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Bed sharing versus no bed sharing for healthy term neonates (Review)

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[Intervention Review]

Bed sharing versus no bed sharing for healthy term neonates

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ABSTRACT

Background

There is great global variation in the sleeping arrangements for healthy newborn infants. Bed sharing is a type of sleeping practice in which the sleeping surface (e.g. bed, couch or armchair, or some other sleeping surface) is shared between the infant and another person. The possible physiological benefits include better oxygen and cardiopulmonary stability, fewer crying episodes, less risk of hypothermia, and a longer duration of breastfeeding. On the other hand, the most important harmful effect of bed sharing is that it may increase the risk of sudden infant death syndrome (SIDS). Studies have found conflicting evidence regarding the safety and efficacy of bed sharing during infancy.

Objectives

To evaluate the efficacy and safety of bed sharing, started during the neonatal period, on breastfeeding status (exclusive and total duration of breastfeeding), incidence of SIDS, rates of hypothermia, neonatal and infant mortality, and long-term neurodevelopmental outcomes.

Search methods

We used the standard search strategy of Cochrane Neonatal to search the Cochrane Central Register of Controlled Trials (CENTRAL 2020, Issue 7) in the Cochrane Library; MEDLINE via PubMed (1966 to 23 July 2020), CINAHL (1982 to 23 July 2020), and LILACS (1980 to 23 July 2020). We also searched clinical trials databases, and the reference lists of retrieved articles, for randomised controlled trials (RCTs) and quasi-RCTS.

Selection criteria

We planned to include RCTs or quasi-RCTs (including cluster-randomised trials) that included term neonates initiated on bed sharing within 24 hours of birth (and continuing to bed share with the mother in the first four weeks of life, followed by a variable time period thereafter), and compared them to a 'no bed sharing' group.

Data collection and analysis

We used standard methodological procedures as recommended by Cochrane. We planned to use the GRADE approach to assess the certainty of evidence.

Main results

Our search strategy yielded 6231 records. After removal of duplicate records, we screened 2745 records by title and abstract. We excluded 2739 records that did not match our inclusion criteria. We obtained six full-text studies for assessment. These six studies did not meet the eligibility criteria and were excluded.

Authors' conclusions

We did not find any studies that met our inclusion criteria. There is a need for RCTs on bed sharing in healthy term neonates that directly assess efficacy (i.e. studies in a controlled setting, like hospital) or effectiveness (i.e. studies conducted in community or home settings) and safety. Future studies should assess outcomes such as breastfeeding status and risk of SIDS. They should also include neonates from high-income countries and low- and middle-income countries, especially those countries where bed sharing is more prevalent because of cultural practices (e.g. Asian countries).

PLAIN LANGUAGE SUMMARY

Is bed sharing an effective and safe method in the care of healthy term neonates?

Review question: we wanted to find out if bed sharing is associated with an increase in the duration and frequency of breastfeeding in babies who are born after 37 weeks of pregnancy (also known as term neonates) and are healthy at birth.

Background: 'bed sharing' is a type of sleeping practice in which the sleeping surface (e.g. bed, couch or armchair, or some other sleeping surface) is shared between the infant and another person. The possible reasons that families choose to bed share include: ease in breastfeeding; temperature regulation (avoidance of hypothermia); spending quality time with the infant; helping the infant sleep and being able to easily comfort the infant in case they become agitated; being able to attend to them quickly in case of any mishap; providing close care during an illness; and promotion of bonding. However, for many families worldwide, the practice of bed sharing is not a choice. In high-income countries, bed sharing is regarded as a controversial practice, and has drawn special attention with regard to its role in sudden infant death syndrome (SIDS). But in low- and middle-income countries, bed sharing has been the standard practice for many groups who could not afford different sleeping surfaces. In these less rich societies, bed sharing is believed to contribute to: longer durations of breastfeeding; increased time and duration of infant arousals; decreased time and duration spent in deep sleep; and increases in the mother's awareness of the infant's condition.

Study characteristics: we searched for studies up to 23 July 2020. The aim of the review was to include randomised controlled studies (RCTS). RCTs are clinical studies where participants are randomly put into one of two or more treatment groups. We planned to include RCTs of term neonates who started to bed share with the mother within 24 hours of birth (and continued to bed share with the mother in the first four weeks of life, followed by a variable time period after). We aimed to compare a 'bed sharing' group to a 'no bed sharing' group. During bed sharing, there is close contact between the mother and infant. The possible physiological benefits include better temperature regulation with less risk of hypothermia, and a longer duration of successful breastfeeding. The harms include sudden infant death as a result of the mother lying on the infant, and use of pillows and comforters.

Key results: we assessed six studies for inclusion in this review. We excluded them for the following reasons: secondary data analysis of primary RCTs (two studies); did not study bed sharing (two studies); not a RCT (one study); and outcomes of interest to the review not studied (one study).

Certainty of evidence: we were unable to judge the certainty of the evidence on bed sharing in healthy term neonates. This is because there were no eligible included studies. There is a need for RCTs on bed sharing in healthy term neonates that directly assess efficacy (i.e. studies in a controlled setting, like hospital) or effectiveness (i.e. studies conducted in community or home settings) and safety. They should also include infants from high-income countries and low- and middle-income countries, especially those countries where bed sharing is more common because of cultural practices (e.g. Asian countries).

BACKGROUND

Description of the condition

Sleeping arrangements for healthy newborn infants vary greatly worldwide.

Description of the intervention

'Bed sharing' is a type of sleeping practice in which the sleeping surface (e.g. bed, couch or armchair, or some other sleeping surface) is shared between the infant and another person (either of the parents or sibling(s)), whereas 'room sharing' is a type of sleeping practice in which the sleeping surface is not shared, but rather the infant sleeps close to the parents in the same room (Joyner 2010). For many families worldwide, the practice of bed sharing is not a choice (Mileva-Seitz 2017; Richardson 2013). The possible reasons that families choose to bed share include: ease in breastfeeding; temperature regulation (avoidance of hypothermia); spending quality time with the infant; helping the infant to sleep and being better able to console or comfort them if they become agitated; quick attention in case of any mishap; providing care during an illness; promotion of bonding; and pregnancy-spacing (Baddock 2006; Mileva-Seitz 2017; Nelson 2001).

In high-income countries, the subject of bed sharing has surfaced repeatedly as a controversial practice, and has drawn special attention with regard to its role in sudden infant death syndrome (SIDS). However, these countries also have high rates of risk behaviours (smoking and alcohol use) that increase the risk of SIDS (Carpenter 2013; Lee 2014). In low- and middle-income countries (LMIC), bed sharing has been the standard practice for many groups who could not afford different sleeping surfaces (Nelson 2001). In these less affluent societies, bed sharing is believed to contribute to longer durations of breastfeeding, increased time and duration of infant arousals, decreased duration of deep sleep, and increase in the mother's awareness of the infant's condition (Nelson 2001). All these effects indirectly contribute, some argue, to a lower risk of SIDS in these societies (Ball 2012; Nelson 2001; Richardson 2013). Those who oppose bed sharing mainly focus on the hazardous aspects of the practice, such as use of an improper sleeping surface (e.g. an adult bed that is not suitable for infant sleep) and the possible risks of infant entrapment, overlaying, and suffocation due to close proximity to soft bedding such as pillows and comforters (Drago 1999; Mitchell 2007).

How the intervention might work

During bed sharing there is a close contact between the mother and infant. The possible physiological benefits include better cardio-pulmonary stability, fewer crying episodes, better temperature regulation with less risk of hypothermia, and a longer duration of successful breastfeeding (Baddock 2019; Mileva-Seitz 2017; Santos 2009). On the other hand, the most important harmful effect of bed sharing is that it increases the risk of SIDS as the parent(s) may lie on the infant(s) sharing the bed with them (AAP 2016; Mileva-Seitz 2017). Results of observational studies suggest various risk factors (e.g. alcohol consumption, drug ingestion, obesity, and fatigue) make parents prone to lie on an infant during bed sharing, irrespective of the type of sleeping surface mentioned above (Blair 2014; Carpenter 2013; Mileva-Seitz 2017). Kangaroo mother care (KMC) is a type of intervention recommended for care of preterm, low birth weight infants, in which the infant spends most of the time on the mother's chest in an upright position. Though the infant spends most of the time being in close contact with the mother, KMC is not same as bed sharing (Charpak 1997).

Observational studies have included mother–infant dyads to provide better insight into the dynamics of breastfeeding and bed sharing. The results have shown positive effects of bed sharing on the frequency and duration of breastfeeding (Baddock 2006; McKenna 2007; Mileva-Seitz 2017). In addition, during bed sharing, mothers have been shown to check their infants more frequently compared to crib-sleeping or room-sharing infants. During bed sharing, however, increased maternal contact/touching of the infant, breastfeeding, and other responses may not always occur in the same manner if the mother is fatigued or under the influence of alcohol or drugs. Researchers have tried to explore the link between breastfeeding and SIDS, to understand whether breastfeeding actually decreases the risk of SIDS or whether it is just a behavioural reflection of the society that chooses to breastfeed. Published data from one of the largest studies conducted in Germany on SIDS found that breastfeeding reduced the risk of SIDS by approximately 50% (Thompson 2017). In a meta-analysis of studies from high-income countries, breastfeeding was found to be strongly associated with a low risk of SIDS (Hauck 2011). However, none of the included studies in the meta-analysis studied the impact of bed sharing on the rate of breastfeeding and SIDS (Hauck 2011; Thompson 2017). In a systematic review conducted by the current author team (Das 2014), we included 21 observational studies, and found the evidence to be of low certainty regarding association of bed sharing with higher rates of breastfeeding (at 28 days of life) as well as SIDS (at all ages).

Although bed sharing can be practised at any time period during infancy, the most vital time is during the initial postnatal days or the neonatal period, during which continuous contact between the mother and the baby allows for spontaneous breastfeeding. This results in both initiation and continuation of successful breastfeeding practice.

Why it is important to do this review

From the evolutionary point of view, humans follow mammalian pattern after birth of the baby, which means mothers sleep in close proximity to their babies (McKenna 2005; Mileva-Seitz 2017; Thoman 2006). Even today, this practice persists in many cultures around the world (Mileva-Seitz 2017; Nelson 2001). However, in the majority of the high-income countries and in some cultures, the common practice is to separate the newborn from its mother immediately after birth, despite mounting evidence that this may have harmful effects (decreased breast milk production, lactation failure or decreased duration of breastfeeding, and decreased maternal bonding) (Ball 2003; McKenna 2005; Mileva-Seitz 2017). There is also a paucity of evidence on the effect of bed sharing on key outcomes during the neonatal period (neonatal mortality, rates of neonatal sepsis, rates of hypothermia) and thereafter (duration of breastfeeding, all-cause mortality, neuro-developmental outcome). Published studies from some LMIC have shown a lower rate of SIDS, in spite of a higher bed-sharing rate (Bubnaitiene 2005; Tan 2011). Whether the lower prevalence is due to the protective effect of breastfeeding or due to other socio-cultural factors is a matter of debate (Crane 2016; McKenna 2005; Mileva-Seitz 2017). The American Academy of Pediatrics (AAP) task force on SIDS recommends avoidance of bed sharing for infants less than three months of age irrespective of parental smoking

status (AAP 2012). Because breastfeeding is associated with a reduced risk of SIDS, the task force at the same time advises mothers to exclusively breastfeed their babies for six months, in accordance with the existing AAP recommendations (AAP 2012; AAP 2016). Parents might find it unfeasible or unacceptable to breastfeed exclusively without bed sharing. Therefore, the aim of the present Cochrane Review is to assess the efficacy and safety of bed sharing compared to no bed sharing for healthy, term neonates.

OBJECTIVES

To assess the effect of bed sharing, started during the neonatal period, on breast-feeding status (exclusive and total duration of breastfeeding), incidence of sudden infant death syndrome (SIDS), rates of hypothermia, neonatal and infant mortality, and long-term neurodevelopmental outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

We planned to include randomised controlled trials (RCTs) or quasi-RCTs, including cluster-randomised trials. We planned to consider studies conducted in the community as well as in hospital settings.

Types of participants

Inclusion criteria

1. We planned to include neonates of 37 weeks' or more gestational age, born to mothers were randomised to either bed sharing or no bed sharing. Bed sharing had to be initiated within 24 hours of birth and continued in the first four weeks of life, followed by a variable time period thereafter.

Exclusion criteria

1. Neonates who bed shared with any person (including father or sibling(s)) other than their mother
2. Neonates with major congenital malformations

Types of interventions

The eligible interventions were: keeping the baby on the same bed as the mother (bed sharing) versus keeping the baby on a separate bed or a cot immediately next to the mother's bed (no bed sharing). We planned to exclude the studies on ‘rooming-in’ (a type of sleeping practice in which the sleeping surface is not shared, but rather the infant sleeps close to the parents in the same room (Joyner 2010)), if they did not report 'bed share' separately. We considered 'bed sharing' for any duration.

Types of outcome measures

Primary outcomes

1. Duration of exclusive breastfeeding

Secondary outcomes

1. Duration of any breastfeeding
2. Proportion of infants exclusively breast fed at six weeks of age
3. Proportion of infants exclusively breast fed at six months of age
4. Incidence of SIDS during first and second year of life
5. Incidence of deaths from parental overlying during first and second year of life
6. Incidence of hypothermia during neonatal period
7. Incidence of neonatal sepsis
8. All-cause mortality during the neonatal period
9. All-cause mortality during first year of life
10. Neurodevelopment at 18 to 24 months of age
11. Gain in anthropometric parameters (e.g. gain in weight, height and head circumference) at 12 to 24 months of age
12. Maternal outcomes: adverse events (postpartum depression, puerperal sepsis, postpartum haemorrhage), sleep duration, rate of breast engorgement, behaviours (level of confidence in parenting, satisfaction) and inter-pregnancy interval)

We defined 'exclusive breastfeeding' as intake of only breast milk by an infant, with or without additional medications or multivitamins; and 'any breastfeeding' as an infant receiving breast milk of any amount.

We defined 'SIDS' as the sudden unexplained death of an apparently healthy infant (aged less than one year), as adopted by AAP (Moon 2007).

We defined 'hypothermia' as the infant having a skin temperature of less than 36.5°C.

We defined 'neonatal mortality' as any infant dying during the neonatal period (within the first 28 days of life); and 'neonatal sepsis' as the occurrence of signs and symptoms of systemic infection in the neonatal period, in the presence or absence of culture positivity.

We defined 'neurodevelopment' as assessed by Bayley or Griffith scales (Bayley 2006; Griffiths 1996), and defined any deviation/disability as either developmental delay (assessed as more than two standard deviations (2 SDs) below the mean) or intellectual impairment (assessed as developmental quotient (DQ) or intelligence quotient (IQ) more than 2 SDs below mean).

For interpretation of 'anthropometric parameters' we used the World Health Organization (WHO) growth charts (WHO 2006) for weight-for-height, height-for-age, weight-for-age, and head circumference, separately for boys and girls. For 'maternal adverse events' we used the standard criteria provided by the WHO.

We defined maternal behaviours as follows: level of confidence in parenting according to the Parenting Sense of Competence Scale (PSOC), or a similar scale, and satisfaction according to the 'Mason or modified Mason survey', or similar scale (Gilmore 2009; Johnson 2002).

Search methods for identification of studies

We used the criteria and standard methods of Cochrane and Cochrane Neonatal (see the Cochrane Neonatal group search strategy for specialised register). We searched for errata or retractions from included studies published in full text on PubMed (www.ncbi.nlm.nih.gov/pubmed), on 23 July 2020. We did not limit the search to any particular geographical region, language or timing of publication.

Electronic searches

We conducted a comprehensive search including: the Cochrane Central Register of Controlled Trials (CENTRAL 2020, Issue 7) in the Cochrane Library; MEDLINE via PubMed (1966 to 23 July 2020); CINAHL (1982 to 23 July 2020), and LILACS (1980 to 23 July 2020) using the following search terms: ((bedshar* OR bed-shar* OR "bedding in" OR co-bedding OR cobedding OR "rooming in" OR co-sleep* OR cosleep* OR "cot nursing" OR "cot nursed" OR (shar* AND (bed OR cot OR cots)))), plus database-specific limiters for RCTs and neonates. See Appendix 1 for the full search strategies for each database. We did not apply language restrictions.

Searching other resources

We scrutinised the bibliographies of included studies in order to identify further relevant clinical trials.

Data collection and analysis

Selection of studies

Two review authors (RRD, MJS) independently reviewed all the trials retrieved using the search strategy described above. We did this in the following three stages:

1. we checked study titles for eligibility;
2. we checked the abstracts of studies; and
3. we scrutinised the full text prior to study selection.

We resolved disagreements at any of these stages through discussion with the third review author (RA). We described the excluded studies in Characteristics of excluded studies tables, along with the reasons for their exclusion. We contacted study authors where we required clarification or additional information.

Data extraction and management

We designed and pilot tested the data extraction form prior to planned extraction of data. For eligible studies, Two review authors (MJS, RRD) planned to independently extract the data using the agreed form. We planned to extract the following information from each study: author; year; location (country); setting (hospital or community); method of recruitment; inclusion criteria; unit of analysis; allocation ratio; risk of bias; participants (age, sex, sample size, bed sharing, no bed sharing, room sharing); intervention (duration, frequency, and cointerventions, if any); outcomes (outcome definition, valid unit of measurement, time points of collection and reporting); loss to follow-up; and miscellaneous (key conclusions, references to other relevant studies, and additional data required).

We planned to resolve any discrepancy through discussion with the third review author (RA). When information regarding any of the above was unclear, we planned to attempt to contact authors of the original reports for further details. For dichotomous data (such as breastfeeding rate), we planned to extract the number of participants experiencing the condition and the total number of participants in each treatment group. For continuous data (duration of breastfeeding), we planned to use the arithmetic mean and SD for each treatment group together with the number of participants in each group. If a standard error (SE) was reported, we planned to convert it to an SD. If a 95% confidence interval (CI) was provided instead of a mean and SD for continuous data, we planned to extract the mean and SD from the 95% CI, as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019).

Assessment of risk of bias in included studies

Two review authors (RRD, MJS) planned to independently assess the risk of bias (low, high, or unclear) of all included trials, using the Cochrane 'Risk of bias' tool (Higgins 2011), for the following domains:

1. sequence generation (selection bias);
2. allocation concealment (selection bias);
3. blinding of participants and personnel (performance bias);
4. blinding of outcome assessment (detection bias);
5. incomplete outcome data (attrition bias);
6. selective reporting (reporting bias); and
7. any other bias.

We planned to resolve disagreements at any of these stages through discussion with the third review author (RA). See Appendix 2 for a more detailed description of risk of bias for each domain.

Measures of treatment effect

We planned to enter the outcome data into Review Manager 5 (Review Manager 2020) for statistical analysis. We planned to use the standard methods of Cochrane Neonatal to synthesise data.

Dichotomous data

Outcomes with dichotomous data included breastfeeding rate. For dichotomous data, we planned to calculate risk ratio (RR) and risk difference (RD), with a 95% CI, to estimate the treatment effect.

Continuous data

Outcomes with continuous data included duration of any and exclusive breastfeeding. For continuous data, we planned to calculate mean difference (MD), with a 95% CI, to estimate the treatment effect. When median, range, and sample size were reported, we planned to estimate the mean and SD using established methods (Hozo 2005).

Unit of analysis issues

Due to global implementation of the WHO and UNICEF (United Nations Children's Fund) Baby-friendly Hospital Initiative (Pérez-Escamilla 2016; WHO 2009), we expected to find cluster-randomised trials where hospitals or postnatal wards were considered the natural unit of randomisation for logistic convenience in the implementation of the intervention. Should they have been identified, we would have included them in the analyses along with individually-randomised trials. We would have adjusted their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions*, using an estimate of the intra-cluster correlation co-efficient (ICC) derived from the trial (if possible), or from a similar trial or from a study of a similar population (Higgins 2019). In case use of ICCs from other sources, we would have reported them and conducted sensitivity analyses to investigate the effect of variation in the ICC.

In case of identification of both cluster-randomised trials and individually-randomised trials, we would have synthesised the relevant information. We would have considered it reasonable to combine the results from both in cases where there was little

heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit was considered to be unlikely. We would have acknowledged heterogeneity in the randomisation unit and performed a subgroup analysis to investigate the effects of the randomisation unit. However, we did not find any cluster-randomised trial for inclusion in the review.

Dealing with missing data

We planned to analyse the data on an intention-to-treat (ITT) basis, where we would analyse participants based on the intervention they were randomised to.

Assessment of heterogeneity

We defined heterogeneity as a significant test of heterogeneity (P value of less than 0.1) and differences in the treatment effects across studies. We planned to apply tests for between-study heterogeneity (including the I^2 statistic). When encountered, we planned to examine possible sources of heterogeneity (as mentioned below). We planned to use the following criteria for describing the heterogeneity based on the I^2 values:

1. less than 25%: no heterogeneity;
2. 25% to 49%: low heterogeneity;
3. 50% to 74%: moderate heterogeneity; and
4. 75% or over: high heterogeneity.

Assessment of reporting biases

We planned to investigate publication bias using funnel plots if at least 10 clinical trials were included in the meta-analysis (Egger 1997; Harbord 2006).

Data synthesis

We planned to use a fixed-effect meta-analysis for combining data where it was reasonable to assume that studies had estimated the same underlying treatment effect (i.e. where studies examined the same intervention, and the studies' populations and methods were judged to be sufficiently similar). If the average treatment effect was not clinically meaningful, we would not have combined the studies. Had moderate or high heterogeneity been present, we planned to use random-effects meta-analyses. We planned to calculate overall effect using inverse variance methods. We planned to present results with the effect size (RR or MD), 95% CI, and Tau^2 and I^2 estimates.

Subgroup analysis and investigation of heterogeneity

If we identify studies eligible for inclusion in future updates of this Cochrane Review, we will attempt to conduct subgroup analyses and investigate sources and causes of heterogeneity. Possible subgroup analyses would involve the following:

1. time of bed sharing (regular versus night-time only);
2. duration of bed sharing (neonatal period only versus first year of life or first and second years of life);
3. infant sleeping allocation (bed sharing versus sofa sharing (or similar surface, including traditional cot);
4. parental addiction (alcohol/drug use versus no use; smoking versus no smoking);
5. birth weight of infants (low birth weight versus normal birth weight);
6. study setting (high-income versus LMIC settings); and
7. kangaroo mother care (KMC) (no KMC versus KMC received during initial hospital stay and/or education on practising KMC at home).

Sensitivity analysis

If we identify studies eligible for inclusion in future updates of this review, we will carry out sensitivity analysis to explore the effect of study quality on results. This will involve excluding studies at risk of selection, performance, detection, attrition, or reporting bias, to assess for any substantive difference to the overall result. We will investigate the effects of the randomisation unit (individual versus cluster) on the outcomes. We will explore the effects of fixed-effect or random-effects analyses for outcomes with statistical heterogeneity, and the effects of any assumptions made, such as the value of the ICC used for cluster-randomised trials. We will use primary outcomes in sensitivity analyses.

Summary of findings and assessment of the certainty of the evidence

We planned to used the GRADE approach, as outlined in Schünemann 2013, to assess the certainty of evidence of the following (clinically relevant) outcomes: breastfeeding status at six months of age; incidence of SIDS during first and second year of life; incidence of hypothermia during the neonatal period; all-cause mortality during the neonatal period or within the first year of life; and neurodevelopment at 18 to 24 months of age.

We planned that two review authors (RRD, MJS) would independently assess the certainty of the evidence for each of the outcomes above. We planned to consider evidence from RCTs as high-certainty, but downgrade the evidence by one level for serious (or two levels for very serious) limitations based upon the following: design (risk of bias), consistency across studies, directness of the evidence, precision of estimates, and presence of publication bias. We planned to use GRADEpro GDT to create 'Summary of findings' tables to report the certainty of the evidence.

The GRADE approach results in an assessment of the certainty of a body of evidence as one of four grades:

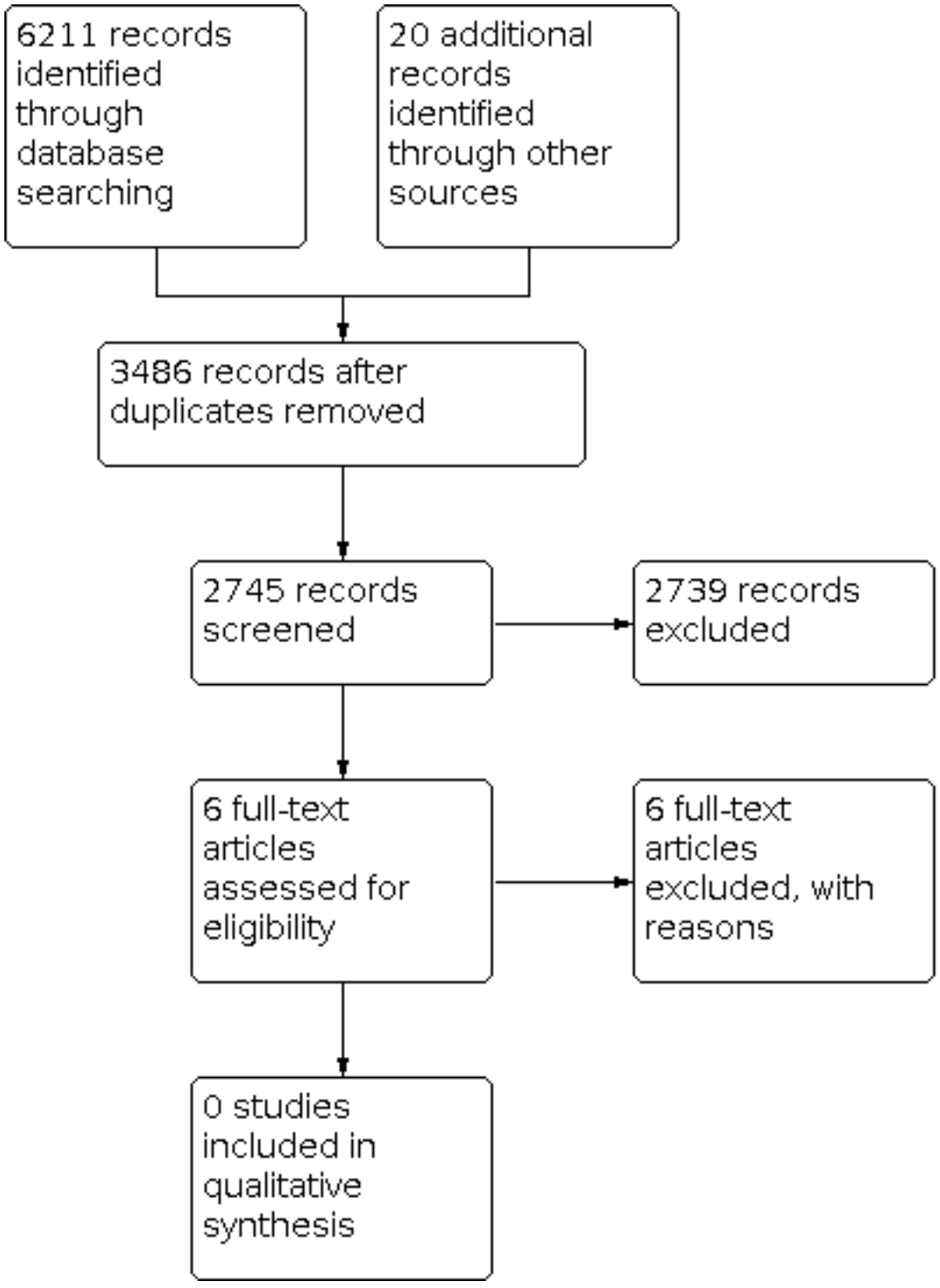
1. high certainty: further research is very unlikely to change our confidence in the estimate of effect;
2. moderate certainty: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate;
3. low certainty: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate; or
4. very low certainty: we are very uncertain about the estimate.

RESULTS

Description of studies

We identified no trials that matched our inclusion criteria. For results of the search, please see the study flow diagram (Figure 1).

Figure 1. Study flow diagram.



Results of the search

Our searches in July 2020 identified 6231 records. After removal of 3486 duplicate records, we screened 2745 records by title and abstract. We excluded 2739 records that did not meet our inclusion criteria. We obtained six full-text studies for assessment. We excluded all six studies as they were not eligible for inclusion in the present review (Baddock 2004; Ball 2006; Ball 2011; Ball 2016; Fischer 1991; Moon 2017). See Figure 1.

Included studies

We identified no trials that matched our inclusion criteria.

Excluded studies

We excluded six studies for the following reasons: secondary data analysis of primary RCTs (Ball 2016; Moon 2017), did not study bed sharing (Ball 2006; Ball 2011), not a RCT (Baddock 2004), and outcomes of interest to the review not studied (Fischer 1991). See: Characteristics of excluded studies.

There are some important observations from two excluded RCTs (Ball 2016; Moon 2017) that merit mention here. In one RCT, which was primarily designed to study the effect of avoidance of bed sharing (the intervention group received enhanced messaging and the control group received standard messaging) on rates and duration of breastfeeding in African-American mothers, the authors found that breastfeeding duration was one to two weeks longer in the bed-sharing group (Moon 2017). While this is statistically significant, the clinical significance is unclear. According to the authors' observation, breast-feeding rate and duration might not be decided by the type of sleeping behaviour/surface alone, and other factors also play a role (e.g. lack of support, discomfort during breastfeeding, and incomplete information about breast-feeding benefits). The other RCT, which was primarily designed to compare two separate sleeping surfaces in UK mothers, followed up the cohorts to study the relationship between bed sharing and breastfeeding (Ball 2016). The authors concluded that consistent (i.e. not intermittent/rare) bed sharing was associated with a longer duration of breastfeeding (12 weeks more for any breastfeeding, and seven weeks more for exclusive breastfeeding), and the consistent bed sharing was due to a strong motivation to breastfeed. Both trials seem to suggest that a desire to breastfeed decides whether a mother is going to bed share or not. Singular messages to avoid bed sharing for SIDS prevention may not help (Aslam 2009; Moon 2010; Crane 2016).

Risk of bias in included studies

No study met the eligibility criteria of this review.

Allocation

No study met the eligibility criteria of this review.

Blinding

No study met the eligibility criteria of this review.

Incomplete outcome data

No study met the eligibility criteria of this review.

Selective reporting

No study met the eligibility criteria of this review.

Other potential sources of bias

No study met the eligibility criteria of this review.

Effects of interventions

No study met the eligibility criteria of this review.

DISCUSSION

Summary of main results

We did not identify any studies that met our inclusion criteria. We have discussed some important observations from two excluded RCTs (Ball 2016; Moon 2017) above.

Overall completeness and applicability of evidence

We could not find any studies eligible for inclusion in the present review. We excluded six studies for the following reasons: secondary data analysis of primary RCTs (Ball 2016; Moon 2017), did not study bed sharing (Ball 2006; Ball 2011), not a RCT (Baddock 2004), and outcomes of interest to the review not studied (Fischer 1991).

Quality of the evidence

We identified no eligible studies for inclusion.

Potential biases in the review process

We used the standard methods of Cochrane Neonatal to conduct this systematic review. There is a potential to miss studies that may have measured bed sharing as part of a broader intervention (rooming in) or as a secondary outcome, under the broader scope of sleeping practices during infancy. We aimed to avoid this scenario by conducting a wide search and carefully assessing the relevance of each paper identified. Given the current rarity of SIDS, feasibility of prospective studies (including RCTs) to measure SIDS outcomes might not possible. Instead, the evidence has to be generated from detailed retrospective studies that look at bed sharing, breastfeeding, and the hazardous circumstances that put babies at risk. However, we did not include any non-randomised (observational) study in the present review.

Agreements and disagreements with other studies or reviews

We published an earlier systematic review on this topic, which included twenty-one observational studies (Das 2014). We concluded that there is low-quality evidence that bed sharing is associated with higher breastfeeding rates at four weeks of age and an increased risk of SIDS. None of the studies reported both the primary outcomes (SIDS and breastfeeding), and we were not able to assess the “net” effect of bed sharing. We urged for more good-quality studies that look at bed sharing, breastfeeding, and hazardous circumstances that put babies at risk. The present Cochrane Review was designed to include RCTs; unfortunately, we identified no such studies for inclusion.

A recent literature review provides extensive discussion of the 'pros' and 'cons' of bed sharing (Mileva-Seitz 2017). The authors explicitly mentioned that the relationship between bed sharing and breastfeeding is a bidirectional model, meaning that bed sharing is both a consequence and facilitator of continued breastfeeding. Regarding the recommendations against bed sharing in order to reduce SIDS, the authors described these as unclear, inconsistent, or contradictory. Though there is no government policy, healthcare professionals often rely on the AAP recommendation of 'no bed-sharing policy' as a safer practice for SIDS reduction. However, recent study findings are in disagreement within the AAP advice and recommendations (AAP 2016; Paul 2017). The Centers for Disease Control and Prevention (CDC) supports the AAP recommendation

about bed sharing (CDC 2020). We could not find any recent WHO recommendation about bed sharing.

There are qualitative studies on parental perception and understanding of SIDS-reduction guidance among various communities (Aslam 2009; Crane 2016; Moon 2010). These studies conclude that the recommendation and guidance regarding SIDS reduction should take into account the diverse socio-cultural factors and parental perception even within a single country.

AUTHORS' CONCLUSIONS

Implications for practice

We are uncertain whether bed sharing is associated with either improved breast feeding rate (exclusivity and duration) or increased risk of SIDS or both given no available trial data from RCTs.

Implications for research

There is a need for RCTs on bed sharing in healthy term neonates that directly assess efficacy (i.e. studies in a controlled setting, like hospital) or effectiveness (i.e. studies conducted in community or home settings) and safety. Such studies should include neonates from high-income countries and low- and middle-income countries, especially those countries where bed sharing is more prevalent because of cultural practices (e.g. Asian countries). Given the rarity of SIDS, it may not be feasible for prospective studies (including RCTs) to measure SIDS outcomes. Instead, the evidence has to be generated from detailed retrospective studies that look at bed sharing, breastfeeding, and the hazardous circumstances that put babies at risk. Diversities in socio-cultural practices and parental perceptions should also be a part of these studies.

ACKNOWLEDGEMENTS

The World Health Organization (WHO) provided funding for conducting systematic reviews so as to formulate certain guidelines and to make policy on issues related to the health of newborns. As a part of this initiative, a systematic review including only observational studies was conducted on the safety and efficacy of bed sharing during the neonatal period (Das 2014).

The Methods section of this review is based on a standard template used by Cochrane Neonatal.

We would like to thank Cochrane Neonatal: Colleen Ovelman (Managing Editor), Jane Cracknell (Assistant Managing Editor), Roger Soll (Co-coordinating editor), and Bill McGuire (Co-coordinating Editor), who provided editorial and administrative support.

Jennifer Spano designed the literature searches, and Carol Friesen (Cochrane Neonatal Information Specialist) peer-reviewed the searches. William McGuire (Cochrane Neonatal Editor) and Danielle Ehret (peer reviewer) have peer-reviewed and offered feedback on this review.

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CHARACTERISTICS OF STUDIES

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Baddock 2004	Not a RCT
Ball 2006	Did not study bed sharing
Ball 2011	Did not study bed sharing
Ball 2016	Secondary/follow-up data analysis of primary RCT
Fischer 1991	The timing of initiation and duration of bed sharing was not clearly defined, and outcomes of interest to the review were not studied.

Study	Reason for exclusion
Moon 2017	Secondary/follow-up data analysis of primary RCT

RCT: randomised controlled trial

APPENDICES

Appendix 1. Cochrane Neonatal standard search strategy

Medline (Ovid)

1. Child, Human/
2. exp Infant/
3. exp Neonate/
4. exp Newborn/
5. exp Neonate/
6. (neonat* or newborn or infant* or child*).tw.
7. or/1-6
8. exp Bedshare/
9. bed share*.tw,nm.
10. (bed* shar* adj1 (cot* or crib* or craddle*)).tw
11. bedding in*.tw,nm.
12. rooming in*.tw,nm.
13. co-sleeping*.tw,nm.
14. (sleep* or shar* or cot* or crib* or bed*).tw,nm.
15. or/8-14
16. 7 and 15

PubMed

((infant, newborn[MeSH] OR newborn OR neonate OR neonatal OR premature OR low birth weight OR VLBW OR LBW or infan* or neonat*) AND (randomized controlled trial [pt] OR controlled clinical trial [pt] OR randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) NOT (animals [mh] NOT humans [mh]))

Embase

(infant, newborn or newborn or neonate or neonatal or premature or very low birth weight or low birth weight or VLBW or LBW or Newborn or infan* or neonat*) AND (human not animal) AND (randomized controlled trial or controlled clinical trial or randomized or placebo or clinical trials as topic or randomly or trial or clinical trial)

CINAHL

(infant, newborn OR newborn OR neonate OR neonatal OR premature OR low birth weight OR VLBW OR LBW or Newborn or infan* or neonat*) AND (randomized controlled trial OR controlled clinical trial OR randomized OR placebo OR clinical trials as topic OR randomly OR trial OR PT clinical trial)

Cochrane Library

(infant or newborn or neonate or neonatal or premature or preterm or very low birth weight or low birth weight or VLBW or LBW)

Appendix 2. 'Risk of bias' tool

We planned to use the standard methods of Cochrane and Cochrane Neonatal to assess the methodological certainty of the trials. For each trial, we planned to seek information regarding the method of randomisation, blinding, and reporting of all outcomes of all the infants enrolled in the trial. We planned to asses each criterion as being at either low, high, or unclear risk of bias. Two review authors separately planned to assess each study and resolve any disagreements through discussion. We planned to add this information to the 'Characteristics of included studies' table. We planned to evaluate the following issues and enter the findings into the 'Risk of bias' table.

1. Sequence generation (checking for possible selection bias). Was the allocation sequence adequately generated?

For each included study, we planned to categorise the method used to generate the allocation sequence as being at:

1. low risk of bias (any truly random process, e.g. random number table; computer random number generator);
2. high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
3. unclear risk of bias.

2. Allocation concealment (checking for possible selection bias). Was allocation adequately concealed?

For each included study, we planned to categorise the method used to conceal the allocation sequence as being at:

1. low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
2. high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth); or
3. unclear risk of bias.

3. Blinding of participants and personnel (checking for possible performance bias). Was knowledge of the allocated intervention adequately prevented during the study?

For each included study, we planned to categorise the methods used to blind study participants and personnel from knowledge of which intervention a participant received. Blinding was assessed separately for different outcomes or class of outcomes. We planned to categorise the methods as being at:

1. low, high, or unclear risk of bias for participants; and
2. low, high, or unclear risk of bias for personnel.

4. Blinding of outcome assessment (checking for possible detection bias). Was knowledge of the allocated intervention adequately prevented at the time of outcome assessment?

For each included study, we planned to categorise the methods used to blind outcome assessment. Blinding was to be assessed separately for different outcomes or class of outcomes. We planned to categorise the methods as being at:

1. low risk of bias for outcome assessors;
2. high risk of bias for outcome assessors; or
3. unclear risk of bias for outcome assessors.

5. Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations). Were incomplete outcome data adequately addressed?

For each included study and for each outcome, we planned to describe the completeness of data including attrition and exclusions from the analysis. We planned to note whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion, where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported or supplied by the trial authors, we planned to re-include missing data in the analyses. We planned to categorise the methods as being at:

1. low risk of bias (less than 20% missing data);
2. high risk of bias (20% missing data or more); or
3. unclear risk of bias.

6. Selective reporting bias. Are reports of the study free of suggestion of selective outcome reporting?

For each included study, we planned to describe how we investigated the possibility of selective outcome reporting bias and what we found. For studies in which study protocols were published in advance, we planned to compare prespecified outcomes versus outcomes eventually reported in the published results. If the study protocol was not published in advance, we planned to contact study authors to gain access to the study protocol. We planned to assess the methods as being at:

1. low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
2. high risk of bias (where not all the study's prespecified outcomes have been reported; one or more reported primary outcomes were not prespecified outcomes of interest and are reported incompletely and so cannot be used; or where the study fails to include results of a key outcome that would have been expected to have been reported); or
3. unclear risk of bias.

7. Other sources of bias. Was the study apparently free of other problems that could put it at a high risk of bias?

For each included study, we planned to describe any important concerns we had about other possible sources of bias (for example, whether there was a potential source of bias related to the specific study design or whether the trial was stopped early due to some data-dependent process). We planned to assess whether each study was free of other problems that could put it at low, high or unclear risk of bias. If needed, we planned to explore the impact of the level of bias through undertaking sensitivity analyses.

HISTORY

Protocol first published: Issue 11, 2017
Review first published: Issue 4, 2021

CONTRIBUTIONS OF AUTHORS

Conceiving the review: Dr Ramesh Agarwal (RA), Dr Mari Jeeva Sankar (MJS)
Co-ordinating the review: RA, Dr Rashmi Ranjan Das (RRD)
Undertaking manual searches: RRD, MJS
Screening search results: RRD, RA
Organising retrieval of papers: RRD, RA
Screening retrieved papers against inclusion criteria: RRD, RA
Appraising quality of papers: MJS, RRD.
Abstracting data from papers: RRD, MJS
Writing to authors of papers for additional information: RRD
Providing additional data about papers: RRD, MJS
Obtaining and screening data on unpublished studies: RRD, RA
Managing data for the review: RRD, MJS
Interpreting data: MJS, RA, RRD
Writing the review: RRD, MJS, RA
Performing previous work that served as the foundation of the present study: RA, MJS
Serving as guarantor for the review: RA
Taking responsibility for reading and checking the review before submission: RA, MJS, RRD

DECLARATIONS OF INTEREST

RRD has no interest to declare.
MJS: the systematic review on bed sharing was one of the many reviews done by the All India Institute of Medical Sciences (AIIMS) for the WHO guidelines on 'Postnatal care of mothers and newborns'. AIIMS received a research grant from WHO, Geneva for doing these reviews.
RA has no interest to declare.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We made the following changes to the published protocol (Das 2017).

1. We kept duration of exclusive breastfeeding as one single primary outcome measure of breastfeeding status, and moved others to secondary outcomes.
2. We provided more detail on the definitions of the outcome measures.
3. We updated the descriptions of the 'Risk of bias' assessment.
4. We refer to certainty of evidence, rather than quality of evidence.
5. We did not search Web of Science as we thought it would not yield any additional citation.

6. We did not search ClinicalTrials.gov or from The World Health Organization's International Clinical Trials Registry Platform (ICTRP); as of July 2019, Cochrane Neonatal no longer searches for randomised controlled trials and controlled clinical trials on ClinicalTrials.gov or ICTRP, as records from both platforms are added to CENTRAL on a monthly basis.
7. Inter-pregnancy interval was added as a secondary outcome.
8. We added a subgroup analysis for kangaroo mother care (KMC).

INDEX TERMS

Medical Subject Headings (MeSH)

*Beds; Infant Care [*methods]; *Term Birth

MeSH check words

Humans; Infant; Infant, Newborn