangaroo care effects. An alignment of future RCTs on reportable kangaroo care key definitions and dimensions is needed for intervention and control groups.

In conclusion, the joint protective effect of kangaroo care on mortality and infections further reinforces the importance of this intervention in routine neonatal care across different settings in line with WHO recommendations. Since some protective effects appear to be mediated through averted infections, kangaroo care integration into standard IPC measures should be considered for neonatal care of high-risk low-birthweight infants globally. High-income settings have a low representation among the included trials, a shared definition for kangaroo care is lacking despite WHO recommendations, and the heterogeneity in conventional care across studies is substantial. Trials capturing the anticipated indirect effects of kangaroo care on bacterial colonisation are needed to further strengthen the evidence on kangaroo care's role as a neonatal IPC intervention. Given substantial variations in current caregiving practices and kangaroo care provision, interventional research could benefit from preplanned

integration of implementation science methods and outcomes.[74] A thorough understanding of the IPC effects of well-implemented kangaroo care is especially critical in situations when kangaroo care might decline due to conflicting standard IPC interventions.[75] Fear of neonatal infection should not preclude kangaroo care, and effectively reframing kangaroo care as being part of IPC practice across all settings will avoid having IPC as a barrier to kangaroo care and family-centred care.

Contributors

Conceptualisation: CM and JAB; methodology: CM, KJ, JAB, and SA; validation: SMS, JAB, and ES; formal analysis: SA; investigation: CM, KJ, and CS; data curation: CM, KJ, and SA; writing—original draft preparation: CM; writing—review and editing: CM, KJ, CS, SA, SMS, JAB, CHvW, and ES; visualisation: SMS, JAB, CS, CHvW, and ES. CM, KJ, and SA directly accessed and verified the underlying data reported in the manuscript; all authors had full access to all the data in the study and shared the final responsibility for the decision to submit for publication.

Declaration of interests

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Data sharing

The datasets generated and analysed during the current study are available in the text and appendix. Rough data supporting the reported results are available from the corresponding author on reasonable request.

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