Effect of Kangaroo Mother Care on the Likelihood of Breastfeeding from Birth up to 6 Months of Age: A Meta-analysis

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ABSTRACT

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Background. One of the World Health Organization (WHO) nutrition target by 2025 is 50% exclusive breastfeeding rate among infants until age 6 months. Kangaroo mother care (KMC) known to increase breastfeeding rates, especially in preterm and low birth weight (LBW) infants.

Objectives. This study determined the effect of KMC to the rate of exclusive breastfeeding among preterm and LBW infants at 6 months of age.

Methods. Conducted searches in MEDLINE and CENTRAL databases, likewise hand searched local publications December 1996 until June 2018. Included several randomized controlled trials and prospective observational studies comparing KMC and conventional care among preterm and LBW infants. The primary outcome was exclusive breastfeeding of infants at six months of age. Two authors independently assessed trial quality and extracted data the statistical analysis applied using Review Manager version 5.3.

Results. Identified nine eligible trials involving 1,202 neonates. All studies had low-to-moderate risk of bias. KMC significantly noted to increase the likelihood of exclusive breastfeeding by 1.9 times at birth up to 6 months (OR 1.93 [1.18,3.17], p=0.009).

Conclusion. KMC can increase exclusive breastfeeding among preterm and LBW infants from birth up to 6 months of age.

Key Words: Kangaroo mother care, kangaroo care, breastfeeding, low birth weight, preterm

BACKGROUND

Around 15 million babies are born too soon, as estimated by the World Health Organization (WHO) in 2018. Furthermore, an estimated of 4 million infants who die each year due to complications of preterm birth. Prematurity noted as the leading cause of global mortality in children under 5 years old. In Southeast Asia, including the Philippines, 14% of live births are preterm, and 12% are low birth weight (LBW) births.²

In low-income settings, infants born prematurely or with LBW are at higher risk of death and morbidity such as impaired growth and development. These are due to the lack of accessible and cost-effective care, which includes warmth, breastfeeding support, and basic needs for infection prevention.³

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Focus on preterm births needed to accelerate their progress thus reducing neonatal mortality. WHO defined "kangaroo mother care" (KMC) as a period of skin-to-skin contact (SSC) wherein the infant clothed only with a diaper and a bonnet, placed on the chest of a mother or caregiver who is lying in a (nearly) horizontal position, with the former held to the mother with a cloth. KMC maintained the entire day. The more holistic definition of KMC includes four components: early, continuous and prolonged skin-to-skin contact between mother-infant dyad, exclusive breastfeeding, early discharge with close monitoring and follow up.^{2,3}

In 1978, Dr. Edgar Sanabria introduced KMC in Bogota, Colombia as an alternative to warmers and incubators for LBW infants. The KMC method decreases newborn mortality and morbidity by preventing infections and hypothermia, and promoting better weight gain thru exclusive breastfeeding.³ It also strengthens the emotional bonding between parents or caregivers, and the infant, hence giving a more stable family unit.

The WHO nutrition targets for 2025 is to increase the exclusive breastfeeding rate by 50% among infants in the first six months of life. The purpose of this policy is to increase awareness, promote cost-effective interventions and strengthen policies that can help member states and their partners improve the rates of exclusive breastfeeding among infants less than six months.⁴

According to a 2014 WHO update, exclusive breast-feeding practice rates vary between different Asia-Pacific regions: Cambodia (74%), Republic of Korea (50%), Fiji (40%), Philippines (34%), Marshall Islands (31%), China (28%) Japan (21%) and Viet Nam (17%). Breastfeeding rates continuously decline as the child reaches two years of age.⁴

A systematic review (Deepak 2017) on the role of KMC in very low birth weight (VLBW) neonates showed not only a positive effect on growth but also an increase in the breastfeeding rates. In a meta-analysis (Boundy 2016) on KMC was found to decrease the risks of mortality, neonatal sepsis, hypothermia, hypoglycemia and hospital readmission. It also showed an increased likelihood of breastfeeding upon discharge and at 1- to 4- month follow up which increased by 39%.^{1,5}

In 2009, a review of the three studies conducted by Conde et al. showed that KMC found to decrease severe illness and lower respiratory tract infection at 6 months. Likewise it also increase the chance of exclusive breastfeeding at discharge (RR =0.4; 95% CI: 0.25 to 0.68) compared to conventional care.⁶ In another review by Moore et al. demonstrated the superior performance of immediate SSC contact over standard care on breastfeeding status, infant physiologic stability after delivery, infant behavior and maternal-infant bonding among healthy newborns.⁷

Previously conducted about four Cochrane reviews. (1) A meta-analysis on neonatal outcomes (Boundy 2016);

(2) a systematic review on role of KMC in growth and

breastfeeding rates in VLBW neonates (Deepak 2017); (3) KMC to reduce morbidity and mortality in LBW infants (Conde-Agudelo 2009); and (4) skin-to-skin contact for mothers and their healthy newborn infants (Moore 2016). All four meta-analyses has no outcome of breastfeeding up to 6 months of age. The previous reviews on KMC involved assessment of outcomes such as mortality, morbidity, length of hospital stay and breastfeeding rates on discharge and on 1- to 4-month follow up of both term and preterm infants. 1,5-7

This meta-analysis aims to review the effect of KMC on exclusive breastfeeding up to 6 months old among LBW infants, which is recommended by the WHO. The results from this meta-analysis would potentially help policy makers to strengthen the policies on KMC and exclusive breastfeeding to achieve our global nutrition target for 2025.

OBJECTIVES

To determine the effectiveness of KMC on exclusive breastfeeding among preterm and LBW at 6 months of age.

METHODS

Criteria for considering studies for this review

Types of studies

We included published and unpublished randomized controlled trials and prospective observational studies.

We excluded prospective and retrospective cohort studies on KMC and duration of breastfeeding without a control group.

Types of participants

We included studies on preterm infants < 36 weeks age of gestation or <2500 grams (LBW) with breastfeeding duration of at least 6 months.

Types of interventions

We included studies that compared KMC to conventional care. KMC is continuous skin-to-skin contact between mother's chest and her diaper-clad infant in a semi-upright position. The back of the infant covered with either a blanket or a cloth sling/binder, inside the mother's clothing. Mothers were encouraged to render KMC for a minimum of eight hours per day. Conventional care refers to infants who received standard nursery care while placed inside an incubator or warmer/cradle with heat lamps until they could maintain their temperature.

Types of outcome measures

Primary outcome:

• Exclusive breastfeeding up to 6 months old, measured by breastfeeding rates.

Secondary Outcome/s:

 Other reported neonatal outcomes include weight gain, infection, mortality, infants' physiologic outcome, length of hospital stay and prolactin level among postpartum mothers. These outcomes cannot be combined.

Search methods used to identify the studies

Electronic Searches

The search strategies for CENTRAL and MEDLINE used MeSH terms for kangaroo care, low birth weight infant, skin-to skin care AND breastfeeding. No language restrictions applied. Other databases and websites searched included: Clinicaltrials.gov, Google Scholar, Oxford Journals, ProQuest, WHO International Clinical Trials Registry and Platform (http://www.who.int/ictrp/search/en/), and HERDIN, with the search terms "kangaroo care" AND "breastfeeding," "kangaroo mother care," "skin to skin care," "low birth weight," "breastfeeding outcomes."

Searching other Resources

Citation lists in review articles, relevant publications, included and excluded studies searched. Conference proceedings and local journals were hand searched for related research. Unpublished research papers submitted to the Philippine Society of Newborn Medicine and Philippine Pediatric Society related to breastfeeding personally requested from the societies.

Selection of studies

Full articles of the studies that satisfied the inclusion criteria retrieved. Abstracts considered if enough information was presented. Any inconsistency regarding inclusion/exclusion of the studies resolved by discussion and unanimity by the principal investigator and the co-authors.

Data extraction and management

For each review, the author independently extracted data and compared entries separately from the included studies and counter-checked. The data included during the review as follows: authors, participants inclusion and exclusion criteria, methodology, interventions and outcomes, as well as the year of publication. Differences encountered during data extraction were discussed and resolved with consensus. Review Manager Version 5.3 (RevMan) software used to enter the data by one review author and data counterchecked by the other author.

Assessment of risk of bias in included studies

The methodological quality of the studies were assessed independently by the review authors, as outlined in the Cochrane Handbook for Systematic Reviews of Intervention.⁸ Any disparity was resolved by discussion or by involving a third assessor.

Sequence generation

The methods done for sequence generation in the included studies noted, to assess possible selection bias. The methods assessed as to:

- Low risk (note of application of randomization in the article, e.g., random number via table or computergenerated);
- High risk (any non-random process, e.g., hospital number); or
- Unclear risk

Allocation concealment

The allocation concealment methods noted to determine whether intervention allocation have been foreseen in advance of, or during recruitment or changed after assignment. The methods assessed as follows:

- Low risk (e.g., phone or central randomization; numbered-sealed envelopes; coding by third party. Computer generated sequence);
- High risk (e.g., not sealed or non-opaque envelopes; alternation)

Blinding

The methods for blinding noted, to determine possible performance and detection bias. Studies considered at low risk of bias if the process of blinding described in the included studies. The methods assessed as:

- · Low, high or unclear risk for personnel; or
- Low, high or unclear risk for outcome assessors

Incomplete outcome data

The completeness of data observed by looking at the number of withdrawals/dropouts and their corresponding reasons for non-inclusion, the numbers included in the analysis compared with the total randomized participants to check for possible attrition bias.

- Low risk (e.g., absence of missing data or where reasons for missing data were described and balanced across groups)
- High risk (e.g., whether missing data are likely to be related to outcomes or are not balanced across groups)
- Unclear (e.g., inadequate reporting of attritions and exclusions)

Selective reporting bias

The methods assessed as:

- Low risk (e.g., report of the study's pre-specified outcomes and all expected outcomes of interest to the review);
- High risk (e.g., whether not all the study's pre-specified outcomes have been reported; outcomes of interest are reported incompletely and so cannot be used; noninclusion of results of an important outcome expected to have been reported)
- Unclear risk

Other sources of bias

Any important concern for other possible sources of bias investigated. The included studies evaluated whether they were free of other problems as:

- Low risk
- High risk
- Unclear risk

Overall risk of bias

According to the criteria given in the *Cochrane Handbook* for Systematic Reviews of Intervention, the authors made a summary to review the overall risk of bias through clear judgment whether the studies were at low, unclear or high risk of bias. The magnitude and direction of bias whether it was likely to make an impact on the findings assessed.

Measures of treatment effect

The authors analyzed dichotomous data and results reflected as summary odds ratios with an odds ratio (OR) 1.93 (1.18-3.17) at 95% confidence intervals (CI).

Unit of analysis issues

Included studies were randomized controlled trials, and prospective cohort studies, both foreign and local, with control and intervention, and with no issues in the unit of analysis were infants as participants receiving more than one intervention, and multiple observations for the same outcome.

Assessment of heterogeneity

To assess the appropriateness of pooling the data, heterogeneity between trials examined by visually checking the forest plots and quantifying the I-squared test. The degree of heterogeneity was roughly categorized based on the value of the I² statistic according to Higgins et al. as: low (25%), moderate (50%), and high (75 %). If statistical heterogeneity noted, the authors planned to explore its possible causes through subgroup analysis (e.g., differences in study quality, participants, intervention regimens or outcome assessments). In case the presence of heterogeneity not explained, a random-effects model used to synthesize the data.⁸

Data synthesis

Statistical analysis performed using the Review Manager software (RevMan 5.3). The Mantel-Haenszel method used for approximations of RR for dichotomous outcomes.

Assessment of publication bias

Visual examination of the funnel plot used to check for publication bias.

Sensitivity analysis

Sensitivity analysis was planned, should there be enough studies available (≥ 10 trials), to determine the effect of trial quality by excluding studies with inadequate randomization,

questionable allocation concealment and significant loss to follow-up.

RESULTS

Description of studies

Results of the search

Out of 308 records from the database search, we removed 68 duplicates, and excluded 201 that were not able to meet the inclusion criteria (Figure 1). Of the remaining 39 studies that were retrieved for full text review, we excluded 17 studies for the qualitative synthesis: 15 studies on term infants, 2 studies that compared intermittent versus continuous KMC. 22 studies were included in the qualitative review: 4 Cochrane reviews, and 9 studies that had breastfeeding outcomes only upon discharge and only up to 4 months old. The remaining 9 studies were eligible for inclusion (Bier 1996; Charpak 2001, Hake-Brook 2008, Roberts 2009, Chiu 2009, Ali 2009, De Almeida 2010, Dumalag 2014, Ghavane 2016) and eventually analyzed for the meta-analysis. 9-17

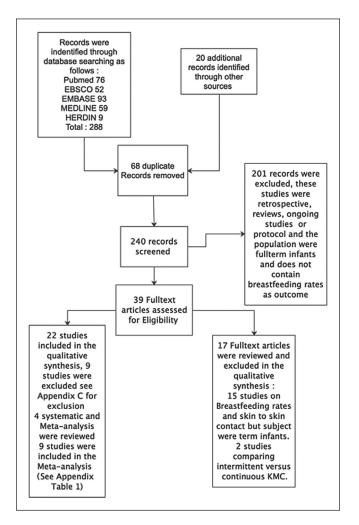


Figure 1. Prisma Flow Chart.

Included studies

We included nine studies (8 RCTs and one prospective cohort study) that contributed data to the meta-analysis. About of 1,202 newborns < 36 weeks age of gestation and < 2500 grams recruited into these trials. The characteristics of included studies are shown in Appendices 1 and 2.

Risk of bias in included studies

Majority of studies had overall low risk of bias. Figures 2 and 3 provided a summary of the risk of bias of included studies in this review.

Funnel plot was symmetrical indicating that publication bias was unlikely (Figure 4).

Effects of intervention

We included nine studies in this review to determine the effects of KMC on exclusive breastfeeding duration among preterm and LBW infants up to 6 months of age (Bier 1996, Charpak 2001, Hake-Brook 2008, Roberts 2009, Chiu 2009, Ali 2009, De Almeida 2010, Dumalag 2014, Ghavane 2016).⁹⁻¹⁷

Primary Outcome

Pooled data showed that KMC significantly increased the odds of exclusive breastfeeding from birth up to 6 months by 1.93x (95% CI, 1.18, 3.17; 9 studies, N=1202; $I^2=46\%$; p=0.009) (Figure 5).

Sensitivity analysis removing the prospective study did not change the direction of the treatment effect and even resulted in higher heterogeneity (I²=49%).

Other Outcomes

Summary measures of other reported neonatal outcomes (weight gain, infants' physiologic outcome, length of hospital stay and prolactin level among postpartum mothers), neurodevelopmental indices as well as reduction in infections and mortality were not pooled since they varied between studies.

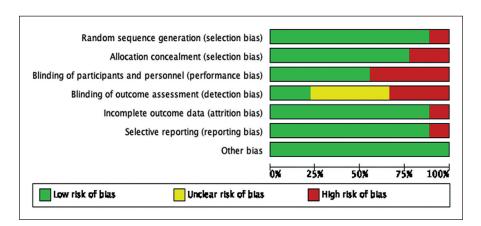


Figure 2. Risk of bias graph: Review authors' judgments about each risk of bias item presented as percentage across all included studies.

DISCUSSION

Summary of Main Results

In this meta-analysis, we were able to include nine studies with 1,202 infants to assess the effect of KMC on exclusive breastfeeding among preterm and LBW infants up to 6 months of age. KMC resulted in a 1.9 times increase in the likelihood of exclusive breastfeeding among preterm infants up to 6 months old (p=0.009).

The presence of moderate heterogeneity (I²=46%) in this study can be attributed to different variables such as the wide range of low birthweight distribution of the included studies, different primary outcome measures and the limitations of blinding. Hence a random-effects model was used to synthesize the data.

This study analyzed 8 RCTs and 1 prospective study. Sensitivity analysis removing the prospective study did not change the direction of the treatment effect and even resulted in higher heterogeneity (I²=49%). As such, the 9 studies were retained in this analysis.

In the meta-analysis of Boundy et al, their results showed that KMC increased the likelihood of infants to exclusive breastfeeding 1.78 times upon hospital discharge or 40 - 41 weeks postmenstrual age and, at 1- 4 month follow up by 1.4 times. However, we searched for studies with exclusive breastfeeding from birth up to 6 months of age since this is the duration of exclusive breastfeeding recommended by WHO Nutritional Targets for 2025.

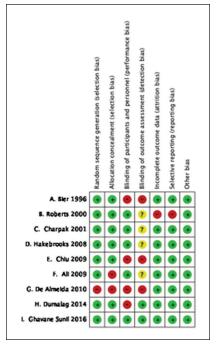


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

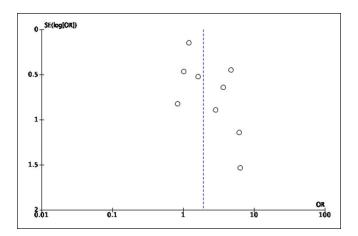


Figure 4. Funnel Plot: Effect of KMC on exclusive breast-feeding until 6 months old.

Other outcome variables measured by the included studies, such as improvement in weight gain per day, nutritional status, physiologic parameters, length of hospital stay, maternal-infant interaction, postpartum prolactin levels and neurodevelopmental indices as well as reduction in infections and mortality were not pooled since they varied between studies. Nevertheless, Ali 2009 an RCT reported that there was a significant effect of KMC in relation to weight gain (KMC: 19.3 + 3.8 g vs. Control: 10.4 + 4.8 g, p < 0.001) thermoregulation (KMC: 1.7% vs. Control 17.9% p <0.003) and reduction in the incidence of nosocomial infection (KMC 6.9 % vs. Control 23.2%, p < 0.015). 10 On the other hand, an RCT by Charpak et al. (N=746 infants) showed a significant improvement in growth, specifically head circumference but no significant difference in the mortality between KMC and traditional care (RR 0.57 95% CI 0.17-1.18). Regarding the length of hospital stay, results were varied. The study by Roberts et al. demonstrated a longer hospital duration in the KMC group compared with the control group (48 ± 28 vs. 46 ± 19 days, p > 0.05), while Bier showed the opposite trend $(69 + 25 \text{ vs. } 73 + 22 \text{ days}, p > 0.05).^{11}$

Overall completeness and applicability of evidence

The participants in all studies have no significant difference in baseline characteristics. All outcome measures analysed and presented. The included studies conducted both in developed and low-to-middle income countries, namely the United States, Mexico, Brazil, Colombia, India, Iran, and the Philippines. In low-to-middle income countries, the incidence of preterm and low birthweight births is high and the breastfeeding rates are often suboptimal. KMC as an intervention to improve breastfeeding rates recommended helping achieve the 2025 Nutritional Target of 50% exclusive breastfeeding for at least 6 months of age.

Quality of the evidence

Three independent reviewers assessed the quality of evidence based in 6 domains: selection bias, performance, detection, attrition, reporting and other bias. The most common limitation in the included studies with highrisk bias was in the area of blinding. The assessors who collected the outcomes measures, monitoring of dropouts, and completeness of follow-up were not blinded. KMC and conventional care were difficult to blind due to the nature of intervention. The other domains were all low risk, hence the overall risk of bias was considered low.

Potential biases in the review process

The eligibility and exclusion criteria clearly specified. A systematic and comprehensive search strategy used in the identification and retrieval of relevant studies included in this meta-analysis. Two review authors independently examined and extracted data from each study included. Any disagreements were resolved through discussion or by a third assessor.

Agreements and disagreements with other studies or reviews

Presently there are no currently published reviews focusing on the effects of KMC on exclusive breastfeeding for preterm and low birth weight infants at 6 months of age.

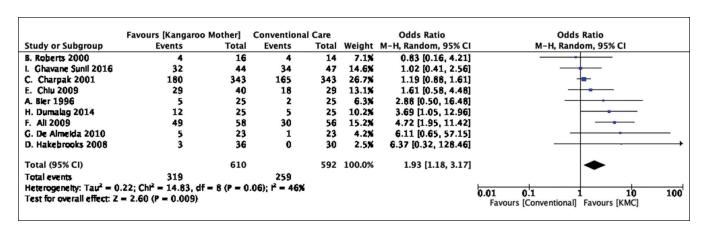


Figure 5. Forest Plot: Effect of KMC on exclusive breastfeeding from birth until 6 months old.

CONCLUSIONS

Implications for practice

Exclusive breastfeeding for six months up to two years or beyond with sufficient and safe complementary foods, is one of the most effective ways to protect child health and promote healthy growth and optimal development in early childhood.

The WHO promotes a complete implementation plan on maternal, infant and young child nutrition. This plan included six global nutrition targets for 2025 and the 5th target is to increase the rate of exclusive breastfeeding by 50% in the first six months.

The global depiction of breastfeeding rates varies widely between low-and middle-income and high-income countries. In countries such as Sri Lanka, Oman, Sweden and Uruguay, almost all their babies are breastfed. On the other hand, countries such as China, Thailand, South Africa, Thailand and Philippines only have 50% and below who are breastfed. 18

Many factors can influence the wide variation of breastfeeding rates among different countries. Provision of a positive environment and strong support from national level such as policies guaranteeing parental leave and right to breastfeed in the workplace, restrictions on the marketing of breastmilk substitutes play a major role in increasing the rates of breastfeeding. Indeed, studies have found that combined implementation of promoting breastfeeding interventions within health systems and the community have the capacity to increase exclusive breastfeeding rates by 2.5 times.¹⁸

In our country, to accelerate the rates of exclusive breast-feeding and improve the outcome of our LBW infants, it requires actions at the level of policy makers, community and health system. The evidence showing that KMC significantly improved the odds of exclusive breastfeeding of LBW infants at 6 months old would enable the policy maker to strengthen the implementation of KMC in their respective institutions in order to achieve our global nutrition target by 2025.

Policies and practices on KMC and breastfeeding in the community, different hospitals and lying-in clinics, especially in a resource-limited setting, need to strengthen through strict implementation, proper monitoring and surveillance by the top management per institution and the Department of Health.

Regular cascading and information dissemination to all pregnant mothers, physicians and allied medical practitioners about the benefits of KMC and breastfeeding will improve their awareness, knowledge and practices, hence improving the outcome of our LBW infants. Empowering ambulatory KMC units in an institution and community will lessen the dropouts in KMC dyads.

Implications for research

Future studies needed to increase the potential applicability of the results and should enroll sufficient infants and account for possible confounders. Long-term follow-up

studies also needed to improve the outcome of exclusivity of breastfeeding at 6 months.

Statement of Authorship

Literature and hand search conducted by primary investigator. Assessment done by primary investigator and second co-author. The third co-author guided the protocol development and consulted for disagreement in trial assessment. All authors approved the final version submitted.

Author Disclosure

All authors declared no conflicts of interest and no affiliation with any pharmaceutical companies.

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APPENDICES

Appendix 1. Table of Included Studies

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Bier 1996	Bier JA, Ferguson AE, Morales Y, Liebling JA, Archer D, Oh W, et al. Comparison of skin-to- skin contact with standard contact in low-birth-weight infants who are breastfed. Arch Pediatr Adolesc Med. 1996 Dec;150(12):1265–9.				
Roberts 2000	Roberts KL, Paynter C, McEwan B. A comparison of kangaroo mother care and conventional cuddling care. Neonatal Network - Journal of Neonatal Nursing 2000;19(4): 31–5.				
Charpak 2001	Charpak N, Ruiz-Pelaez JG, Figueroa de C Z, Charpak Y. A randomized, controlled trial of kangaroo mother care: Resfollow-up at 1 year of corrected age. Pediatrics. 2001Nov;108(5):1072–9.				
Hake-Brook 2008	Hake-Brooks, S. J., & Anderson, G. C. (2008). Kangaroo care and breast-feeding of mother-preterm infant dyads 0-18 months: A randomized, controlled trial. Neonatal Network. 2008 June; 27 (3):151-159.				
Chiu 2009	Chiu SH, Anderson GC. Effect of early skin-to-skin contact on mother-preterm infant interaction through 18 months: randomized controlled trial. International Journal of Nursing Studies 2009 September;46(9):1168–80.				
Ali Syed 2009	Ali SM, Sharma J, Sharma R, Alam S. Kangaroo Mother Care as compared to conventional care for low birth weight babies. Dicle Med J. 2009 February; 36(3): 155-160.				
De Almeida 2010	Almeida H, Venancio SI, Sanches MT, Onuki D. The impact of kangaroo care on exclusive breastfeeding in low birth weight newborns. J Pediatr (Rio J). 2010;86(3):250–253.				
Dumalag 2014	Dumalag JA, Raguindin P, Uy ME. Low Birth Weight Infants Admitted to a Level II Neonatal Intensive Care Unit of the Philippine General Hospital Who Underwent Kangaroo Mother Care 2015. Acta Medica Philippina. Forthcoming 2021				
Ghavane 2016	Ghavani Sunil, Eklare Deepak, Mohammad Haseeb. Long Term Outcomes of Kangaroo Mother Care in Very Low Birth Weight Infants. Journal of Clinical and Diagnostic Research. 2016 Dec, 10(12): SC13-SC15				

Appendix 2. Characteristics of Included Studies

Author	Type of Study	Country Of Study	Inclusion	Exclusion	Intervention vs. Control	Outcomes
Bier 1996	RCT	Rhode Island, New England Region of United States	Infants with BW < 1500 g and whose mothers planned to breastfeed	Mother's positive history of illicit drug use, mental illness, human immunodeficiency virus (HIV) infection, or receiving any medications contraindicated to breastfeeding. In addition, any infants who had a positive toxicology screen for cocaine or other illicit drugs or were showing drug withdrawal symptoms at birth were excluded.	KMC or skin-to- skin versus control	Primary Outcome: Infant physiological data, i.e., oxygen saturation, heart rate, respiratory rate, and axillary temperature; maternal milk production; and duration of breastfeeding Secondary outcome: Percentage of mothers who continued breast-feeding for the duration of their infants' hospitalization and 1, 3, and 6 months after discharge from the hospital
Roberts 2000	RCT	Australia	Infants born > 30 weeks AOG, clinically stable and cleared by the unit specialist.	Infants who are not stable or with congenital anomalies	KMC vs. conventional cuddling care	Main outcomes: Infant weight gain, temperature maintenance during KMC and CCC, and length of hospital stay. Secondary outcomes: breastfeeding at discharge, 6 weeks, 3 months and 6 months.

Appendix 2. Characteristics Of Included Studies (continued)

Author	Type of Study	Country Of Study	Inclusion	Exclusion	Intervention vs. Control	Outcomes
Charpak 2001	RCT	Colombia	All liveborn infants who weighed 2000 g and were eligible for KMC and whose mother or a relative was able to understand and was willing to follow the general instructions for taking care of a premature infant and complying with a 1-year follow-up schedule	Referral to another institution, plans to leave Bogota' in the near future, lethal or major malformations, early major conditions arising from perinatal problems (e.g., severe hypoxic ischemic encephalopathy, pulmonary hypertension), and parental or family refusal to comply with the follow-up program or, in those assigned to KMC, with the intervention	KMC vs. Control, infants kept in the incubators	Main outcomes: Morbidity, mortality, growth, development, breastfeeding, hospital stay, and sequelae Secondary outcomes: Length of hospital stay, the overall incidence of infection the incidence of severe nosocomial infections or severe infections detected after discharge Proportion of infants entirely or partially breastfed up to 12 months old
Hakebrooks 2008	RCT	Cleveland Ohio, Northern America	Mothers: English speaking, 18 years or older, anticipating a singleton birth, and healthy enough to experience KMC. Infants were included if they had 5 min Apgar ≥6 and were 1,300-3,000 g at birth, 32-36 completed weeks gestation, and healthy enough to experience KMC	Mothers with known drug abusers during pregnancy or if they had eclampsia, uncontrolled seizure disorder, severe depression or mental illness refractory to treatment, or maternal disease requiring transport to an intensive care unit post birth Infants were excluded if they had a condition that could prevent KMC post birth or if they were diagnosed with a severe congenital anomaly.	KMC versus control infants were either on the postpartum unit or in the NICU, were wrapped in blankets whenever they were held	Main outcome variables: Breastfeeding status at hospital discharge and at 1.5, 3, 6, 12, and 18 months as measured by the Index of breastfeeding status
Chui 2009	RCT	Cleveland Ohio, Northern America	Healthy preterm infants 32-36 weeks' gestation and their mothers.	Infants with congenital anomalies	KMC versus control group (infants kept warm in incubators, warmer beds, bassinets or held wrapped in blankets)	Mother-preterm infant interaction (MPI) is measured by mean scores on the Nursing Child Assessment Satellite Training Program (NCAST) Feeding and Teaching scales at 6,12 and 18 months post birth (reported in Chiu 2009 using the same data set). Breastfeeding status (exclusivity) at hospital discharge, 6 weeks and 3, 6 and 12 months
Ali 2009	RCT	India	Infants delivered by spontaneous vaginal delivery with weight 1200 grams to 1800 grams	Neonates delivered by caesarean section, with major life threatening congenital mal- formation, severe perinatal complication and pa- rental refusal for KMC intervention were excluded from the study.	KMC versus conventional care	Effect on growth, physiologic parameters, length of hospital stay, mortality, morbidity and exclusive breastfeeding rates at 40 weeks post-conceptual age, 3 and 6 months
De Almeida 2010	Prospective cohort	Brazil	Infants weighing < 2,000 g and staying in the neonatal unit for at least 7 days	Refusal to do KMC	Control group is conventional care prior to implementation of KMC.	Primary Outcome: Exclusive breastfeeding after discharge, 40 weeks, 3 months and 6 months

Appendix 2. Characteristics Of Included Studies (continued)

Author	Type of Study	Country Of Study	Inclusion	Exclusion	Intervention vs. Control	Outcomes
Dumalag 2014	RCT	Philippines	Infants weighing ≤ 2000g, and with Apgar score ≥ 7 at 5 minutes of life	Unstable infants namely extremely low birth weight (ELBWs), infants with chromosomal and life threatening congenital anomalies, and infants with oxygen or cardiovascular support, b) mothers who are clinically unstable who cannot render KMC, c) mothers who have contraindication for breastfeeding, and finally d) mothers diagnosed with Prolactinoma.	KMC Group versus Control Group (routine newborn care)	Primary outcome: Prolactin levels of mothers in KMC versus ControlMilk volume production on the 3rd and 7 th dayMean length of stay Secondary outcome: Exclusive breastfeeding until 6 months old.
Ghavane Sunil 2016	RCT	Southern India	Infants with birth weight <1500gm were enrolled. Inborn, singleton, VLBW (birth weight <1500gm) infants, who are tolerating feeding and hemodynamically stable	Infants with major malformation were excluded	KMC versus control infants placed inside the incubator or under the warmer	Primary outcome: Growth outcomes Secondary Outcome: Nutritional indicators: Malnutrition, wasting, stunting and duration of exclusive breastfeeding at 40 weeks post conceptual aging, 3 months and 6 months old

Appendix 3. References to Excluded Studies

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