

Kangaroo mother care to reduce morbidity and mortality in low birthweight infants (Review)

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[Intervention Review]

Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

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ABSTRACT

Background

Kangaroo mother care (KMC), originally defined as skin-to-skin contact between a mother and her newborn, frequent and exclusive or nearly exclusive breastfeeding, and early discharge from hospital, has been proposed as an alternative to conventional neonatal care for low birthweight (LBW) infants.

Objectives

To determine whether there is evidence to support the use of KMC in LBW infants as an alternative to conventional neonatal care.

Search strategy

The standard search strategy of the Cochrane Neonatal Group was used. This included searches of MEDLINE, EMBASE, LILACS, POPLINE, CINAHL databases (from inception to January 31, 2011), and the Cochrane Central Register of Controlled Trials (*The Cochrane Library*, Issue 1, 2011). In addition, we searched the web page of the Kangaroo Foundation, conference and symposia proceedings on KMC, and Google scholar.

Selection criteria

Randomized controlled trials comparing KMC versus conventional neonatal care, or early onset KMC (starting within 24 hours after birth) versus late onset KMC (starting after 24 hours after birth) in LBW infants.

Data collection and analysis

Data collection and analysis were performed according to the methods of the Cochrane Neonatal Review Group.

Main results

Sixteen studies, including 2518 infants, fulfilled inclusion criteria. Fourteen studies evaluated KMC in LBW infants after stabilization, one evaluated KMC in LBW infants before stabilization, and one compared early onset KMC with late onset KMC in relatively stable LBW infants. Eleven studies evaluated intermittent KMC and five evaluated continuous KMC. At discharge or 40 - 41 weeks' postmenstrual age, KMC was associated with a reduction in the risk of mortality (typical risk ratio (RR) 0.60, 95% confidence interval (CI) 0.39 to 0.93; seven trials, 1614 infants), nosocomial infection/sepsis (typical RR 0.42, 95% CI 0.24 to 0.73), hypothermia (typical RR 0.23, 95% CI 0.10 to 0.55), and length of hospital stay (typical mean difference 2.4 days, 95% CI 0.7 to 4.1). At latest follow up, KMC was associated with a decreased risk of mortality (typical RR 0.68, 95% CI 0.48 to 0.96; nine trials, 1952 infants) and severe infection/sepsis (typical RR 0.57, 95% CI 0.40 to 0.80). Moreover, KMC was found to increase some measures of infant growth, breastfeeding, and mother-infant attachment.

Authors' conclusions

The evidence from this updated review supports the use of KMC in LBW infants as an alternative to conventional neonatal care mainly in resource-limited settings. Further information is required concerning effectiveness and safety of early onset continuous KMC in unstabilized LBW infants, long term neurodevelopmental outcomes, and costs of care.

PLAIN LANGUAGE SUMMARY

Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Kangaroo mother care (KMC) is an effective and safe alternative to conventional neonatal care in low birthweight (LBW) infants mainly in resource-limited countries.

Low birthweight (LBW) (less than 2500 g) is associated with an increased risk of neonatal morbidity and mortality, neurodevelopmental disabilities, and cardiovascular disease at adulthood. Conventional neonatal care of LBW infants is expensive and needs both highly skilled personnel and permanent logistic support. The major component of KMC is skin-to-skin contact (SSC) between a mother and her newborn. The other two components of KMC are frequent and exclusive or nearly exclusive breastfeeding and attempt of early discharge from hospital. Compared with conventional neonatal care, KMC was found to reduce mortality at discharge or 40 - 41 weeks' postmenstrual age and at latest follow up, severe infection/sepsis, nosocomial infection/sepsis, hypothermia, severe illness, lower respiratory tract disease, and length of hospital stay. Moreover, KMC increased weight, head circumference, and length gain, breastfeeding, mother satisfaction with method of infant care, some measures of maternal-infant attachment, and home environment. There was no difference in neurodevelopmental outcomes at one year of corrected age.

BACKGROUND

Description of the condition

Low birthweight (LBW), defined as weight at birth of less than 2500 g irrespective of gestational age, has an adverse effect on child survival and development, and may even be an important risk factor for adult diseases (Barker 1995). About 20.6 million infants worldwide, representing 15.5% of all births, were born with LBW in 2000, 95.6% of them in developing countries (UNICEF/WHO 2004). LBW is a major contributor to infant mortality accounting for 60 to 80% of neonatal deaths (Lawn 2005) and about two thirds of infant deaths (Guyer 1998). A complex process of care

named either conventional or modern neonatal care includes interventions already proven to lower the burden of both neonatal morbidity and mortality. Conventional neonatal care of LBW infants is expensive and needs both trained personnel and permanent logistic support. This complexity is critical mainly during the stabilization period, until the infant has adapted to autonomous extrauterine life. In low- and middle- income countries, financial and human resources for neonatal care are limited and hospital wards for LBW infants are often overcrowded. Thus, interventions for LBW infants that reduce neonatal morbidity and mortality and costs would be an important advance in care.

Description of the intervention

In 1978, Edgar Rey (Rey 1983) proposed and developed kangaroo mother care (KMC) at Instituto Materno Infantil in Santa Fe de Bogotá, Colombia, as an alternative to the conventional contemporary method of care for LBW infants. KMC was initially conceived to address the lack of incubators, high rate of nosocomial infections, and infant abandonment in the local hospital. The term KMC is derived from similarities to marsupial caregiving. The mothers are used as “incubators” to maintain the infants’ body temperature and as the main source of food and stimulation for LBW infants while they mature enough to face extrauterine life in similar conditions as those born at term. Initially, the method was applied only after the LBW infant had stabilized since LBW infants need a variable period of conventional care before being eligible for KMC. Respiratory, thermal and feeding stabilization have been considered crucial for the success of this intervention. The definition of stabilization is not precise, and has been defined as independent of gestational age and weight, which are the main variables associated with those vital functions. Some recent studies, however, have evaluated the effectiveness of early onset KMC (as soon as possible after birth) in LBW infants born in hospitals with little neonatal intensive care capacity (Worku 2005; Nagai 2010). The major component of KMC is skin-to-skin contact (SSC) in which infants are placed vertically between the mother’s breasts firmly attached to the chest and below her clothes. SSC is offered to infants as far as the mother-infant dyad can tolerate it. Mothers can share the role of provider of SSC with others, especially the babies’ fathers. The aim is to empower the mother (parents or caregivers) by gradually transferring the skills and responsibility for becoming the child’s primary caregiver and meeting every physical and emotional need (Nyqvist 2010). The other two components of KMC are frequent and exclusive or nearly exclusive breastfeeding and attempt of early discharge from hospital regardless of weight or gestational age with strict follow up. However, these two last components are less frequently identified as part of KMC.

Different modalities of KMC have been adopted around the world (Charpak 1996) according to the needs of the settings. This diversity includes exclusive and non-exclusive breastfeeding, breast or gavage feedings, completely or partially naked, continuous (≥ 20 hours per day) or intermittent (for short periods once or a few times per day and for a variable number of days) SSC with variable duration of exposure, and early-or-not hospital discharge.

KMC has been reported to be associated with similar neonatal mortality after stabilization, some reduction of neonatal morbidity, greater quality of mother to child bonding and lower hospital stay and costs compared with standard, conventional care of LBW infants. Some researchers have claimed that KMC is the best option if neonatal care units are unavailable, or if they are available but overwhelmed by demand, KMC would allow rationalization of resources by freeing up incubators for sicker infants (Ruiz-Peláez

2004)

This updated review covered all the randomized controlled trials of KMC with all its components irrespective of duration of intervention, breastfeeding patterns, and time at discharge from hospital. Moreover, we have included subgroup analyses for the primary outcome mortality at discharge or 40 - 41 weeks’ postmenstrual age and at latest follow up according to type of KMC (intermittent versus continuous), infant age at initiation of KMC (≤ 10 days versus > 10 days), setting in which the trial was conducted (low/middle income countries versus high income countries), and infant stabilization (before versus after). For all outcomes in stabilized LBW infants we performed subgroup analyses according to type of KMC (intermittent versus continuous). In addition, we included randomized controlled trials that compared early onset (starting within 24 hours after birth) versus late onset (starting after 24 hours after birth) KMC.

How the intervention might work

The intervention assumes that the mother maintains the infant’s body temperature and is the main source of nutrition and stimulation, which are the main components of the conventional neonatal care (Rey 1983). SSC would allow that infant’s demands for care may trigger neuropsychobiological paths that increase maternal behavior and immediate response to its needs as well as increased lactogenesis (Diaz-Rossello 2008). In addition, KMC would empower the mother (parents or caregivers) by gradually transferring the skills and responsibility for becoming the child’s primary caregiver and meeting every physical and emotional need (Nyqvist 2010).

Why it is important to do this review

This systematic review was undertaken because of the need to determine if KMC reduces morbidity and mortality in LBW infants. We believe that this review provides a valuable resource for clinicians and policy makers in summarizing current best evidence and highlighting gaps in the research.

OBJECTIVES

To determine whether there is evidence to support the use of KMC in LBW infants as an alternative to conventional neonatal care before or after the initial period of stabilization with conventional care. Beneficial and adverse effects were assessed.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials, including cluster randomized trials, in which KMC was compared with conventional neonatal care in LBW infants. Moreover, we included randomized trials that compared early onset (starting within 24 hours after birth) versus late onset (starting after 24 hours after birth) KMC. Trials were excluded if they were quasi-randomized, or if they evaluated the effect of KMC in healthy full-term infants or with birthweight \geq 2500 g which is the subject of a separate review (Moore 2007), or if they had crossover design, or if they only reported results for physiological parameters, or if they only evaluated the effect of KMC on procedural pain in infants which is the subject of a separate review (Johnston 2010). In addition, we did not include studies in which KMC was part of a package of interventions for newborn care. In the previous version of this review, we included only trials that evaluated continuous kangaroo mother care (KMC) after infant stabilization. For the 2011 update, we have also included studies that evaluated KMC before infant stabilization and intermittent KMC.

Where trials were reported in abstracts we planned to include them, provided that there was sufficient information on study methods to allow us to assess eligibility and risk of bias. If there was insufficient information reported, then we attempted to contact trial authors requesting further information before deciding to exclude any study.

Types of participants

LBW infants (defined as birthweight less than 2500 g) regardless of gestational age.

Types of interventions

1. Comparisons of KMC with conventional neonatal care in LBW infants. This was regardless of duration of intervention, breastfeeding patterns, and irrespective of whether discharge from hospital was early or not.
2. Comparisons of early onset KMC (starting within 24 hours post-birth) with late onset KMC (starting after 24 hours post-birth) in LBW infants, irrespective of infant stabilization status.

Types of outcome measures

We chose primary outcomes to be most representative of the clinically important measures of effectiveness and safety for the infants. Secondary outcomes included other clinical measures of effectiveness, mother-infant attachment or interaction, satisfaction with care, home environment and father involvement, and costs of care.

Primary outcomes

1. Mortality
 - At discharge or 40 - 41 weeks' postmenstrual age (from randomization until discharge or 40 - 41 weeks' postmenstrual age).
 - At six months of age or six months follow up (from randomization until six months of age or six months follow up).
 - At 12 months' corrected age (from randomization until 12 months' corrected age).
 - At latest follow up (from randomization until last follow up).
2. Severe infection/sepsis (as defined in the individual studies).
3. Severe illness (as defined in the individual studies).
4. Infant growth
 - Weight gain at latest follow up.
 - Weight at discharge or 40 - 41 weeks' postmenstrual age.
 - Weight at six months' corrected age.
 - Weight at 12 months' corrected age.
 - Length gain at latest follow up.
 - Length at discharge or 40 - 41 weeks' corrected gestational age.
 - Length at six months' corrected age.
 - Length at 12 months' corrected age.
 - Head circumference gain at latest follow up.
 - Head circumference at discharge or 40 - 41 weeks' postmenstrual age.
 - Head circumference at six months' corrected age.
 - Head circumference at 12 months' corrected age.
5. Neurodevelopmental disability (measured by Griffith's Psychomotor Developmental Scales at 12 months' corrected age and review of clinical charts).

Secondary outcomes

1. Nosocomial infection/sepsis (as defined in the individual studies).
2. Mild/moderate infection or illness (as defined in the individual studies).
3. Lower respiratory tract disease (as defined in the individual studies).
4. Diarrhea (as defined in the individual studies).
5. Hypothermia (as defined in the individual studies).
6. Readmission to hospital.
7. Breastfeeding.
8. Length of hospital stay.
9. Mother-infant attachment (measured by interviews and observations).
10. Mother-infant interaction (measured by Still-Face Paradigm).
11. Parental and familiar satisfaction (measured by interviews).
12. Home environment and father involvement (measured by interviews).

13. Costs of care.

Search methods for identification of studies

Electronic searches

The standard search strategy for the Cochrane Neonatal review Group was used. This included searches of MEDLINE, EMBASE, LILACS, POPLINE, and CINAHL databases (all from inception to January 31, 2011), and the Cochrane Central Register of Controlled Trials (*The Cochrane Library*, Issue 1, 2011) using a combination of keywords and text words related to KMC or SSC and LBW or preterm infants. To ensure maximum sensitivity we placed no limits or filters on the searches.

INDEX TERMS

Text words

Kangaroo mother care; kangaroo mother method; kangaroo care; skin-to-skin contact, skin-to-skin care

Medical Subject Headings (MeSH)

*Infant, Low Birth Weight; *Infant Mortality; *Breast Feeding; *Mother-Child Relations; Infant, Newborn; Infant care [*Methods]; Length of Stay; Physical Stimulation; [*Methods]; Randomized Controlled Trials as Topic; Weight Gain

MeSH check words

Humans; Infant

We searched for ongoing trials most recently in January 2011 in the following databases using the terms “kangaroo care” and “skin-to-skin contact” :

- The metaRegister of Controlled Trials www.controlled-trials.com.
- The US National Institutes of Health ongoing trials register www.clinicaltrials.gov.
- The National Research Register (NRR) Archive <http://www.nihr.ac.uk>,
- The Australian and New Zealand Clinical Trials Registry www.anzctr.org.au.
- UMIN Clinical Trials Registry www.umin.ac.jp/ctr.
- The World Health Organization International Clinical Trials Registry platform www.who.int/trialsearch.

Searching other resources

Web page of the Kangaroo Foundation, International Network of Kangaroo Care, conference and symposia proceedings on KMC, reference lists of identified studies, textbooks, review articles, and

Google scholar were also searched. In addition, we performed journal hand searching and contacted investigators involved in the field to locate unpublished studies. No language restrictions were applied. For studies with multiple publications, the data from the most complete report were used and supplemented if additional information appeared in other publications.

Data collection and analysis

Selection of studies

The standard methods of the Cochrane Collaboration and its Neonatal Review Group were used. All studies deemed suitable were retrieved and reviewed independently by the two review authors to determine inclusion. Disagreements were resolved through consensus.

Data extraction and management

Data were extracted in duplicate from all reports and recorded on a piloted form independently by the two review authors. There was no blinding of authorship. The following data were extracted for each trial: authors; year of publication; country; inclusion and exclusion criteria; study characteristics; mean or median weight and gestational age at birth, and infant age at enrollment by group; description of interventions; co-interventions; mean or median duration of KMC; number randomized and analyzed; number and reasons of withdrawals; and outcomes. Differences among reviewers in data extracted were resolved by discussion and consensus was reached. Additional information was sought from the individual investigators where the published information did not contain the required detail. One review author (A.C-A.) entered data into Review Manager software (RevMan 2008) and the other review author (J.L.D-R.) checked for accuracy. We processed included trial data as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009).

Assessment of risk of bias in included studies

The risk of bias in each included trial was assessed individually by the two review authors who were not associated with any of the trials. Methodological assessments were not conducted blind to author, institution, journal of publication or results, as the reviewers were familiar with most of the studies. When differences in assessment of risk of bias existed, a consensus was reached. We assessed risk of bias using the dimensions outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009). Five domains related to risk of bias were assessed in each included trial since there is evidence that these are associated with biased estimates of treatment effect: (1) sequence generation, (2) allocation

concealment, (3) blinding of participants, clinical staff and outcome assessors, (4) incomplete outcome data, (5) selective outcome reporting, and (6) other potential threats to validity. We assigned a judgment relating to the risk of bias by answering a pre-specified question about the adequacy of the study in relation to the entry, such that a judgment of “Yes” indicates low risk of bias, “No” indicates high risk of bias, and “Unclear” indicates unclear or unknown risk of bias.

(1) Sequence generation

“YES”: the investigators described a random component in the sequence generation process such as random number table, computer random number generator, shuffling cards or envelopes, drawing of lots, or computerized minimization.

“NO”: the investigators described a non-random component in the sequence generation process such as odd or even date of birth, based on date or day of admission, based on hospital or clinical record number, or allocation by judgment of the clinician, preference of the participant, availability of the intervention, and based on the results of laboratory tests.

“UNCLEAR”: Insufficient information to permit judgment of “Yes” or “No”.

(2) Allocation concealment

“YES”: the investigators used an adequate method to conceal allocation such as central allocation (including telephone or web-based randomization) or sequentially numbered, opaque, sealed envelopes.

“NO”: the investigators used a non-adequate method to conceal allocation such as open random allocation schedule (e.g. a list of random numbers), assignment envelopes without appropriate safeguards, alternation or rotation, date of birth, or case record number.

“UNCLEAR”: Insufficient information to permit judgment of “Yes” or “No”.

(3) Blinding of participants, clinical staff and outcome assessors

“YES”: since KMC cannot be implemented masked, we considered adequate blinding any one of the following: (1) no blinding, but the review authors judged that the outcome and the outcome measurement were not likely to be influenced by lack of blinding; or (2) either participants or some study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

“NO”: any one of the following: (1) no blinding or incomplete blinding, and the outcome or outcome measurement was likely to be influenced by lack of blinding; or (2) either participants or some study personnel were not blinded, and the non-blinding of others likely to introduce bias.

“UNCLEAR”: Insufficient information to permit judgment of “Yes” or “No”.

We assessed blinding separately for each outcome or class of outcomes (objective and subjective).

(4) Incomplete outcome data

“YES”: any one of the following: (1) no missing outcome data; (2) reasons for missing outcome data unlikely to be related to true outcome; (3) missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; (4) for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; (5) for continuous outcome data, plausible effect size among missing outcomes not enough to have a clinically relevant impact on observed effect size; or (6) missing data were imputed using appropriate methods.

“NO”: any one of the following: (1) reasons for missing outcome data likely to be related to true outcome with either imbalance in numbers or reasons for missing data across intervention groups, with similar reasons for missing data across groups; (2) for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; (3) for continuous outcome data, plausible effect size among missing outcomes enough to induce clinically relevant bias impact in observed effect size; (4) “as-treated” analysis done with substantial departure of the intervention received from that assigned at randomization; or (5) potentially inappropriate application of simple imputation.

“UNCLEAR”: Insufficient information to permit judgment of “Yes” or “No”.

(5) Selective outcome reporting

“YES”: any one of the following: (1) the study protocol was available and all of the study’s pre-specified outcomes that were of interest in the review were reported in the pre-specified way; or (2) the study protocol was not available but it was clear that the published reports included all expected outcomes, including those that were pre-specified.

“NO”: any one of the following: (1) Not all of the study’s pre-specified primary outcomes were reported; (2) one or more primary outcomes were reported using measurements, analysis methods or subsets of the data that were not pre-specified; (3) one or more reported primary outcomes were not pre-specified; (4) one or more outcomes of interest in the review were reported incompletely so that they could not be entered in a meta-analysis; or (5) the study reported fails to include results for a key outcome that would be expected to have been reported for such a study.

“UNCLEAR”: Insufficient information to permit judgment of “Yes” or “No”.

The investigators independently assessed risk of bias in included studies, and discrepancies were resolved through discussion. We made explicit judgments about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2009) and explored the impact of the level of bias through undertaking sensitivity analyses - see [Sensitivity analysis](#).

(6) Other potential threats to validity

“YES”: the study appears to be free of other sources of bias.

“NO”: there is a least one important risk of bias. For example,

the study: (1) had a potential source of bias related to the specific study design used; or (2) stopped early (whether or not as a result of a formal stopping rule); or (3) had extreme baseline imbalance; or (4) used blocked randomization in unblinded trials; or (5) had differential diagnostic activity; or (6) had some other problem.

“UNCLEAR”: There may be a risk of bias but there is either insufficient information to assess whether an important risk of bias exists or insufficient rationale or evidence that an identified problem will introduce bias.

The investigators independently assessed risk of bias in included studies, and discrepancies were resolved through discussion. We made explicit judgments about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2009) and explored the impact of the level of bias through undertaking sensitivity analyses - see *Sensitivity analysis*.

Measures of treatment effect

For dichotomous data, we present results as risk ratio (RR) with 95% confidence interval (CI). For continuous data, we have used mean difference (MD) with 95% CIs. The number needed to treat (NNT) for benefit or harm was calculated for outcomes for which there was a statistically significant reduction in risk difference.

Unit of analysis issues

The unit on analysis is the participating infant in individually randomized trials. We had planned to include cluster randomized trials in the analyses along with individually randomized trials, but none of such trials met inclusion criteria.

We considered that crossover trials would not be feasible for this intervention and consequently such trials were not included.

Dealing with missing data

For included studies, we noted levels of attrition in the [Characteristics of included studies](#) table. We analyzed outcomes on an intention-to-treat basis. If this was not clear from the original article then we carried out re-analysis where possible. Authors were contacted for missing data.

Assessment of heterogeneity

Heterogeneity of the results among studies was tested with the quantity I^2 , which describes the percentage of total variation across studies that is due to heterogeneity rather than chance (Higgins 2003). A value of 0% indicates no observed heterogeneity whereas I^2 values of 50% or more indicate a substantial level of heterogeneity. We planned to pool data across studies using the fixed-effects model if substantial statistical heterogeneity was not present. If there was substantial heterogeneity (I^2 values $\geq 50\%$), we used a random-effects model to pool data and made an attempt to identify potential sources of heterogeneity based on subgroup analysis

by type of KMC, infant age at initiation of KMC, setting in which the trial was conducted, and risk of bias of trial.

Assessment of reporting biases

We assessed publication and related biases visually by examining the symmetry of funnel plots and statistically by using the Egger test (Egger 1997). The larger the deviation of the intercept of the regression line from zero, the greater was the asymmetry and the more likely it was that the meta-analysis would yield biased estimates of effect. We considered $P < 0.1$ to indicate significant asymmetry, as suggested by Egger.

Data synthesis

We performed statistical analyses using the Review Manager software (RevMan 2008). We analyzed outcomes on an intention-to-treat basis. If data for similar outcomes from two or more separate studies were available, we combined data in a meta-analysis and calculated a typical RR or MD with associated 95% CIs.

Subgroup analysis and investigation of heterogeneity

Pre-specified subgroup analyses for the primary outcome mortality at discharge or 40 - 41 weeks' corrected gestational age and at latest follow up were performed according to type of KMC (intermittent versus continuous), infant age at initiation of KMC (≤ 10 days versus > 10 days), setting in which the trial was conducted (low/middle-income countries versus high-income countries), and infant stabilization status at trial entry (before versus after). For all outcomes in stabilized LBW infants we performed subgroup analyses according to type of KMC (intermittent versus continuous). We also compared early onset KMC (starting within 24 hours post-birth) with late onset KMC (starting after 24 hours post-birth).

It was not possible to perform the planned subgroup analyses according to birthweight, gestational age, and type of LBW due to limited availability of information.

Sensitivity analysis

A planned sensitivity analysis was carried out to explore the impact of risk of bias on the general direction of findings or the size of the treatment effect for the main outcomes where more than one study contributed data. This was performed by excluding trials with high risk of bias in their results as judged by the reviewers. For the primary outcomes “mortality at discharge or 40 - 41 weeks' corrected gestational age”, “mortality at latest follow up”, “severe infection/sepsis at latest follow up”, and “infant growth”, we performed sensitivity analyses by excluding trials with unclear allocation concealment and high levels of attrition ($> 20\%$).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification.

See Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification.

Results of the search

In previous versions of this review (Conde-Agudelo 2000; Conde-Agudelo 2003), we included three trials (Cattaneo 1998; Charpak 1997; Sloan 1994) and excluded 11 (Arandia 1993; Bergman 1994; Charpak 1994; Chwo 2002; Dala Sierra 1994; Feldman 2002; Kambarami 1998; Legault 1995; Ohgi 2002; Ramanathan 2001; Roberts 2000). For this update, the search strategy identified a further 38 reports, representing 35 studies for possible inclusion. Eleven new studies were included (Ali 2009; Blaymore Bier 1996; Boo 2007; Gathwala 2008; Kadam 2005; Nagai 2010; Neu 2010; Rojas 2003; Suman 2008; Whitelaw 1988; Worku 2005), and another 24 studies were excluded (Ahn 2010; Anderson 2003; Bergman 2004; Chiu 2009; Christensson 1998; Darmstadt 2006; de Almeida 2010; de Macedo 2007; Hake Brooks 2008; Huang 2006; Ibe 2004; Kumar 2008; Lai 2006; Lamy Filho 2008; Legault 1993; Lincetto 2000; Ludington-Hoe 1991; Ludington-Hoe 2000; Ludington-Hoe 2004; Ludington-Hoe 2006; Miles 2006; Miltersteiner 2005; Sloan 2008; Tallandini 2006). In addition, two trials that were excluded in the original review (Ramanathan 2001; Roberts 2000) because they did not evaluate continuous KMC, were now included because we have considered trials evaluating intermittent KMC for inclusion in this update. Finally, two papers by Tessier et al (published in 2003 and 2009) and one by Gathwala et al (published in 2010), reported additional results of previously included studies (Charpak 1997 and Gathwala 2008, respectively).

Included studies

Sixteen studies, including 2518 infants, fulfilled inclusion criteria of which 14 evaluated KMC in LBW infants after stabilization (Ali 2009; Blaymore Bier 1996; Boo 2007; Cattaneo 1998; Charpak 1997; Gathwala 2008; Kadam 2005; Neu 2010; Ramanathan 2001; Roberts 2000; Rojas 2003; Sloan 1994; Suman 2008; Whitelaw 1988), one evaluated KMC in LBW infants before stabilization (Worku 2005), and one compared early onset KMC with late onset KMC (Nagai 2010) in relatively stable LBW infants. Eleven studies were conducted in low or middle-income countries (India [Ali 2009; Gathwala 2008; Kadam 2005; Ramanathan 2001; Suman 2008]; Ethiopia [Cattaneo 1998, Worku 2005]; Malaysia [Boo 2007]; Madagascar [Nagai 2010]; Indonesia [Cattaneo 1998]; Ecuador [Sloan 1994]; Colombia

[Charpak 1997]; and Mexico [Cattaneo 1998]) and five in high-income countries (United States [Blaymore Bier 1996; Neu 2010; Rojas 2003]; United Kingdom [Whitelaw 1988]; and Australia [Roberts 2000]). The sample size ranged from 28 (Ramanathan 2001) to 777 (Charpak 1997) (median, 100). Five studies included infants from multiple pregnancies (Ali 2009; Blaymore Bier 1996; Boo 2007; Charpak 1997; Whitelaw 1988). Infants with major congenital malformations or severe perinatal complications, and parental refusal to participate in the study were reported as exclusion criteria in the great majority of included studies.

Five studies did not provide data on percentage of LBW infants that met eligibility criteria. Among studies conducted in low or middle-income countries, 43% (Boo 2007) to 81% (Ali 2009) of LBW infants met eligibility criteria whereas in studies conducted in high-income countries the percentages ranged from 19% (Rojas 2003) to 50% (Whitelaw 1988). The mean or median age of LBW infants at enrollment varied from 10 hours (Worku 2005) to 32 days (Roberts 2000) (median, nine days). Median or mean infant age at enrollment was ≤ 10 days in eight studies (Ali 2009; Cattaneo 1998; Charpak 1997; Gathwala 2008; Kadam 2005; Nagai 2010; Suman 2008; Worku 2005;), 11 to 20 days in five studies (Ramanathan 2001; Neu 2010; Rojas 2003; Sloan 1994; Whitelaw 1988), and 20 to 32 days in three studies (Blaymore Bier 1996; Boo 2007; Roberts 2000). In the study that compared early onset KMC with late onset KMC (Nagai 2010), the mean age at initiation of KMC was 19.8 hours in the early onset KMC group and 33.0 hours in the late onset KMC. The mean or median weight of infants at recruitment ranged from 968 g (Blaymore Bier 1996) to 2076 g (Nagai 2010) (median, 1595 g).

The trials were conducted under a variety of hospital conditions, regulations, and routines. However, there was remarkable consistency in the descriptions of the KMC intervention across the trials. In all instances, the intervention included SSC and encouraged breastfeeding. Early neonatal discharge from hospital was only considered in the Colombian study (Charpak 1997). Among studies evaluating KMC in stabilized LBW infants, 11 used intermittent KMC (Ali 2009; Blaymore Bier 1996; Boo 2007; Gathwala 2008; Kadam 2005; Neu 2010; Ramanathan 2001; Roberts 2000; Rojas 2003; Suman 2008; Whitelaw 1988) and three used continuous KMC (Cattaneo 1998; Charpak 1997; Sloan 1994). A detailed definition of stabilization was provided in only one study (Nagai 2010). The mean or median duration of KMC per day was < 2 hours in six studies (Boo 2007; Blaymore Bier 1996; Neu 2010; Roberts 2000; Rojas 2003; Whitelaw 1988), four to eight hours in two studies (Ali 2009; Ramanathan 2001), 10 to 14 hours in three studies (Gathwala 2008; Kadam 2005; Suman 2008), and ≥ 20 hours in three studies (Cattaneo 1998; Charpak 1997; Sloan 1994). The studies that evaluated KMC in LBW infants before stabilization (Worku 2005) and compared early onset KMC with late onset KMC (Nagai 2010) used continuous KMC. In studies evaluating intermittent KMC, the intervention was a combination of SSC and radiant warmer/incubator. The standard

neonatal care included infant stay in incubator only (Blaymore Bier 1996; Boo 2007; Charpak 1997; Neu 2010; Roberts 2000; Rojas 2003; Whitelaw 1988) or in radiant warmer only (Ali 2009; Kadam 2005; Suman 2008; Worku 2005) or in incubator or radiant warmer (Cattaneo 1998; Gathwala 2008; Ramanathan 2001; Sloan 1994). Information provided to mothers in the conventional neonatal care group on promotion of breastfeeding and facilitation and promotion of maternal involvement in the care of the neonate, which are critical for the outcomes measured, was not reported in five trials (Blaymore Bier 1996; Charpak 1997; Nagai 2010; Suman 2008; Worku 2005).

The main characteristics of the included studies are shown in the table [Characteristics of included studies](#).

group of infants with birthweight < 2500 g, five (Bergman 2004; Ludington-Hoe 1991; Ludington-Hoe 2000; Ludington-Hoe 2004; Ludington-Hoe 2006) because they reported only physiological outcomes, two (Kambarami 1998; Miltersteiner 2005) because the method of generation of allocation to treatment was quasi-randomized, two (Darmstadt 2006; Kumar 2008) because KMC was part of a preventive package of interventions for essential newborn care, two (Legault 1993; Miles 2006) because allocation was by a crossover design, and one (Christensson 1998) because it evaluated only KMC for rewarming hypothermic infants. The main characteristics of the excluded studies are presented in the table [Characteristics of excluded studies](#).

Excluded studies

We excluded 33 studies: 14 (Ahn 2010; Arandia 1993; Bergman 1994; Charpak 1994; Dala Sierra 1994; de Almeida 2010; de Macedo 2007; Feldman 2002; Ibe 2004; Lamy Filho 2008; Legault 1995; Lincetto 2000; Ohgi 2002; Tallandini 2006) because they were non-randomized trials, seven (Anderson 2003; Chiu 2009; Chwo 2002; Hake Brooks 2008; Huang 2006; Lai 2006; Sloan 2008) because they included infants with birthweight \geq 2500 g and did not report results separately for sub-

Risk of bias in included studies

The risk of bias in included studies is depicted in [Figure 1](#) and [Figure 2](#). Only one study (Nagai 2010) was considered to be free of main sources of bias. The methodological quality of the included trials was mixed and we have carried out a sensitivity analysis to examine the impact of excluding trials at high risk of bias. *See Sensitivity analysis*. The main threats to validity were performance bias (by the lack of blinding of participants, clinicians, and assessors) and selection bias (by the lack of information on methods used for concealment of treatment allocation).

Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

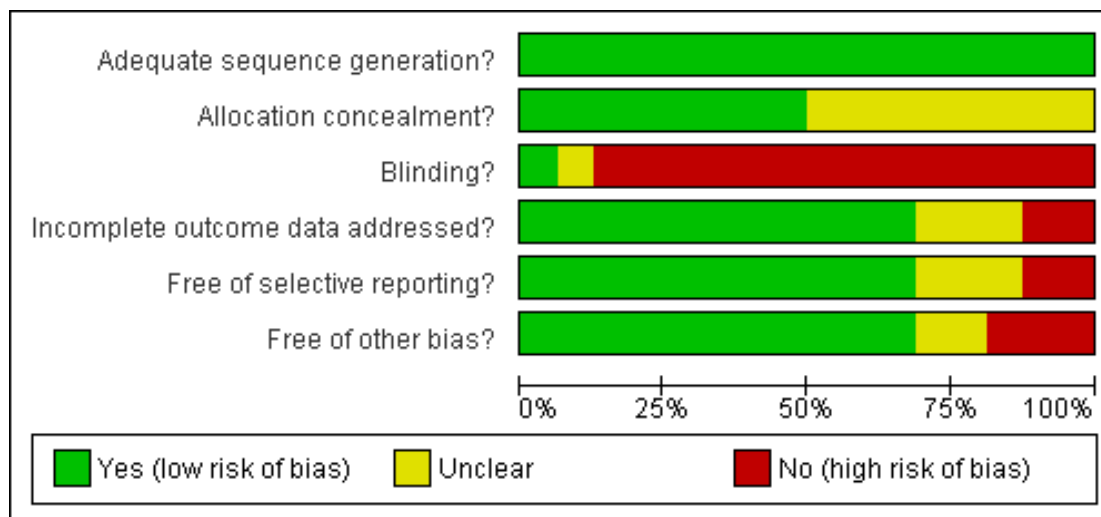


Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Adequate sequence generation?	Allocation concealment?	Blinding?	Incomplete outcome data addressed?	Free of selective reporting?	Free of other bias?
Ali 2009	+	?	-	+	-	-
Blaymore Bier 1996	+	?	-	+	+	+
Boo 2007	+	+	-	-	+	+
Cattaneo 1998	+	?	-	?	+	?
Charpak 1997	+	?	-	+	+	-
Gathwala 2008	+	?	-	?	+	+
Kadam 2005	+	+	-	+	+	+
Nagai 2010	+	+	+	+	+	+
Neu 2010	+	+	?	+	+	+
Ramanathan 2001	+	?	-	+	?	+
Roberts 2000	+	+	-	+	+	+
Rojas 2003	+	+	-	+	+	+
Sloan 1994	+	?	-	+	?	-
Suman 2008	+	+	-	-	+	?
Whitelaw 1988	+	+	-	+	?	+
Worku 2005	+	?	-	?	-	+

Allocation

Most of the included studies used adequate methods to generate allocation sequence. Random number tables were used in seven studies (Cattaneo 1998; Charpak 1997; Gathwala 2008; Ramanathan 2001; Rojas 2003; Sloan 1994; Worku 2005) and shuffling envelopes in four studies (Blaymore Bier 1996; Boo 2007; Roberts 2000; Whitelaw 1988). Other methods of sequence generation used were computer random number generator (Neu 2010), minimization computerized technique (Nagai 2010), block randomization technique (Ali 2009), sealed envelope method (Kadam 2005), and simple randomization (Suman 2008).

Sealed envelopes were used in seven studies (Boo 2007; Kadam 2005; Neu 2010; Roberts 2000; Rojas 2003; Suman 2008; Whitelaw 1988) for concealment of treatment allocation although only in three studies (Neu 2010; Rojas 2003; Whitelaw 1988) it was explicitly stated the envelopes were opaque, sealed and numbered. Allocation was concealed by using a software that provided automatically random allocation (minimization method) in only one study (Nagai 2010). The method of allocation concealment was not reported in eight studies (Ali 2009; Blaymore Bier 1996; Cattaneo 1998; Charpak 1997; Gathwala 2008; Ramanathan 2001; Sloan 1994; Worku 2005).

Blinding

Since KMC cannot be implemented masked, there was lack of blinding of participants and clinical staff in all included studies. Only one study (Nagai 2010) reported that a neonatologist who was masked to allocation of participants and did not have any contact with participants, independently determined the classification of morbidities based on the interview records and medical charts. Neu 2010 reported that four researchers assessed outcome measures of which two were blinded to the hypotheses of the study but not to group assignment of the mother-infant dyads. The other two researchers were blinded to group assignment and hypotheses. The remaining trials did not state if any attempt was made to "blind" outcome assessment.

We consider that performance and observer bias cannot be excluded due to the lack of blinding of participants and clinicians. However, while this could affect the assessment of subjective outcomes such as parental and familiar satisfaction, mother-infant attachment, and social and home environment, or objective outcomes such as breastfeeding, length of hospital length, and readmission to hospital after discharge, it is much less likely to have affected the primary outcomes of this review (infant mortality, severe infection/sepsis, severe illness, infant growth, and neurodevelopmental disability) and some secondary outcomes (nosocomial infection, mild/moderate infection or illness, and hypothermia).

Incomplete outcome data

Six trials had no losses to follow up or exclusions post-randomization (Kadam 2005; Nagai 2010; Ramanathan 2001; Roberts 2000; Rojas 2003; Whitelaw 1988). In five studies, 2 to 10% of recruited infants were lost to follow up (Ali 2009; Blaymore Bier 1996; Charpak 1997; Gathwala 2008; Sloan 1994). In the study by Boo 2007, 12.3% of infants in the KMC group were excluded because SSC sessions were carried out on less than 50% of hospital stay days after recruitment. Two trials (Cattaneo 1998; Worku 2005) did not report the number of infants lost to follow up or excluded after randomization. The study by Suman 2008 had a high risk of attrition bias because 22.3% of infants were lost to follow up. Moreover, there was imbalance in numbers for losses to follow up across intervention groups (KMC 10.2%; control 33.9%). In addition, 6.4% of infants were omitted from reports of analyses because they did not receive assigned care. The Neu 2010 study also had high risk of attrition bias because 9.2% of infants were lost to follow up and 16.1% were excluded post-randomization.

Selective reporting

No study protocols were available. We compared outcomes listed in the Methods section of the articles with those reported in the Results section. Eleven studies (Blaymore Bier 1996; Boo 2007; Cattaneo 1998; Charpak 1997; Gathwala 2008; Kadam 2005; Nagai 2010; Neu 2010; Roberts 2000; Rojas 2003; Suman 2008) reported all outcomes listed in the Methods section and we assume that the reports probably included all of the pre-specified variables. In two studies (Ali 2009; Worku 2005) there was a high risk of bias due to selection outcome reporting. Worku 2005 did not report the great majority of outcomes listed in the Methods section such as mild/moderate and severe illness, sepsis, diarrhea, pneumonia, aspiration, weight gain, and mother's feelings. In Ali 2009, non-significant results such as infant mortality (primary outcome), and weight, length, and head circumference at discharge and follow up (secondary outcomes) were mentioned but not reported adequately. In the remaining three studies some secondary outcomes listed in the Methods section were not reported (Ramanathan 2001) or mentioned but not reported adequately (Sloan 1994; Whitelaw 1988).

Other potential sources of bias

We did not identify other potential sources of biases in 11 studies (Blaymore Bier 1996; Boo 2007; Gathwala 2008; Kadam 2005; Nagai 2010; Neu 2010; Ramanathan 2001; Roberts 2000; Rojas 2003; Whitelaw 1988; Worku 2005). Two studies (Ali 2009; Charpak 1997) used blocked randomization for sequence generation. When blocked randomization is used in an unblinded trial,

and when the assignments are revealed subsequent to the person recruiting into the trial, then it is sometimes possible to predict future assignments. This is particularly the case when blocks are of a fixed size. In [Cattaneo 1998](#), randomization was carried out in blocks of six and stratifying by weight in one of the three participating centers. The trial performed by [Sloan 1994](#) was stopped early because a highly significant difference in severe morbidity was found at two and six months. Randomized controlled trials that are stopped early are more likely to be associated with greater effect sizes than randomized controlled trials not stopped early ([Bassler 2010](#)). This difference is independent of the presence of statistical stopping rules and is greatest in smaller studies. In the study by [Suman 2008](#), the groups were significantly different at baseline in weight and age at enrollment.

Effects of interventions

The comparison between KMC and conventional neonatal care included 15 studies (2445 infants) and 47 outcomes, of which 23 were reported in more than one study. One study (73 infants), with eight outcomes, was included for the comparison early onset KMC versus late onset KMC.

Comparison 1: KMC versus conventional neonatal care

I. Mortality (outcomes 1.1 - 1.4)

Seven trials (1614 infants) reported on mortality at discharge or 40 - 41 weeks' postmenstrual age, two (354 infants) on mortality at six months of age or six months follow up, 1 (693 infants) on mortality

at 12 months' corrected age, and nine (1952 infants) on mortality at latest follow up. Overall, KMC was associated with a statistically significant reduction in the risk of mortality at discharge or 40 - 41 weeks' postmenstrual age (3.4% vs 5.7%; typical RR 0.60, 95% CI 0.39 to 0.93; $I^2 = 0\%$; NNT for benefit 43, 95% CI 28 to 251) ([Figure 3](#)), and at latest follow up (4.7% vs 7.1%; typical RR 0.68, 95% CI 0.48 to 0.96; $I^2 = 0\%$; NNT for benefit 44, 95% CI 27 to 353) ([Figure 4](#)). The significantly decreased risk of death at discharge or 40 - 41 weeks' postmenstrual age, and at latest follow up was also demonstrated in the subgroup of studies that used continuous KMC (mortality at discharge or 40 - 41 weeks' postmenstrual age: three trials, 1117 infants; typical RR 0.60, 95% CI 0.38 to 0.96; $I^2 = 0\%$; mortality a latest follow up: four trials, 1384 infants; typical RR 0.67, 95% CI 0.46 to 0.98; $I^2 = 0\%$), the subgroup of studies in which KMC was initiated within 10 days post-birth (mortality at discharge or 40 - 41 weeks' corrected gestational age: five trials, 1426 infants; typical RR 0.57, 95% CI 0.36 to 0.89; $I^2 = 0\%$; mortality a latest follow up: five trials, 1410 infants; typical RR 0.57, 95% CI 0.37 to 0.86; $I^2 = 0\%$), the subgroup of studies conducted in low/middle income countries (mortality at discharge or 40 - 41 weeks' corrected gestational age: six studies, 1554 infants; typical RR 0.58, 95% CI 0.37 to 0.90; $I^2 = 0\%$; mortality a latest follow up: seven trials, 1821 infants; typical RR 0.65, 95% CI 0.45 to 0.93; $I^2 = 0\%$), and the trial in which KMC was used in unstabilized infants (RR 0.57, 95% CI 0.33 to 1.00). The beneficial effect of KMC on both mortality at discharge or 40 - 41 weeks' corrected gestational age and mortality at latest follow up was not demonstrated in the subgroup of trials that used intermittent KMC, or that initiated KMC after 10 days post-birth, or that were conducted in high-income countries, or that used KMC in stabilized infants.

Figure 3. Forest plot of comparison: I Kangaroo mother care versus conventional neonatal care, outcome: I.1 Mortality at discharge or 40-41 weeks' corrected gestational age.

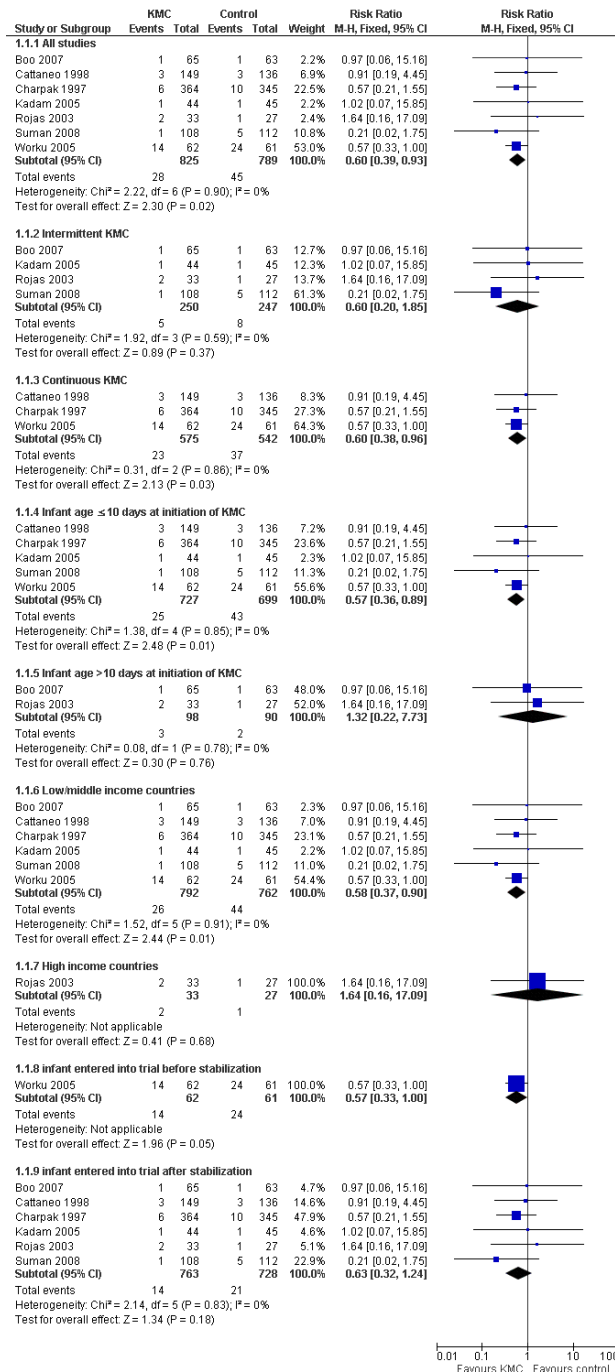
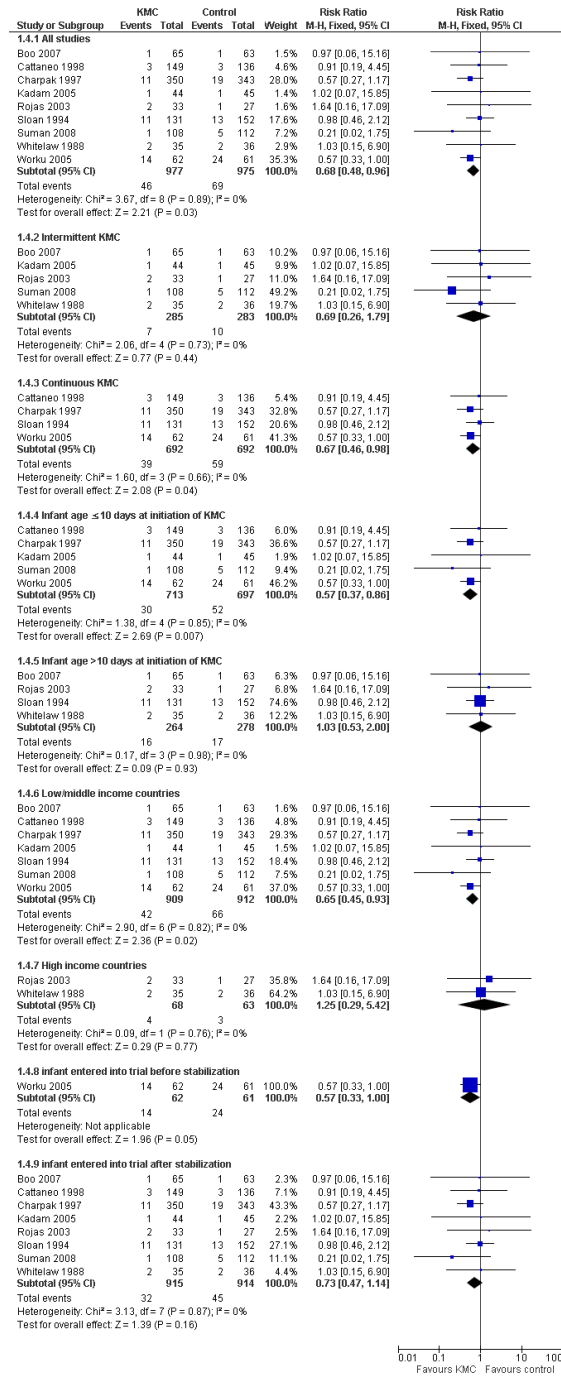


Figure 4. Forest plot of comparison: I Kangaroo mother care versus conventional neonatal care, outcome: I.4 Mortality at latest follow up.

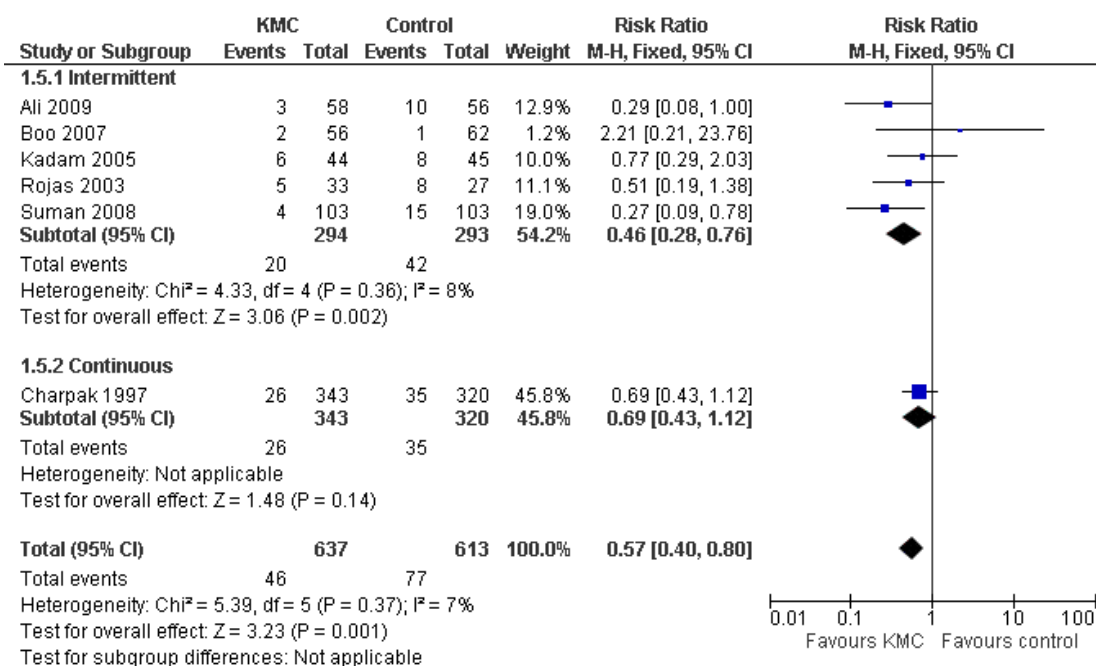


In the sensitivity analysis limited to the studies with low risk of attrition bias, there was a similar reduction in mortality at discharge or 40 - 41 weeks' postmenstrual age, and at latest follow up although this was not statistically significant (mortality at discharge or 40 - 41 weeks' postmenstrual age: six trials; typical RR 0.65, 95% CI 0.42 to 1.01; $I^2 = 0\%$; mortality at latest follow up: eight trials; typical RR 0.71, 95% CI 0.50 to 1.01; $I^2 = 0\%$). Similar results were obtained when we excluded studies with unclear method of allocation concealment (mortality at discharge or 40 - 41 weeks' postmenstrual age: five studies; typical RR 0.60, 95% CI 0.20 to 1.85; $I^2 = 0\%$; mortality at latest follow up: five studies; typical RR 0.69, 95% CI 0.26 to 1.79; $I^2 = 0\%$). There was no overall difference in the risk of mortality at six months of age or 6 months follow up (Analysis 1.2), and at 12 months' corrected age (Analysis 1.3) between KMC infants and controls.

2. Infection/illness (outcomes 1.5 - 1.12)

In stabilized LBW infants, KMC was associated with a statistically significant reduction in severe infection/sepsis at latest follow up (7.2% vs 12.6%; typical RR 0.57, 95% CI 0.40 to 0.80; $I^2 = 7\%$; NNT for benefit 19, 95% CI 13 to 40; six trials, 1250 infants) (Figure 5), severe illness at six months follow up (5.3% vs 17.8%; RR 0.30, 95% CI 0.14 to 0.67; NNT for benefit 8, 95% CI 7 to 17; one trial, 283 infants) (Analysis 1.6), nosocomial infection/sepsis at discharge or 40 - 41 weeks' corrected gestational age (4.2% vs 10.1%; typical RR 0.42, 95% CI 0.24 to 0.73; $I^2 = 0\%$; NNT for benefit 17, 95% CI 13 to 37; two trials, 777 infants) (Analysis 1.7), lower respiratory tract disease at six months follow up (4.6% vs 12.5%; RR 0.37, 95% CI 0.15 to 0.89; NNT for benefit 13, 95% CI 9 to 73; one trial, 283 infants) (Analysis 1.9), and hypothermia at discharge or 40 - 41 weeks' corrected gestational age (7.6% vs 32.0%; typical RR 0.23, 95% CI 0.10 to 0.55; $I^2 = 56\%$; NNT for benefit 4, 95% CI 3 to 7; four trials, 469 infants;) (Analysis 1.11).

Figure 5. Forest plot of comparison: I Kangaroo mother care versus conventional neonatal care, outcome: 1.5 Severe infection/sepsis at latest follow up - stabilized infants.



The significantly reduced risk of severe infection/sepsis at latest follow up and hypothermia was demonstrated in the subgroup of trials that used intermittent KMC but not in the subgroup of trials that used continuous KMC. The reduced risk of nosocomial

infection/sepsis at discharge or 40 - 41 weeks' postmenstrual age was statistically significant in the subgroups of trials that used either intermittent or continuous KMC.

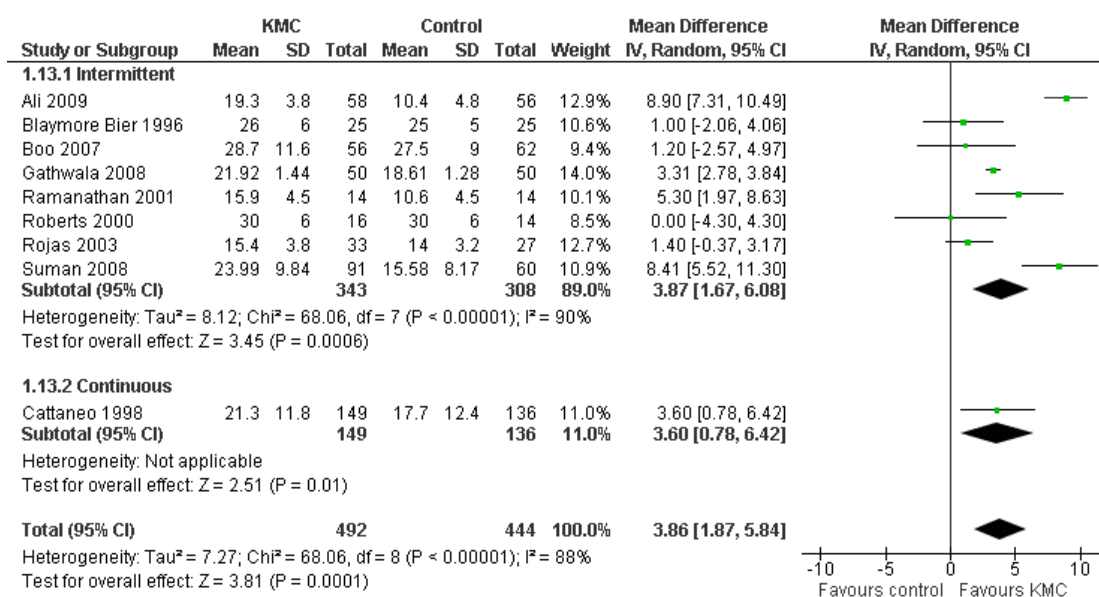
There was no overall difference in the risk of mild/moderate infection or illness at latest follow up (typical RR 1.28, 95% CI 0.87 to 1.88) (Analysis 1.8), diarrhea at six months follow up (RR 0.65, 95% CI 0.35 to 1.20) (Analysis 1.10), and readmission to hospital (typical RR 0.60, 95% CI 0.34 to 1.06) (Analysis 1.12) between KMC infants and controls.

Sensitivity analysis using only studies with adequate allocation concealment demonstrated a similar result for severe infection/sepsis at latest follow up (typical RR 0.51, 95% CI 0.29 to 0.88; $I^2 = 16\%$) and hypothermia (typical RR 0.26, 95% CI 0.10 to 0.67; $I^2 = 63\%$). An additional sensitivity analysis did not indicate that removing the study with high risk of attrition bias (Suman 2008) had any important impact on overall effects of KMC on severe infection/sepsis at latest follow up (typical RR 0.64, 95% CI 0.44 to 0.92; $I^2 = 0\%$) and hypothermia (typical RR 0.33, 95% CI 0.18 to 0.59; $I^2 = 40\%$).

3. Infant growth (outcomes 1.13 - 1.24)

KMC infants gained more weight per day (typical MD 3.9 g, 95% CI 1.9 to 5.8; nine trials, 936 infants) (Figure 6), and length (typical MD 0.29 cm, 95% CI 0.27 to 0.31; two trials, 251 infants) (Analysis 1.17) and head circumference (typical MD 0.18 cm, 95% CI 0.09 to 0.27; three trials, 369 infants) (Analysis 1.21) per week than controls. Moreover, one trial (Charpak 1997) reported that KMC infants had a larger head circumference at six months' corrected age than controls (MD 0.34 cm, 95% CI 0.11 to 0.57; 592 infants) (Analysis 1.23). Nevertheless, there was considerable heterogeneity ($I^2 = 88\%$) among trials reporting weight gain. No differences were observed in weight, length, or head circumference at discharge or 40 - 41 weeks' postmenstrual age (Analysis 1.14; Analysis 1.18; Analysis 1.22) or at 12 months' corrected age (Analysis 1.16; Analysis 1.20; Analysis 1.24), or in weight or length at six months' corrected age (Analysis 1.15; Analysis 1.19). Sloan 1994 reported "there were no significant differences between the groups in growth indices during the six month follow up".

Figure 6. Forest plot of comparison: I Kangaroo mother care versus conventional neonatal care, outcome: 1.13 Weight gain at latest follow up (g/day) - stabilized infants.



We undertook sensitivity analysis by excluding studies with unclear allocation concealment and high risk of attrition bias to examine the impact on gain of both weight and head circumference. There were no differences in the overall direction of the findings.

4. Neurodevelopmental disability (outcomes 1.25 - 1.28)

Only one study (Charpak 1997) reported neurodevelopmental results at one year of corrected age. No statistically significant differences were found between KMC infants and controls in Griffith

quotients for psychomotor development (Analysis 1.25), cerebral palsy (Analysis 1.26), deafness (Analysis 1.27), and visual impairment (Analysis 1.28). A secondary publication of the Charpak 1997 trial reported that subgroup of KMC infants with birth-weight ≤ 1800 g had a higher general developmental quotient than controls at one year of corrected age ($P < 0.01$).

5. Breastfeeding (outcomes 1.29 - 1.37)

Mothers of KMC infants were more likely to be breastfeeding at discharge or 40 - 41 weeks' corrected gestational age and at 1 - 3 months follow up than mothers in the control group. Compared with conventional care, KMC was associated with an increase in the likelihood of exclusive breastfeeding at discharge or 40 - 41 weeks' postmenstrual age (67.4% vs 56.8%; typical RR 1.21, 95% CI 1.08 to 1.36; $I^2 = 57\%$; four studies, 1197 mothers) (Analysis 1.29) and at 1 - 3 months follow up (86.9% vs 76.5%; typical RR 1.20, 95% CI 1.01 to 1.43; $I^2 = 76\%$; five studies, 600 mothers) (Analysis 1.30) or any (exclusive and/or partial) breastfeeding at discharge or 40 - 41 weeks' postmenstrual age (88.4% vs 74.8%; typical RR 1.25, 95% CI 1.06 to 1.47; $I^2 = 84\%$; eight studies, 1440 mothers) (Analysis 1.32), at 1 - 2 months follow up (77.9% vs 67.9%; typical RR 1.33, 95% CI 1.00 to 1.78; $I^2 = 78\%$; six studies, 538 mothers) (Analysis 1.33), and at three months follow up (79.7% vs 69.8%; typical RR 1.14, 95% CI 1.06 to 1.23; $I^2 = 41\%$; five studies, 924 mothers) (Analysis 1.34). However, it is noted that there was substantial heterogeneity ($I^2 > 50\%$) among trials reporting breastfeeding. No statistically significant differences were seen for exclusive or any breastfeeding at 6 - 12 months follow up (Analysis 1.31; Analysis 1.35; Analysis 1.36), and onset of breastfeeding (Analysis 1.37).

The statistically significant positive effects of KMC on breastfeeding were demonstrated in the subgroup of trials that used intermittent KMC but not in the subgroup of trials that used continuous KMC. In addition, the increase in the likelihood of any breastfeeding at 1 - 2 months follow up was also demonstrated in the subgroup of three trials (131 infants) conducted in high income countries (typical RR 2.02, 95% CI 1.28 to 3.21; $I^2 = 23\%$).

6. Length of hospital stay (outcome 1.38)

KMC decreased length of hospital stay by 2.4 days (95% CI 0.7 to 4.1) in a meta-analysis of nine studies that used intermittent KMC (Analysis 1.38). The mean hospital stay from randomization to 41 weeks' postmenstrual age was 4.5 days for KMC infants and 5.6 for control infants in the Charpak 1997 study. No standard deviations were provided. Cattaneo 1998 only reported median hospital stay, which was 11 days in the KMC group, compared to 13 days in the control group. Length of hospital stay was two days greater in KMC infants than in control infants in the Sloan 1994 study.

7. Parental and familial satisfaction (outcome 1.39)

Only one study (Cattaneo 1998) evaluated parental and familial satisfaction with method of infant care. Mothers of the KMC group were more satisfied with method of care than mothers of the control group (91% versus 78%; RR 1.17, 95% CI 1.05 to 1.30; 269 mothers) (Analysis 1.39). There were no significant differences in satisfaction with method of care between fathers and families of KMC and control groups.

8. Mother-infant attachment or interaction (outcomes 1.40 - 1.46)

Three studies (Charpak 1997; Gathwala 2008; Roberts 2000) reported results about mother-infant attachment, and one (Neu 2010) on mother-infant interaction.

A secondary publication of the Charpak 1997 trial reported two series of outcomes that were assessed as manifestations of mother-infant attachment. The first was the mother's feelings and perceptions of her premature birth experience, measured through a "mother's perception of premature birth questionnaire" using a Likert scale (1 to 5), 24 hours after birth and when the infant reached 41 weeks' postmenstrual age. The second outcome was derived from observations made of the mother and child's responsiveness to each other during breastfeeding, using a "nursing child assessment feeding scale". A total of nine items were compared between KMC and control group according to interval between birth and start of intervention (1 - 2 days, 3 - 14 days, and > 14 days) and admission of infant to neonatal intensive care unit (NICU) (yes or not) for a total of 45 comparisons. Overall, scores of six comparisons (mother's sense of competence [interval between birth and start of intervention of 1 - 2 days, infant admitted or not admitted to NICU], mother's feelings of worry and stress [interval between birth and start of intervention of 1 - 2 days], mother's sensitivity [interval between birth and start of intervention > 14 days], and infant responsiveness [interval between birth and start of intervention > 14 days]) were significantly higher in KMC than in control group. Scores of two comparisons (mother's perceptions of social support [interval between birth and start of intervention > 14 days, and infant not admitted to NICU]) were significantly lower in KMC group than in control group. There were no significant differences in scores of the remaining 37 comparisons (Analysis 1.40; Analysis 1.41; Analysis 1.42).

Gathwala 2008 evaluated mother-infant attachment at three months follow up through a structured maternal interview that used attachment questions scored in such a manner that a higher score indicated a greater attachment. The total attachment score in the KMC group (24.46 ± 1.64) was significantly higher than that obtained in the control group (18.22 ± 1.79) (Analysis 1.43). Roberts 2000 measured maternal stress levels in NICU and mothers' perceptions of their maternal competence. Only the score on scale "relationship with the infant" was significantly higher in the KMC group (4.4 ± 0.46) than in control group (3.4 ± 1.16).

There was no significant difference between the KMC and control groups' scores on nursery environment, infant appearance, staff behavior and communication, and parental confidence in their parenting abilities (Analysis 1.44; Analysis 1.45).

The trial by Neu 2010 evaluated the mother-infant interaction at six months of age by using the Still-Face Paradigm tool. Mother-infant dyads in the KMC group showed more symmetrical, and less asymmetrical coregulation than mother-infant dyads in the control group. (Analysis 1.46). Multivariate analysis showed no differences between groups in infant vitality during the neutral face portion of the Still-Face procedure.

9. Home environment and father involvement (outcome 1.47)

One trial (Charpak 1997) evaluated home environment and father involvement at 12 months' corrected age through a structured interview administered to parents during a home visit. The total Home Observation for Measurement of the Environment (HOME) score was significantly higher in Kangaroo families (0.28 ± 0.24) than in conventional care families (-0.51 ± 0.26) (Analysis 1.47). Scores on father involvement were not reported but authors claimed that KMC increased father involvement (father's sense of responsibility and competence).

10. Costs of care

No study reported data on mean (SD) total medical and non-medical costs. The overall cost was "about 50% less for KMC" in the Cattaneo 1998 study. Specifically, it was US\$ 19,289 for KMC and US\$ 39,764 for conventional care. In the Sloan 1994 study, "costs of neonatal care were greater in the control than in the KMC group". Overall, the cost of hospital stay and post-neonatal care at five months was US\$ 741 greater for the control than KMC group. However, data were available for only 49 infants (24 KMC, 25 control) at six month follow up.

All funnel plots showed no asymmetry, either visually or in terms of statistical significance ($P > .10$ for all, by Egger test)

Comparison 2: Early onset versus late onset KMC in relatively stable infants

There was only one trial (Nagai 2010), considered as high quality, that compared early onset KMC versus late onset KMC in relatively stable LBW infants. Early continuous KMC was begun as soon as possible, within 24 hours post-birth, and late continuous KMC was begun after complete stabilization (generally after 24 hours post-birth). A total of 73 LBW infants (early 37, late 36) were included. No statistically significant differences were found between early onset KMC and late onset KMC for mortality (RR 1.95, 95% CI 0.18 to 20.53) (Analysis 2.1), morbidity (RR 0.49, 95% CI 0.18 to 1.28) (Analysis 2.2), severe infection (RR 0.42, 95% CI 0.12 to 1.49) (Analysis 2.3), readmission to hospital (RR

1.95, 95% CI 0.18 to 20.53) (Analysis 2.4), hypothermia (RR 0.58, 95% CI 0.15 to 2.27) (Analysis 2.5), weight gain (MD 58.9 g, 95% CI -116.9 to 234.6) (Analysis 2.6), and exclusive breastfeeding (RR 0.94, 95% CI 0.85 to 1.04) (Analysis 2.7) at four weeks of age. However, compared with late onset KMC, early onset KMC was associated with a statistically significant reduction in body weight loss from birth to 48 hours post-birth (MD 43.3 g, 95% CI 5.5 to 81.1) (Analysis 2.6) and length of hospital stay (MD -0.9 days, 95% CI -1.2 to -0.6) (Analysis 2.8).

DISCUSSION

Summary of main results

This updated systematic review of 15 randomized controlled trials comparing KMC and conventional neonatal care found compelling evidence that KMC is associated with a reduction in mortality at discharge or 40 - 41 weeks' postmenstrual age and at latest follow up, severe infection/sepsis, hypothermia, and length of hospital stay, and an increase in weight gain and exclusive or any breastfeeding at discharge or 40 - 41 weeks' postmenstrual age and at one to three months follow up. Moreover, there was some evidence that KMC reduces the risk of nosocomial infection/sepsis at discharge or 40 - 41 weeks' corrected gestational age, and increases head circumference gain, maternal satisfaction with the method, maternal-infant attachment, and home environment. One trial (Charpak 1997) reported no significant differences between KMC infants and controls in a variety of neurodevelopmental outcomes at one year of corrected age.

Overall, continuous KMC led to a reduction in mortality at discharge or 40 - 41 weeks' postmenstrual age and at latest follow up, nosocomial infection/sepsis, severe illness, and lower respiratory tract disease, and an increase in weight gain, maternal satisfaction with the method, and some measures of mother-infant attachment and home environment. On the other hand, intermittent KMC was associated with a decrease in the risk of severe infection/sepsis, nosocomial infection/sepsis, hypothermia, and length of hospital stay, and an increase in weight, length, and head circumference gain, exclusive or any breastfeeding at discharge or 40 - 41 weeks' postmenstrual age and at one to three months follow up, and mother-infant attachment at three months follow up.

Subgroup analyses showed that decreased risk of death at discharge or 40 - 41 weeks' postmenstrual age and at latest follow up was demonstrated in the subgroup of trials in which KMC was initiated within 10 days post-birth, the subgroup of trials conducted in low/middle-income countries, and the trial in which KMC was used in unstabilized infants. Sensitivity analysis suggested that the inclusion of studies with high risk of bias did not affect the general direction of findings or the size of the treatment effect although the beneficial effect of KMC on mortality turned non significant.

One small high quality trial (Nagai 2010) suggested that early onset KMC, compared with late onset KMC, is associated with a significant reduction in body weight loss from birth to 48 hours post-birth and length of hospital stay, with no significant difference in mortality, morbidity, severe infection, readmission to hospital, hypothermia, and exclusive breastfeeding at four weeks of age.

Overall completeness and applicability of evidence

The participants in the included trials reflect the population for which this intervention is currently considered, that is LBW infants. Eleven trials, including all four trials that evaluated continuous KMC, were conducted in hospitals in low/middle income countries. Mortality at discharge was the only outcome reported in the sole trial (Worku 2005) that compared KMC with conventional neonatal care in LBW infants before stabilization. The remaining 46 outcomes were reported in 14 trials that evaluated KMC in stabilized LBW infants. We were unable to draw conclusions about the effectiveness of KMC in unstabilized LBW infants. Given these factors, the great majority of results of our meta-analysis can only be applied in stabilized LBW infants in low/middle-income countries. However, the beneficial effect of KMC on any breastfeeding at one to two months follow up was also found in stabilized LBW infants in high income countries.

As only a small trial compared early onset KMC with late onset KMC, firm conclusions cannot be drawn on any apparent differences between these two managements.

The effect of community-based KMC on overall neonatal mortality, infant mortality, and LBW neonatal mortality was assessed in one randomized controlled cluster trial (Sloan 2008) in which 4165 infants in rural Bangladesh were assigned to community-based KMC or control without KMC. Unfortunately, this study was not included in the review because 40% overall and 65% of newborns who died were not weighed at birth, and missing birthweight was differential for study group. There was no difference in overall neonatal mortality rate or infant mortality rate. However, for infants whose modeled birthweight was ≤ 2000 g, the neonatal mortality rate was 9.5% in the community-based KMC group and 22.5% in the control group (adjusted odds ratio 0.37, 95% CI 0.16 to 0.86).

Quality of the evidence

We assessed risk of bias in included studies by addressing six specific domains (sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other potential sources of bias) discussed in the section [Risk of bias in included studies](#). Eight studies were judged by the reviewers to address adequately ≥ 4 domains (Blaymore Bier 1996; Boo 2007; Kadam 2005; Nagai 2010; Neu 2010; Roberts 2000; Rojas

2003; Whitelaw 1988). Four studies addressed adequately three domains (Charpak 1997; Gathwala 2008; Ramanathan 2001; Suman 2008) and four addressed adequately ≤ 2 domains (Ali 2009; Cattaneo 1998; Sloan 1994; Worku 2005).

Overall, the quality of the studies was mixed, although sensitivity analysis suggests that the inclusion of studies with high risk of bias did not affect the general direction of findings or the size of the treatment effect. Nevertheless, the lack of blinding of outcome assessors in most of the studies and the unclear method of allocation concealment might be a problem in terms of the overall quality of the evidence. Further progress must be made to improve research quality.

For some of the results described in the review (hypothermia, weight gain, breastfeeding, and length of hospital stay), there was evidence of high levels of statistical heterogeneity. Some of this heterogeneity may have occurred as a result of clinical heterogeneity; for example, different definitions of hypothermia used or women may not have been asked about breastfeeding in the same way in different trials. Results from meta-analysis with substantial heterogeneity should be interpreted cautiously.

Potential biases in the review process

We attempted to reduce bias in the reviewing process wherever possible. Two review authors independently assessed the risk of bias and the findings of the included studies. We tried to contact authors of studies with missing data with limited response. Despite differences in the timing of the outcome measurements among studies, we proceeded with the meta-analyses for several outcomes as the intervention effects were consistent among studies, although to varying degrees. About 50% of outcomes evaluated in the review were reported in only one study precluding drawing convincing conclusions on the effect of KMC on such outcomes.

The beneficial effects of KMC on mortality at discharge or 40 - 41 weeks' postmenstrual age and at latest follow up, severe infection/sepsis, and nosocomial infection found in our meta-analyses are enhanced by the impressive statistical homogeneity among trials ($I^2 = 0\%$ to 7%).

Up to now, only one study (Charpak 1997) reported neurodevelopmental results at one year of corrected age. Longer term assessments of neurodevelopmental outcomes have not been published yet, and some caution should perhaps be exercised in applying these findings at 12 months corrected age since it has been suggested that assessments done at a relatively young age may be insufficiently predictive of longer term neurodevelopmental outcomes, particularly with regard to cognitive functioning (Roberts 2010).

Agreements and disagreements with other studies or reviews

Previous versions of this review

Our assessment of the evidence differs from that used in previous versions of this review (Conde-Agudelo 2000; Conde-Agudelo 2003) which concluded that "there was insufficient evidence to recommend the routine use of KMC in LBW infants". In the current version of this review, we included 12 additional trials and more data from individual studies in meta-analyses, and performed subgroup analysis according to type of KMC (intermittent versus continuous) for all outcomes of the comparison KMC versus conventional neonatal care and sensitivity analysis according to risk of bias of included studies. Moreover, we have used the recent methodology introduced for Cochrane reviews in 2008, which assesses risk of bias in the individual studies more carefully than in the past (Higgins 2009).

The findings of the current version of this review allow us to conclude that there is sufficient evidence to recommend the use of KMC in stabilized LBW infants.

Other systematic reviews on KMC

Lawn 2010 performed a systematic review and meta-analysis to estimate the effect of KMC on neonatal mortality due to direct complications of preterm birth. This review included observational studies and excluded randomized controlled trials which initiated KMC after the first week of life. In the meta-analysis of randomized controlled trials, which included three studies (Charpak 1997; Suman 2008; Worku 2005) that provided data on neonatal specific mortality, KMC was associated with a reduction in neonatal death in infants < 2000 g (RR 0.49, 95% CI 0.29 to 0.82; $I^2 = 0\%$; 988 infants). In the meta-analysis of three observational studies, KMC was also associated with a decreased risk of neonatal death in infants < 2000 g (RR 0.68, 95% CI 0.58 to 0.79; $I^2 = 54\%$; 8151 infants). Other meta-analysis, which included five randomized controlled trials, showed that KMC reduced significantly the risk of severe morbidity (RR 0.34, 95% CI 0.17 to 0.65; $I^2 = 70\%$; 1520 infants). The results of the present review also suggest that KMC reduces the risk of mortality at discharge or 40 - 41 weeks' corrected gestational age and at latest follow up. However, our estimated effect was smaller than that of Lawn 2010. Differences in our findings compared to this review reflect the addition of more studies which reported mortality (all causes) from randomization until one year of corrected age.

AUTHORS' CONCLUSIONS

Implications for practice

The results of this updated review indicate that, currently, there is sufficient evidence to support the use of KMC in stabilized LBW infants as an alternative to conventional neonatal care in resource limited settings. Although current evidence is mainly limited to

the use of KMC in low/middle income countries, there is emerging evidence that use of KMC could improve breastfeeding rates in high income countries. Subgroup analyses suggest that both continuous and intermittent KMC are beneficial for stabilized LBW infants. Since the control group in studies evaluating continuous KMC was in incubators or radiant warmers, the potential beneficial effects of KMC on morbidity and mortality of LBW infants would be expected to be greatest in settings in which conventional neonatal care is unavailable.

Implications for research

There are several areas which require further study in the light of the results of this review.

- Methodologically rigorous trials are needed to further explore the effectiveness of early onset continuous KMC in unstabilized or relatively stabilized LBW infants in low income settings. Studies should provide detailed information on inclusion and exclusion criteria, methods used to generate and conceal the allocation sequence, measures used to blind outcome assessors to allocation of participants, completeness of outcome data for each main outcome (attrition and exclusions), definition of infant stabilization, infant age at initiation of KMC, frequency, daily duration and total duration of the intervention, and to report adequately all pre-specified outcomes in the study protocol.
- Only five randomized controlled trials, including a total of 256 infants, which were conducted in developed countries and reported clinical outcome measures, met minimal inclusion criteria. (Blaymore Bier 1996; Neu 2010; Roberts 2000; Rojas 2003; Whitelaw 1988). Thereby, there is a clear need for randomized trials with an adequate sample size that evaluate the use of continuous or intermittent KMC in high income settings and report results mainly on infant morbidity.
- Although some data are available on long term neurodevelopmental outcomes, continuing follow up and additional data of randomized children are justified as more subtle differences in later childhood may become apparent (Roberts 2010).
- Further well-designed economic evaluations are needed to assess the cost-effectiveness of KMC in low, middle, and high income settings.
- Further exploration of mother-infant attachment should be included in future trials as this element was inconsistently evaluated across studies.

- Additional trials in different settings ensuring baseline comparability of mortality, adequate KMC implementation, and birthweight assessment are required to clarify the effect of community-based KMC on LBW neonatal mortality before implementation of community-based KMC programs or inclusion of community-based KMC in essential newborn care.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ali 2009

Methods	Randomized controlled trial carried out in the neonatal section of a teaching hospital in India.	
Participants	<p>114 infants. Inclusion criteria: hemodynamically stable infants delivered by vaginal route with birthweight between 1200 and 1800 g.</p> <p>Infant's stabilization status at trial entry: stabilized</p> <p>Exclusion criteria: neonates delivered by cesarean section, major life threatening congenital malformations, severe perinatal complications, and parental refusal for KMC intervention.</p> <p>81% of LBW infants met eligibility criteria. Mean age and weight at recruitment was 4.7 ± 2.9 and 4.8 ± 2.4 days, and 1607 ± 211 and 1615 ± 179 g for KMC and control infants, respectively.</p>	
Interventions	<p>(1) KMC group (n = 58): SSC between the mother's breasts in an upright position. Infants were dressed with a cap, socks, and diaper and supported in bottom with a sling/binder. The duration of KMC during hospital stay was 6.3 ± 1.5 hours (range, 4-12) per day, and was given for a period of 25.7 ± 6.9 (range, 15-43) days after enrollment in the study.</p> <p>(2) control group (n = 56): infants were kept in radiant warmers or open cots in warm rooms.</p> <p>In both groups, mothers were allowed to handle their babies at any hour of the day and breast feed them by nasogastric tube, paladai or directly. Babies in both groups were provided with vitamins and mineral supplementation.</p>	
Outcomes	Duration of hospital stay, weight gain, head circumference, length, exclusive breastfeeding, nosocomial sepsis, hypothermia, mild/moderate infection, severe infection, and mortality.	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Block randomization technique.
Allocation concealment?	Unclear	No information provided.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: unclear.

Ali 2009 (Continued)

Incomplete outcome data addressed? All outcomes	Yes	10 infants (8.8%) were lost at 40 weeks' corrected gestational age follow up (KMC 4, control 6), 21 (18.4%) were lost at 3 months' corrected age (KMC 10, control 11), and 39 (34.2%) were lost at 6 months' corrected age (KMC 19, control 20).
Free of selective reporting?	No	Non-significant results such as infant mortality (weight, length, and head circumference at discharge and follow up (secondary outcomes listed in Methods) were mentioned but not reported adequately.
Free of other bias?	No	Use of blocked randomization which could make it possible to predict future assignments in an unblinded trial when the assignments are revealed subsequent to the person recruiting into the trial.

Blaymore Bier 1996

Methods	Randomized controlled trial carried out in the special care nursery of a hospital in Providence, United States.
Participants	<p>50 infants. Inclusion criteria: medically stable infants from singleton or multiple pregnancy with birth weight <1500 g and whose mothers planned to breast-feed. The infants were no longer ventilator dependent and without chest tubes, and they no longer required continuous positive airway pressure when the study was begun.</p> <p>Infant's stabilization status at trial entry: stabilized</p> <p>Exclusion criteria: mother's positive history of illicit drug use, mental illness, human immunodeficiency virus (HIV) infection, or receiving any medications contraindicative to breast-feeding. In addition, any infants who had a positive toxicologic screen for cocaine or other illicit drugs or were showing drug withdrawal symptoms at birth were excluded.</p> <p>No data on percentage of LBW infants that met eligibility criteria. Mean age and weight at recruitment was 29 and 30 days, and 993 ± 275 and 942 ± 322 g for KMC and control infants, respectively.</p>
Interventions	<p>(1) KMC group (n = 25): SSC involved the infant clothed in only a diaper and hat, held upright between the mother's breasts, with the mother and infant covered with a blanket.</p> <p>(2) control group (n = 25): standard contact involved a fully clothed infant wrapped in a blanket and held cradled in his or her mother's arms.</p> <p>During the study, the mother-infant dyad was observed participating in SSC or standard contact once each weekday until bottle and breast-feedings were initiated or for a maximum of 10 days. The duration of the SSC and standard contact sessions was 10 minutes per day.</p>

Blaymore Bier 1996 (Continued)

Outcomes	Breastfeeding and physiological data.	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Shuffling envelopes.
Allocation concealment?	Unclear	No information provided.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: unclear.
Incomplete outcome data addressed? All outcomes	Yes	21 mothers of 25 infants were allocated to KMC group, and 20 mothers of 25 infants were allocated to standard contact group. One mother in the KMC group was lost to follow up after discharge. Two mothers in the control group were excluded because they wanted to participate in KMC group.
Free of selective reporting?	Yes	
Free of other bias?	Yes	Other biases have not been identified.

Boo 2007

Methods	Randomized controlled trial carried out in the NICU of a tertiary teaching hospital in Malaysia.
Participants	128 infants. Inclusion criteria: very low birthweight infants (<1501 g) in stable condition, nursed in a closed incubator, not requiring ventilatory support other than nasal continuous positive airway pressure, able to tolerate enteral feeds of at least 50% of the required fluid volume, and having at least one parent or guardian who was willing to participate in the study. Infant's stabilization status at trial entry: stabilized Exclusion criteria included lethal or major malformations, severe perinatal asphyxia, with evidence of hypoxic ischemic encephalopathy, transfer to another hospital, abandoned by parents or parental refusal to participate. 43% of LBW infants met eligibility criteria. Median age and weight at recruitment was 24.5 and 20.5 days, and 1514 and 1492 g for KMC and control infants, respectively.
Interventions	(1) KMC group (n = 65): parent held the infant prone on their naked chest, in a semi-upright position and between his/her breasts. Infants wore only a nappy and a bonnet.

Boo 2007 (Continued)

	Both parent and infant were covered with a thermal blanket. Median duration of SSC was 1 hour per day with a mean total duration of 12.7 ± 5.0 days. (2) control group (n = 63): infants were not exposed to SSC while in the NICU. All mothers were encouraged to breast feed their infants.	
Outcomes	Duration of hospital stay, weight gain, weekly increase in head circumference, breast-feeding rate at discharge, sepsis, and mortality at discharge.	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Shuffling envelopes.
Allocation concealment?	Yes	Numbered sealed envelopes.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: unclear.
Incomplete outcome data addressed? All outcomes	No	8 infants in the KMC group (12.3%) were excluded because SSC sessions were carried out on less than 50% of hospital stay days after recruitment.
Free of selective reporting?	Yes	
Free of other bias?	Yes	Other biases have not been identified.

Cattaneo 1998

Methods	Multicentre randomized controlled trial carried out in 3 tertiary hospitals in Addis Ababa (Ethiopia), Yogyakarta (Indonesia), and Merida (Mexico).
Participants	285 infants. Inclusion criteria: infants with birthweight between 1000 and 1999 g without gestational age limits, no dependency on oxygen, and/or i.v. fluids, ability (at least partial) to feed, no visible major malformation, and mother present and willing to collaborate. Infant's stabilization status at trial entry: stabilized Exclusion criteria were not described. 44% of LBW infants met eligibility criteria. Median age (range) and mean weight (SD) at recruitment was 10 (1-74) and 8 (1-40) days, and 1584 (223) and 1574 (251) g for KMC and control infants, respectively.

Cattaneo 1998 (Continued)

Interventions	(1) KMC group (n = 149): infants were kept in close and continuous SSC, between the mother's breasts, naked except for a diaper and a hat covered across their backs with their mother's clothes, day and night, for an average of about 20 hours/day, including when the mother was asleep. The mother was occasionally replaced, for few hours, by another person usually the father or a member of the family. For short absences of the mother (<1 hour) the baby was left on the mother's bed, covered by a blanket. (2) Control group (n = 136): infants were kept in a warm room in Addis Ababa, with open cribs and the possibility of rewarming in a bulb-heated cot, and in incubators in the other two hospitals. SSC with their mothers was not allowed.	
Outcomes	Severe illness, hypothermia, hyperthermia, breastfeeding, weight gain, neonatal death, acceptability to health workers, acceptability to mothers, and costs.	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random number table.
Allocation concealment?	Unclear	No information provided.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: Unclear.
Incomplete outcome data addressed? All outcomes	Unclear	It was not reported the number of infants lost to follow up or excluded after randomization.
Free of selective reporting?	Yes	
Free of other bias?	Unclear	In Indonesia, randomization was carried out in blocks of six and stratifying by weight which could make it possible to predict future assignments in an unblinded trial when the assignments are revealed subsequent to the person recruiting into the trial.

Charpak 1997

Methods	Randomized controlled trial carried out in a single tertiary centre in Bogotá, Colombia.
Participants	777 infants. Inclusion criteria: Infants from singleton or multiple pregnancy with birth weights <2001 g, with a mother or a relative able to understand and willing to follow the general program instructions.

Charpak 1997 (Continued)

	<p>Infant's stabilization status at trial entry: stabilized</p> <p>Exclusion criteria: being referred to another institution, plans to leave Bogota in the near future, life-threatening or major malformations, early-detected major conditions arising from perinatal problems, and parental or family refusal to comply with the follow up program or, for those assigned to the KMC group, refusal to comply with the specifics of the intervention.</p> <p>72% of LBW infants met eligibility criteria. Median age (range) and mean weight (SD) at recruitment was 4 (1-60) and 3 (1-55) days, and 1678 (226) and 1715 (228) g for KMC and control infants, respectively.</p>	
Interventions	<p>(1) KMC group (n = 396): infants were kept 24 hours a day in a strict upright position, in SSC firmly attached to the mother's chest. Infants were breast fed regularly, although premature formula supplements were administered if necessary. Infants were discharged as soon as they overcame major adaptations to extrauterine life, received proper treatment for infection or concomitant condition, sucked and swallowed properly, and achieved a positive weight gain.</p> <p>(2) Control group (n = 381): infants were kept in an incubator until they were able to regulate temperature and were thriving. The parent's access to their babies was severely restricted.</p>	
Outcomes	<p>1. At 40-41 weeks' corrected gestational age: mortality, infant growth, length of hospital stay, infection, breastfeeding, and mother-infant attachment.</p> <p>2. At 12 months corrected age: neurodevelopmental disability, and social and home environment.</p>	
Notes	<p>Informed consent was not asked to parents of infants allocated to the control group. Additional data provided by Dr Nathalie Charpak.</p>	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random number table.
Allocation concealment?	Unclear	The person managing allocation was aware of weight at birth and whether the infant was a twin or triplet.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: unclear.
Incomplete outcome data addressed? All outcomes	Yes	31 infants (4%) (KMC 14, control 17) were excluded after randomization due to pre-existing neurologic impairment, or fetal intrauterine infection not detected at time of randomization. follow up at 40 to 41 weeks' corrected gestational age was incomplete for 67 (8.6%) survivor infants

Charpak 1997 (Continued)

		(KMC 33, control 34), but mortality data were available in 30 of these, giving mortality data for 364 vs 345.
Free of selective reporting?	Yes	
Free of other bias?	No	Use of blocked randomization which could make it possible to predict future assignments in an unblinded trial when the assignments are revealed subsequent to the person recruiting into the trial.

Gathwala 2008

Methods	Randomized controlled trial carried out in a single centre in Rohtak, India.	
Participants	<p>110 infants. Inclusion criteria: Infants with birthweight ≤ 1800 g, stable cardiopulmonary status, Apgar score ≥ 7 at 1 and 5 minute, tolerating enteral feeds, and maintaining temperature.</p> <p>Infant's stabilization status at trial entry: stabilized</p> <p>Exclusion criteria: infants sick, unstable, or with major congenital malformations, or whose mothers were unwell and unable to come or refused consent.</p> <p>No data on percentage of LBW infants that met eligibility criteria. Mean age at recruitment was 1.7 ± 0.5 days. Mean birthweight was 1690 ± 110 and 1690 ± 120 g for KMC and control infants, respectively.</p>	
Interventions	<p>(1) KMC group (n = 50): Infants were kept in SSC, between the mother's breasts, naked except for a cap and nappy, for at least 6 hours per day. The duration of KMC in the first month was 10.2 ± 1.5 hours per day, in the second month was 10.0 ± 1.6, and in the third month was 9.0 ± 1.4. The gown covered the baby's trunk and extremities but not the head. The KMC was given for a minimum of one hour at a stretch and continued for as long as it was comfortable to baby and mother. When not receiving KMC the infants received standard care under a warmer or incubator.</p> <p>(2) Control group (n = 50): infants were kept in a warmer or incubator. Mothers were allowed to visit their babies and touch and handle them.</p> <p>Babies in the KMC group continued to receive KMC after they were shifted to the mother in the ward. Babies in the control group were also shifted to the mother in her bed but did not receive KMC.</p>	
Outcomes	Attachment between mother and infant at 3 months follow up, duration of hospital stay, breastfeeding, and weight, length and circumference head gain.	
Notes		
Risk of bias		
Item	Authors' judgement	Description

Gathwala 2008 (Continued)

Adequate sequence generation?	Yes	Random number table.
Allocation concealment?	Unclear	No information provided.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: unclear.
Incomplete outcome data addressed? All outcomes	Unclear	10 infants (9.1%) were lost to follow up. It was not reported the number of infants lost to follow up in each intervention group. Out of the remaining 100, 50 received KMC and 50 received standard care.
Free of selective reporting?	Yes	
Free of other bias?	Yes	Other biases have not been identified.

Kadam 2005

Methods	Randomized controlled trial carried out in a tertiary care centre in Mumbai, India.
Participants	89 infants. Inclusion criteria: Infants with birthweight ≤ 1800 g, stable cardiopulmonary status, Apgar score ≥ 7 at 5 minute, and on feeds (breast feeds or spoon <i>wati</i> feeds with expressed breast milk). Infant's stabilization status at trial entry: stabilized Exclusion criteria: infants sick and unstable, or with major congenital malformations, or whose parents refused consent. No data on percentage of LBW infants that met eligibility criteria. The mean age (range) at enrolment was 3.2 (1-8) days for both groups. Mean birthweight was 1467 ± 228 and 1461 ± 217 g for KMC and control infants, respectively.
Interventions	(1) KMC group (n = 44): infants were placed on mother's chest in between the breasts in vertical position supported by a cloth <i>dupatta</i> , with mothers seating in a semi-reclining position, for a mean of 9.8 ± 3.7 hours per day. In case of any problem the baby was transferred to conventional care and after stabilization was transferred back to KMC, which was continued until discharge (2) Control group (n = 45): infants were kept in radiant warmers. More than 95% of babies in both groups received exclusive breastfeeding and the remaining were supplemented by banked human milk. Mothers in both groups were allowed to enter and handle the babies at any hour of the day, change diapers, and breast feed the babies.
Outcomes	Mortality, morbidity (hypothermia, hyperthermia, sepsis, apnea), onset of breastfeeding, duration of hospital stay, and weight at discharge.
Notes	

Risk of bias

Kadam 2005 (Continued)

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Sealed envelope method.
Allocation concealment?	Yes	Sealed envelopes.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: unclear.
Incomplete outcome data addressed? All outcomes	Yes	There were no infants lost to follow up.
Free of selective reporting?	Yes	
Free of other bias?	Yes	Other biases have not been identified.

Nagai 2010

Methods	Randomized controlled trial carried out in a referral hospital in Mahajanga, Madagascar.
Participants	73 infants. Inclusion criteria: infants with birthweight <2500 g, less than 24 hours post birth, no serious malformation, relatively stable clinical condition (oxygen saturation \geq 95%; heart rate >100 beats/min; respiratory rate <60 times/min; capillary refilling time <3 sec), and healthy mother and/or other family members willing to practice KMC. Infant's stabilization status at trial entry: relatively stabilized Exclusion criteria: prolonged apnea (>20 sec) and intravenous infusion 52% of LBW infants met eligibility criteria. Mean age and weight at recruitment was 19.8 \pm 14.3 and 33.0 \pm 13.2 hours, and 2075 \pm 272 and 2078 \pm 292 g for early onset KMC and late onset KMC infants, respectively.
Interventions	(1) Early KMC group (n = 37): infants were kept in direct and continuous SSC (without any underwear, except for a diaper, a warm hat, and socks for the baby) for as long as possible. SSC was begun as soon as possible, within 24 hours post birth. (2) Late KMC group (n = 36): initially, infants were kept in incubator or radiant warmer. Later, infants were covered with cotton cloth and laid beside the mothers. KMC was begun after complete stabilization (generally after 24 hours post birth) of infant. After initiating KMC, all participants were encouraged to continue KMC for as long as possible during hospitalization and after discharge. Other family members assisted the mother occasionally in performing continuous KMC.
Outcomes	Primary outcomes: mortality at 4 weeks of age. Secondary outcomes: morbidities (severe infection treated with antibiotics, high fever diagnosed as malaria, and both anorexia and hypoactivity with subsequent re-hospitalization) and adverse events (hypothermia, hyperthermia, bradycardia and/or tachycardia, and prolonged apnea) at 4 weeks of age, body weight changes from birth to 24 hours, 48 hours, 14 days, and 28 days post birth, duration of hospital stay, discharge within 7

Nagai 2010 (Continued)

	days post birth, and feeding methods from birth to 24 and 48 hours.	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Minimization method by software "minim".
Allocation concealment?	Yes	Software automatically provided the random allocation for each participant.
Blinding? All outcomes	Yes	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: a neonatologist who was masked to the allocation of participants and who did not have any contact with participants, determined the classification of morbidities based on the interview records and medical charts.
Incomplete outcome data addressed? All outcomes	Yes	There were no infants lost to follow up.
Free of selective reporting?	Yes	
Free of other bias?	Yes	Other biases have not been identified.

Neu 2010

Methods	Randomized controlled trial carried out in Aurora (Colorado), United States.
Participants	60 infants. Inclusion criteria: healthy infants with gestational age between 32 and 34 weeks, oxygen requirement <½ liter O ₂ per nasal cannula, infant without umbilical lines, intraventricular hemorrhage, physical anomalies, or anticipated major surgery, mother fluent in English or Spanish without recorded or stated illicit drug use, or diagnosis of serious chronic illness. Infant's stabilization status at trial entry: stabilized Exclusion criteria were not described. Approximately 60% of mothers who were approached declined to be in the study. Mean age at recruitment and birthweight was 15.0 ± 6.7 and 15.0 ± 4.9 days, and 1990 ± 450 and 1880 ± 340 g for KMC and control infants, respectively.
Interventions	An 8-week home intervention encouraged daily 1-hour, uninterrupted holding with either KMC (baby in SSC on mother's chest) (n = 31) or mother's arms (baby wrapped in blanket and held in mother's arms) (n = 29). In both conditions, weekly home visits by and experienced Registered Nurse included encouragement to hold the infant, emotional

Neu 2010 (Continued)

	support, and information about infant behavior and development. Other control group received brief social visits, had no holding constraints and participated in all assessments. In the meta-analysis, we excluded results from this last control group.	
Outcomes	Mother-infant interaction at six months follow up and infant vitality during the neutral-face period of the Still-Face Procedure.	
Notes		
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer random number generator.
Allocation concealment?	Yes	Opaque sealed envelopes.
Blinding? All outcomes	Unclear	Four researchers assessed outcome measures. Two outcome assessors were blinded to the hypotheses of the study but not to group assignment of the mother-infant dyads. The other two researchers were blinded to group assignment and hypotheses.
Incomplete outcome data addressed? All outcomes	Yes	87 infants were randomized, 31 to KMC group, 29 to traditional holding and 36 to control group. At 6 months of age, 8 infants (9.2%) were lost to follow up and 14 (16.1%) were excluded (8 withdrawn by maternal reasons and 6 due to technical problems videotaping).
Free of selective reporting?	Yes	
Free of other bias?	Yes	Other biases have not been identified.

Ramanathan 2001

Methods	Randomized controlled trial carried out in a single centre in New Delhi, India.
Participants	28 infants. Inclusion criteria: Infants with birthweight <1500 g, stable cardiopulmonary status, tolerating enteral feeds and maintaining temperature in the thermoneutral environment. Infant's stabilization status at trial entry: stabilized Exclusion criteria: infants whose mothers were unable to come to the nursery because of illness or disability. No data on percentage of LBW infants that met eligibility criteria. The median age at

Ramanathan 2001 (Continued)

	initiation of KMC was 11.8 days. Mean birthweight was 1219 ± 186 and 1271 ± 170 g for KMC and control infants, respectively.
Interventions	(1) KMC group (n = 14): infants were kept between the mother's breasts, for at least 4 hours per day in not more than 3 sittings. The gown covered the baby's trunk and extremities but not the head. When not receiving KMC the infants received standard care under a warmer or incubator. (2) Control group (n = 14): infants were kept in a warmer or incubator. Mothers were allowed to visit their babies and touch and handle them. Breastfeeding guidelines were followed for both groups and lactation counseling was emphasized to ensure breast milk feeding.
Outcomes	Weight gain, breastfeeding, and duration of hospital.
Notes	Infants in the KMC group required positive pressure ventilation, continuous positive airway pressure, and oxygen therapy for more duration of time than the infants in the control group indicating that these infants were sicker before enrollment.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random number table.
Allocation concealment?	Unclear	No information provided.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: unclear.
Incomplete outcome data addressed? All outcomes	Yes	There were no infants lost to follow up.
Free of selective reporting?	Unclear	Despite neonatal complications prospectively recorded, they were not reported.
Free of other bias?	Yes	Other biases have not been identified.

Roberts 2000

Methods	Randomized controlled trial carried out in two neonatal nurseries in Darwin, Australia.
Participants	30 infants. Inclusion criteria: premature or small for gestational age infants born at 30 or more weeks gestation or corrected age, with a five-minute Apgar of at least 5, medically stable, without congenital abnormalities or central nervous system impairment. Infants could have nasal continuous positive airway pressure in place or a nasal cannula. No data on percentage of LBW infants that met eligibility criteria. Infant's stabilization status at trial entry: stabilized

Roberts 2000 (Continued)

	Exclusion criteria: phototherapy within the previous 24 hours, resuscitated infants, and mothers with a history of drug use. No data on percentage of LBW infants that met eligibility criteria. Mean age and weight at recruitment was 31.5 ± 2.7 days and 1690 ± 333 g, respectively.
Interventions	(1) KMC group (n = 16): infants were dressed only in a diaper, with addition of a bonnet for smaller infants. They were then placed on the mother's skin and covered with a light blanket. Mean duration of KMC was 1.6 ± 0.9 hours per day, five days a week. (2) control group (n = 14): infants were swaddled in infant clothing and a light blanket. They had contact with the mother only through normal clothing. Breastfeeding was permitted as desired in both groups.
Outcomes	Weight gain, length of stay in hospital, temperature, and breastfeeding.
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Shuffling envelopes.
Allocation concealment?	Yes	Numbered envelopes.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: unclear.
Incomplete outcome data addressed? All outcomes	Yes	There were no infants lost to follow up.
Free of selective reporting?	Yes	
Free of other bias?	Yes	Other biases have not been identified.

Rojas 2003

Methods	Randomized controlled trial carried out in a tertiary NICU at Yale New Haven Hospital in Connecticut, United States.
Participants	60 infants. Inclusion criteria: very low birthweight infants (<1501 g) with gestational age ≤ 32 weeks, with minimal ventilatory support or extubated on nasal continuous positive airway pressure or nasal canula, and hemodynamic stability. 19% of LBW infants met eligibility criteria. Infant's stabilization status at trial entry: stabilized Exclusion criteria: mother's age <18 years, or if there was a history of illicit drug use during pregnancy, clinical evidence of perinatal asphyxia, potential transfer within the first month after birth, presence of a major congenital anomaly, planned adoption, Grade

Rojas 2003 (Continued)

	III or IV intraventricular hemorrhage, fetal growth restriction, or suspected sepsis. 19% of LBW infants met eligibility criteria. Mean age and weight at trial entry was 19 days, and 1021 ± 268 and 1002 ± 219 g for KMC and control infants, respectively.
Interventions	(1) KMC group (n = 33): infants were held in a prone semi-upright position at approximately a 45° angle, in direct SSC with the parent's chest. The infants wore only a diaper, and their backs were covered with a blanket. Mean duration of KMC was 1.3 ± 0.7 hours per day for an average of 15 ± 16 days. (2) control group (n = 27): parents removed their infants from the incubator and held them in their arms in supine position with eye-to-eye contact. The infant wore diapers and T-shirts and were wrapped in a blanket.
Outcomes	Mortality at discharge, sepsis, necrotizing enterocolitis, intraventricular hemorrhage, weight, head circumference, and length at discharge, rate of weight gain and head circumference growth, total weight gain and head circumference growth, breastfeeding at discharge, and hospital stay

Notes

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random number table.
Allocation concealment?	Yes	Numbered, sealed, opaque envelopes.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: no.
Incomplete outcome data addressed? All outcomes	Yes	There were no infants lost to follow up.
Free of selective reporting?	Yes	
Free of other bias?	Yes	Other biases have not been identified.

Sloan 1994

Methods	Randomized controlled trial carried out in a single centre in Quito, Ecuador.
Participants	300 infants. Inclusion criteria: singleton infants weighing less than 2000 g, with no serious congenital abnormalities or respiratory, metabolic, or infectious disease. Infants had to be stabilized for the 24 h before enrolment (temperature between 36.5 and 37.0 °C); acceptable tolerance of food; and stable weight. Infant's stabilization status at trial entry: stabilized Exclusion criteria were not described.

Sloan 1994 (Continued)

	53% of LBW infants met eligibility criteria. Mean age and weight at recruitment was 13.0 ± 10.5 days, and 1618 ± 317 g, respectively.	
Interventions	(1) KMC group (n = 140): infants were kept in an upright position, in SSC contact (diapers allowed) against the mother's breasts and had frequent breastfeeding. SSC was reported by 68% of mothers at 1 month, 47% at 1.5 months, 20% at 2 months, and 7% at 3 months follow up. (2) Control group (n = 160): infants stayed in an incubator or thermal crib and were breast fed at scheduled times.	
Outcomes	Severe illnesses (lower respiratory tract disorders, apnea, aspiration, pneumonia, septicemia, general infections), moderate illness (urinary infections), mild illnesses (upper respiratory tract disorders, dermatitis, jaundice, hip displacement), diarrhea, infant growth (weight, length, upper arm and head circumference), duration of hospital stay, re-admission, and costs of care.	
Notes	Additional data provided by Dr Nancy L. Sloan.	
Risk of bias		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random number table.
Allocation concealment?	Unclear	No information provided.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: unclear.
Incomplete outcome data addressed? All outcomes	Yes	Outcome data were reported for 131 KMC infants and 152 controls. 17 infants (5.7%) lost to follow up (KMC 9, control 8); no exclusions.
Free of selective reporting?	Unclear	Secondary outcomes such as Infant growth indices at follow up and costs of care were mentioned but not reported adequately.
Free of other bias?	No	The trial was stopped early because a highly significant difference (p<0.02 at 2 months, p<0.005 at 6 months) in severe morbidity arose. No information about whether this was a planned interim analysis.

Suman 2008

Methods	Randomized controlled trial carried out in a single centre in Mumbai, India.
Participants	220 infants. Inclusion criteria: singleton infants with birthweight less than 2000 g. 63% of LBW infants met eligibility criteria. Infant's stabilization status at trial entry: stabilized Exclusion criteria: infants critically ill requiring ventilatory or inotropic support, or with chromosomal and life threatening congenital anomalies, or requiring transfer, or whose mothers were critically ill, or unable to comply with the follow up schedule. Mean age and weight at recruitment was 3.7 ± 2.8 and 2.3 ± 1.9 days, and 1608 ± 278 and 1691 ± 273 g for KMC and control infants, respectively.
Interventions	(1) KMC group (n = 108): infants were kept in SSC using a specially tailored "kangaroo bag" made of soft flannel cloth on the reclining cot in the semi-upright position with the help of pillows. Mothers were encouraged to keep the baby in KMC as long as possible during the day and night with a minimum period of one to two hours at a time. When the baby was not in KMC, the baby was placed either under a servo controlled radiant warmer or in a cradle under hot lamp adequately clothed and covered. Mean duration of KMC was 13.5 hours per day with a mean total duration of 33.8 ± 15.1 days. (2) Control group (n = 112): infants were managed under a servo controlled radiant warmer or in a cradle under hot lamp in NICU adequately clothed and covered. All babies were exclusively breast fed. Infants who developed a life threatening event or required phototherapy were temporarily withdrawn from the KMC group.
Outcomes	Infant growth (weight, length, head, chest, and mid-arm circumference, and foot length), mortality, morbidity (hypothermia, hyperthermia, hypoglycemia, sepsis, apnea in <1500 g, other minor illness), and duration of hospital stay.
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Simple randomization.
Allocation concealment?	Yes	Sealed envelopes.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: no.
Incomplete outcome data addressed? All outcomes	No	49 infants (22.3%) were lost to follow up (KMC 11[10.2%], control 38 [33.9%]); 14 babies (6.4%) were excluded (KMC 5, control 9) because they did not receive assigned care.
Free of selective reporting?	Yes	

Suman 2008 (Continued)

Free of other bias?	Unclear	The groups were different at baseline in two important variables: (1) weight at enrolment (1608 ± 278 and 1691 ± 273 g for KMC and control infants, respectively; $P=0.03$) and (2) age at enrolment (3.7 ± 2.8 and 2.3 ± 1.9 days for KMC and control infants, respectively; $P<0.01$).
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Whitelaw 1988

Methods	Randomized controlled trial carried out in a neonatal unit of a single centre in London, United Kingdom.
Participants	71 infants. Inclusion criteria: infants from singleton or twin pregnancy with weight less than 1500 g, stable breathing with no oxygen requirement, and a least one parent speaking fluent English. Stable infants were not excluded if they had congenital malformations such as hydronephrosis or scoliosis, nor if they had intracranial lesions such as periventricular leukomalacia or ventricular dilatation. Infant's stabilization status at trial entry: stabilized Exclusion criteria were not described. 50% of LBW infants met eligibility criteria. The mean (range) age at enrolment was 16 (1-66) days. Mean birthweight was 1152 ± 220 and 1135 ± 263 g for KMC and control infants, respectively.
Interventions	(1) KMC group (n = 35): infants were kept in an upright position, in SSC between the mother's breasts with a cardiac or respiration monitor attached. Mean (range) duration of KMC was 0.6 (0-1.5) hours per day. (2) Control group (n = 36): mother was encouraged to visit as much as she liked and helped to take her baby out of the incubator for a cuddle. However, baby and mother remained clothed. Care was taken that the normal contact group would have no less attention from the nursing staff.
Outcomes	Breastfeeding and infant's behaviour at 6 months of age, and mother's feelings about the infant at discharge and 6 months of age.
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Shuffling envelopes.
Allocation concealment?	Yes	Sequentially numbered, sealed, opaque envelopes.

Whitelaw 1988 (Continued)

Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: no.
Incomplete outcome data addressed? All outcomes	Yes	There were no infants lost to follow up.
Free of selective reporting?	Unclear	Non-significant results such as mother's feelings about the infant at discharge and at 6 months follow up, were mentioned but not reported adequately.
Free of other bias?	Yes	Other biases have not been identified.

Worku 2005

Methods	Randomized controlled trial carried out in a neonatal unit of a single centre in Addis Ababa, Ethiopia.
Participants	123 infants. Infants with birthweight less than 2000 g, singletons unless one of the twins died, no major congenital malformation, and mother healthy and willing to participate. Infant's stabilization status at trial entry: non stabilized Exclusion criteria were not described. 48% of LBW infants met eligibility criteria. The mean age at enrolment and birthweight was 10.0 and 9.8 hours, and 1515 and 1472 g for KMC and control infants, respectively.
Interventions	(1) Early KMC group (n = 62): infants were kept in continuous SSC with their mother beginning immediately after birth or within the first 24 hours of life (before stabilization). The mother kept her newborn infant between the breasts, in close contact with her body and covered with her clothes day and night. Breastfeeding was the standard feeding method. However, the mother could also feed her baby with formula milk using tube or cup when needed. KMC could be combined with a heated room during low environmental temperatures. (2) Control group (n = 61): infants were kept in a heated room overhead lamp warmers with oxygen therapy, and breast, tube, cup, or mixed feeding. The two methods of care were applied and continued until the baby was considered stabilized (stable temperature, stabilized cardiovascular status, satisfactory ability to suck, and good general condition) and then both groups of babies were transferred to the ward routine Kangaroo care service. KMC was continued at home after discharge in both groups.
Outcomes	Death, serious illness (sepsis, diarrhea, pneumonia, aspiration, pneumonia), and mothers' feeling towards the method of care.
Notes	
Risk of bias	

Worku 2005 (Continued)

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Random number table.
Allocation concealment?	Unclear	No information provided.
Blinding? All outcomes	No	Blinding of participants: no/unfeasible; blinding of clinical staff: no/unfeasible; blinding of outcome assessors: no.
Incomplete outcome data addressed? All outcomes	Unclear	There was no information on infants lost to follow up or exclusions.
Free of selective reporting?	No	The great majority of outcomes listed in the Methods section of the article, such as weight gain, mild/moderate and severe illness, sepsis, diarrhea, pneumonia, aspiration, and mother's feelings, were collected but not reported.
Free of other bias?	Yes	Other biases have not been identified.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Ahn 2010	Non-randomized trial
Anderson 2003	The study compared SSC (N=48) and standard care (N=43) in preterm infants born at 32-36 weeks' gestation with birth weight between 1300 and 3000 g. No data on daily duration of KMC. Study did not report results for clinical outcomes.
Arandia 1993	Non-randomized trial
Bergman 1994	Non-randomized trial
Bergman 2004	The study compared SSC (N=21) from birth and standard care (N=14) in LBW infants. The study period was 6 hours. The study only reported results for physiological parameters. Newborns receiving SSC from birth were significantly advantaged in some measures of cardiorespiratory stability.
Charpak 1994	Non-randomized trial
Chiu 2009	The study compared early KMC (N=52) and standard care (N=48) in late preterm infants (32 to <37 weeks' gestation). The study included infants with birthweight \geq 2500 g. No data for subgroup of infants <2500 g at birth. KMC infants had lower infant teaching scores at six months than controls, a difference that disappeared

(Continued)

	thereafter. Feeding scores at 6 and 12 months follow up were similar for KMC infants and controls.
Christensson 1998	The study compared SSC and incubator care for rewarming in 80 low-risk hypothermic infants (clinically stable with admission weight of ≥ 1500 g).
Chwo 2002	The study compared SSC (N=17) and standard contact (N=17) in infants born at 34-36 weeks' gestation. 20 of 34 included infants (59%) had a birthweight >2500 g. No data for the remaining 14 LBW infants.
Dala Sierra 1994	Non-randomized trial
Darmstadt 2006	The study evaluated acceptance of KMC within a trial of impact of a package of essential newborn care.
de Almeida 2010	Non-randomized trial
de Macedo 2007	Non-randomized trial
Feldman 2002	Non-randomized trial
Hake Brooks 2008	The study compared KMC (N=36) and standard care (N=30) in preterm infants. The study included infants with birthweight of 1300-3000 g. 39% of included infants had a gestational age of 36 weeks. No data for subgroup of infants <2500 g at birth. KMC was associated with a significant longer breastfeeding duration and a higher frequency of exclusive breastfeeding at discharge, and at 1.5, 3, and 6 months.
Huang 2006	The study compared early KMC (N=39) and use of radiant warmers (N=39) in term infants with hypothermia problems. Mean (SD) birthweight was 3072 (393) and 2808 (428) g for KMC and control infants, respectively. After 4 hours, more infants in the KMC group had reached normal body temperature.
Ibe 2004	Non-randomized trial
Kambarami 1998	Quasi-random allocation to treatment (alternation). 74 (37 per group) infants were subjected to KMC or incubator care. Infants in the KMC group had higher mean daily weight gain, shorter stay in hospital, and better survival rates.
Kumar 2008	Cluster randomized controlled trial in which SSC was part of a preventive package of interventions for essential newborn care.
Lai 2006	The study compared music during KMC (N=15) and standard care (N=15) in preterm infants. The study included infants with birthweight of 1505-3285 g. No data for subgroup of infants <2500 g at birth. In addition, the study did not report results for clinical outcomes.
Lamy Filho 2008	Non-randomized trial.
Legault 1993	Participant allocation was by a crossover recruitment design. Study did not report results for clinical outcomes.
Legault 1995	Non-randomized trial.
Lincetto 2000	Non-randomized trial.

(Continued)

Ludington-Hoe 1991	Randomized controlled trial that compared KMC and standard care in cardiorespiratory, thermal and state effects in preterm infants. No data on neonatal morbidity and mortality.
Ludington-Hoe 2000	Randomized controlled trial that compared KMC (N=16) and standard care (N=13) in maintenance of body warmth in preterm infants. No data on neonatal morbidity and mortality.
Ludington-Hoe 2004	Randomized controlled trial that compared KMC (N=11) and standard care (N=13) for assessment of cardiorespiratory and thermal responses in preterm infants. No data on neonatal morbidity and mortality.
Ludington-Hoe 2006	Randomized controlled trial that compared KMC (N=14) and standard care (N=14) for assessment of neonatal sleep organization in preterm infants. No data on neonatal morbidity and mortality.
Miles 2006	The study was a pragmatic, controlled trial in which participant allocation was by a crossover, cluster recruitment design between two tertiary referral NICUs. Each hospital remained in KMC or control group for 4 months and then crossed over following a wash-out phase, during which no recruitment was undertaken. No significant difference was found in any infant or maternal measure at any time point.
Milstersteiner 2005	Quasi-random allocation to treatment (even or odd number). Length of hospital stay was 8±1 days for the KMC group and 10±1.9 days for the control group (P=0.004).
Ohgi 2002	Non-randomized trial.
Sloan 2008	Randomized controlled cluster trial in which 4165 infants were assigned to community-based KMC or control. 40% overall and 65% of newborns who died were not weighed at birth, and missing birthweight was differential for study group. 68.6% of weighed infants had a birthweight ≥2500 g. There was no difference in overall neonatal mortality rate or infant mortality rate.
Tallandini 2006	Non-randomized trial.

Characteristics of studies awaiting assessment [ordered by study ID]

Udani 2008

Methods	Randomized controlled trial performed in Mumbai, India between June 2001 and December 2001.
Participants	One hundred LBW infants <1800 g.
Interventions	KMC using a kangaroo bag which was tailored to hold the baby doubly secured in between the mother's breast compared with conventional method of care.
Outcomes	Serious illness, sepsis, hypothermia.
Notes	Available in abstract form. The study was presented at the VII International Workshop on Kangaroo Mother Care. Uppsala, Sweden. October 6-7, 2008. Additional information on study methods and outcomes was requested to authors by e-mail.

DATA AND ANALYSES

Comparison 1. Kangaroo mother care versus conventional neonatal care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality at discharge or 40-41 weeks' postmenstrual age	7		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 All studies	7	1614	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.39, 0.93]
1.2 Intermittent KMC	4	497	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.20, 1.85]
1.3 Continuous KMC	3	1117	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.38, 0.96]
1.4 Infant age ≤10 days at initiation of KMC	5	1426	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.36, 0.89]
1.5 Infant age >10 days at initiation of KMC	2	188	Risk Ratio (M-H, Fixed, 95% CI)	1.32 [0.22, 7.73]
1.6 Low/middle income countries	6	1554	Risk Ratio (M-H, Fixed, 95% CI)	0.58 [0.37, 0.90]
1.7 High income countries	1	60	Risk Ratio (M-H, Fixed, 95% CI)	1.64 [0.16, 17.09]
1.8 infant entered into trial before stabilization	1	123	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.33, 1.00]
1.9 infant entered into trial after stabilization	6	1491	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.32, 1.24]
2 Mortality at 6 months of age or 6 months follow up	2	354	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.48, 2.02]
2.1 Intermittent	1	71	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.15, 6.90]
2.2 Continuous	1	283	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.46, 2.12]
3 Mortality at 12 months' corrected age	1	693	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.27, 1.17]
3.1 Intermittent	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.2 Continuous	1	693	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.27, 1.17]
4 Mortality at latest follow up	9		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 All studies	9	1952	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.48, 0.96]
4.2 Intermittent KMC	5	568	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.26, 1.79]
4.3 Continuous KMC	4	1384	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.46, 0.98]
4.4 Infant age ≤10 days at initiation of KMC	5	1410	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.37, 0.86]
4.5 Infant age >10 days at initiation of KMC	4	542	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.53, 2.00]
4.6 Low/middle income countries	7	1821	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.45, 0.93]
4.7 High income countries	2	131	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [0.29, 5.42]
4.8 infant entered into trial before stabilization	1	123	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.33, 1.00]
4.9 infant entered into trial after stabilization	8	1829	Risk Ratio (M-H, Fixed, 95% CI)	0.73 [0.47, 1.14]
5 Severe infection/sepsis at latest follow up - stabilized infants	6	1250	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.40, 0.80]
5.1 Intermittent	5	587	Risk Ratio (M-H, Fixed, 95% CI)	0.46 [0.28, 0.76]

5.2 Continuous	1	663	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.43, 1.12]
6 Severe illness at 6 months follow up - stabilized infants	1	283	Risk Ratio (M-H, Fixed, 95% CI)	0.30 [0.14, 0.67]
6.1 intermittent	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.2 Continuous	1	283	Risk Ratio (M-H, Fixed, 95% CI)	0.30 [0.14, 0.67]
7 Nosocomial infection/sepsis at discharge or 40-41 weeks' postmenstrual age - stabilized infants	2	777	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.24, 0.73]
7.1 Intermittent	1	114	Risk Ratio (M-H, Fixed, 95% CI)	0.30 [0.10, 0.86]
7.2 Continuous	1	663	Risk Ratio (M-H, Fixed, 95% CI)	0.49 [0.25, 0.93]
8 Mild/moderate infection or illness at latest follow up - stabilized infants	4	1266	Risk Ratio (M-H, Random, 95% CI)	1.28 [0.87, 1.88]
8.1 Intermittent	2	320	Risk Ratio (M-H, Random, 95% CI)	1.52 [0.43, 5.38]
8.2 Continuous	2	946	Risk Ratio (M-H, Random, 95% CI)	1.42 [0.53, 3.79]
9 Lower respiratory tract disease at 6 months follow up - stabilized infants	1	283	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.15, 0.89]
9.1 Intermittent	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.2 Continuous	1	283	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.15, 0.89]
10 Diarrhea at 6 months follow up - stabilized infants	1	283	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.35, 1.20]
10.1 Intermittent	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10.2 Continuous	1	283	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.35, 1.20]
11 Hypothermia at discharge or 40-41 weeks' postmenstrual age - stabilized infants	4	469	Risk Ratio (M-H, Random, 95% CI)	0.23 [0.10, 0.55]
11.1 Intermittent	4	469	Risk Ratio (M-H, Random, 95% CI)	0.23 [0.10, 0.55]
11.2 Continuous	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
12 Readmission to hospital at latest follow up - stabilized infants	2	946	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.34, 1.06]
12.1 Intermittent	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
12.2 Continuous	2	946	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.34, 1.06]
13 Weight gain at latest follow up (g/day) - stabilized infants	9	936	Mean Difference (IV, Random, 95% CI)	3.86 [1.87, 5.84]
13.1 Intermittent	8	651	Mean Difference (IV, Random, 95% CI)	3.87 [1.67, 6.08]
13.2 Continuous	1	285	Mean Difference (IV, Random, 95% CI)	3.60 [0.78, 6.42]
14 Weight at discharge or 40-41 weeks' postmenstrual age (g) - stabilized infants	4	1097	Mean Difference (IV, Fixed, 95% CI)	21.65 [-15.98, 59.27]
14.1 Intermittent	2	149	Mean Difference (IV, Fixed, 95% CI)	63.54 [-2.58, 129.67]
14.2 Continuous	2	948	Mean Difference (IV, Fixed, 95% CI)	1.59 [-44.16, 47.34]
15 Weight at 6 months' corrected age (g) - stabilized infants	1	591	Mean Difference (IV, Fixed, 95% CI)	78.19 [-52.26, 208.64]
15.1 Intermittent	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
15.2 Continuous	1	591	Mean Difference (IV, Fixed, 95% CI)	78.19 [-52.26, 208.64]

16	Weight at 12 months' corrected age (g) - stabilized infants	1	596	Mean Difference (IV, Fixed, 95% CI)	31.46 [-135.08, 198.00]
	16.1 Intermittent	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
	16.2 Continuous	1	596	Mean Difference (IV, Fixed, 95% CI)	31.46 [-135.08, 198.00]
17	Length gain at latest follow up (cm/week) - stabilized infants	2	251	Mean Difference (IV, Fixed, 95% CI)	0.29 [0.27, 0.31]
	17.1 Intermittent	2	251	Mean Difference (IV, Fixed, 95% CI)	0.29 [0.27, 0.31]
	17.2 Continuous	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
18	Length at discharge or 40-41 weeks' postmenstrual age (cm) - stabilized infants	2	720	Mean Difference (IV, Fixed, 95% CI)	0.06 [-0.28, 0.39]
	18.1 Intermittent	1	57	Mean Difference (IV, Fixed, 95% CI)	0.40 [-0.48, 1.28]
	18.2 Continuous	1	663	Mean Difference (IV, Fixed, 95% CI)	Not estimable
19	Length at 6 months' corrected age (cm) - stabilized infants	1	590	Mean Difference (IV, Fixed, 95% CI)	0.23 [-0.18, 0.64]
	19.1 Intermittent	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
	19.2 Continuous	1	590	Mean Difference (IV, Fixed, 95% CI)	0.23 [-0.18, 0.64]
20	Length at 12 months' corrected age (cm) - stabilized infants	1	586	Mean Difference (IV, Fixed, 95% CI)	0.31 [-0.17, 0.79]
	20.1 Intermittent	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
	20.2 Continuous	1	586	Mean Difference (IV, Fixed, 95% CI)	0.31 [-0.17, 0.79]
21	Head circumference gain at latest follow up (cm/week) - stabilized infants	3	369	Mean Difference (IV, Random, 95% CI)	0.18 [0.09, 0.27]
	21.1 Intermittent	3	369	Mean Difference (IV, Random, 95% CI)	0.18 [0.09, 0.27]
	21.2 Continuous	0	0	Mean Difference (IV, Random, 95% CI)	Not estimable
22	Head circumference at discharge or 40-41 weeks' postmenstrual age (cm) - stabilized infants	2	720	Mean Difference (IV, Random, 95% CI)	0.39 [-0.28, 1.07]
	22.1 Intermittent	1	57	Mean Difference (IV, Random, 95% CI)	0.80 [0.20, 1.40]
	22.2 Continuous	1	663	Mean Difference (IV, Random, 95% CI)	0.10 [-0.14, 0.34]
23	Head circumference at 6 months' corrected age (cm) - stabilized infants	1	592	Mean Difference (IV, Fixed, 95% CI)	0.34 [0.11, 0.57]
	23.1 Intermittent	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
	23.2 Continuous	1	592	Mean Difference (IV, Fixed, 95% CI)	0.34 [0.11, 0.57]
24	Head circumference at 12 months' corrected age (cm) - stabilized infants	1	597	Mean Difference (IV, Fixed, 95% CI)	0.39 [-0.00, 0.78]
	24.1 Intermittent	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
	24.2 Continuous	1	597	Mean Difference (IV, Fixed, 95% CI)	0.39 [-0.00, 0.78]
25	Psychomotor development (Griffith quotients) at 12 months' corrected age	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
	25.1 Locomotion	1	579	Mean Difference (IV, Fixed, 95% CI)	2.25 [-0.45, 4.95]
	25.2 Personal, social	1	579	Mean Difference (IV, Fixed, 95% CI)	0.97 [-1.27, 3.21]
	25.3 Hand-eye coordination	1	579	Mean Difference (IV, Fixed, 95% CI)	0.57 [-1.25, 2.39]
	25.4 Audition, language	1	579	Mean Difference (IV, Fixed, 95% CI)	1.29 [-0.98, 3.56]
	25.5 Execution	1	579	Mean Difference (IV, Fixed, 95% CI)	0.30 [-1.50, 2.10]
	25.6 All criteria	1	579	Mean Difference (IV, Fixed, 95% CI)	1.05 [-0.75, 2.85]

26 Cerebral palsy at 12 months' corrected age	1	588	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.21, 2.02]
27 Deafness at 12 months' corrected age	1	588	Risk Ratio (M-H, Fixed, 95% CI)	0.30 [0.03, 2.90]
28 Visual impairment at 12 months' corrected age	1	588	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.53, 1.56]
29 Exclusive breast feeding at discharge or 40-41 weeks' postmenstrual age - stabilized infants	4	1197	Risk Ratio (M-H, Random, 95% CI)	1.21 [1.08, 1.36]
29.1 Intermittent	2	255	Risk Ratio (M-H, Random, 95% CI)	1.29 [1.15, 1.44]
29.2 Continuous	2	942	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.92, 1.42]
30 Exclusive breast feeding at 1-3 months follow up - stabilized infants	5	600	Risk Ratio (M-H, Random, 95% CI)	1.20 [1.01, 1.43]
30.1 Intermittent	3	221	Risk Ratio (M-H, Random, 95% CI)	1.36 [1.12, 1.65]
30.2 Continuous	2	379	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.96, 1.10]
31 Exclusive breast feeding at 6-12 months follow up - stabilized infants	3	810	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [0.95, 1.76]
31.1 Intermittent	1	75	Risk Ratio (M-H, Fixed, 95% CI)	1.52 [1.10, 2.10]
31.2 Continuous	2	735	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.66, 1.86]
32 Any breast feeding at discharge or 40-41 weeks' postmenstrual age - stabilized infants	8	1440	Risk Ratio (M-H, Random, 95% CI)	1.25 [1.06, 1.47]
32.1 Intermittent	6	498	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.11, 1.55]
32.2 Continuous	2	942	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.93, 1.40]
33 Any breast feeding at 1-2 months follow up - stabilized infants	6	538	Risk Ratio (M-H, Random, 95% CI)	1.33 [1.00, 1.78]
33.1 Intermittent	4	159	Risk Ratio (M-H, Random, 95% CI)	1.89 [1.30, 2.75]
33.2 Continuous	2	379	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.96, 1.10]
34 Any breast feeding at 3 months follow up - stabilized infants	5	924	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [1.06, 1.23]
34.1 Intermittent	4	261	Risk Ratio (M-H, Fixed, 95% CI)	1.35 [1.15, 1.59]
34.2 Continuous	1	663	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [1.00, 1.17]
35 Any breast feeding at 6 months follow up - stabilized infants	5	952	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.98, 1.29]
35.1 Intermittent	3	143	Risk Ratio (M-H, Fixed, 95% CI)	1.50 [1.08, 2.08]
35.2 Continuous	2	809	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.92, 1.24]
36 Any breast feeding at 12 months follow up - stabilized infants	1	589	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.65, 1.21]
36.1 Intermittent	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
36.2 Continuous	1	589	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.65, 1.21]
37 Onset of breast feeding (days) - stabilized infants	2	295	Mean Difference (IV, Random, 95% CI)	0.03 [-1.64, 1.70]
37.1 Intermittent	2	295	Mean Difference (IV, Random, 95% CI)	0.03 [-1.64, 1.70]
37.2 Continuous	0	0	Mean Difference (IV, Random, 95% CI)	Not estimable
38 Length of hospital stay (days) - stabilized infants	9	795	Mean Difference (IV, Random, 95% CI)	-2.41 [-4.11, -0.71]
38.1 Intermittent	9	795	Mean Difference (IV, Random, 95% CI)	-2.41 [-4.11, -0.71]

38.2	Continuous	0	0	Mean Difference (IV, Random, 95% CI)	Not estimable
39	Parental and familiar satisfaction (continuous KMC)	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
39.1	Mother satisfied with method	1	269	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [1.05, 1.30]
39.2	Father satisfied with method	1	269	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.91, 1.14]
39.3	Family satisfied with method	1	269	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.83, 1.13]
40	Mother-infant attachment: mother's feelings and perceptions according to interval between birth and start of intervention, and infant admission to NICU	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
40.1	Sense of competence - interval of 1-2 days	1	170	Mean Difference (IV, Fixed, 95% CI)	0.41 [0.14, 0.68]
40.2	Sense of competence - interval of 3-14 days	1	177	Mean Difference (IV, Fixed, 95% CI)	0.25 [-0.08, 0.58]
40.3	Sense of competence - interval >14 days	1	141	Mean Difference (IV, Fixed, 95% CI)	0.21 [-0.17, 0.59]
40.4	Sense of competence - infant admitted to NICU	1	82	Mean Difference (IV, Fixed, 95% CI)	0.54 [0.07, 1.01]
40.5	Sense of competence - infant not admitted to NICU	1	406	Mean Difference (IV, Fixed, 95% CI)	0.24 [0.05, 0.43]
40.6	Worry and stress - interval of 1-2 days	1	170	Mean Difference (IV, Fixed, 95% CI)	0.31 [0.04, 0.58]
40.7	Worry and stress - interval of 3-14 days	1	177	Mean Difference (IV, Fixed, 95% CI)	0.09 [-0.20, 0.38]
40.8	Worry and stress - interval >14 days	1	141	Mean Difference (IV, Fixed, 95% CI)	-0.29 [-0.70, 0.12]
40.9	Worry and stress - infant admitted to NICU	1	82	Mean Difference (IV, Fixed, 95% CI)	-0.1 [-0.60, 0.40]
40.10	Worry and stress - infant not admitted to NICU	1	406	Mean Difference (IV, Fixed, 95% CI)	0.12 [-0.06, 0.30]
40.11	Social support - interval of 1-2 days	1	170	Mean Difference (IV, Fixed, 95% CI)	-0.06 [-0.35, 0.23]
40.12	Social support - interval of 3-14 days	1	177	Mean Difference (IV, Fixed, 95% CI)	-0.06 [-0.34, 0.22]
40.13	Social support - interval >14 days	1	141	Mean Difference (IV, Fixed, 95% CI)	-0.47 [-0.84, -0.10]
40.14	Social support - infant admitted to NICU	1	82	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.52, 0.42]
40.15	Social support - infant not admitted to NICU	1	406	Mean Difference (IV, Fixed, 95% CI)	-0.2 [-0.39, -0.01]
41	Mother-infant attachment: mother's responses to the infant according to interval between birth and start of intervention, and infant admission to NICU	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

41.1 Mother's sensitivity - interval of 1-2 days	1	170	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.02, 0.06]
41.2 Mother's sensitivity - interval of 3-14 days	1	177	Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.05, 0.03]
41.3 Mother's sensitivity - interval >14 days	1	141	Mean Difference (IV, Fixed, 95% CI)	0.06 [0.01, 0.11]
41.4 Mother's sensitivity - infant admitted to NICU	1	82	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.04, 0.08]
41.5 Mother's sensitivity - infant not admitted to NICU	1	406	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.00, 0.04]
41.6 Mother's response to child's distress - interval of 1-2 days	1	170	Mean Difference (IV, Fixed, 95% CI)	-0.03 [-0.08, 0.02]
41.7 Mother's response to child's distress - interval of 3-14 days	1	177	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.03, 0.05]
41.8 Mother's response to child's distress - interval >14 days	1	141	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.04, 0.06]
41.9 Mother's response to child's distress - infant admitted to NICU	1	82	Mean Difference (IV, Fixed, 95% CI)	0.05 [-0.01, 0.11]
41.10 Mother's response to child's distress - infant not admitted to NICU	1	406	Mean Difference (IV, Fixed, 95% CI)	-0.02 [-0.05, 0.01]
41.11 Mother's response to child's socioemotional growth fostering - interval of 1-2 days	1	170	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.04, 0.06]
41.12 Mother's response to child's socioemotional growth fostering - interval of 3-14 days	1	177	Mean Difference (IV, Fixed, 95% CI)	-0.02 [-0.06, 0.02]
41.13 Mother's response to child's socioemotional growth fostering - interval >14 days	1	141	Mean Difference (IV, Fixed, 95% CI)	0.05 [-0.00, 0.10]
41.14 Mother's response to child's socioemotional growth fostering - infant admitted to NICU	1	82	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.12, 0.02]
41.15 Mother's response to child's socioemotional growth fostering - infant not admitted to NICU	1	406	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.01, 0.05]
41.16 Mother's response to child's cognitive growth fostering - interval of 1-2 days	1	170	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.04, 0.08]
41.17 Mother's response to child's cognitive growth fostering - interval of 3-14 days	1	177	Mean Difference (IV, Fixed, 95% CI)	-0.04 [-0.10, 0.02]
41.18 Mother's response to child's cognitive growth fostering - interval >14 days	1	141	Mean Difference (IV, Fixed, 95% CI)	0.07 [0.00, 0.14]

41.19	Mother's response to child's cognitive growth fostering - infant admitted to NICU	1	82	Mean Difference (IV, Fixed, 95% CI)	-0.07 [-0.17, 0.03]
41.20	Mother's response to child's cognitive growth fostering - infant not admitted to NICU	1	406	Mean Difference (IV, Fixed, 95% CI)	0.03 [-0.01, 0.07]
42	Mother-infant attachment: infant's responses to the mother according to interval between birth and start of intervention, and infant admission to NICU	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
42.1	Clarity of cues - interval of 1-2 days	1	170	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.04, 0.06]
42.2	Clarity of cues - interval of 3-14 days	1	177	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.03, 0.07]
42.3	Clarity of cues - interval >14 days	1	141	Mean Difference (IV, Fixed, 95% CI)	Not estimable
42.4	Clarity of cues - infant admitted to NICU	1	82	Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.07, 0.05]
42.5	Clarity of cues - infant not admitted to NICU	1	406	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.01, 0.05]
42.6	Responsiveness - interval of 1-2 days	1	170	Mean Difference (IV, Fixed, 95% CI)	-0.02 [-0.06, 0.02]
42.7	Responsiveness - interval of 3-14 days	1	177	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.02, 0.06]
42.8	Responsiveness - interval >14 days	1	141	Mean Difference (IV, Fixed, 95% CI)	0.05 [0.01, 0.09]
42.9	Responsiveness - infant admitted to NICU	1	82	Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.07, 0.05]
42.10	Responsiveness - infant not admitted to NICU	1	406	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.01, 0.05]
43	Mother-infant attachment at 3 months follow-up	1	100	Mean Difference (IV, Fixed, 95% CI)	6.24 [5.57, 6.91]
43.1	Total attachment score at 3 months follow-up	1	100	Mean Difference (IV, Fixed, 95% CI)	6.24 [5.57, 6.91]
44	Mother-infant attachment: stress in NICU	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
44.1	Nursery environment score	1	30	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.51, 0.71]
44.2	Infant appearance score	1	30	Mean Difference (IV, Fixed, 95% CI)	Not estimable
44.3	Relationship with the infant score	1	30	Mean Difference (IV, Fixed, 95% CI)	1.00 [0.35, 1.65]
44.4	Staff behavior and communication score	1	30	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.95, 1.15]
45	Mother-infant attachment: parenting skills	1	30	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-0.89, 0.09]
45.1	Total score at discharge	1	30	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-0.89, 0.09]
46	Mother-infant interaction at 6 months follow-up	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

46.1 Symmetrical coregulation	1	45	Mean Difference (IV, Fixed, 95% CI)	16.38 [13.61, 19.15]
46.2 Asymmetrical coregulation	1	45	Mean Difference (IV, Fixed, 95% CI)	-18.31 [-21.42, -15.20]
46.3 Unilateral regulation	1	45	Mean Difference (IV, Fixed, 95% CI)	2.12 [-1.24, 5.48]
47 Social and home environment	1	338	Mean Difference (IV, Fixed, 95% CI)	0.79 [0.74, 0.84]
47.1 HOME environment total score at 12 months' corrected age	1	338	Mean Difference (IV, Fixed, 95% CI)	0.79 [0.74, 0.84]

Comparison 2. Early versus late kangaroo mother care in relatively stable LBW infants

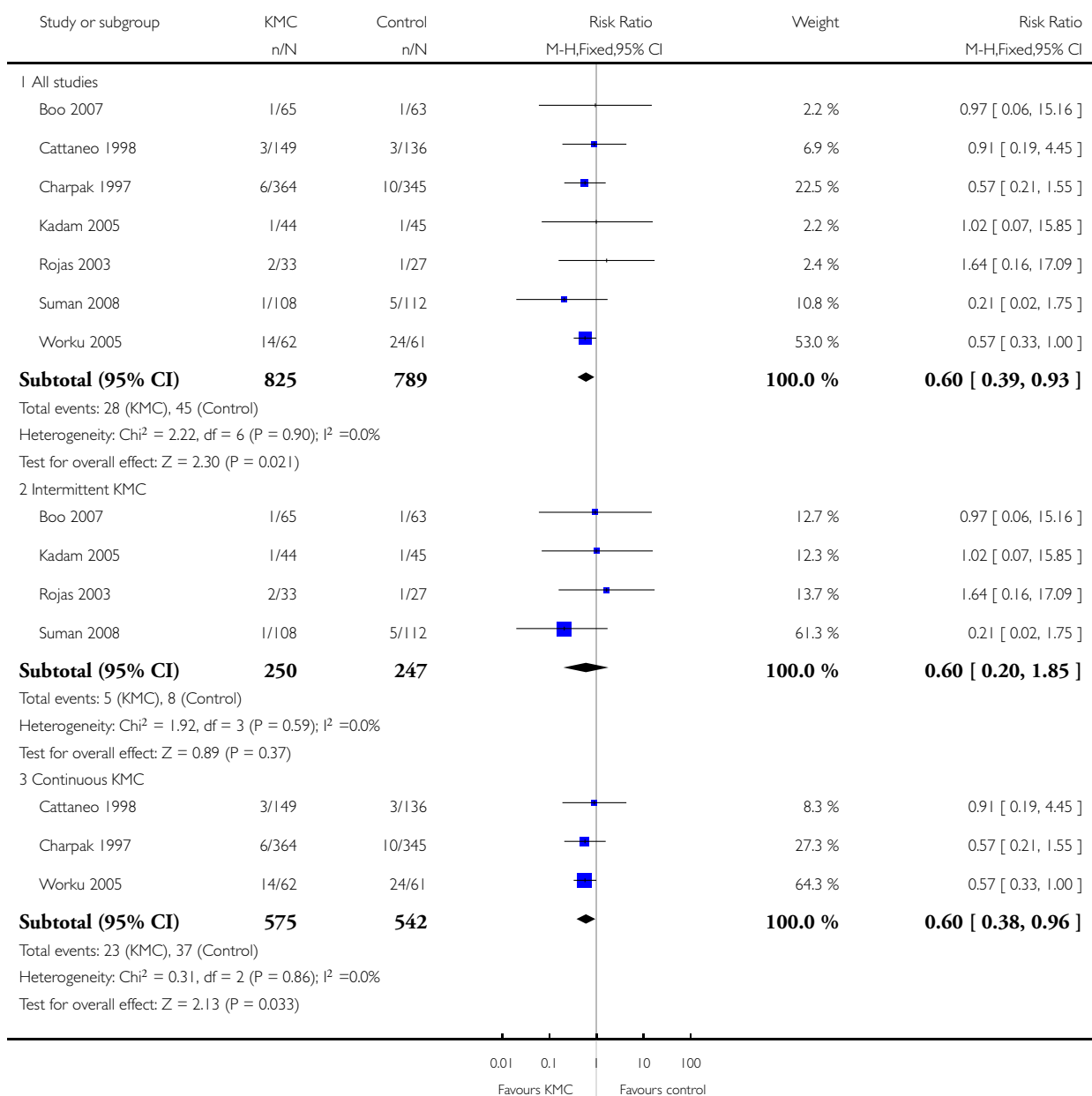
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality at 4 weeks of age	1	73	Risk Ratio (M-H, Fixed, 95% CI)	1.95 [0.18, 20.53]
2 Morbidity at 4 weeks of age	1	73	Risk Ratio (M-H, Fixed, 95% CI)	0.49 [0.18, 1.28]
3 Severe infection at 4 weeks of age	1	73	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.12, 1.49]
4 Re-admission to hospital at 4 weeks of age	1	73	Risk Ratio (M-H, Fixed, 95% CI)	1.95 [0.18, 20.53]
5 Hypothermia	1	73	Risk Ratio (M-H, Fixed, 95% CI)	0.58 [0.15, 2.27]
6 Weight gain (grams)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
6.1 At 24 hours postbirth	1	73	Mean Difference (IV, Fixed, 95% CI)	39.16 [11.11, 67.21]
6.2 At 48 hours postbirth	1	73	Mean Difference (IV, Fixed, 95% CI)	43.3 [5.49, 81.11]
6.3 At 2 weeks of age	1	73	Mean Difference (IV, Fixed, 95% CI)	12.14 [-83.18, 107.46]
6.4 At 4 weeks of age	1	73	Mean Difference (IV, Fixed, 95% CI)	58.85 [-116.93, 234.63]
7 Exclusive breast feeding	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
7.1 At 24 hours of age	1	73	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.67, 1.57]
7.2 At 2 weeks of age	1	71	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.89, 1.12]
7.3 At 4 weeks of age	1	67	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.85, 1.04]
8 Length of hospital stay (days)	1	73	Mean Difference (IV, Fixed, 95% CI)	-0.90 [-1.24, -0.56]

Analysis 1.1. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 1 Mortality at discharge or 40-41 weeks' postmenstrual age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

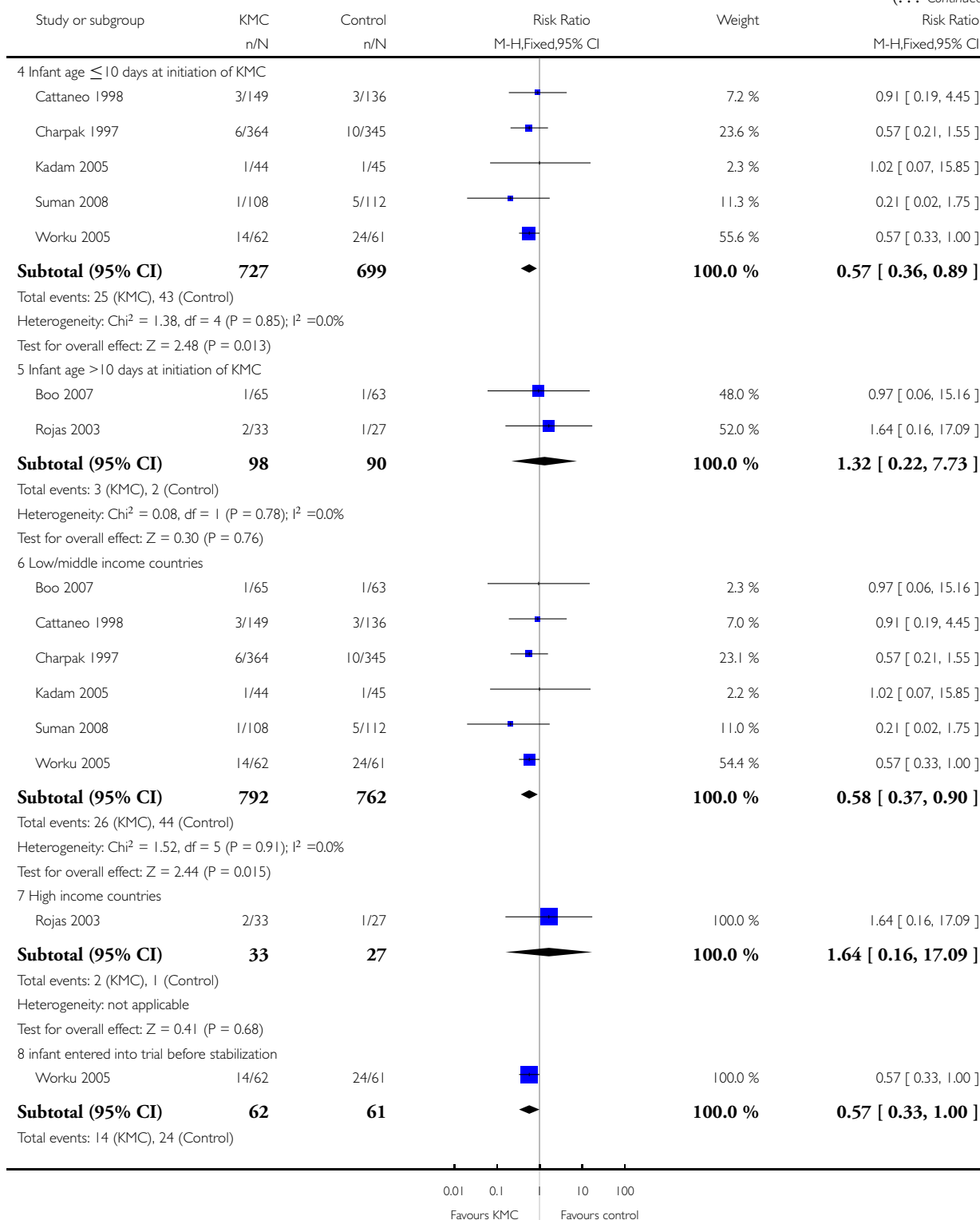
Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 1 Mortality at discharge or 40-41 weeks' postmenstrual age

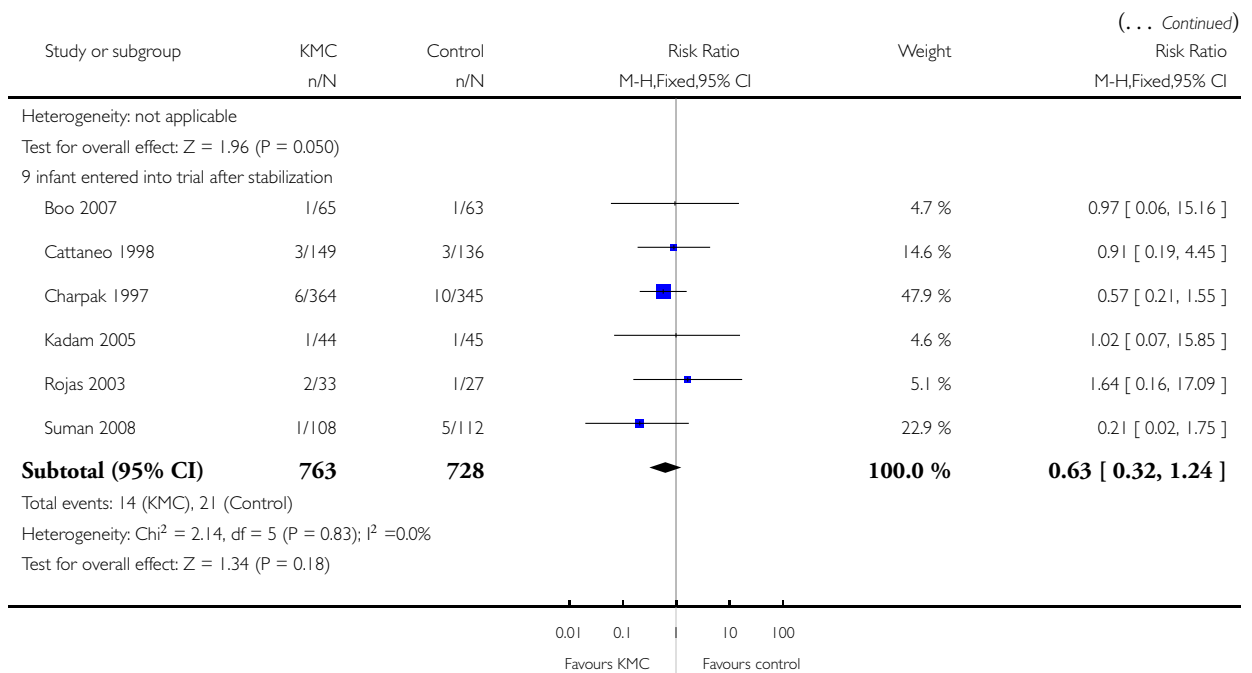


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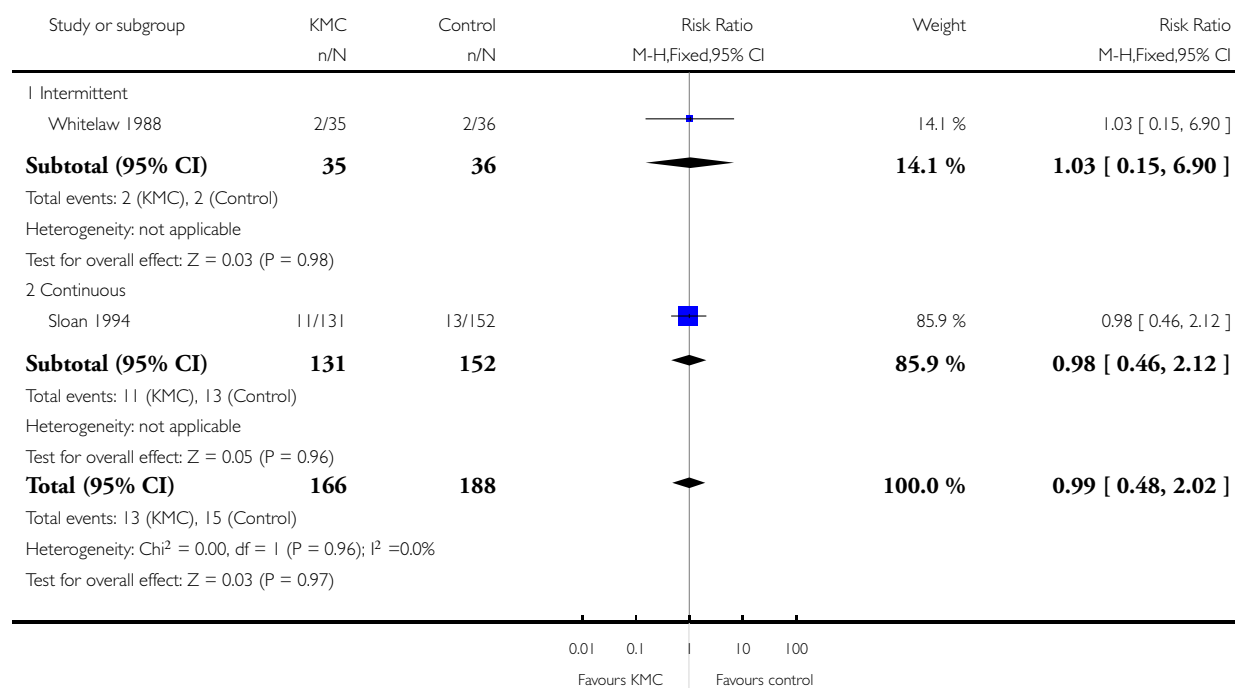


Analysis 1.2. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 2 Mortality at 6 months of age or 6 months follow up.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 2 Mortality at 6 months of age or 6 months follow up

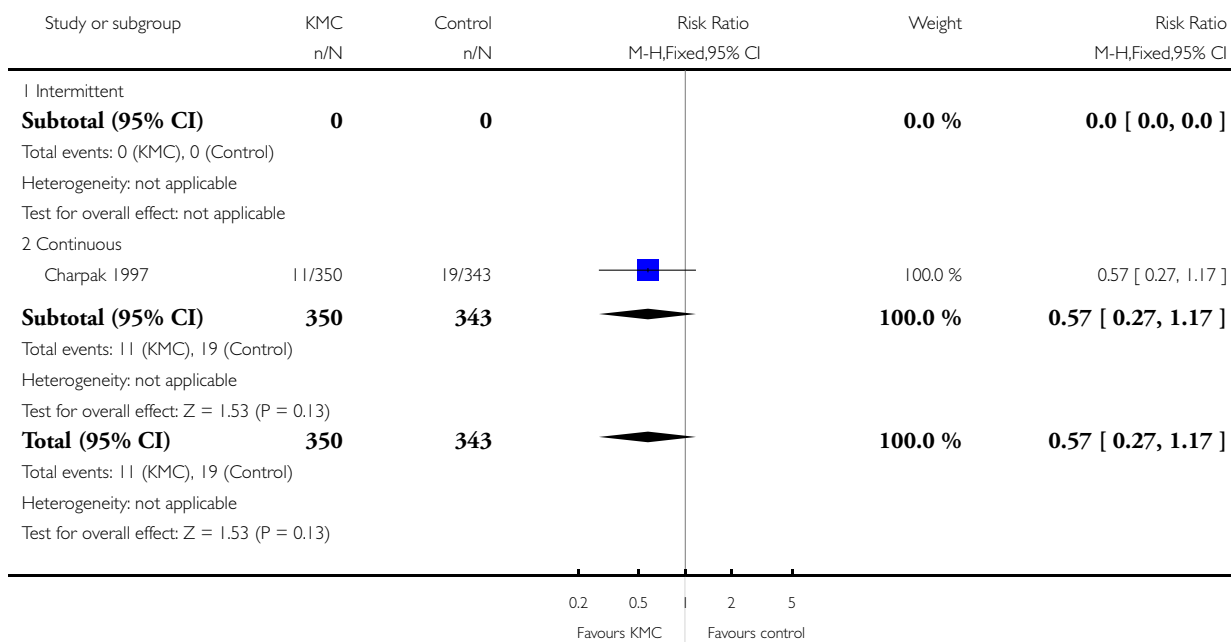


Analysis 1.3. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 3 Mortality at 12 months' corrected age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 3 Mortality at 12 months' corrected age

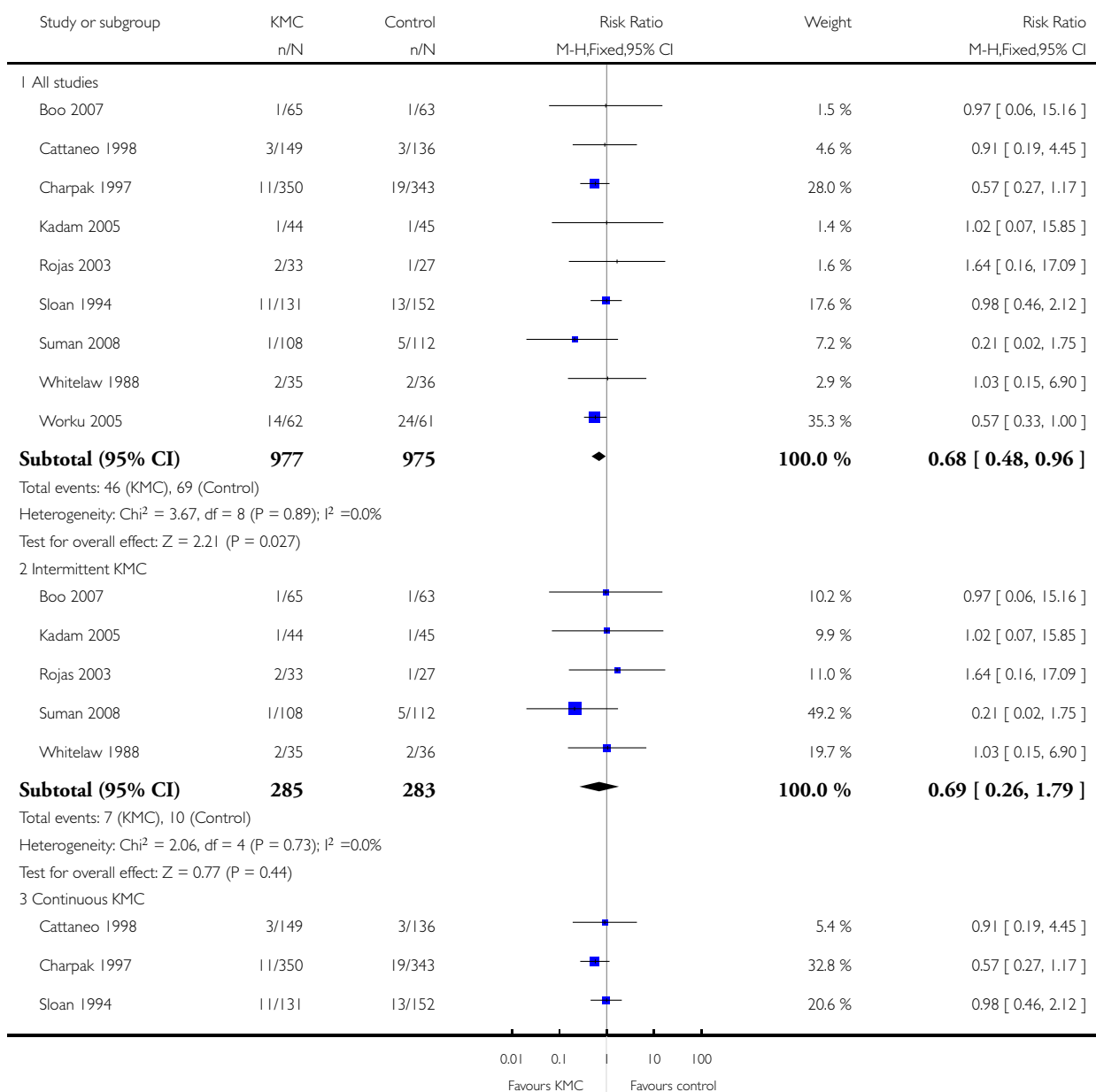


Analysis 1.4. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 4 Mortality at latest follow up.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

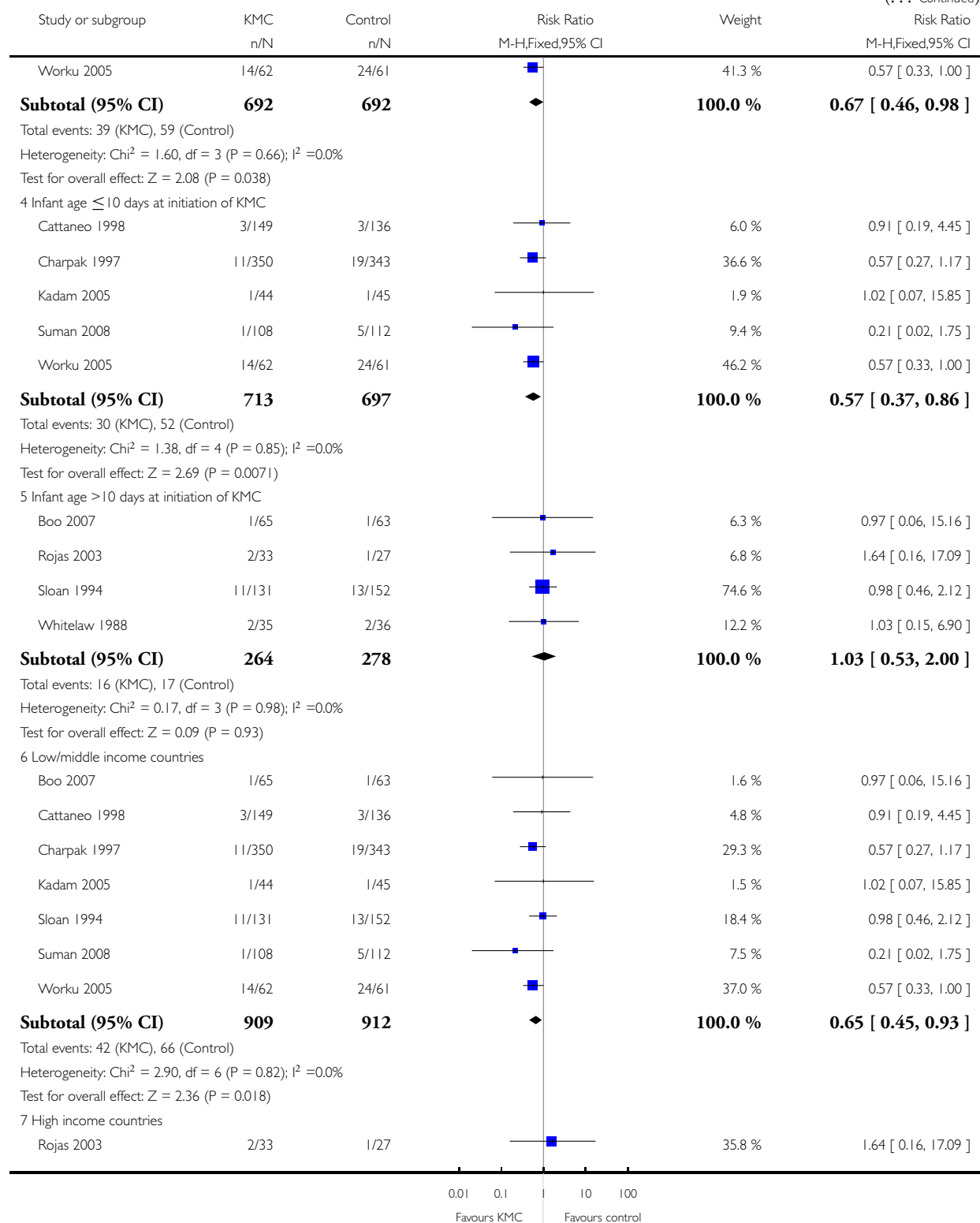
Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 4 Mortality at latest follow up



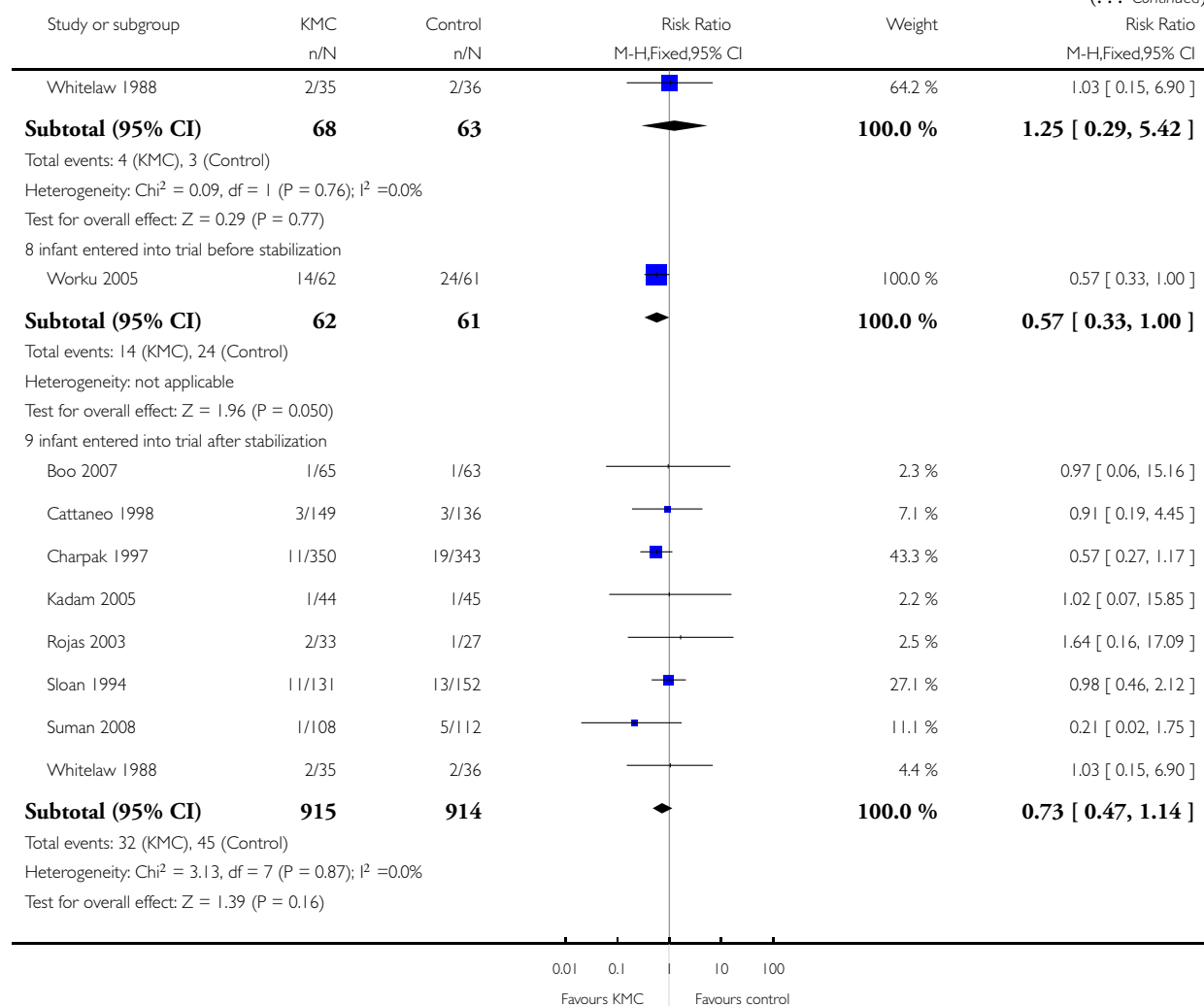
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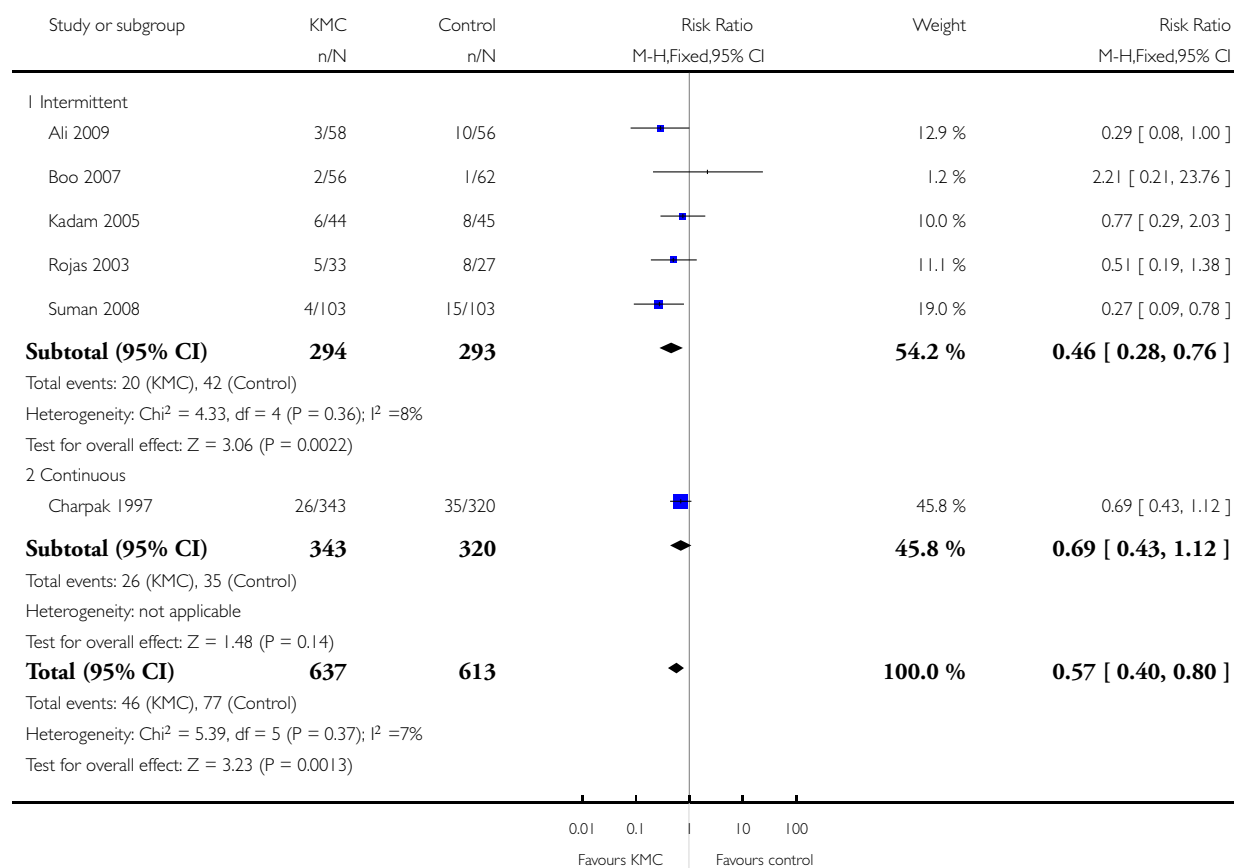


Analysis I.5. Comparison I Kangaroo mother care versus conventional neonatal care, Outcome 5 Severe infection/sepsis at latest follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: I Kangaroo mother care versus conventional neonatal care

Outcome: 5 Severe infection/sepsis at latest follow up - stabilized infants

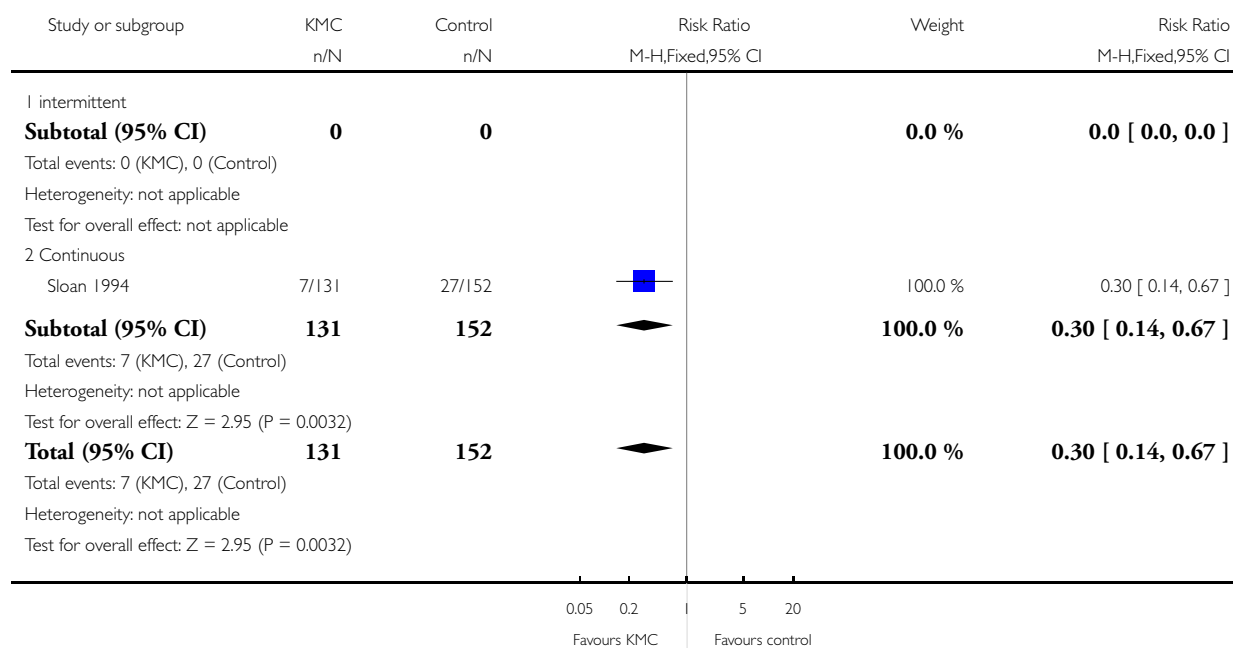


Analysis 1.6. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 6 Severe illness at 6 months follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 6 Severe illness at 6 months follow up - stabilized infants

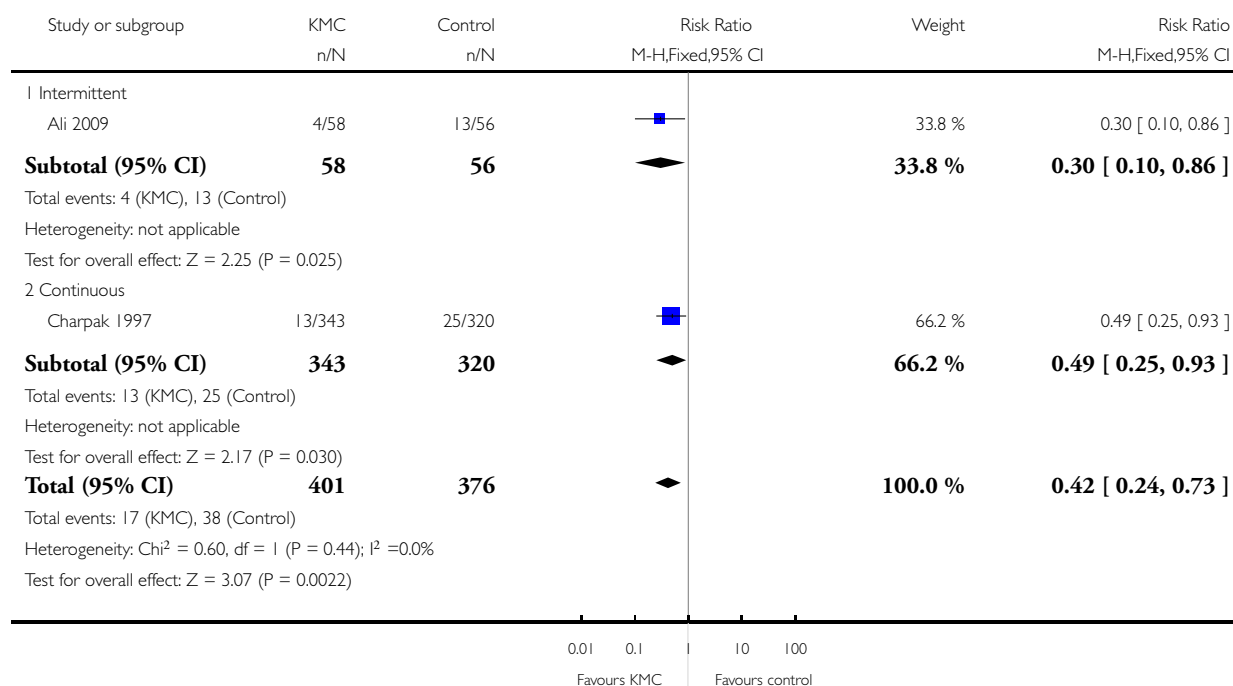


Analysis 1.7. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 7 Nosocomial infection/sepsis at discharge or 40-41 weeks' postmenstrual age - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 7 Nosocomial infection/sepsis at discharge or 40-41 weeks' postmenstrual age - stabilized infants

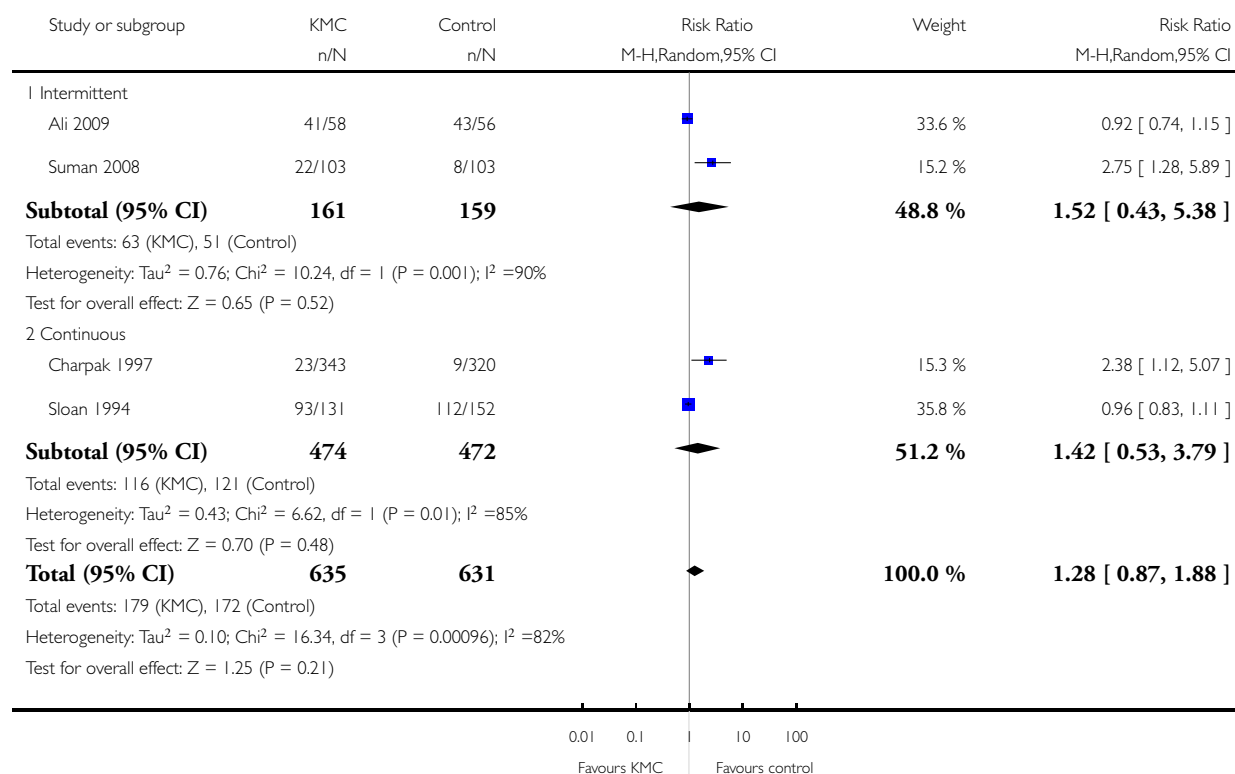


Analysis 1.8. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 8 Mild/moderate infection or illness at latest follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 8 Mild/moderate infection or illness at latest follow up - stabilized infants

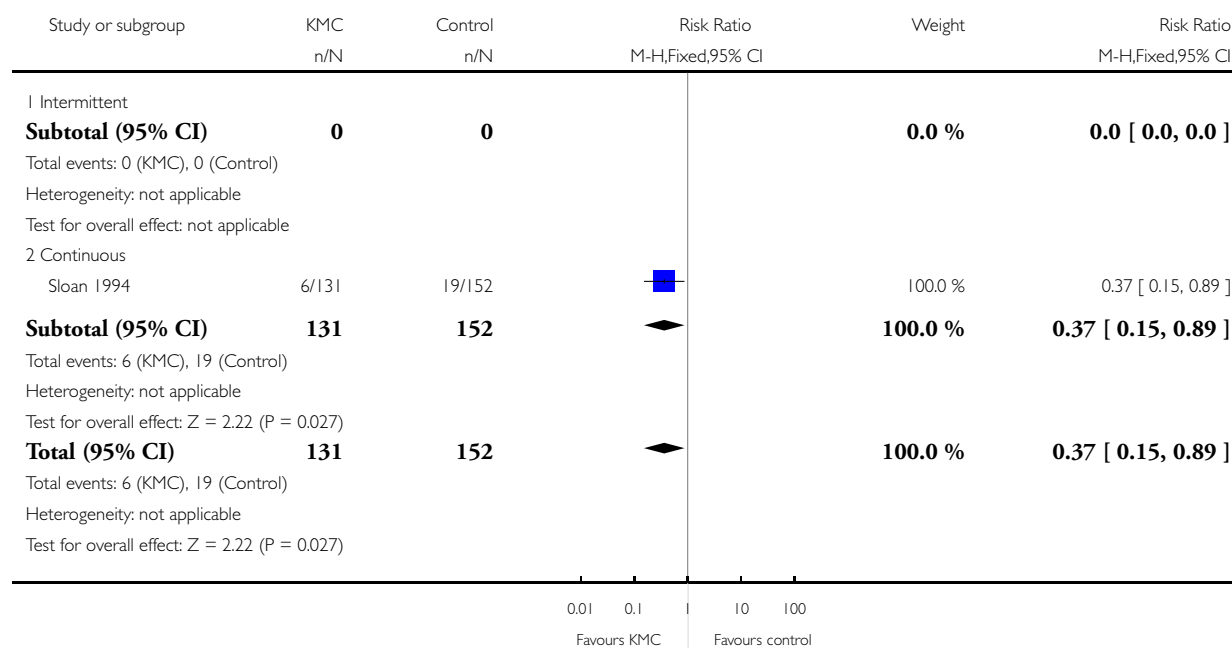


Analysis 1.9. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 9 Lower respiratory tract disease at 6 months follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 9 Lower respiratory tract disease at 6 months follow up - stabilized infants

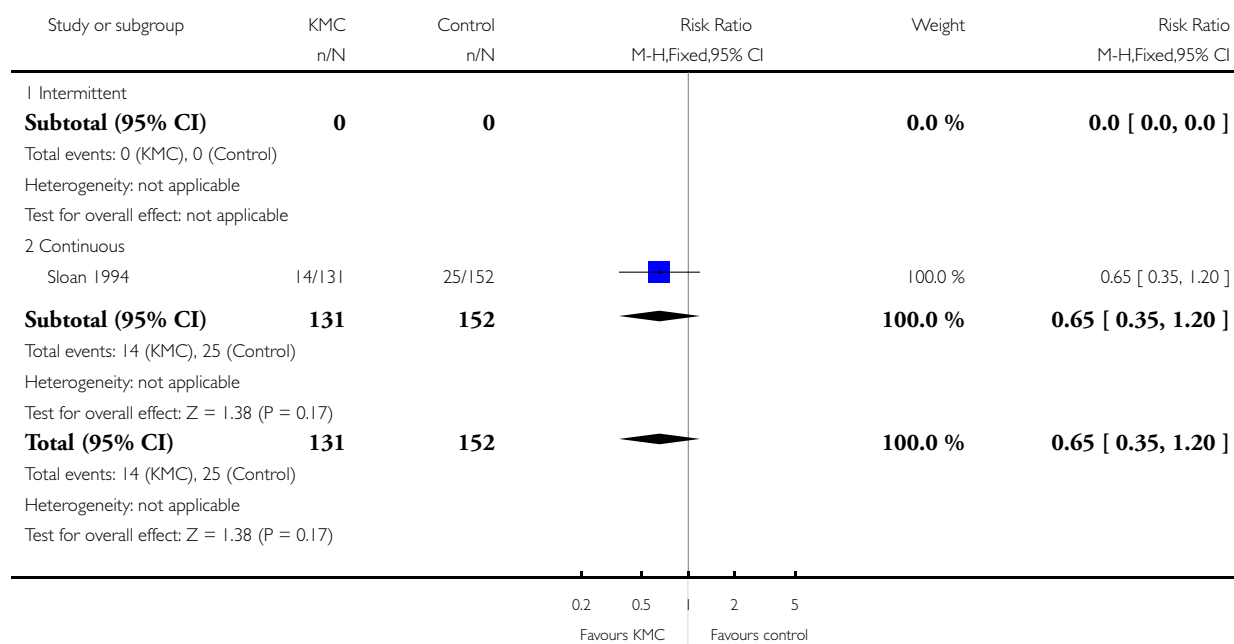


Analysis 1.10. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 10 Diarrhea at 6 months follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 10 Diarrhea at 6 months follow up - stabilized infants

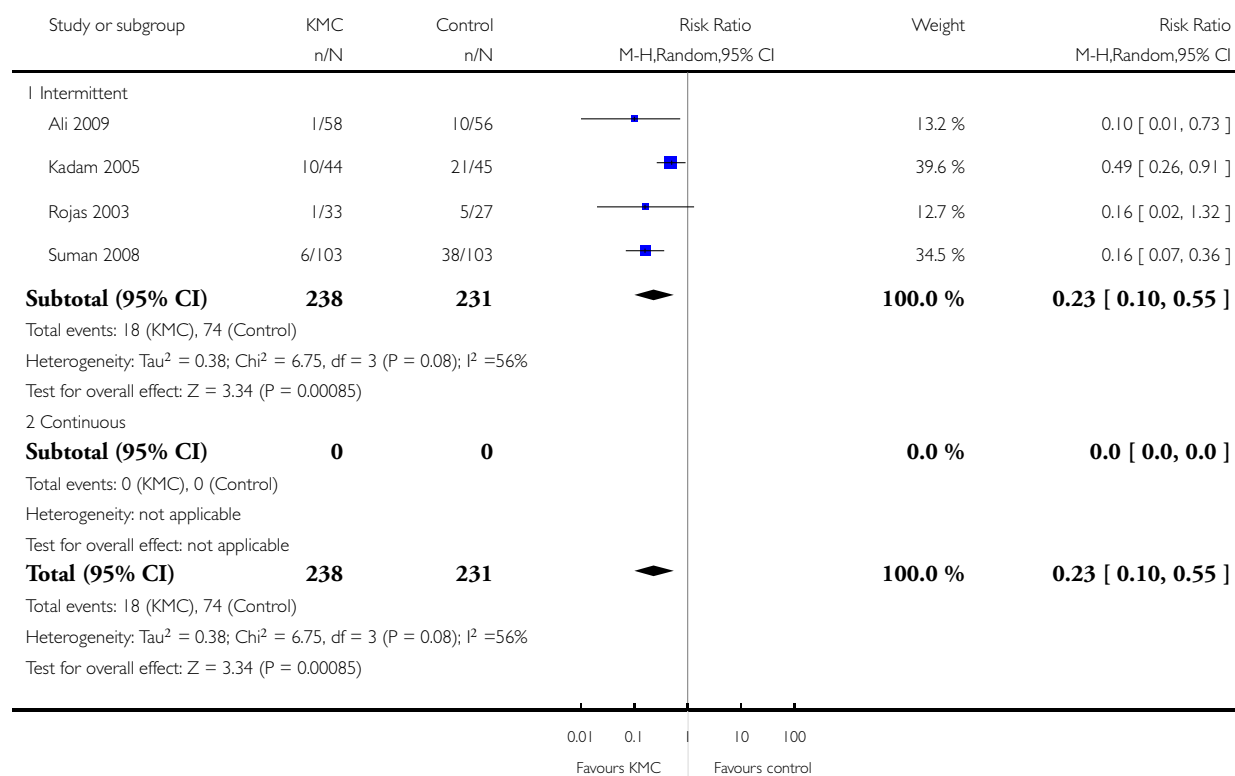


Analysis 1.11. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 11 Hypothermia at discharge or 40-41 weeks' postmenstrual age - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 11 Hypothermia at discharge or 40-41 weeks' postmenstrual age - stabilized infants

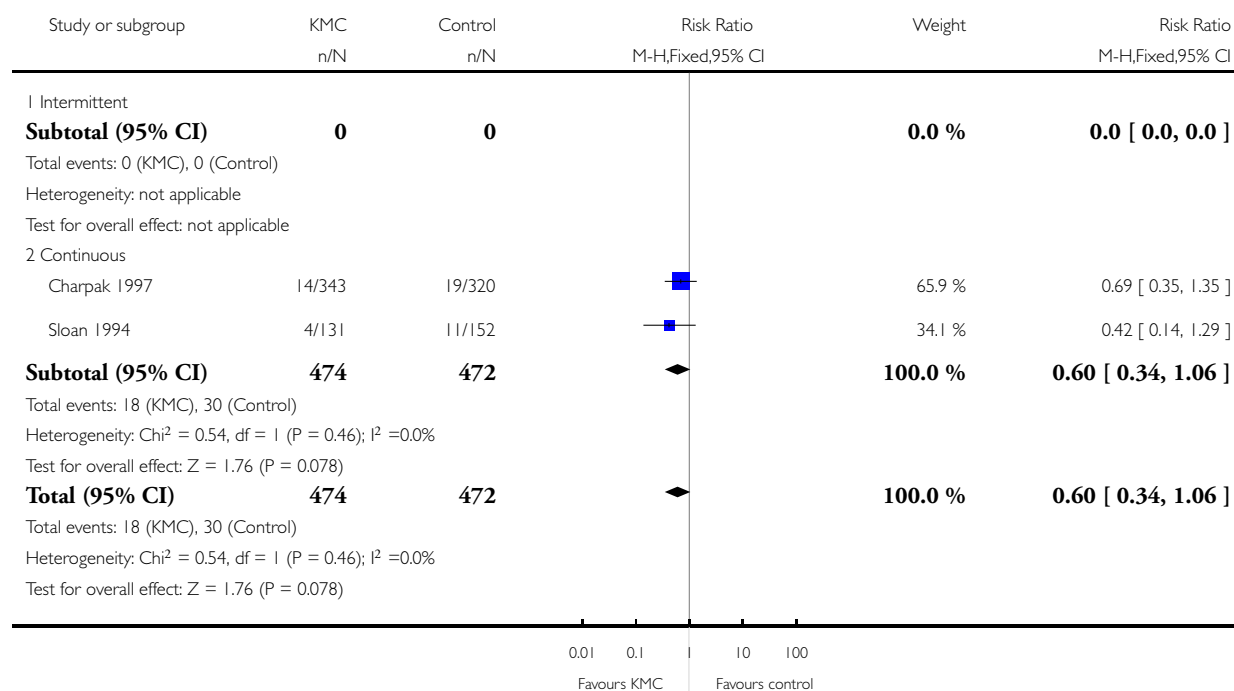


**Analysis 1.12. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 12
Readmission to hospital at latest follow up - stabilized infants.**

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 12 Readmission to hospital at latest follow up - stabilized infants

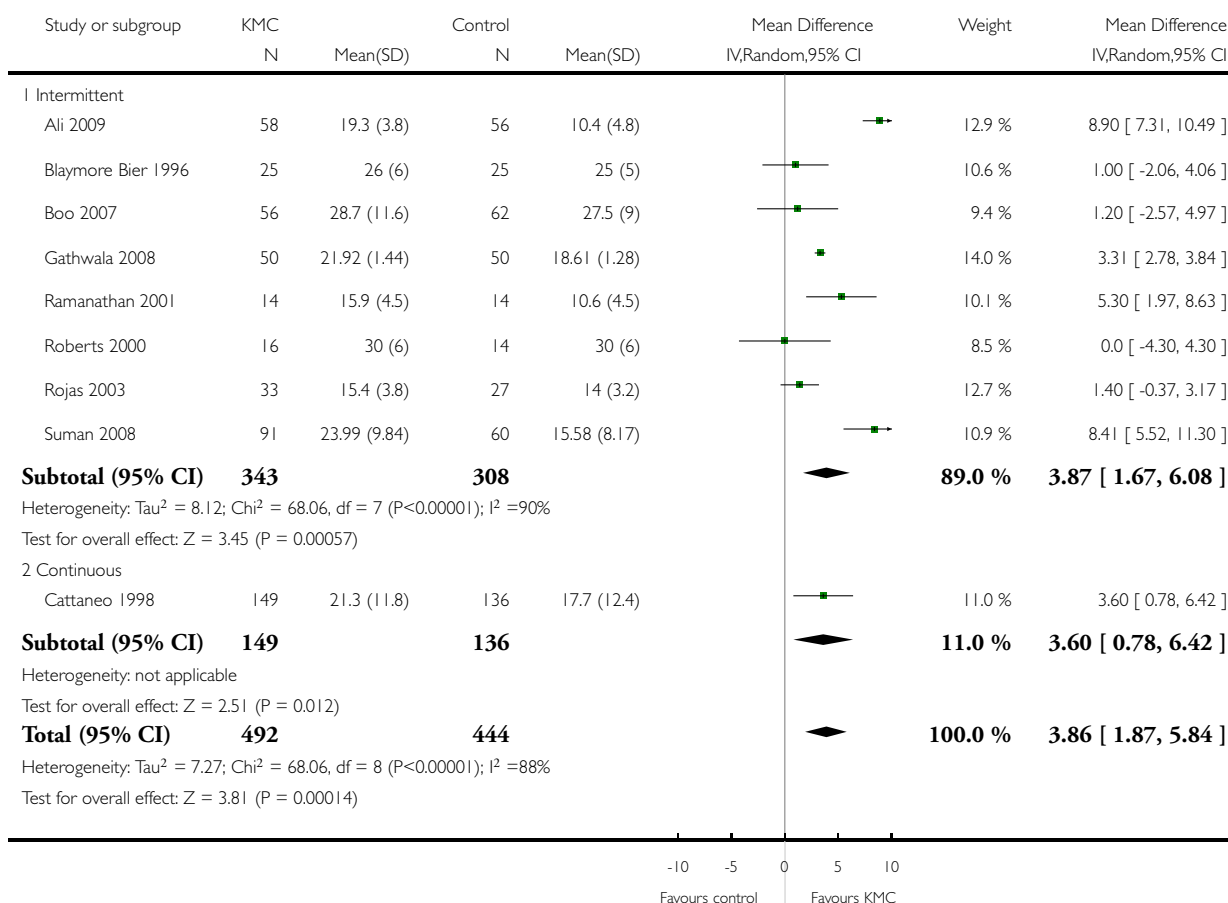


Analysis 1.13. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 13 Weight gain at latest follow up (g/day) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 13 Weight gain at latest follow up (g/day) - stabilized infants

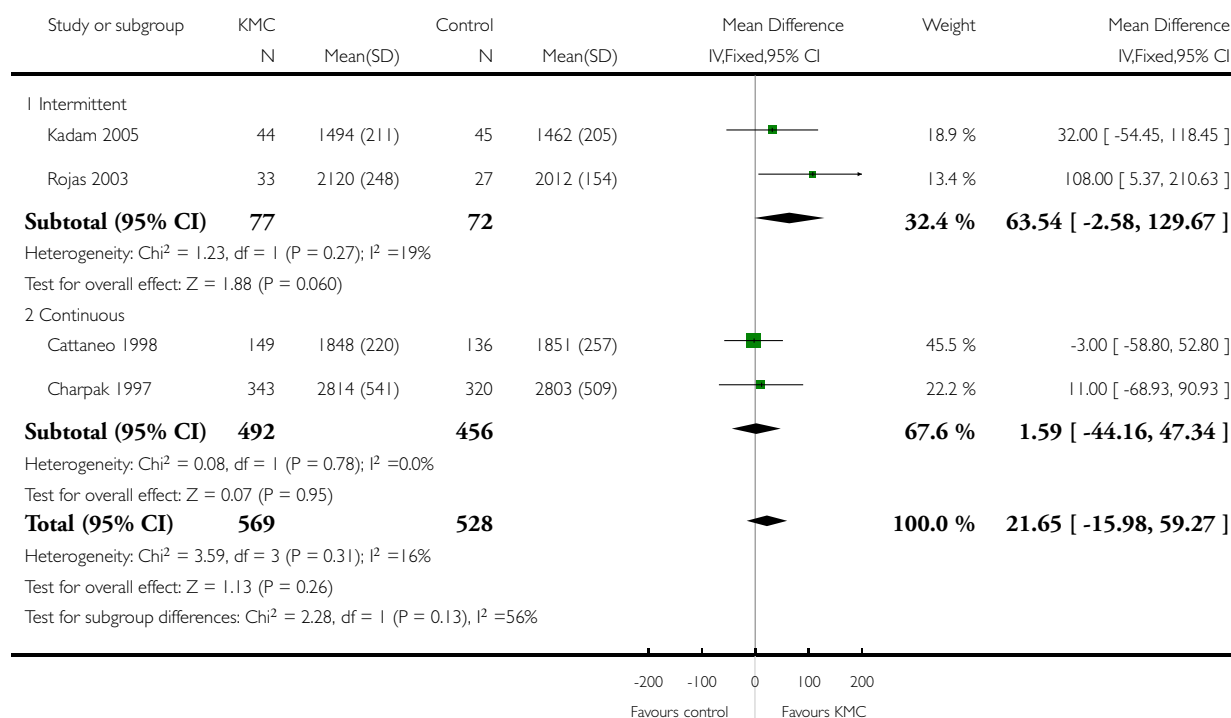


Analysis 1.14. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 14 Weight at discharge or 40-41 weeks' postmenstrual age (g) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 14 Weight at discharge or 40-41 weeks' postmenstrual age (g) - stabilized infants

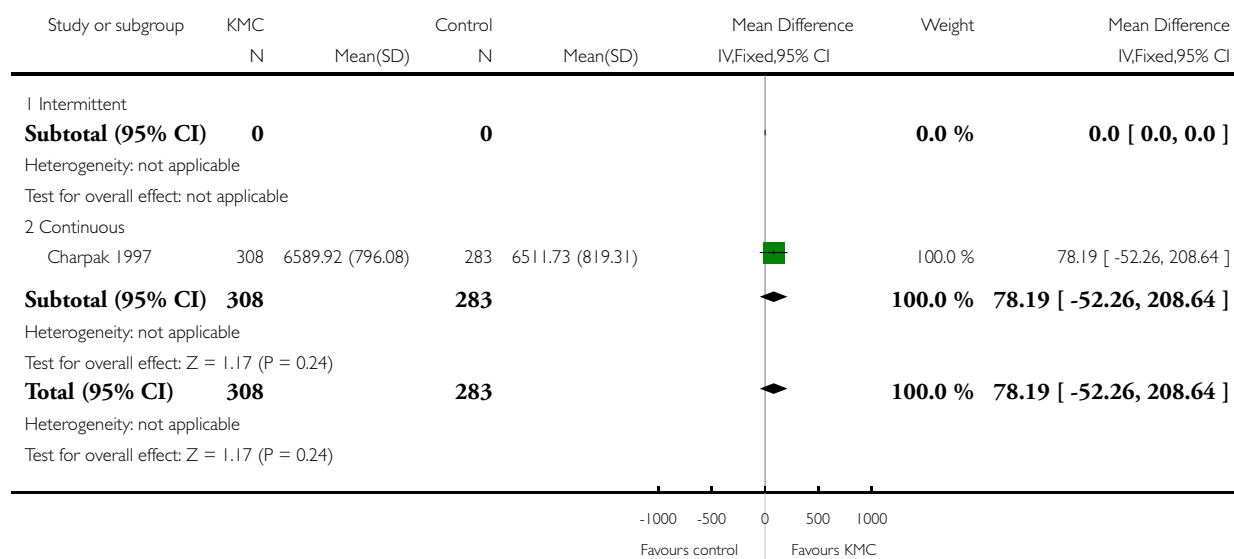


Analysis 1.15. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 15 Weight at 6 months' corrected age (g) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 15 Weight at 6 months' corrected age (g) - stabilized infants

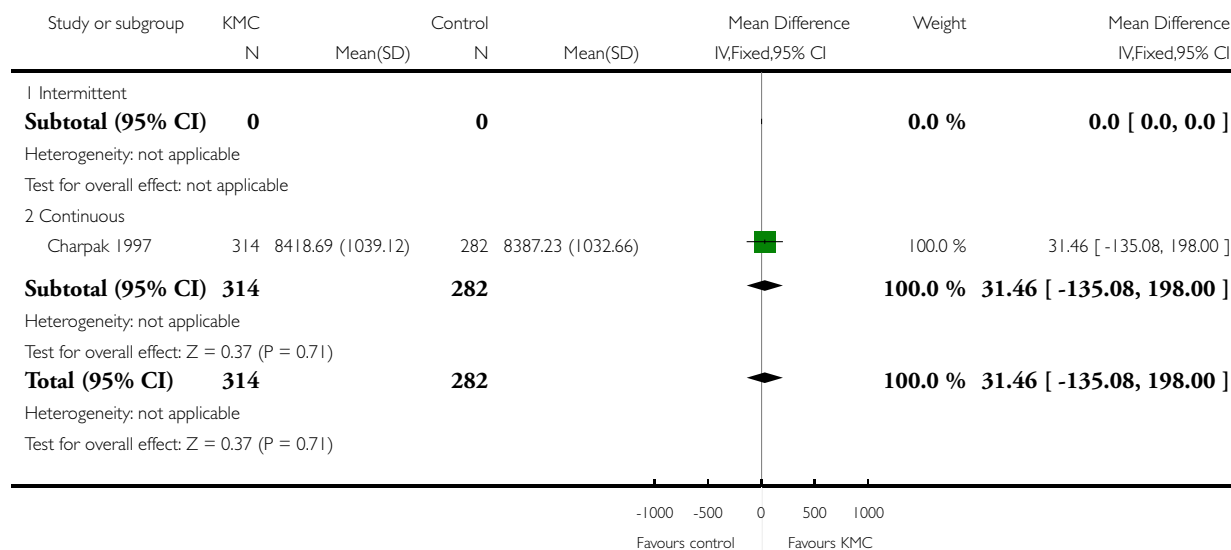


Analysis 1.16. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 16 Weight at 12 months' corrected age (g) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 16 Weight at 12 months' corrected age (g) - stabilized infants

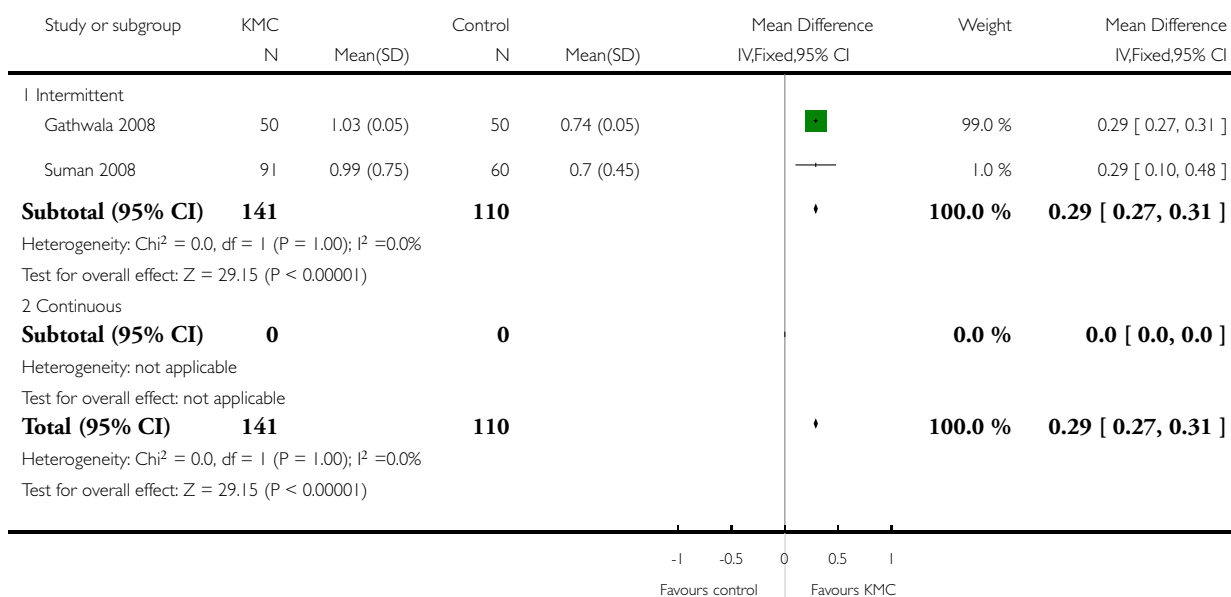


Analysis 1.17. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 17 Length gain at latest follow up (cm/week) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 17 Length gain at latest follow up (cm/week) - stabilized infants

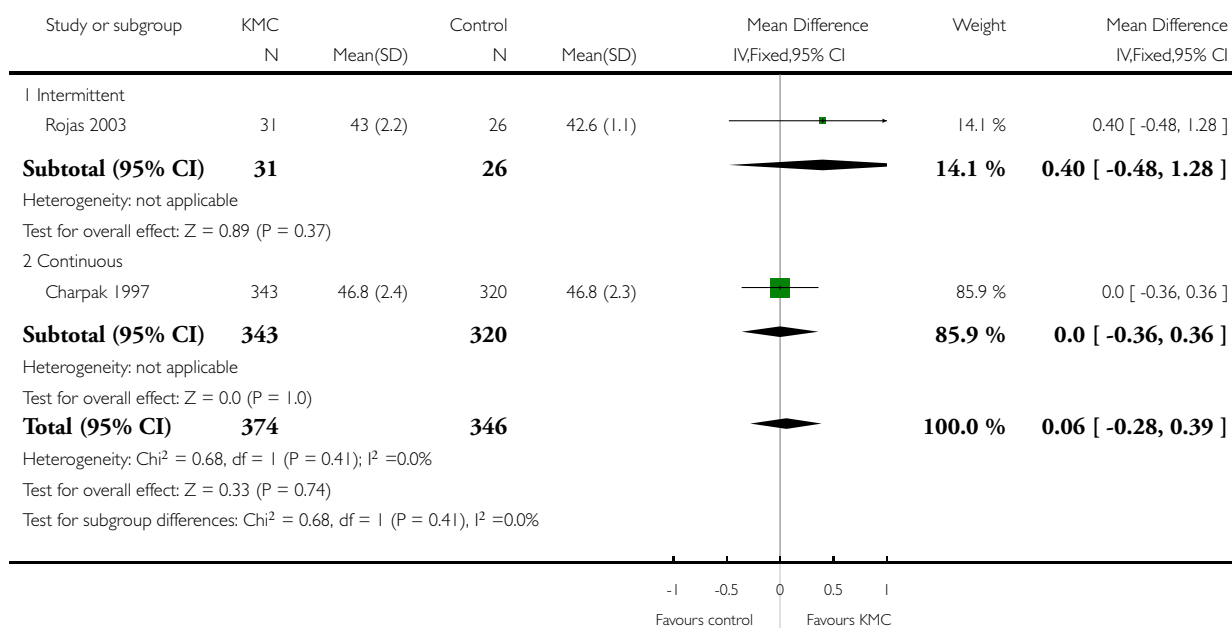


Analysis 1.18. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 18 Length at discharge or 40-41 weeks' postmenstrual age (cm) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 18 Length at discharge or 40-41 weeks' postmenstrual age (cm) - stabilized infants

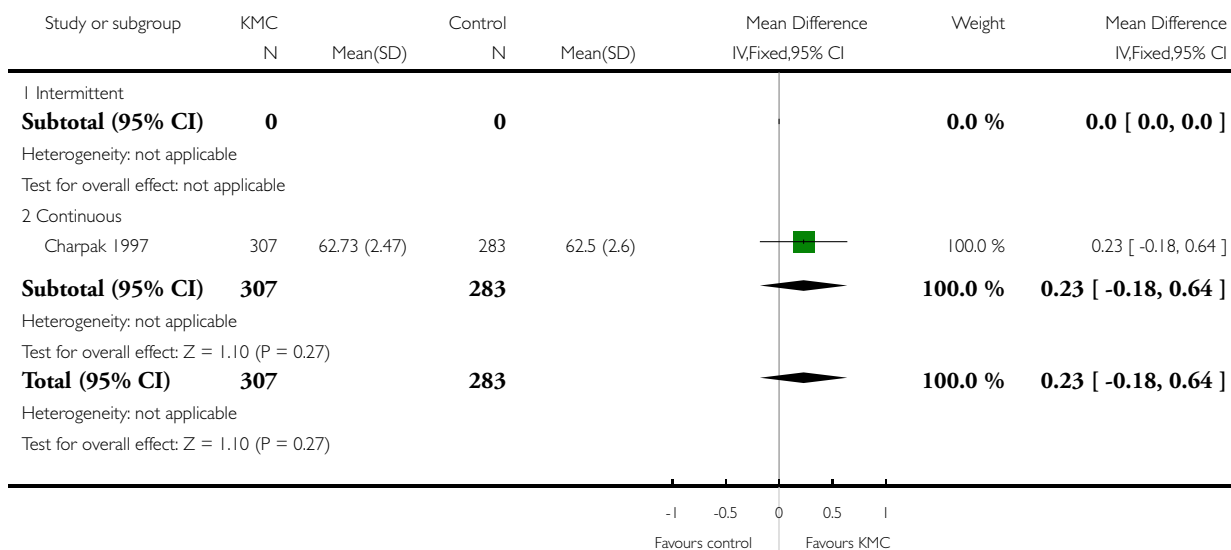


Analysis 1.19. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 19 Length at 6 months' corrected age (cm) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 19 Length at 6 months' corrected age (cm) - stabilized infants

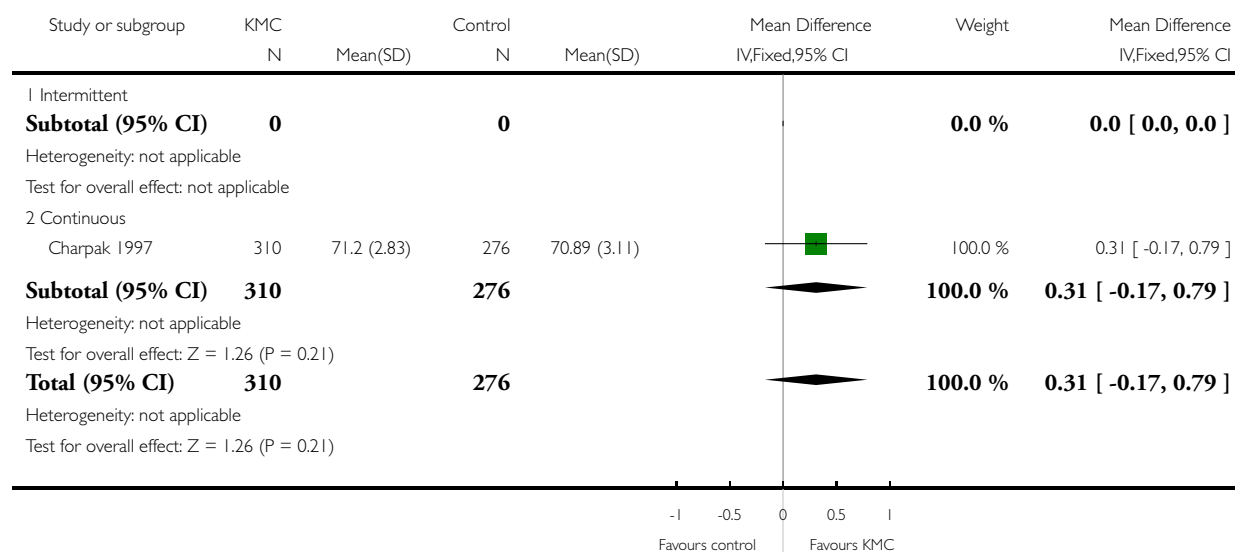


Analysis 1.20. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 20 Length at 12 months' corrected age (cm) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 20 Length at 12 months' corrected age (cm) - stabilized infants

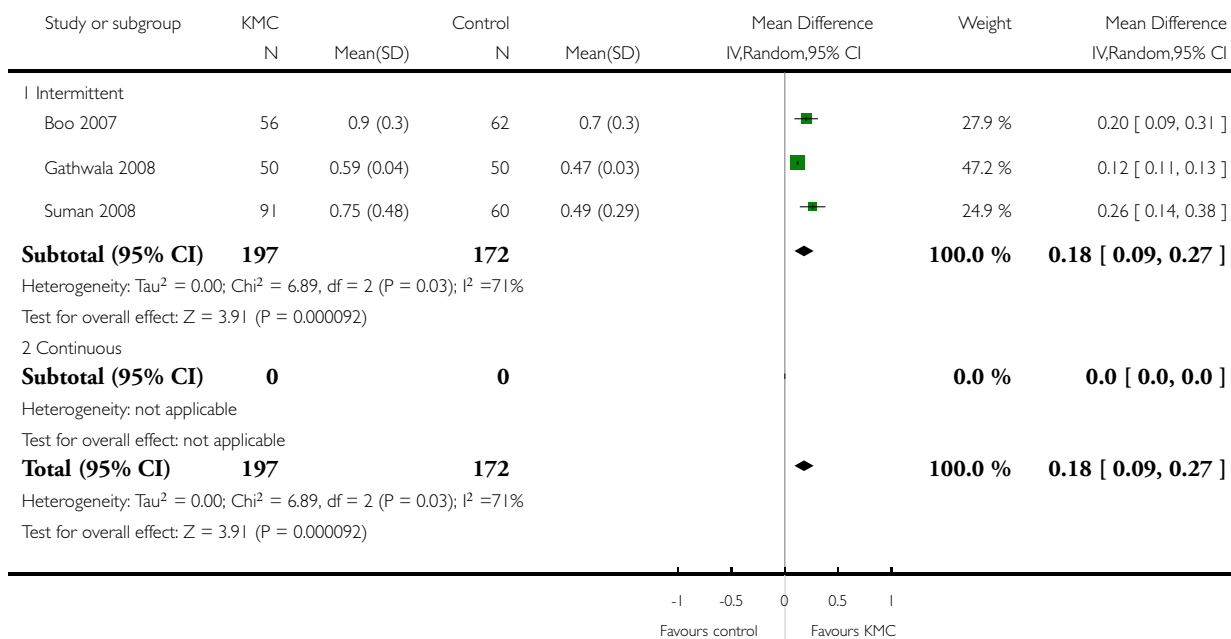


Analysis 1.21. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 21 Head circumference gain at latest follow up (cm/week) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 21 Head circumference gain at latest follow up (cm/week) - stabilized infants

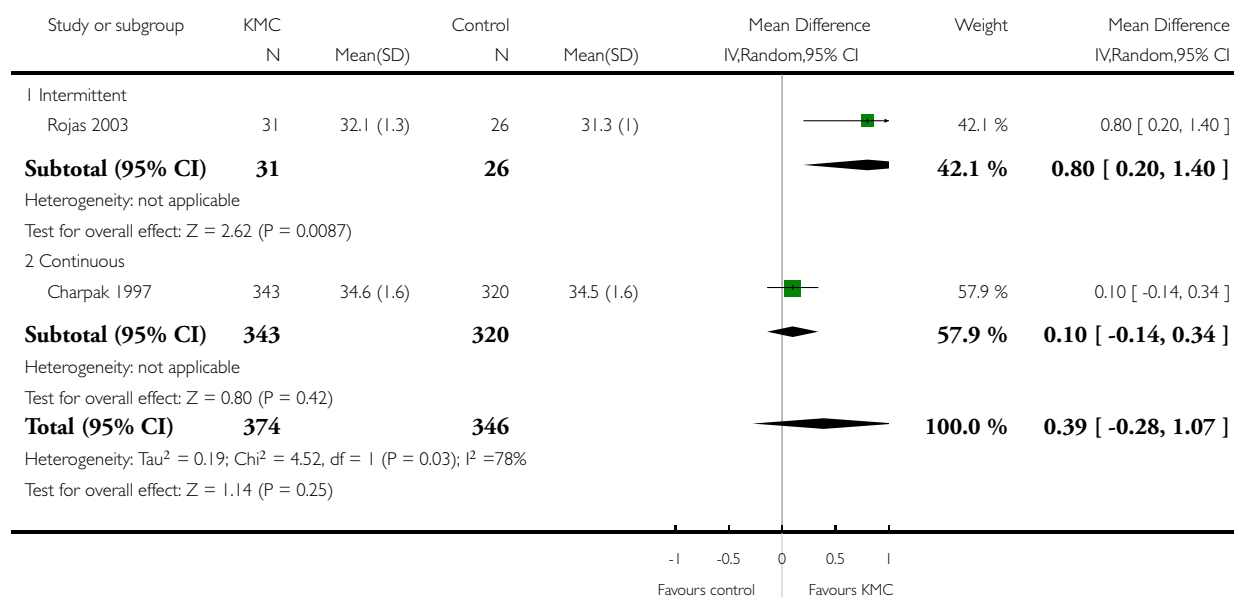


Analysis 1.22. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 22 Head circumference at discharge or 40-41 weeks' postmenstrual age (cm) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 22 Head circumference at discharge or 40-41 weeks' postmenstrual age (cm) - stabilized infants

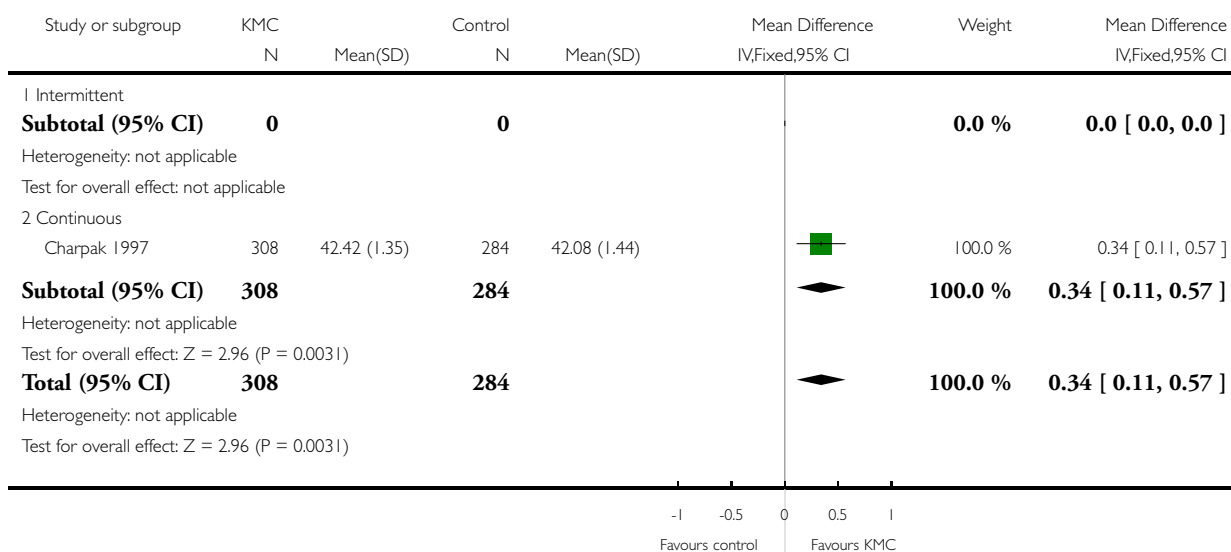


Analysis 1.23. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 23 Head circumference at 6 months' corrected age (cm) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 23 Head circumference at 6 months' corrected age (cm) - stabilized infants

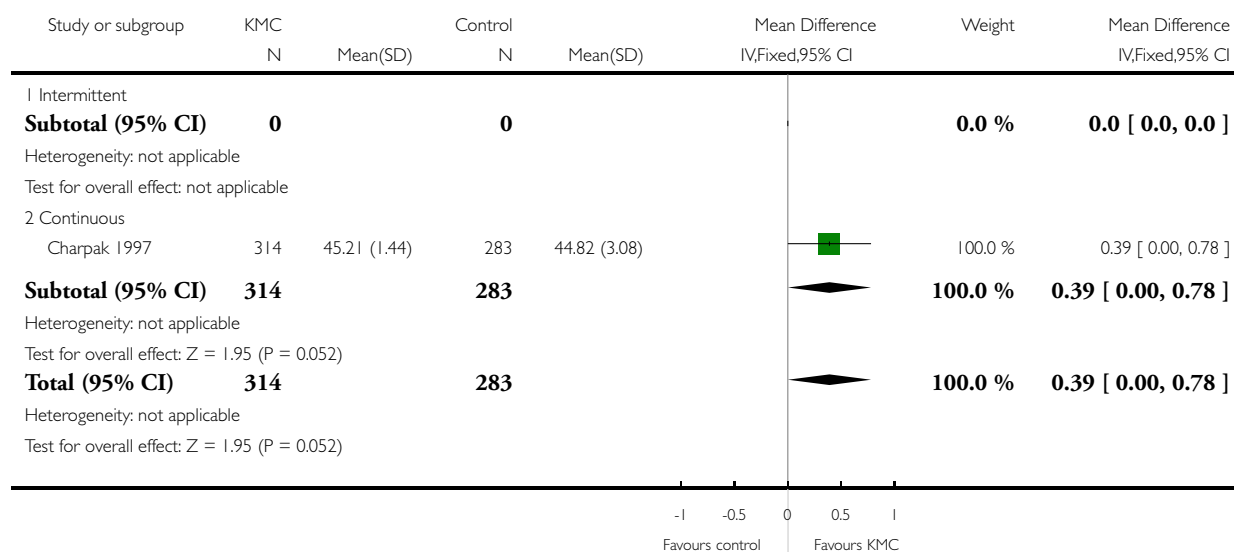


Analysis 1.24. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 24 Head circumference at 12 months' corrected age (cm) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 24 Head circumference at 12 months' corrected age (cm) - stabilized infants

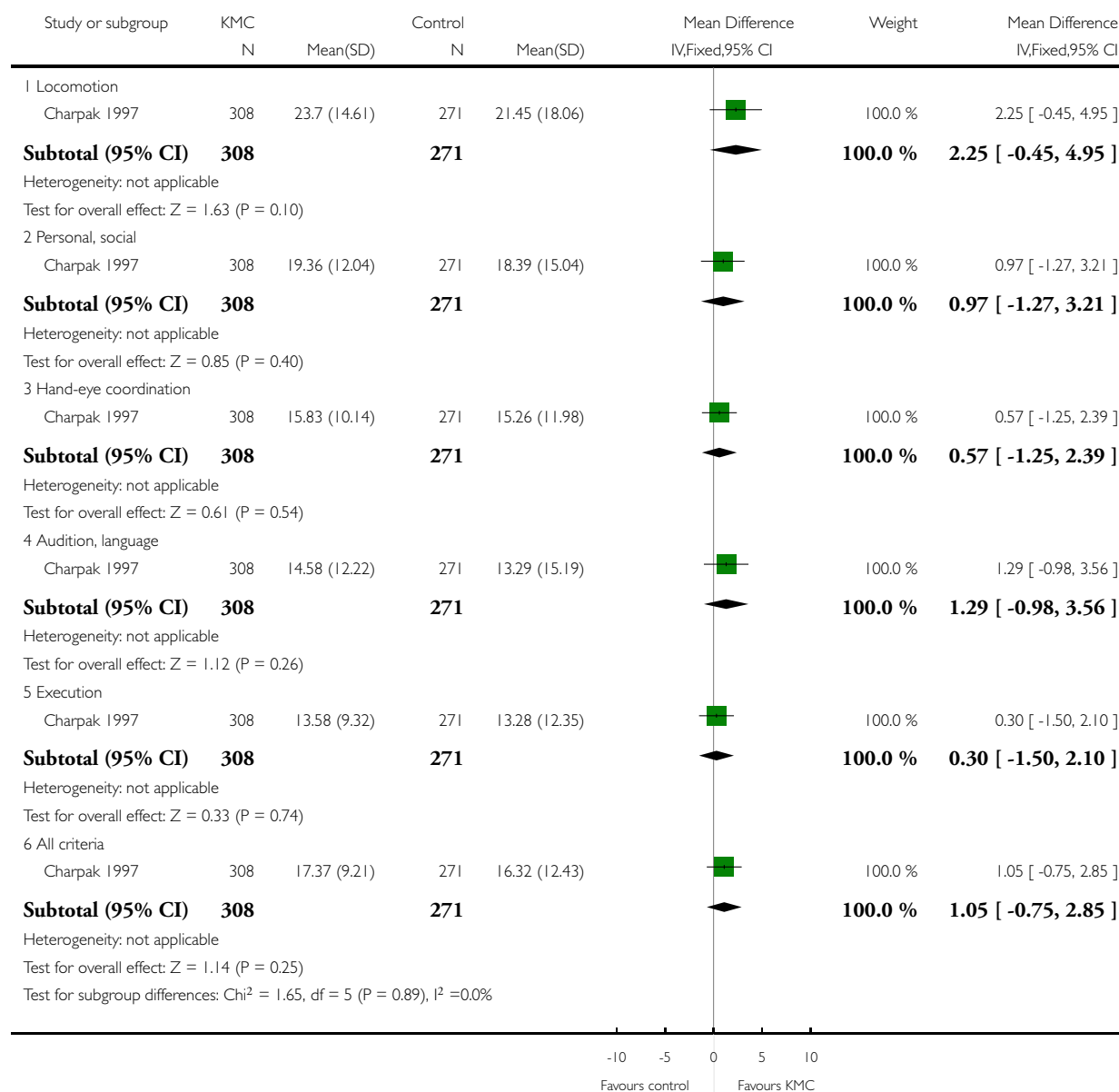


Analysis 1.25. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 25 Psychomotor development (Griffith quotients) at 12 months' corrected age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 25 Psychomotor development (Griffith quotients) at 12 months' corrected age

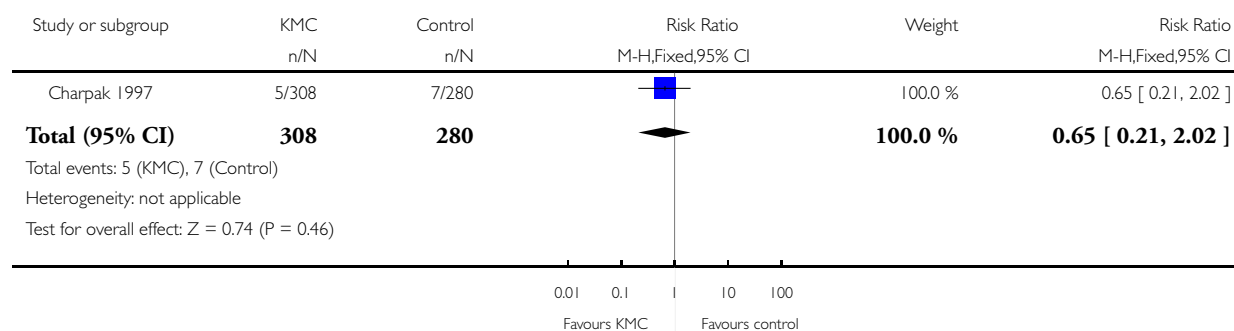


Analysis 1.26. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 26 Cerebral palsy at 12 months' corrected age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 26 Cerebral palsy at 12 months' corrected age

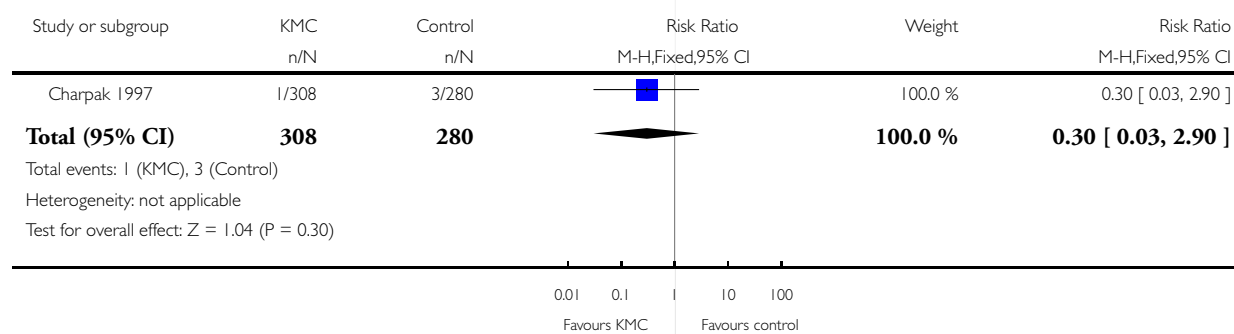


Analysis 1.27. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 27 Deafness at 12 months' corrected age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 27 Deafness at 12 months' corrected age

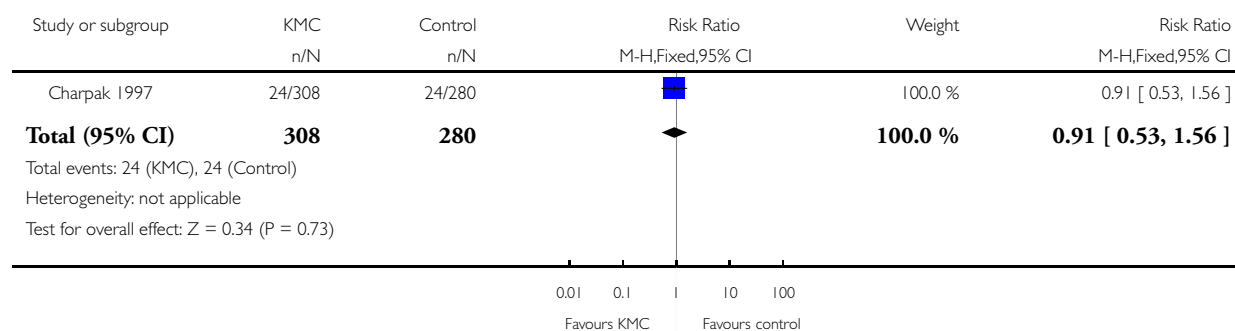


Analysis 1.28. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 28 Visual impairment at 12 months' corrected age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 28 Visual impairment at 12 months' corrected age

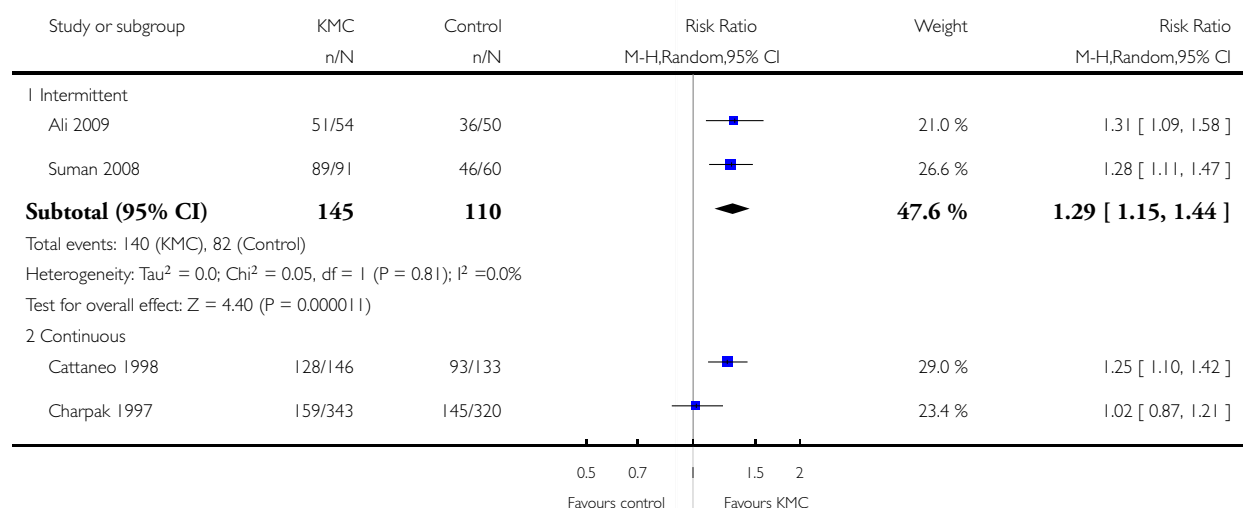


Analysis 1.29. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 29 Exclusive breast feeding at discharge or 40-41 weeks' postmenstrual age - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

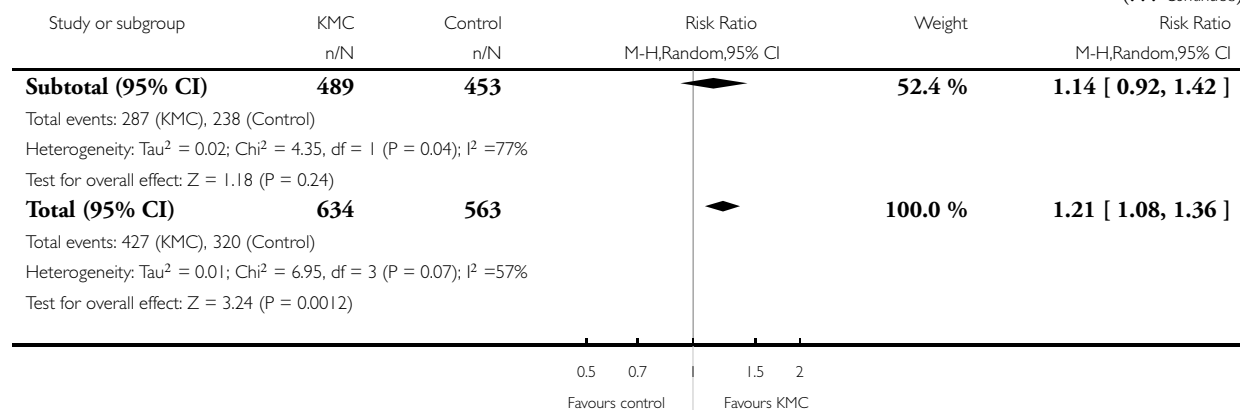
Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 29 Exclusive breast feeding at discharge or 40-41 weeks' postmenstrual age - stabilized infants



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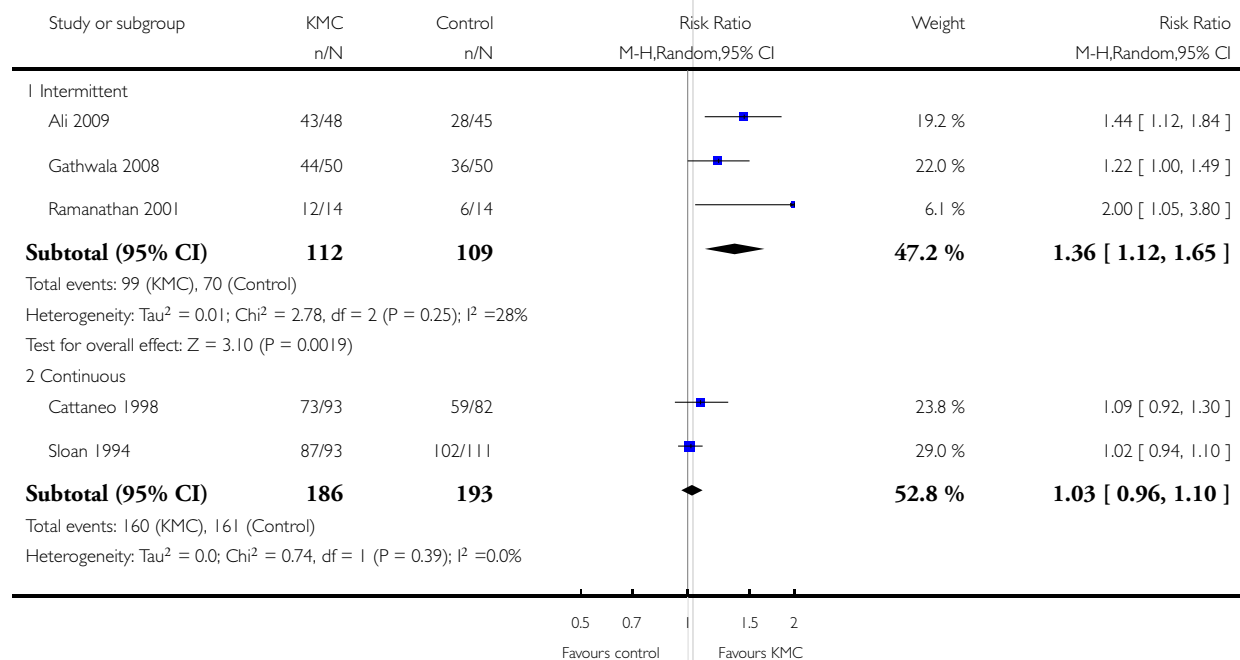


Analysis 1.30. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 30 Exclusive breast feeding at 1-3 months follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

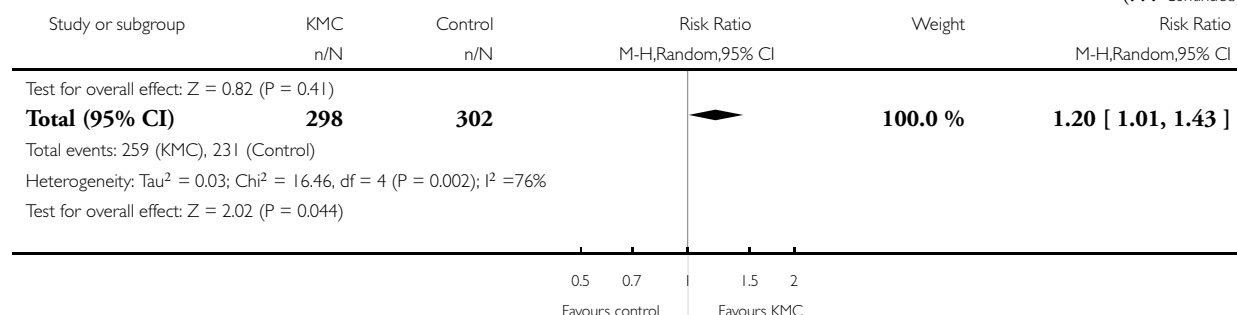
Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 30 Exclusive breast feeding at 1-3 months follow up - stabilized infants



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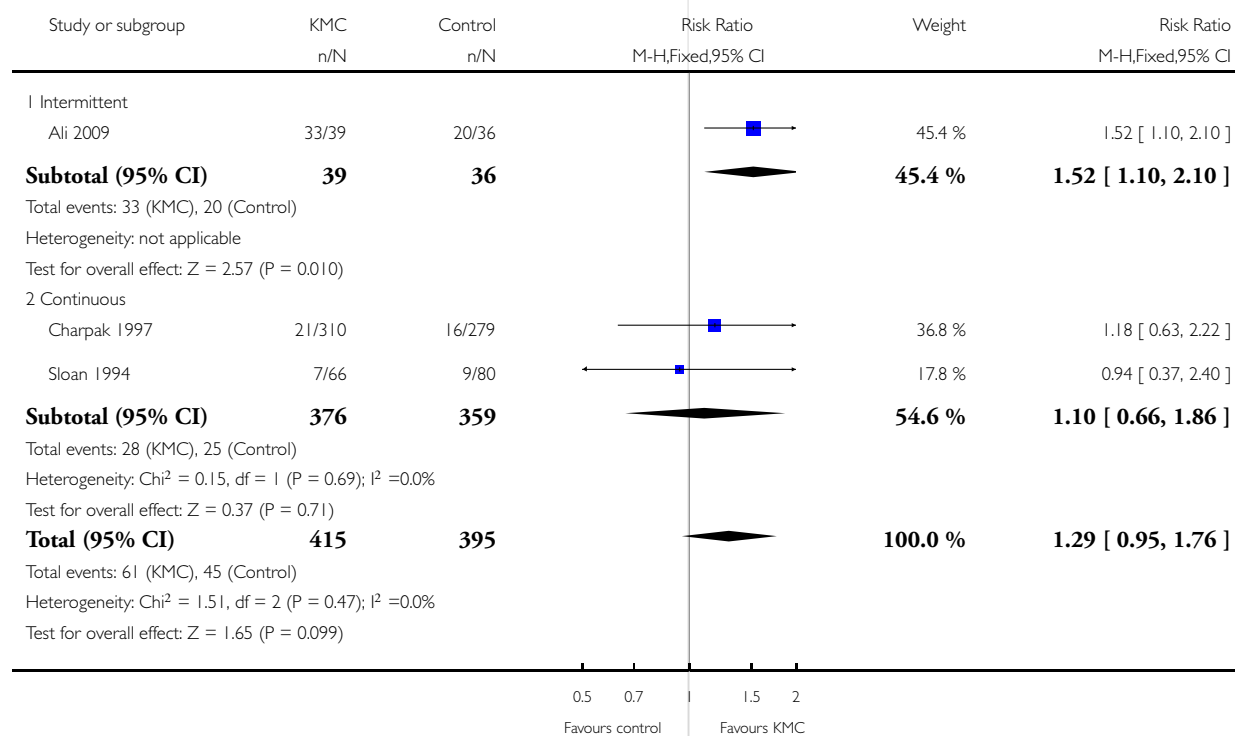


Analysis 1.31. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 31 Exclusive breast feeding at 6-12 months follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 31 Exclusive breast feeding at 6-12 months follow up - stabilized infants

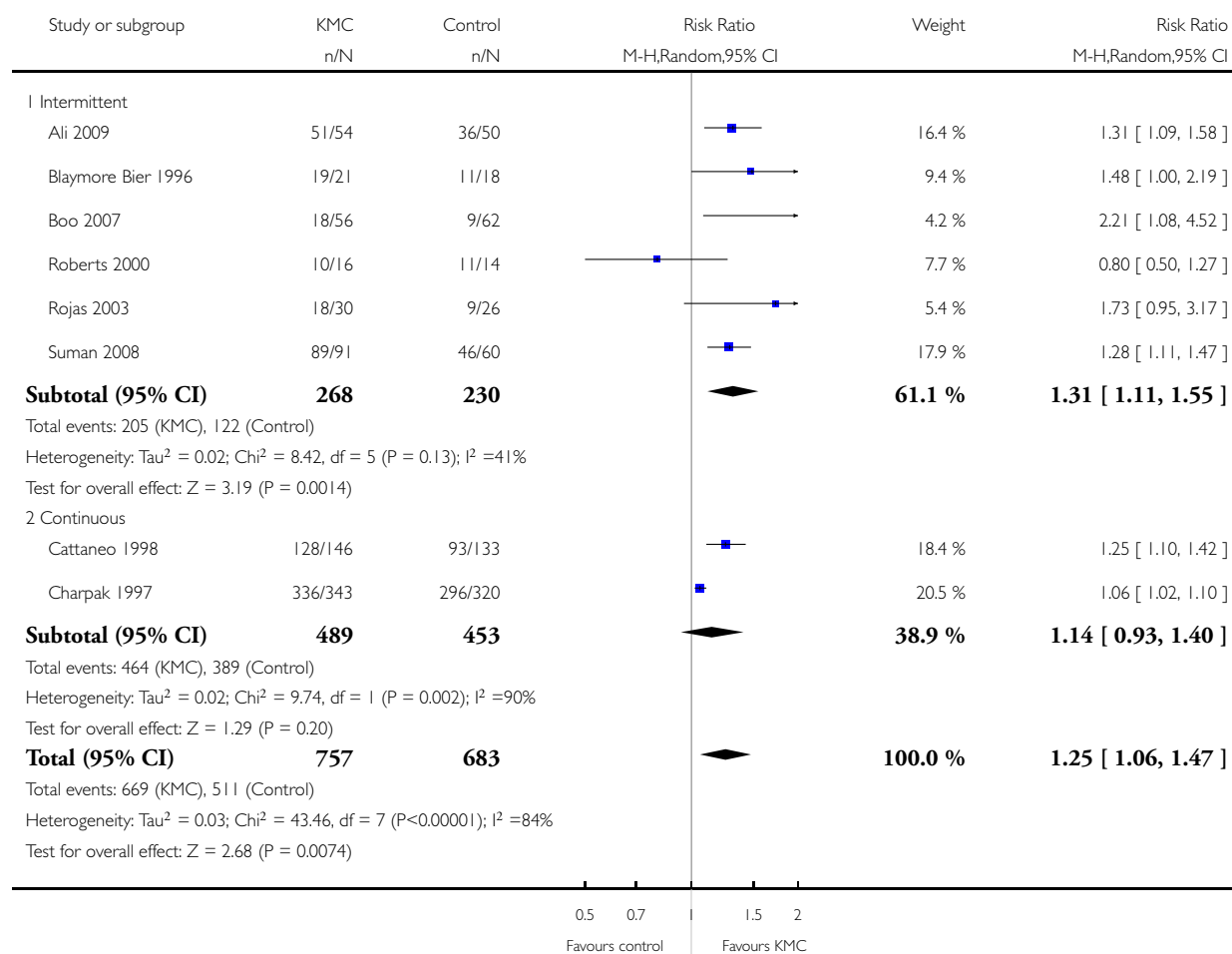


Analysis 1.32. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 32 Any breast feeding at discharge or 40-41 weeks' postmenstrual age - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 32 Any breast feeding at discharge or 40-41 weeks' postmenstrual age - stabilized infants

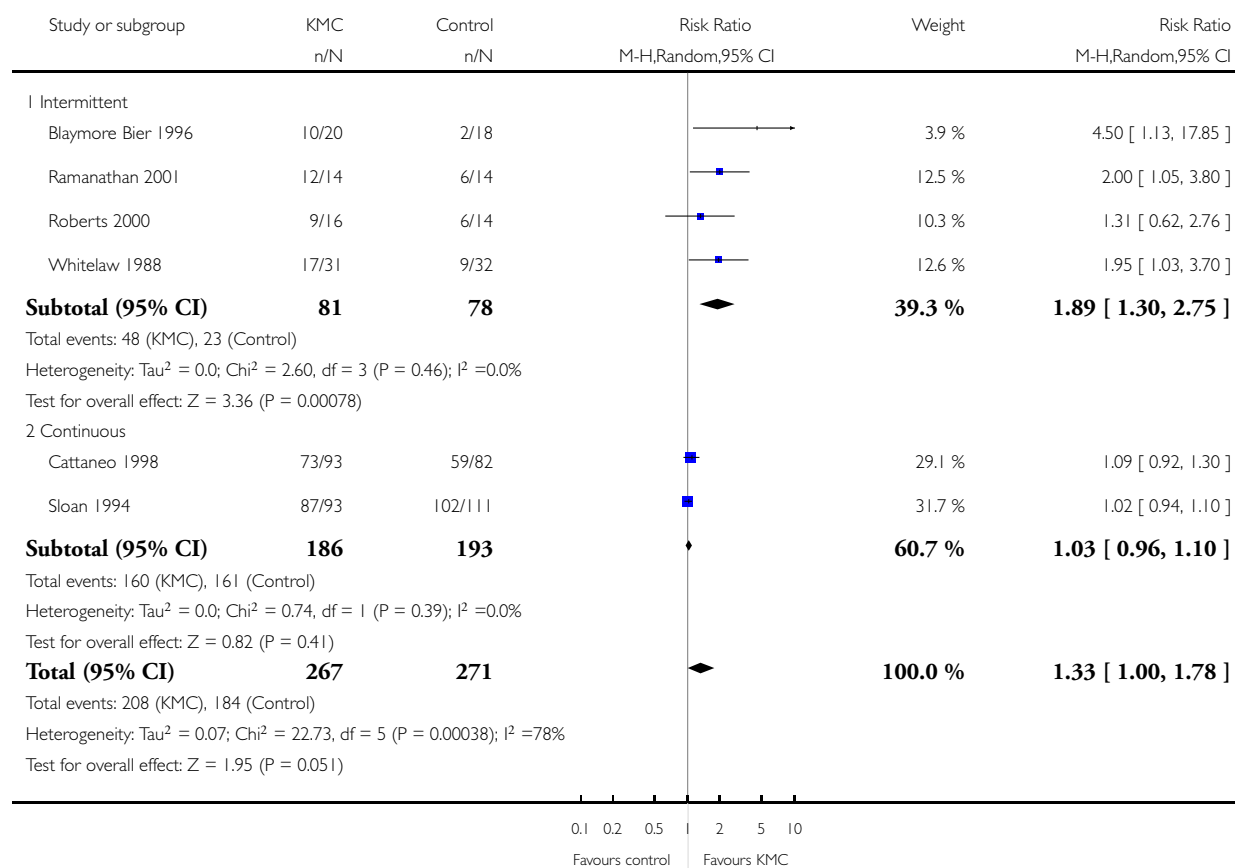


Analysis 1.33. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 33 Any breast feeding at 1-2 months follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 33 Any breast feeding at 1-2 months follow up - stabilized infants

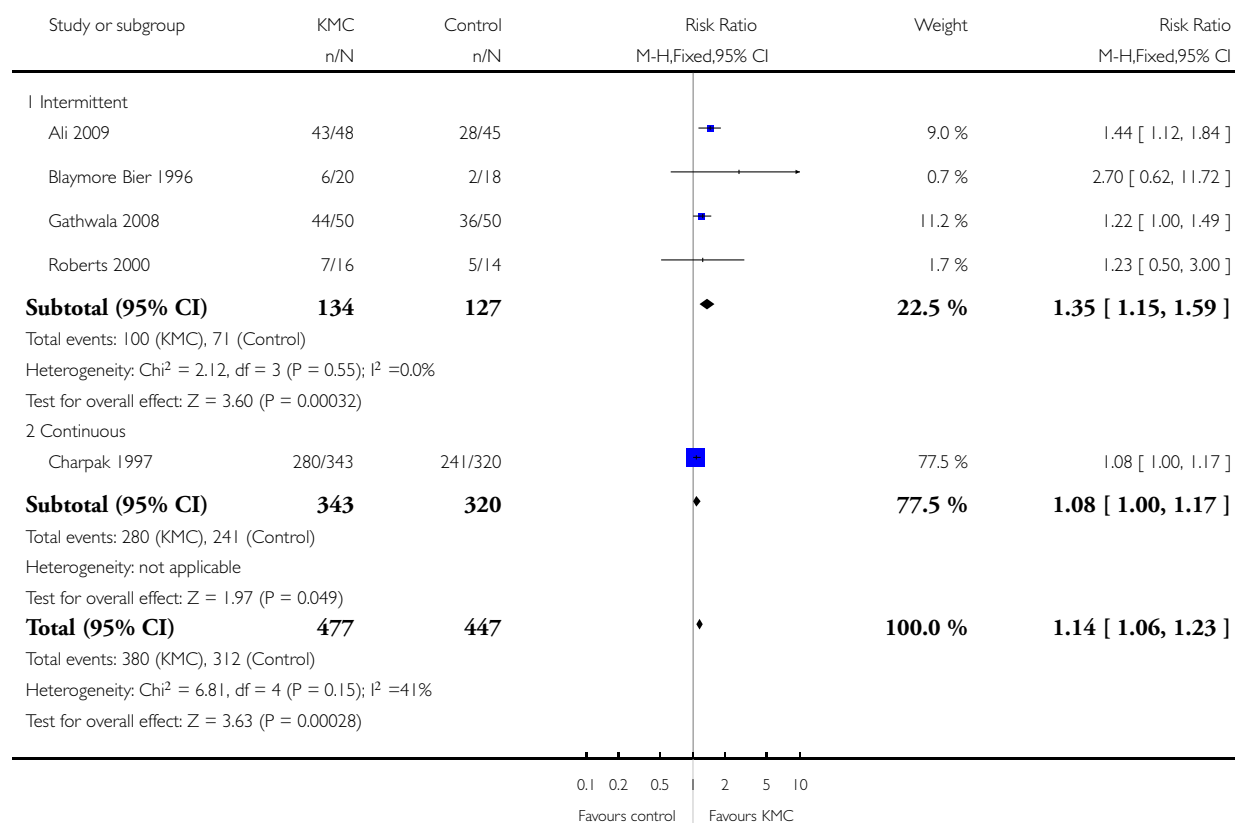


Analysis 1.34. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 34 Any breast feeding at 3 months follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 34 Any breast feeding at 3 months follow up - stabilized infants

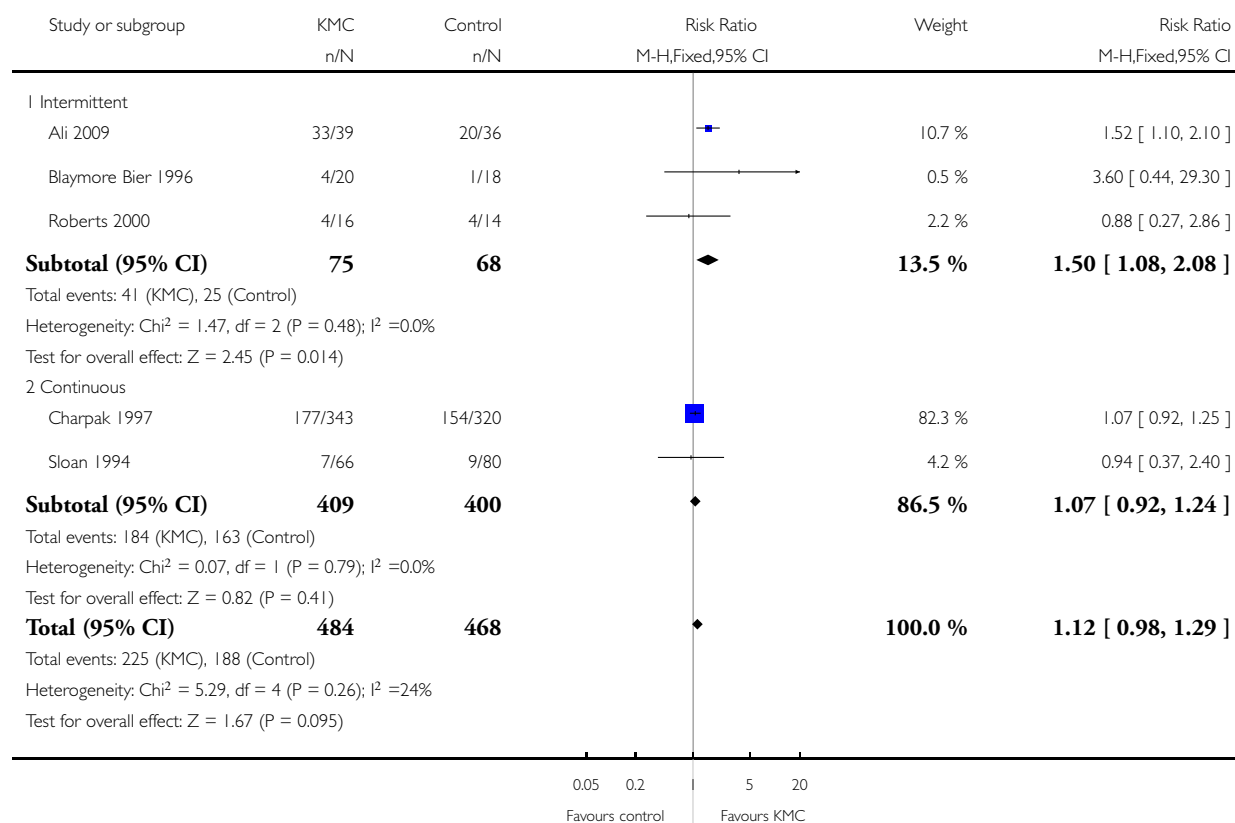


Analysis 1.35. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 35 Any breast feeding at 6 months follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 35 Any breast feeding at 6 months follow up - stabilized infants

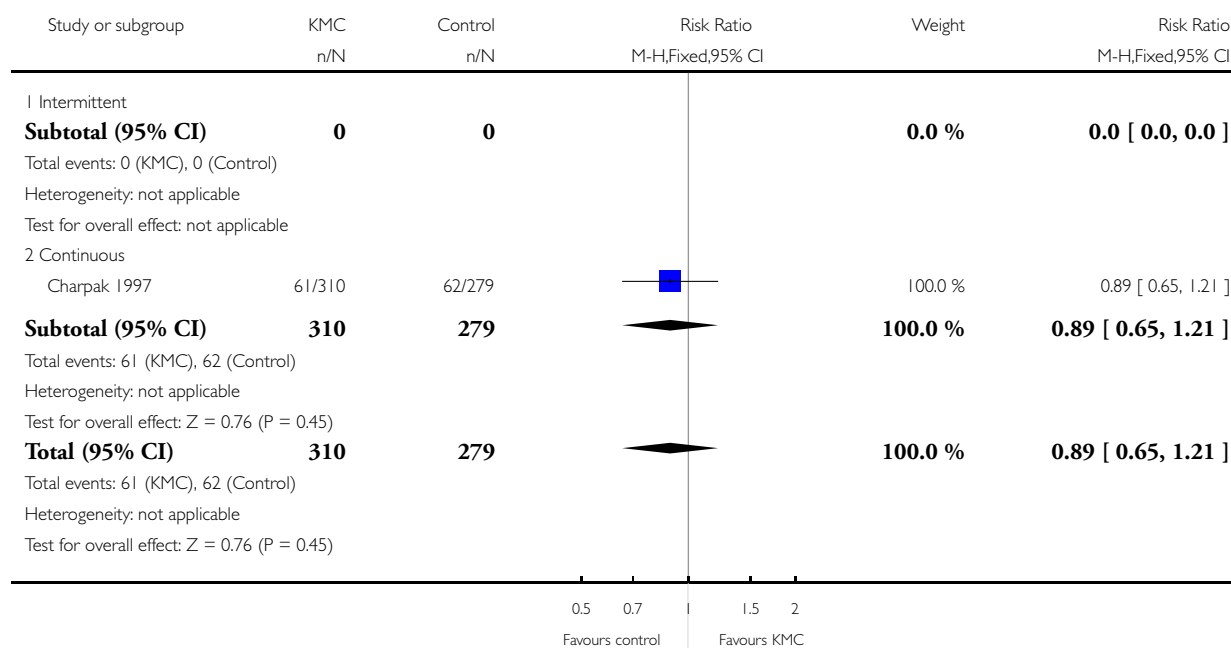


Analysis 1.36. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 36 Any breast feeding at 12 months follow up - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 36 Any breast feeding at 12 months follow up - stabilized infants

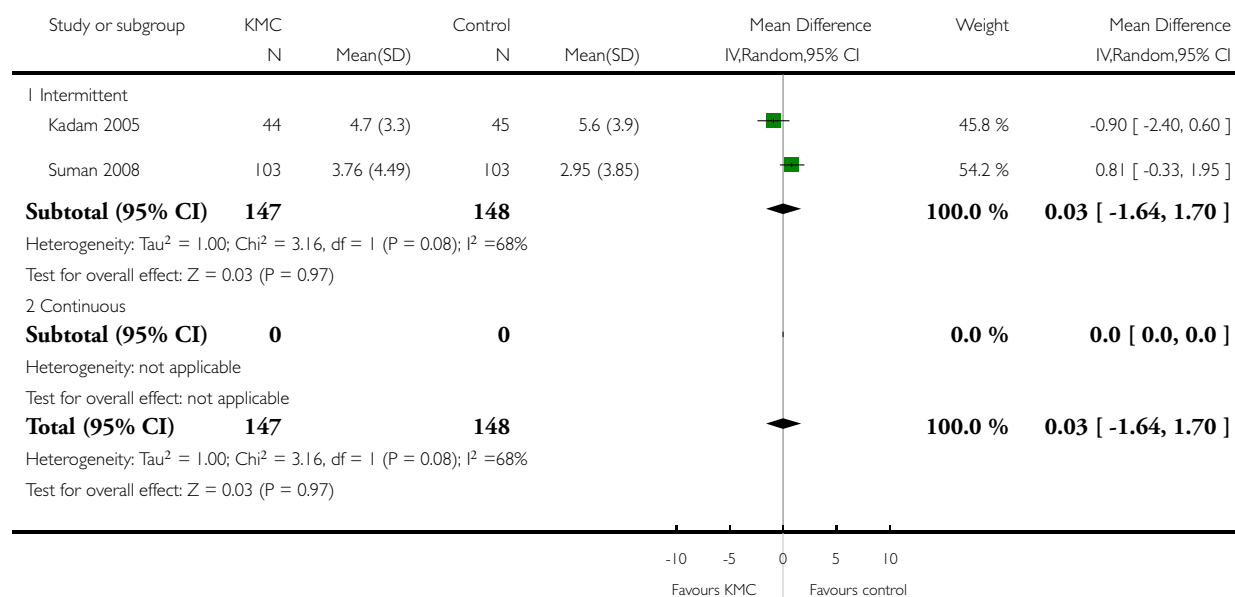


Analysis 1.37. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 37 Onset of breast feeding (days) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 37 Onset of breast feeding (days) - stabilized infants

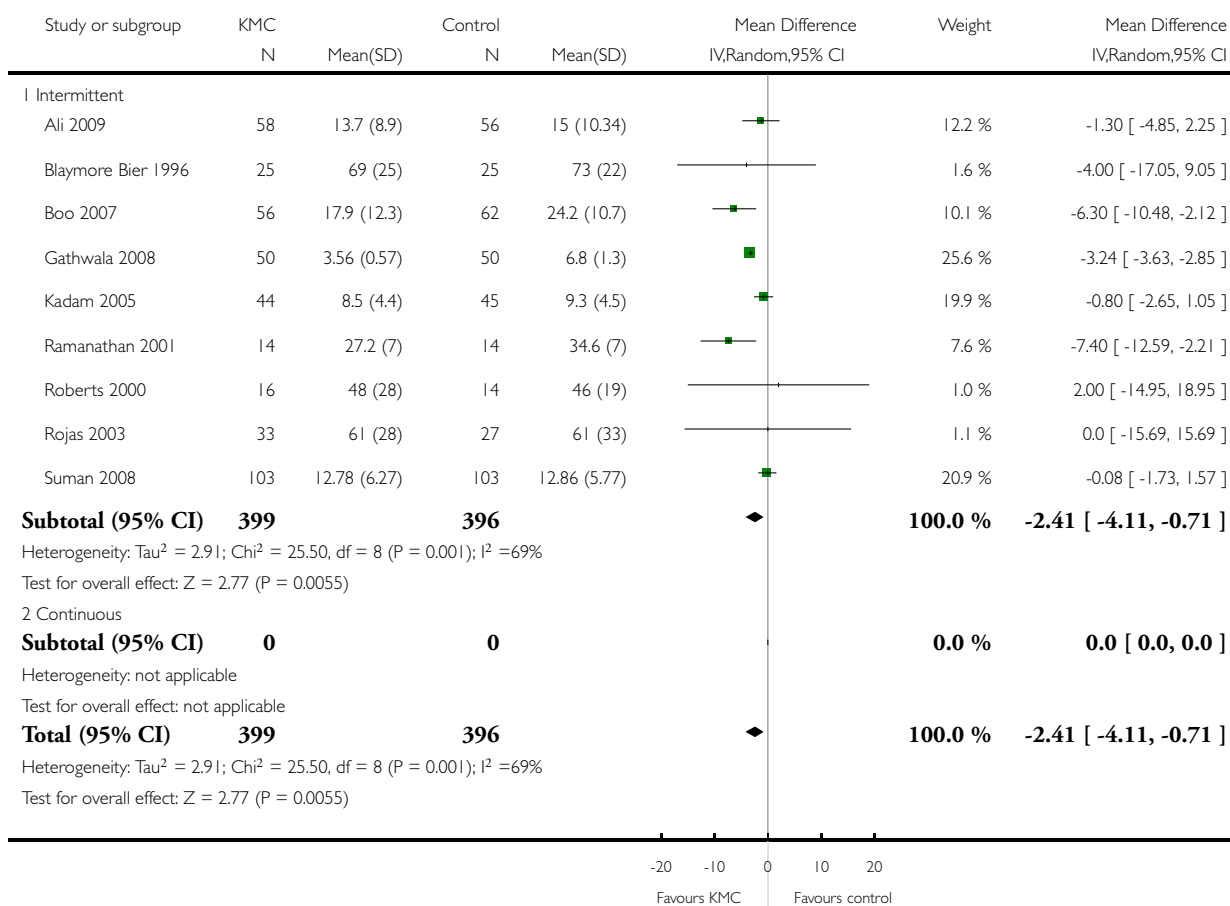


Analysis 1.38. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 38 Length of hospital stay (days) - stabilized infants.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 38 Length of hospital stay (days) - stabilized infants

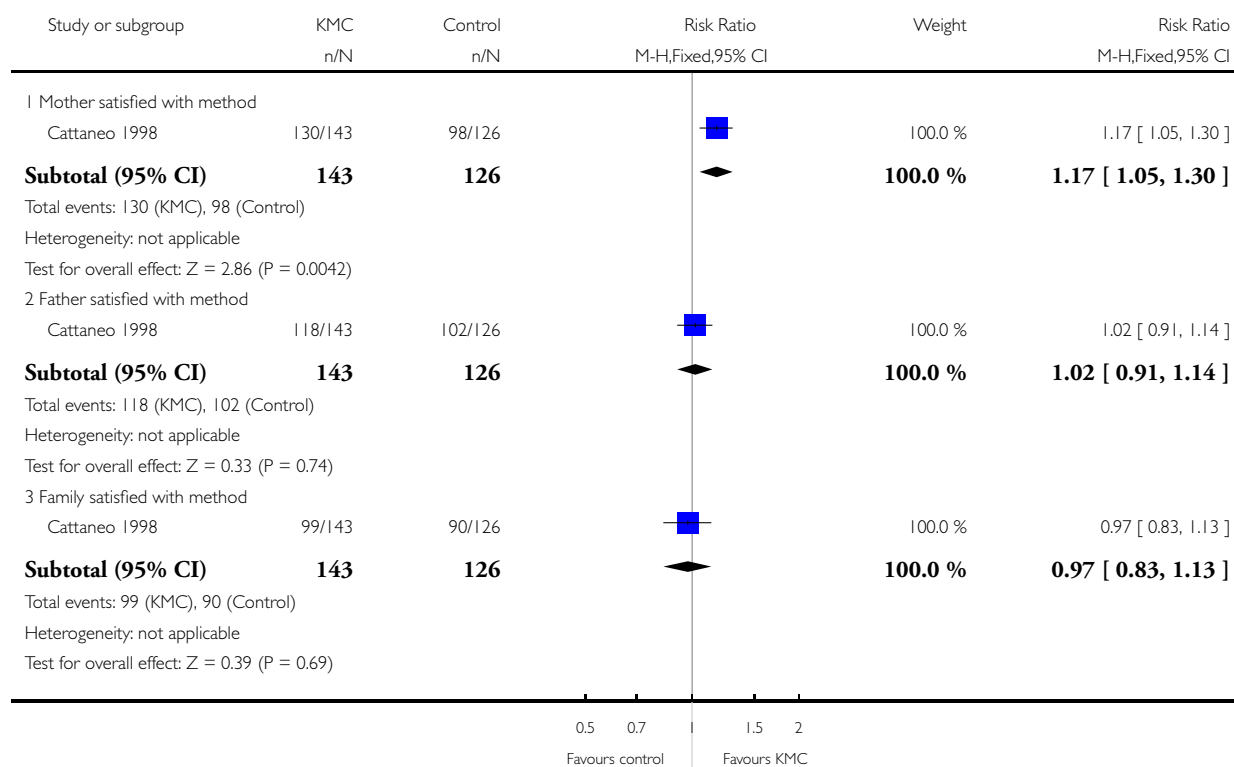


Analysis 1.39. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 39 Parental and familiar satisfaction (continuous KMC).

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 39 Parental and familiar satisfaction (continuous KMC)



Analysis 1.40. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 40 Mother-infant attachment: mother's feelings and perceptions according to interval between birth and start of intervention, and infant admission to NICU.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

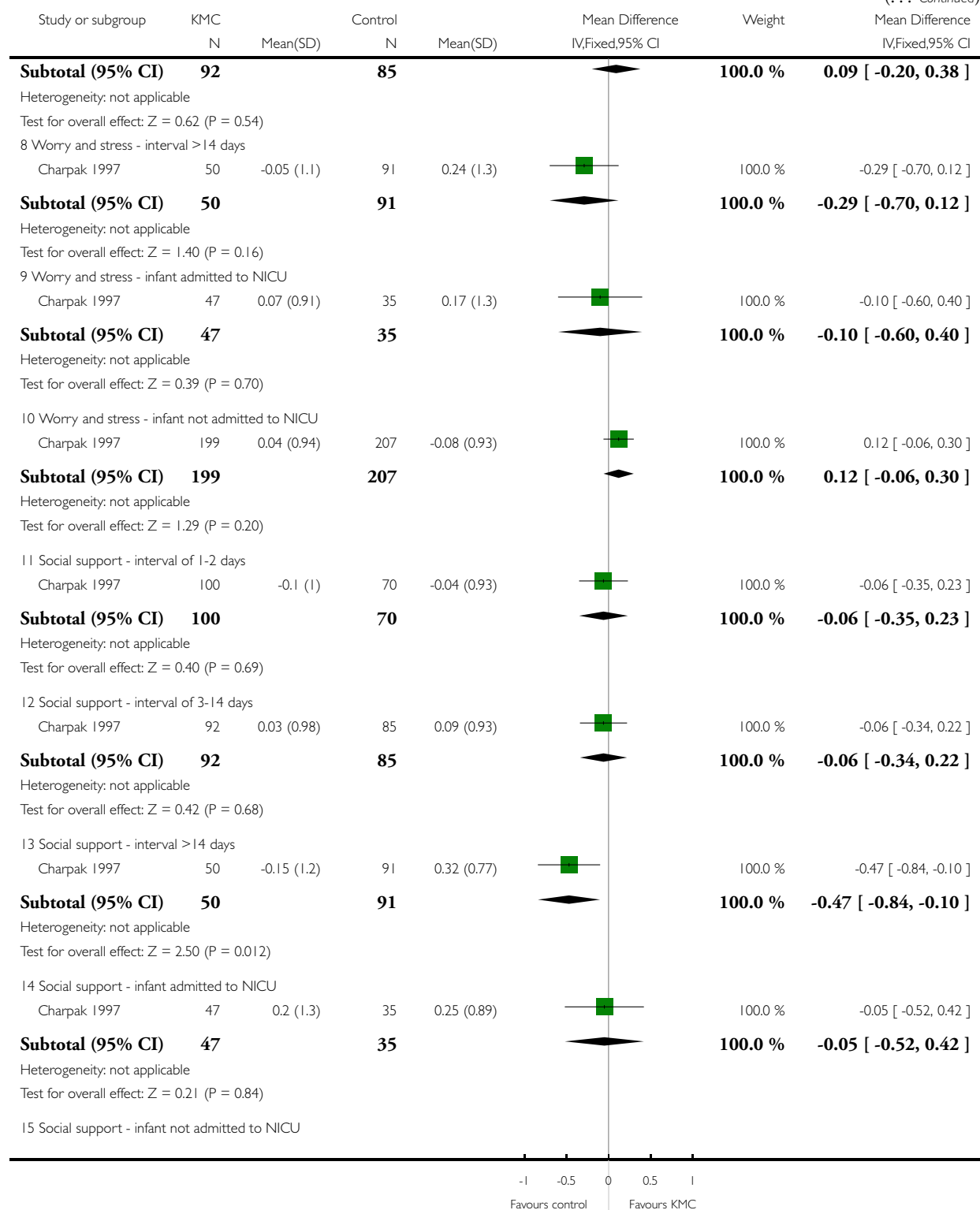
Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 40 Mother-infant attachment: mother's feelings and perceptions according to interval between birth and start of intervention, and infant admission to NICU

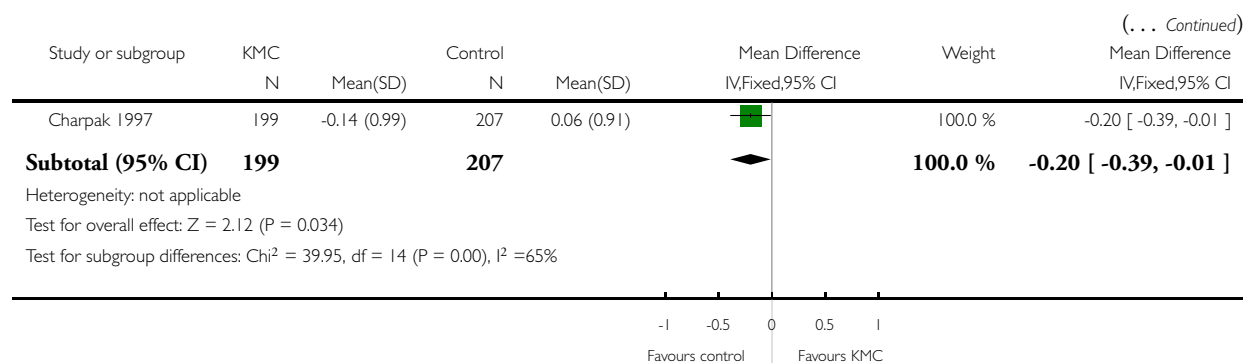


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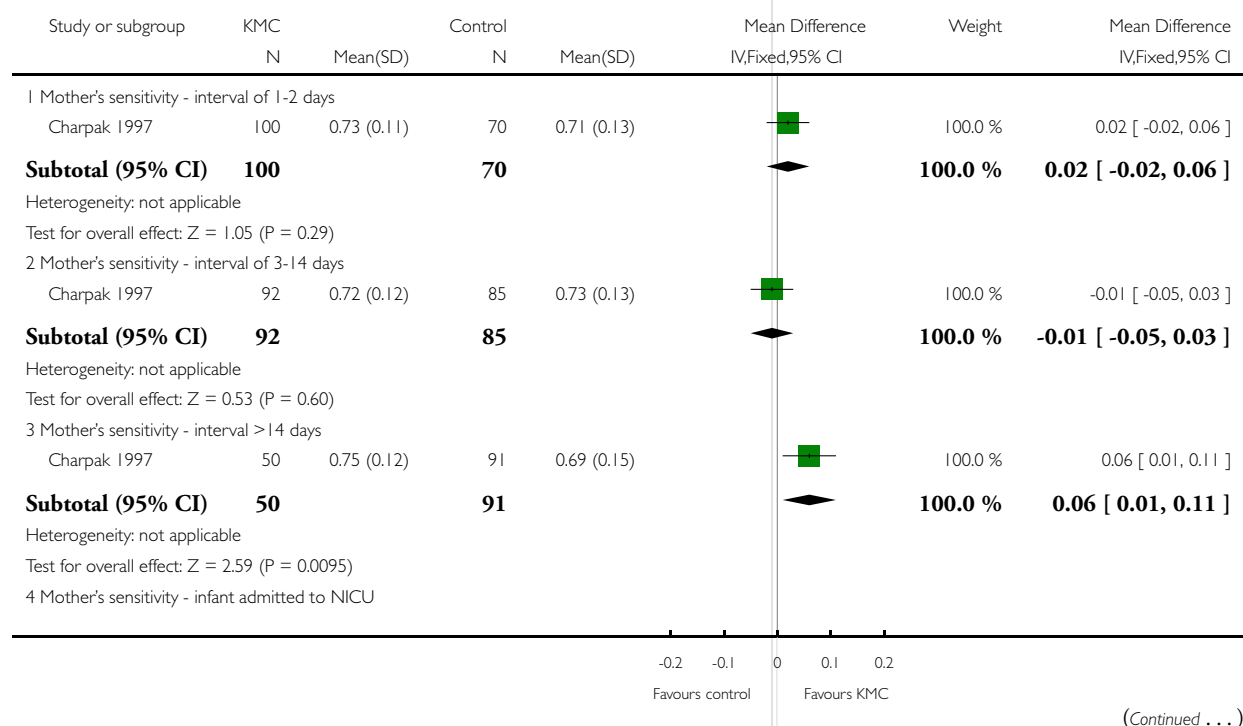


Analysis 1.41. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 41 Mother-infant attachment: mother's responses to the infant according to interval between birth and start of intervention, and infant admission to NICU.

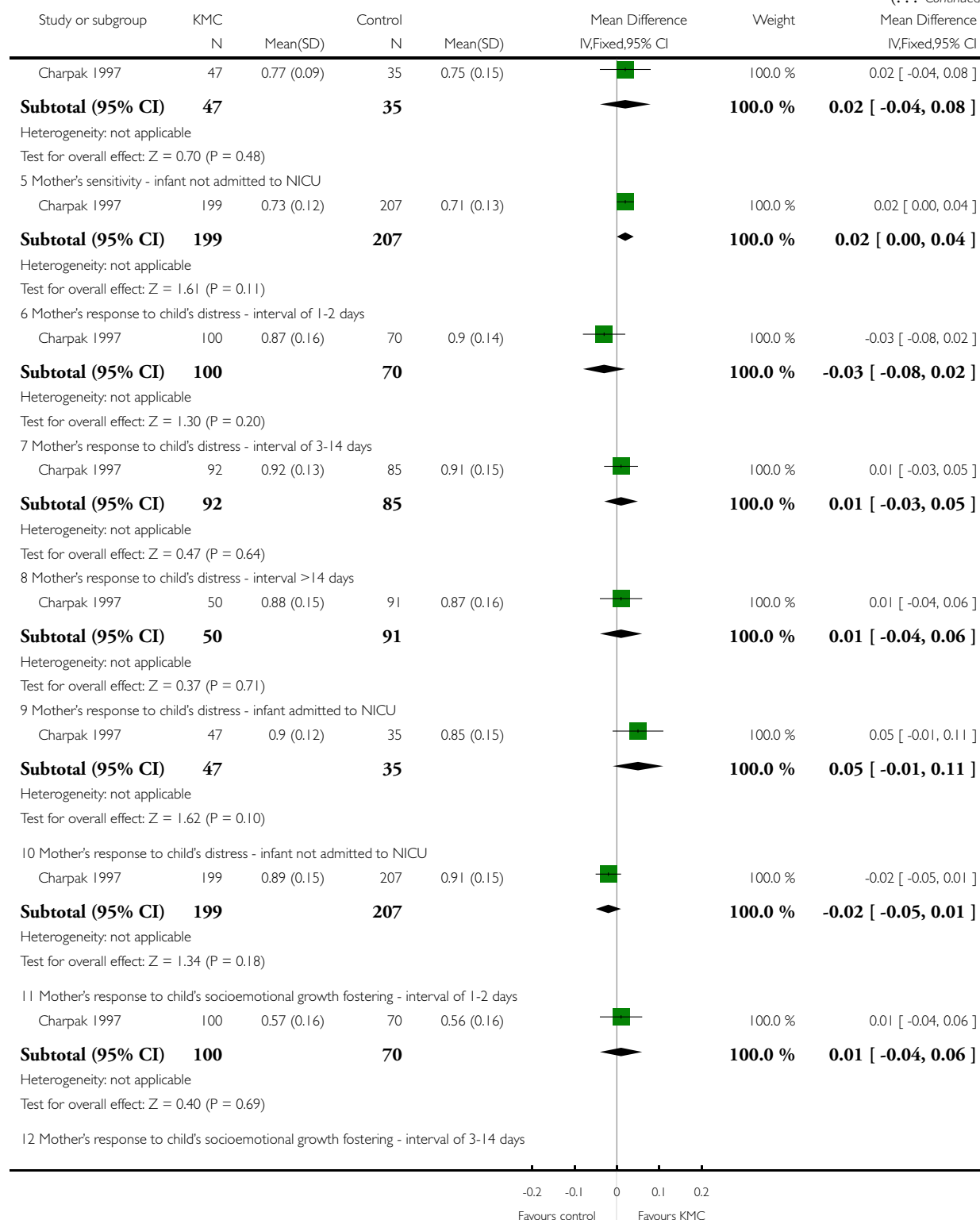
Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 41 Mother-infant attachment: mother's responses to the infant according to interval between birth and start of intervention, and infant admission to NICU

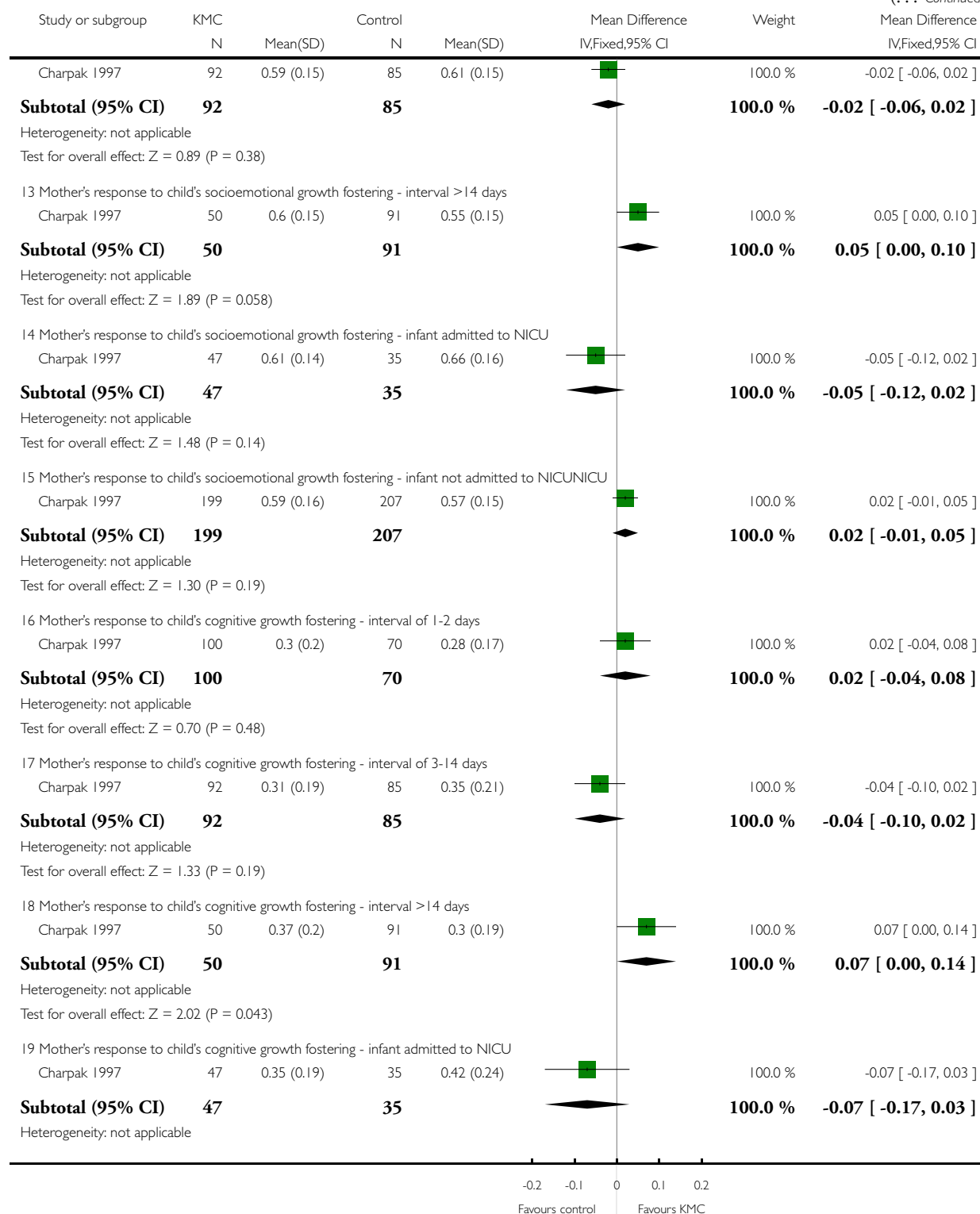


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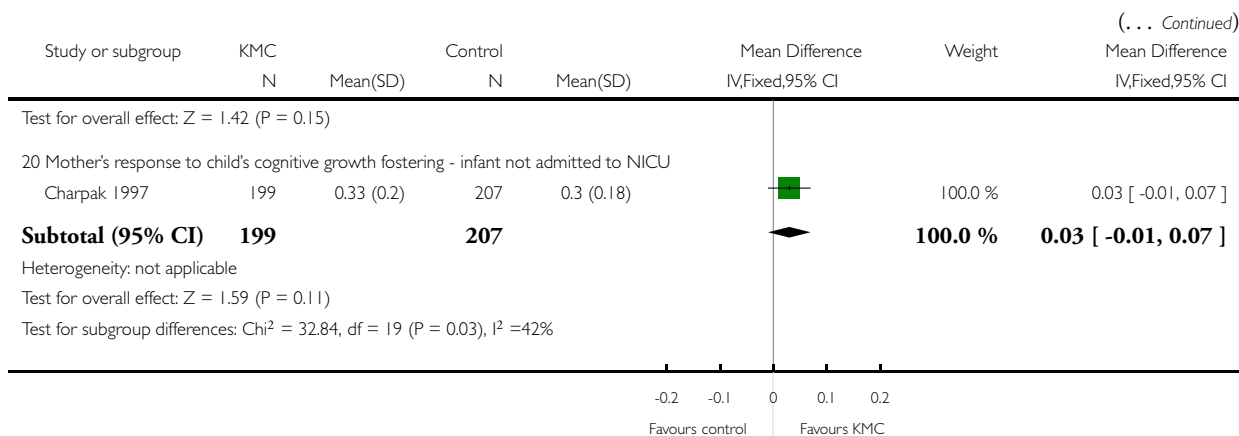


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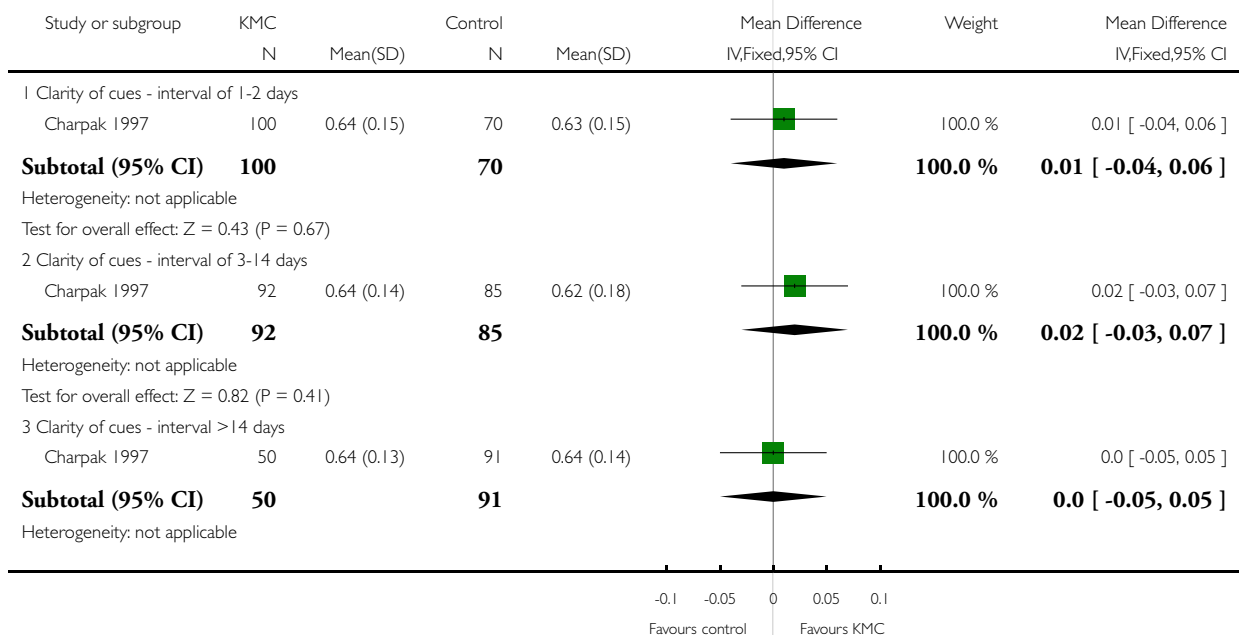


Analysis 1.42. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 42 Mother-infant attachment: infant's responses to the mother according to interval between birth and start of intervention, and infant admission to NICU.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

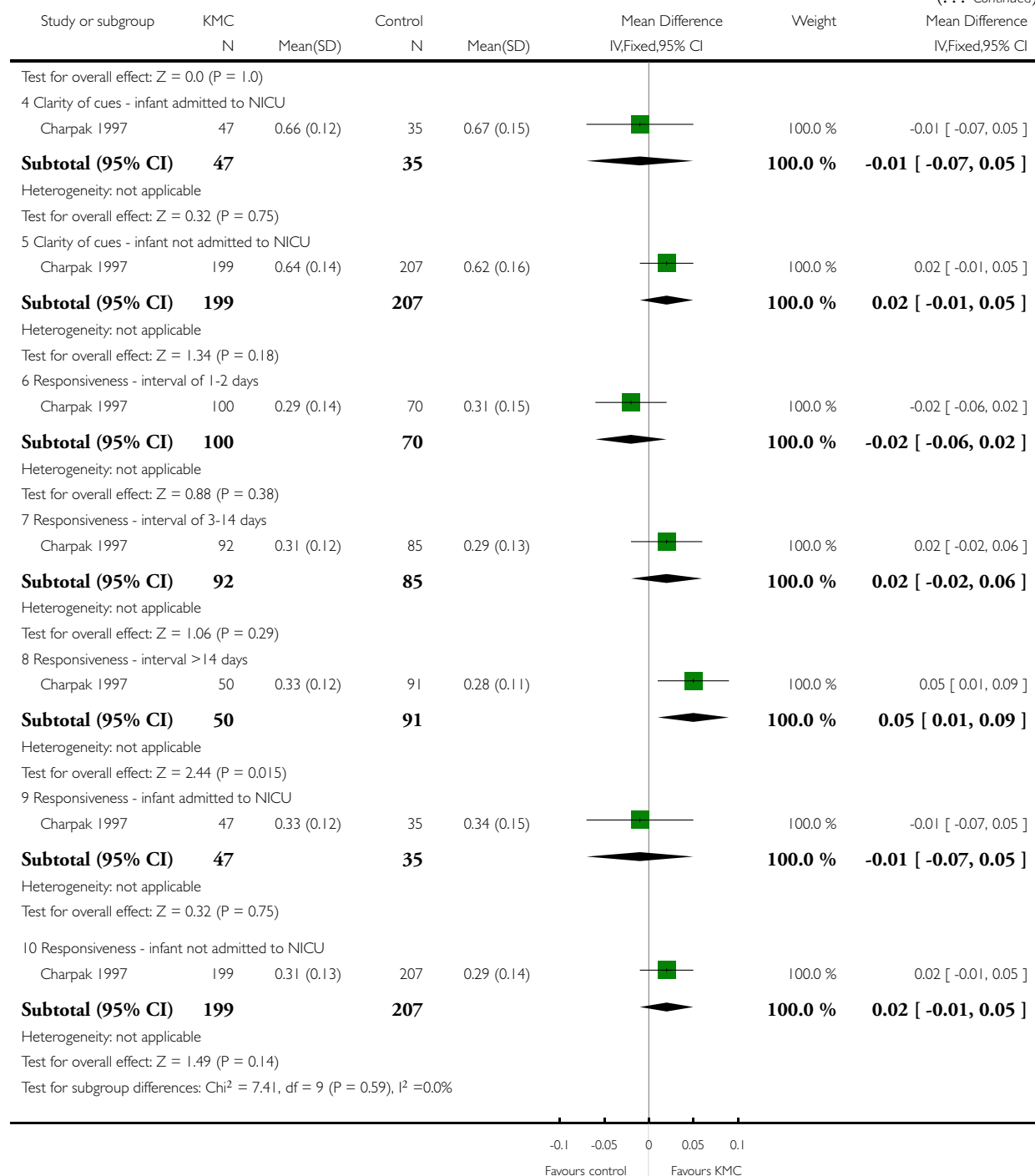
Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 42 Mother-infant attachment: infant's responses to the mother according to interval between birth and start of intervention, and infant admission to NICU



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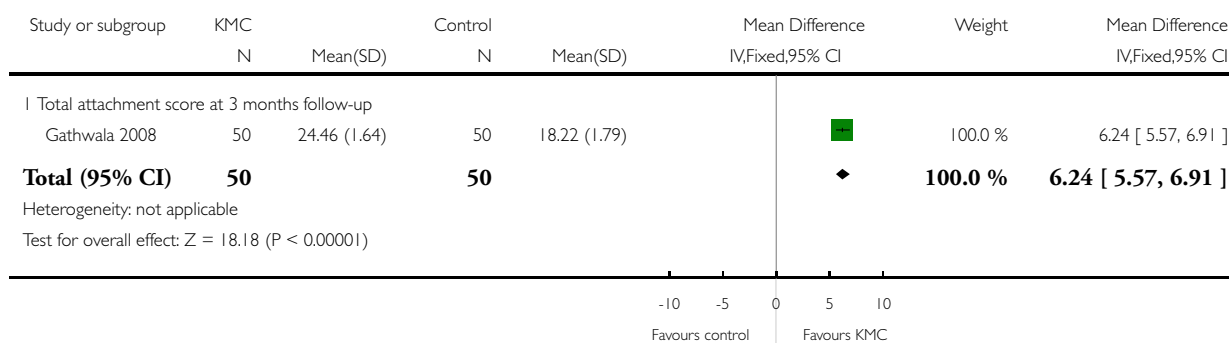


Analysis 1.43. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 43 Mother-infant attachment at 3 months follow-up.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 43 Mother-infant attachment at 3 months follow-up

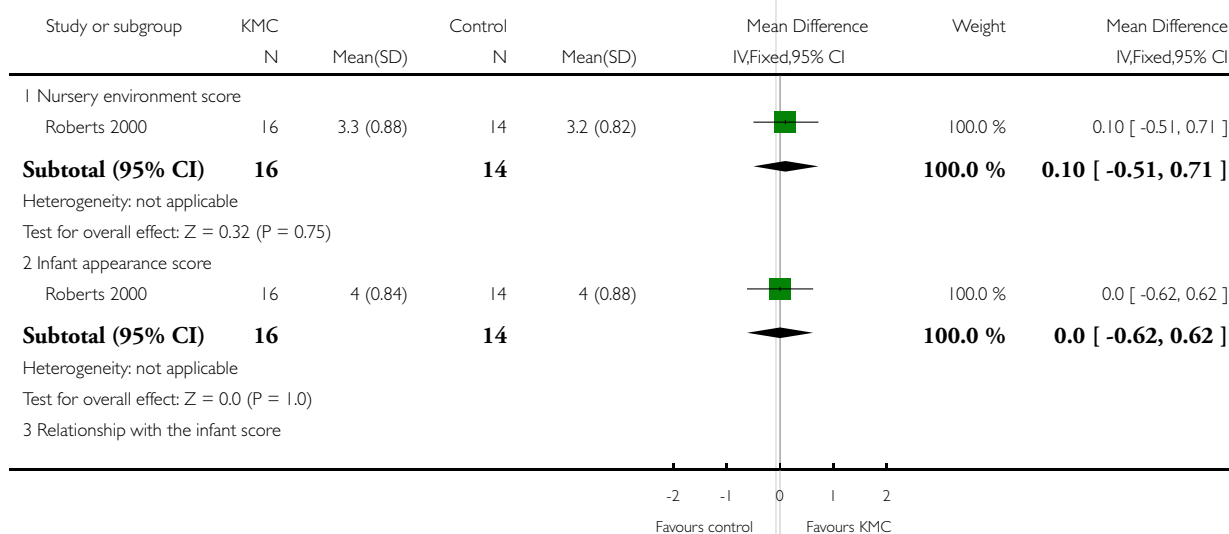


Analysis 1.44. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 44 Mother-infant attachment: stress in NICU.

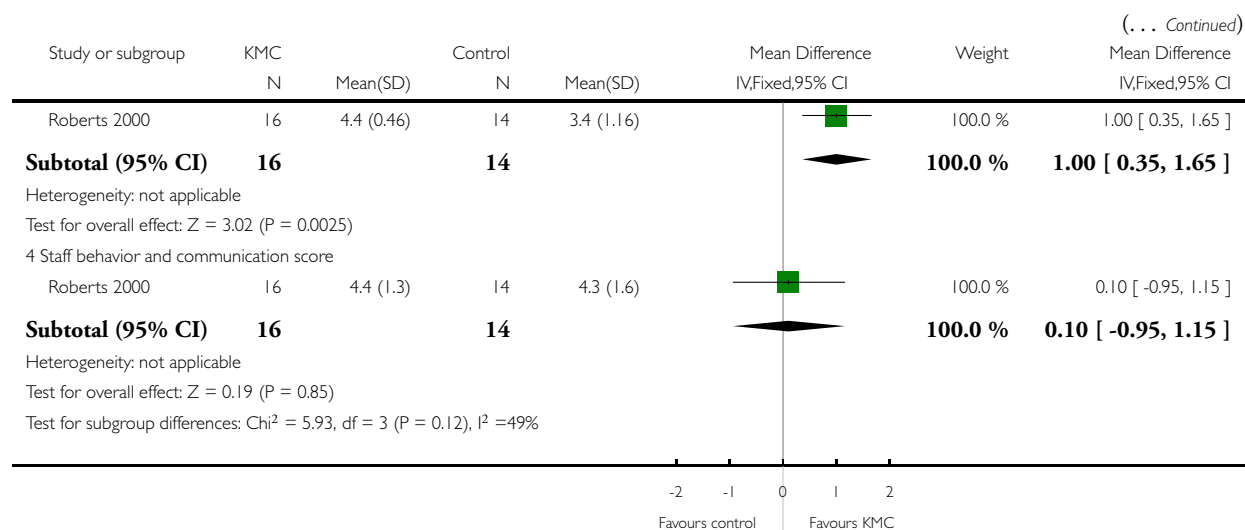
Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 44 Mother-infant attachment: stress in NICU



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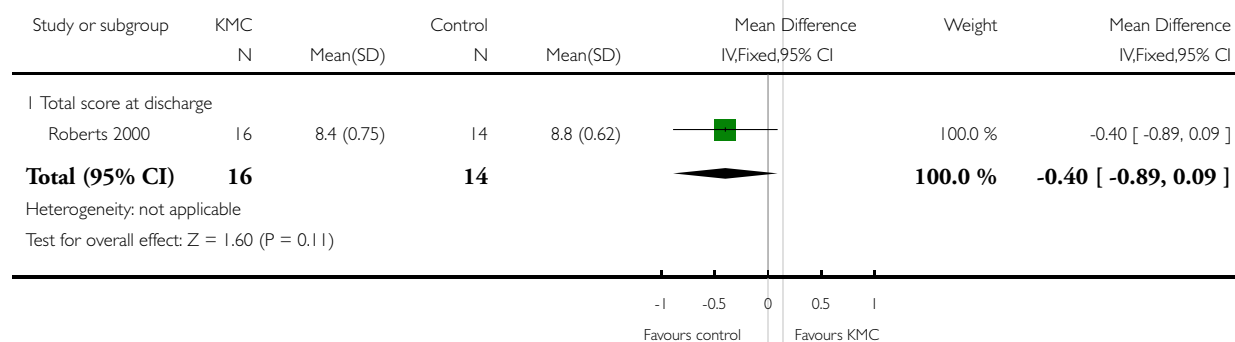


Analysis 1.45. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 45 Mother-infant attachment: parenting skills.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 45 Mother-infant attachment: parenting skills

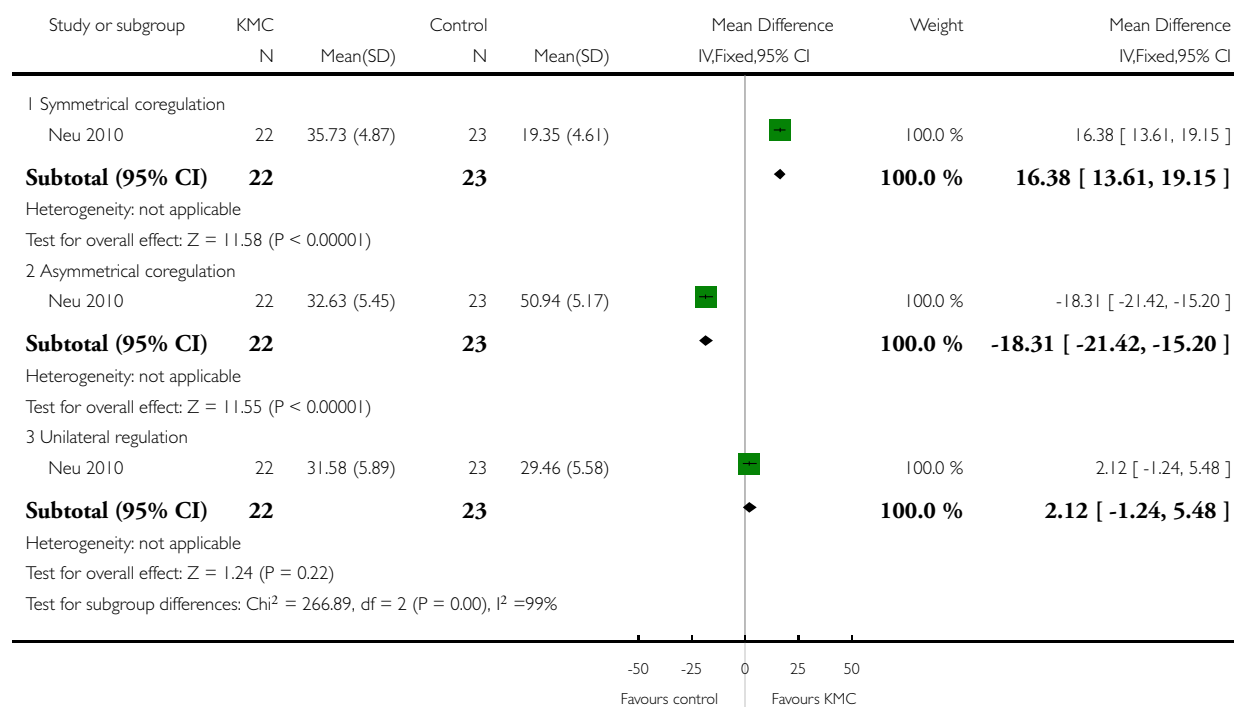


**Analysis 1.46. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 46
Mother-infant interaction at 6 months follow-up.**

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 46 Mother-infant interaction at 6 months follow-up

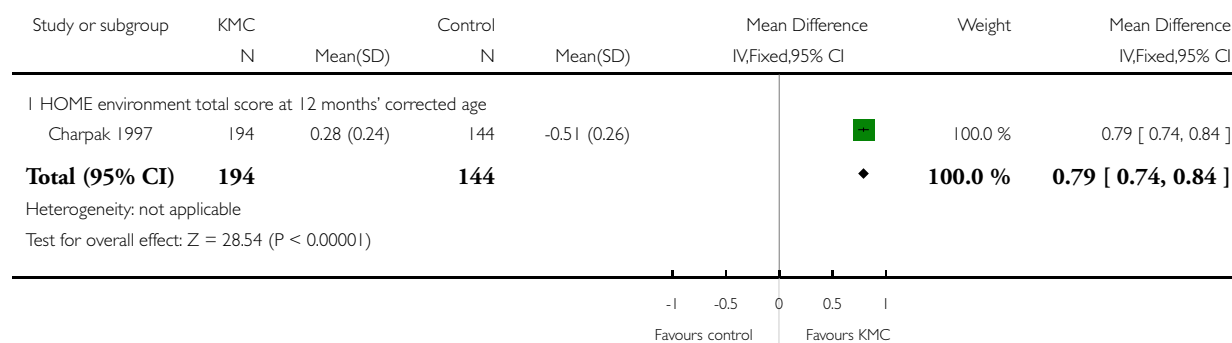


Analysis 1.47. Comparison 1 Kangaroo mother care versus conventional neonatal care, Outcome 47 Social and home environment.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 1 Kangaroo mother care versus conventional neonatal care

Outcome: 47 Social and home environment

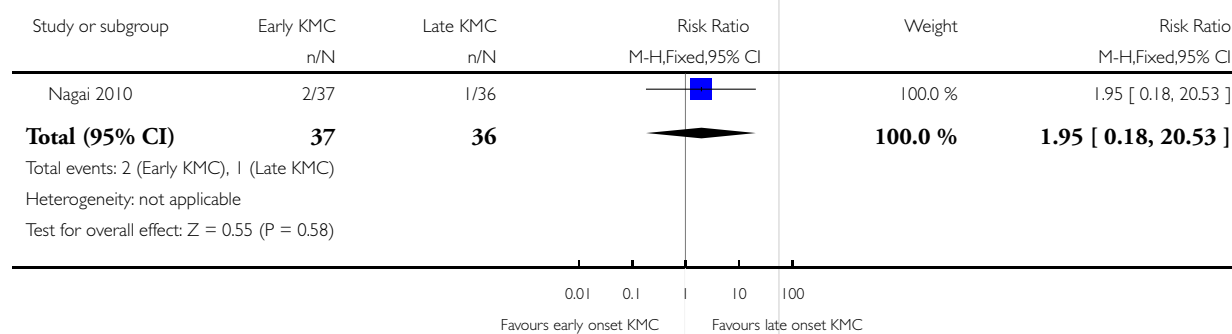


Analysis 2.1. Comparison 2 Early versus late kangaroo mother care in relatively stable LBW infants, Outcome 1 Mortality at 4 weeks of age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 2 Early versus late kangaroo mother care in relatively stable LBW infants

Outcome: 1 Mortality at 4 weeks of age

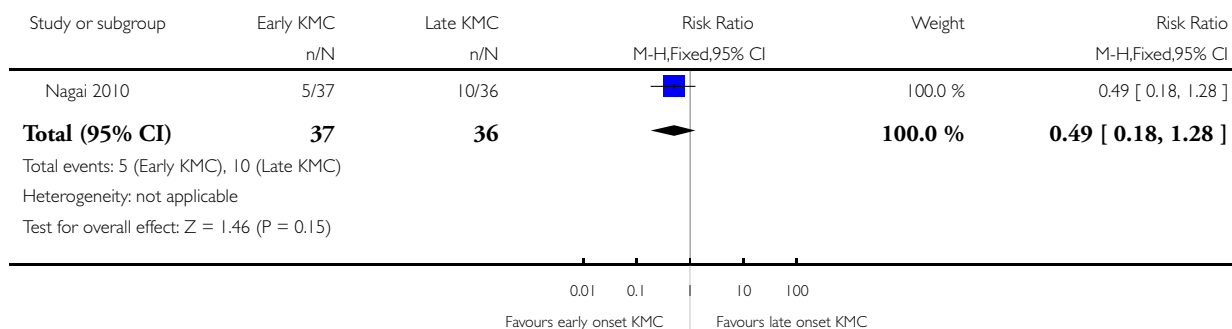


Analysis 2.2. Comparison 2 Early versus late kangaroo mother care in relatively stable LBW infants, Outcome 2 Morbidity at 4 weeks of age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 2 Early versus late kangaroo mother care in relatively stable LBW infants

Outcome: 2 Morbidity at 4 weeks of age

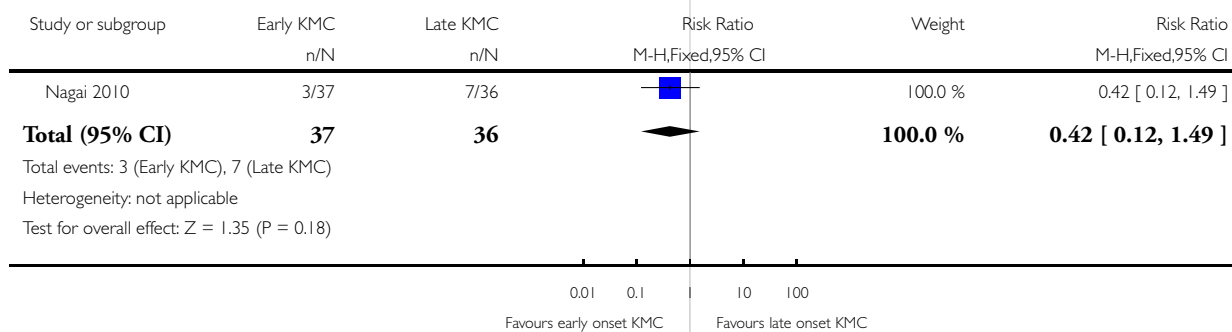


Analysis 2.3. Comparison 2 Early versus late kangaroo mother care in relatively stable LBW infants, Outcome 3 Severe infection at 4 weeks of age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 2 Early versus late kangaroo mother care in relatively stable LBW infants

Outcome: 3 Severe infection at 4 weeks of age

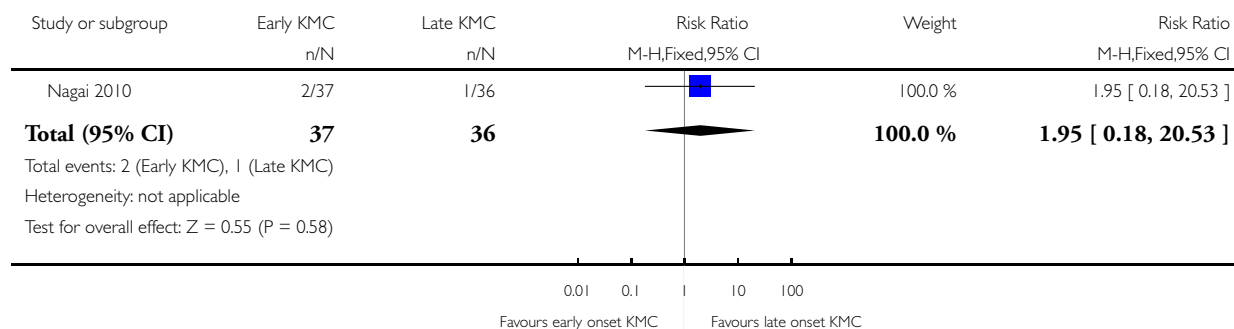


Analysis 2.4. Comparison 2 Early versus late kangaroo mother care in relatively stable LBW infants, Outcome 4 Re-admission to hospital at 4 weeks of age.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 2 Early versus late kangaroo mother care in relatively stable LBW infants

Outcome: 4 Re-admission to hospital at 4 weeks of age

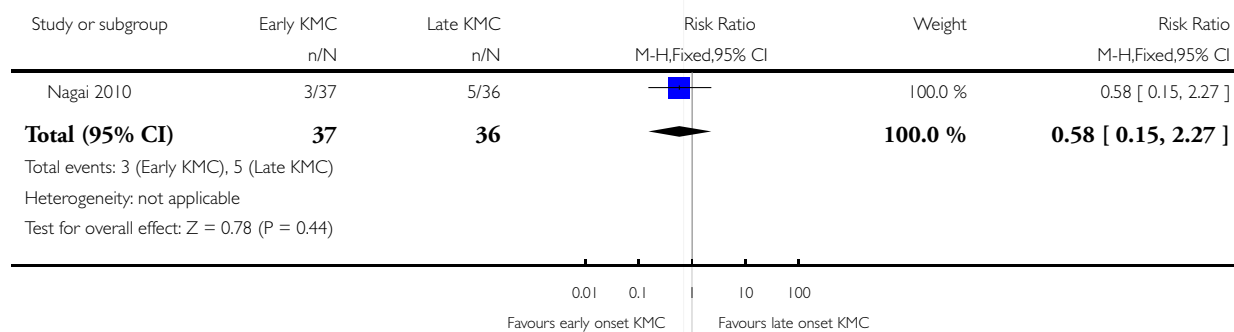


Analysis 2.5. Comparison 2 Early versus late kangaroo mother care in relatively stable LBW infants, Outcome 5 Hypothermia.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 2 Early versus late kangaroo mother care in relatively stable LBW infants

Outcome: 5 Hypothermia

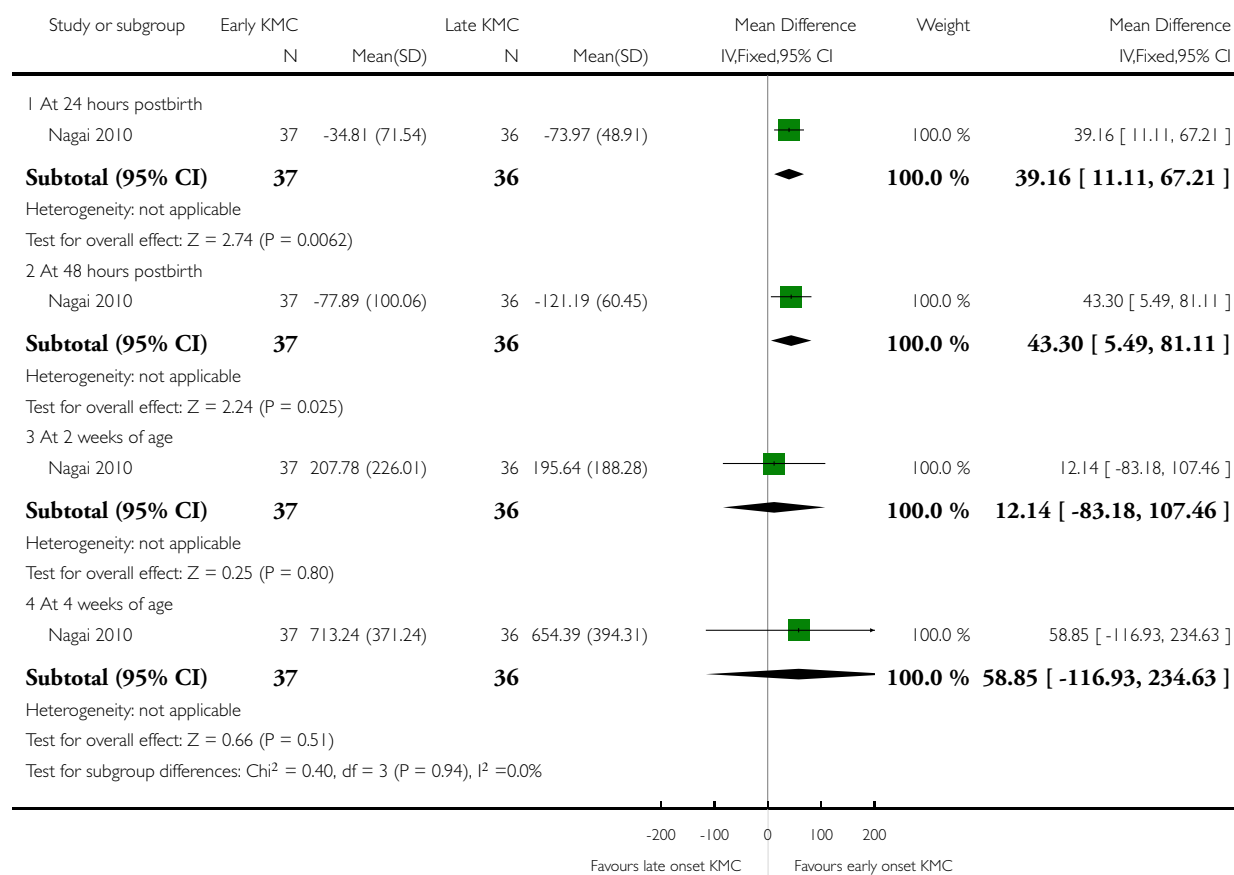


Analysis 2.6. Comparison 2 Early versus late kangaroo mother care in relatively stable LBW infants, Outcome 6 Weight gain (grams).

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 2 Early versus late kangaroo mother care in relatively stable LBW infants

Outcome: 6 Weight gain (grams)

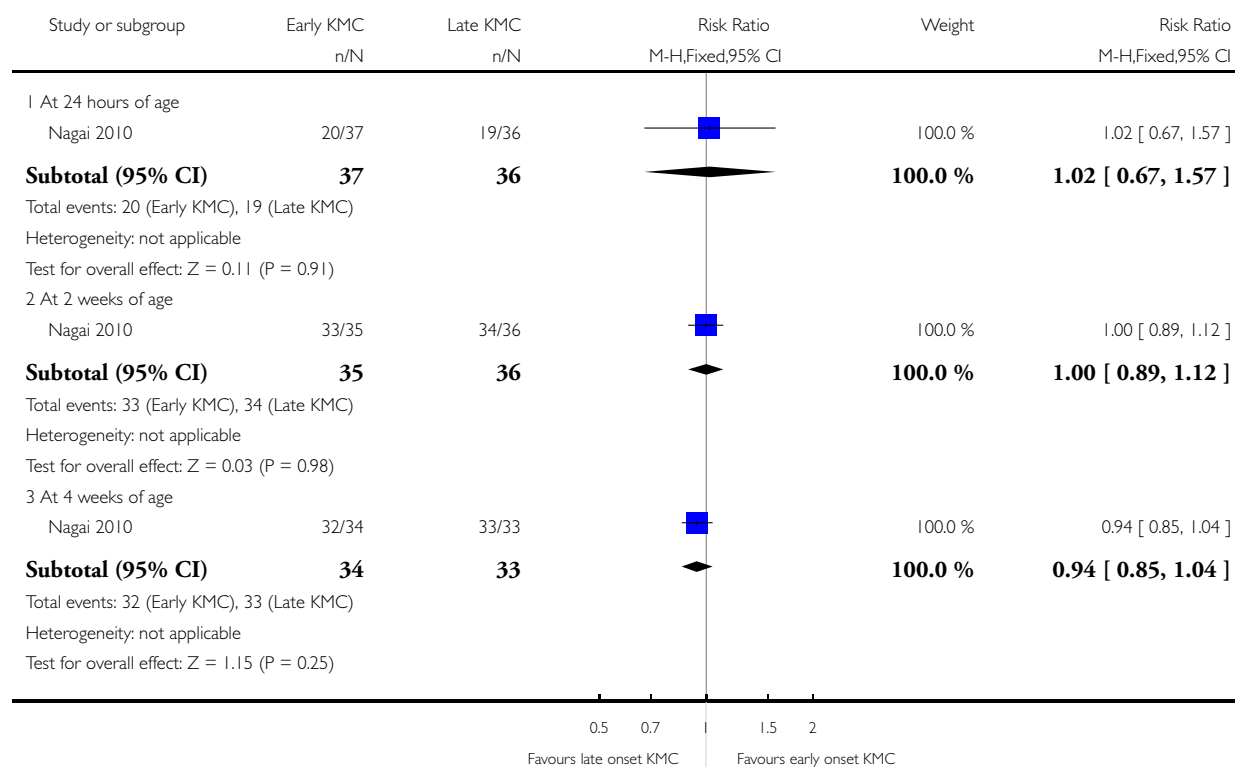


Analysis 2.7. Comparison 2 Early versus late kangaroo mother care in relatively stable LBW infants, Outcome 7 Exclusive breast feeding.

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 2 Early versus late kangaroo mother care in relatively stable LBW infants

Outcome: 7 Exclusive breast feeding

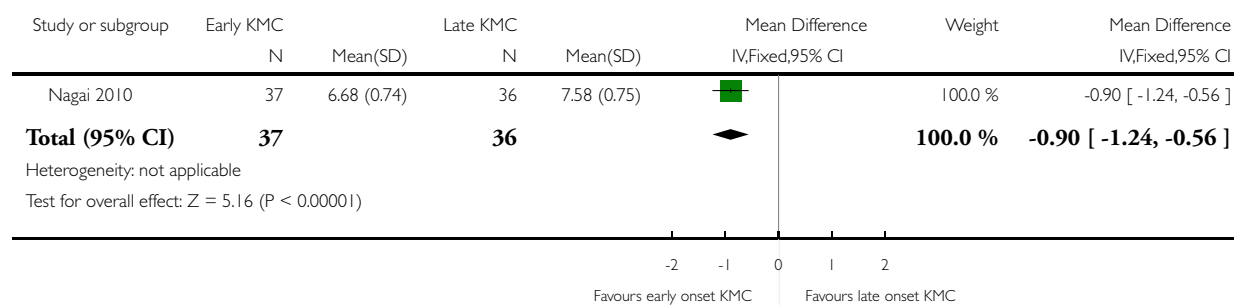


Analysis 2.8. Comparison 2 Early versus late kangaroo mother care in relatively stable LBW infants, Outcome 8 Length of hospital stay (days).

Review: Kangaroo mother care to reduce morbidity and mortality in low birthweight infants

Comparison: 2 Early versus late kangaroo mother care in relatively stable LBW infants

Outcome: 8 Length of hospital stay (days)



WHAT'S NEW

Last assessed as up-to-date: 30 January 2011.

Date	Event	Description
31 January 2011	New search has been performed	<p>This updates the review "Kangaroo mother care to reduce morbidity and mortality in low birthweight infants" published in The Cochrane Database of Systematic Reviews (Conde-Agudelo 2003).</p> <p>In the previous versions of this review, we included only trials that evaluated continuous kangaroo mother care (KMC) after infant stabilization. For the 2011 update, we have also included studies that evaluated KMC before infant stabilization and intermittent KMC. In addition, we have changed the labels for several primary and secondary outcomes and have performed new subgroup and sensitivity analysis. As the time of measurement for several primary and secondary outcomes varied across trials, we have grouped these outcomes as "outcome at latest follow up". For the primary outcomes mortality at discharge or 40-41 weeks' postmenstrual age and at latest follow up, we have included subgroup analyses according to type of KMC (intermittent versus continuous), infant age at initiation of KMC (≤ 10 days versus > 10 days), setting in which the trial was conducted (low/middle income countries versus high income countries), and infant stabilization (before versus after). For all outcomes in</p>

(Continued)

		stabilized LBW infants we performed subgroup analyses according to type of KMC (intermittent versus continuous). Finally, we have included randomized controlled trials that compared early onset (starting within 24 hours after birth) versus late onset (starting after 24 hours after birth) KMC.
31 January 2011	New citation required and conclusions have changed	<p>New search has been performed. In addition to the three studies (Cattaneo 1998; Charpak 1997; Sloan 1994) included in previous versions of the review, we have included 13 new studies (Ali 2009; Blaymore Bier 1996; Boo 2007; Gathwala 2008; Kadam 2005; Nagai 2010; Neu 2010; Ramanathan 2001; Roberts 2000; Rojas 2003; Suman 2008; Whitelaw 1988; Worku 2005).</p> <p>We have excluded another 24 studies (Ahn 2010; Anderson 2003; Bergman 2004; Chiu 2009; Christensson 1998; Darmstadt 2006; de Almeida 2010; de Macedo 2007; Hake Brooks 2008; Huang 2006; Ibe 2004; Kumar 2008; Lai 2006; Lamy Filho 2008; Legault 1993; Lincetto 2000; Ludington-Hoe 1991; Ludington-Hoe 2000; Ludington-Hoe 2004; Ludington-Hoe 2006; Miles 2006; Miltersteiner 2005; Sloan 2008; Tallandini 2006).</p> <p>The updated review used updated methods, includes results for new comparisons, and includes new subgroup and sensitivity analyses.</p>

HISTORY

Protocol first published: Issue 3, 1999

Review first published: Issue 4, 2000

Date	Event	Description
26 September 2008	Amended	Converted to new review format

CONTRIBUTIONS OF AUTHORS

The original review was carried out by Agustin Conde-Agudelo, Jose L. Diaz-Rossello, and Jose Belizan ([Conde-Agudelo 2000](#)).

The same authors updated the review in 2003 ([Conde-Agudelo 2003](#)).

Agustin Conde-Agudelo, Jose L. Diaz-Rossello, and José M. Belizán undertook the 2011 revision and update.

For this update, Dr Agustin Conde-Agudelo wrote the first draft of the review and revised subsequent drafts in response to feedback.

Drs Jose L. Diaz-Rossello and José M. Belizán commented on the first draft of the updated review and contributed to the writing of the final draft.

DECLARATIONS OF INTEREST

None.

SOURCES OF SUPPORT

Internal sources

- (AC-A) Perinatology Research Branch, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development/ National Institutes of Health/Department of Health and Human Services, Bethesda, MD and Detroit, MI, USA.
- (JLD-R) Department of Neonatology, University Hospital, Montevideo, Uruguay.
- (JMB) Department of Mother and Child Health Research, Institute for Clinical Effectiveness and Health Policy (IECS), Buenos Aires, Argentina.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The background and methods sections have been updated. After the protocol was published, a new version of the Cochrane Handbook recommended a new approach to assess the risk of bias. We changed our method of assessment to be consistent with the recommendations. We decided to group studies into continuous KMC and intermittent KMC after looking at the variation in the interventions. We have changed the labels for most primary and secondary outcomes and have performed several new subgroup and sensitivity analysis. In the protocol and previous versions of this review, we did not include studies that evaluated KMC before stabilization and intermittent KMC. In this updated review, we have also included studies that evaluated KMC before stabilization and intermittent KMC.

INDEX TERMS

Medical Subject Headings (MeSH)

*Infant Mortality; *Infant, Low Birth Weight; Infant Care [*methods]; Infant, Newborn; Length of Stay; Physical Stimulation [*methods]; Randomized Controlled Trials as Topic; Weight Gain

MeSH check words

Humans