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Early skin-to-skin contact for mothers and their healthy newborn infants

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Abstract

Background—Mother-infant separation postbirth is common in Western culture. Early skin-to-skin contact (SSC) begins ideally at birth and involves placing the naked baby, head covered with a dry cap and a warm blanket across the back, prone on the mother's bare chest. According to mammalian neuroscience, the intimate contact inherent in this place (habitat) evokes neurobehaviors ensuring fulfillment of basic biological needs. This time may represent a psychophysiologically 'sensitive period' for programming future physiology and behavior.

Objectives—To assess the effects of early SSC on breastfeeding, physiological adaptation, and behavior in healthy mother-newborn dyads.

Search methods—We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 November 2011), made personal contact with trialists, and consulted the bibliography on kangaroo mother care (KMC) maintained by Dr. Susan Ludington.

Selection criteria—Randomized controlled trials comparing early SSC with usual hospital care.

Data collection and analysis—We independently assessed trial quality and extracted data. Study authors were contacted for additional information.

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CONTRIBUTIONS OF AUTHORS: For this update, Dr Elizabeth Moore wrote the first draft of the review and revised subsequent drafts in response to extensive feedback. Dr Gene Anderson and Dr Nils Bergman commented on the first draft of the updated review and contributed to the writing of the final draft. Therese Dowswell contributed to study assessment, analysis and drafting text.
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DECLARATIONS OF INTEREST: Three of the review authors have been active trialists in this area and have personal contact with many groups in this field, including the International Network for Kangaroo Mother Care based in Trieste, Italy; Bogota, Colombia; and Cleveland, Ohio. Dr Bergman has received reimbursement for lectures that he has conducted on Kangaroo Mother Care and from the sale of KMC related products.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW: The protocol has been updated. We have modified outcomes and used updated methods. Quasi- randomized controlled trials are no longer part of the inclusion criteria so Anisfeld 1983 has now been excluded.

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Main results—Thirty-four randomized controlled trials were included involving 2177 participants (mother-infant dyads). Data from more than two trials were available for only eight outcome measures. For primary outcomes, we found a statistically significant positive effect of early SSC on breastfeeding at one to four months postbirth (13 trials; 702 participants) (risk ratio (RR) 1.27, 95% confidence interval (CI) 1.06 to 1.53, and SSC increased breastfeeding duration (seven trials; 324 participants) (mean difference (MD) 42.55 days, 95% CI −1.69 to 86.79) but the results did not quite reach statistical significance (P = 0.06). Late preterm infants had better cardio-respiratory stability with early SSC (one trial; 31 participants) (MD 2.88, 95% CI 0.53 to 5.23). Blood glucose 75 to 90 minutes following the birth was significantly higher in SSC infants (two trials, 94 infants) (MD 10.56 mg/dL, 95% CI 8.40 to 12.72).

The overall methodological quality of trials was mixed, and there was high heterogeneity for some outcomes.

Authors' conclusions—Limitations included methodological quality, variations in intervention implementation, and outcomes. The intervention appears to benefit breastfeeding outcomes, and cardio-respiratory stability and decrease infant crying, and has no apparent short- or long-term negative effects. Further investigation is recommended. To facilitate meta-analysis, future research should be done using outcome measures consistent with those in the studies included here. Published reports should clearly indicate if the intervention was SSC with time of initiation and duration and include means, standard deviations and exact probability values.

Medical Subject Headings (MeSH)

*Breast Feeding; *Object Attachment; *Skin Physiological Processes; Infant, Newborn; Kangaroo-Mother Care Method [*methods]; Mother-Child Relations; Mothers; Randomized Controlled Trials as Topic; Touch [*physiology]

MeSH check words

Female; Humans; Infant

BACKGROUND

Description of the condition

In humans, routine mother-infant separation shortly after birth is unique to the 20th century. This practice diverges from evolutionary history, where neonatal survival depended on close and virtually continuous maternal contact. Although from an evolutionary perspective skin-to-skin contact (SSC) is the norm, separating the newborn from its mother soon after birth has now become common practice in many industrialized societies. Therefore, for the purpose of this review, SSC has to be the experimental intervention. Ironically, and importantly, the experimental intervention in studies with all other mammals is to *separate* newborns from their mothers.

Description of the intervention

Early SSC is the placing of the naked baby prone on the mother's bare chest at birth or soon afterwards. In the evolutionary context, this would have been "immediate and continuous". In the current care context, initiation and duration are not defined. The concept of "care" does not change; only the place where such care is provided changes. Further, although a dose-response effect has not been documented in randomized controlled trials (RCTs), the general belief is that SSC should continue until the end of the first successful breastfeeding to show an effect and to enhance early infant self-regulation (Widstrom 2011).

How the intervention might work

The rationale for SSC comes from animal studies in which some of the innate behaviors of neonates that are necessary for survival are shown to be habitat dependent (Alberts 1994). In mammalian biology, maintenance of the maternal milieu following birth is required to elicit innate behaviors from the neonate and the mother that lead to successful breastfeeding, and thus survival. Separation from this milieu results in immediate distress cries (Alberts 1994) and “protest-despair” behavior. Human infants placed in a cot cry 10 times more than SSC infants. Their cry is similar to the vocalizations of separated rat pups (Michelsson 1996). In rodent studies, the pups who had the least attentive contact from their mothers were the ones whose health and intelligence were compromised across the lifespan (Francis 1999; Liu 1997; Liu 2000; Meaney 2005; Plotsky 2005). Also in the report by Liu 2000 a cross-fostering study provided evidence for a direct relationship between maternal behavior and hippocampal development in the offspring.

Healthy, full term infants employ a species-specific set of innate behaviors immediately following delivery when placed in SSC with the mother (Righard 1990; Varendi 1994; Varendi 1998; Widstrom 1987; Widstrom 1990). They localize the nipple by smell and have a heightened response to odor cues in the first few hours after birth (Porter 1999; Varendi 1994; Varendi 1997). More recently Widstrom 2011 described the sequence of nine innate behaviors as the birth cry, relaxation, awakening and opening the eyes, activity (looking at the mother and breast, rooting, hand to mouth movements, soliciting sounds), a second resting phase, crawling towards the nipple, touching and licking the nipple, suckling at the breast and finally falling asleep. This ‘sensitive period’ predisposes or primes mothers and infants to develop a synchronous reciprocal interaction pattern, provided they are together and in intimate contact. Infants who are allowed uninterrupted SSC immediately after birth and who self-attach to the mother’s nipple may continue to nurse more effectively. Effective nursing increases milk production and infant weight gain (De Carvalho 1983; Dewey 2003). Anderson 2004a used SSC as an intervention for 48 healthy mother/full term infant dyads with breastfeeding problems identified between 12 to 24 hours postbirth. SSC was provided during the next three consecutive breastfeedings. Breastfeeding was successful, even in this racially disparate sample (Chiu 2008) and was exclusive in 81% of these dyads at hospital discharge, 73% at one week, and 52% at one month postbirth. Temperatures were taken before (baseline), during, and after each SSC breastfeeding. Baseline temperatures reached, and remained in thermoneutral range (Chiu 2005) suggesting that mothers have the ability to modulate infant temperature if given the opportunity to breastfeed in SSC. Because these mothers and their infants were having breastfeeding difficulties, hospital staff and parents can logically be reassured that healthy newborn infants, with or without breastfeeding difficulties, may safely breastfeed in SSC so far as temperature is concerned. In a study of infrared thermography of the whole body during the first hour postbirth, Christidis 2003 found that SSC was as effective as radiant warmers in preventing heat loss in healthy full term infants.

SSC through sensory stimuli such as touch, warmth, and odor is a powerful vagal stimulant, which among other effects releases maternal oxytocin (Uvnas-Moberg 1998; Winberg 2005). Oxytocin causes the skin temperature of the mother’s breast to rise, providing warmth to the infant (Uvnas-Moberg 1996). When operating in a safe environment, oxytocin, and direct SSC stimulation of vagal efferents, are probably part of a broader neuro-endocrine milieu (Porges 2007). A global physiological regulation of the autonomic nervous system is achieved, supporting growth and development, (homeorhesis). Under conditions perceived by the newborn to be dangerous, stress mechanisms come into operation, with the focus on survival rather than development (allostasis). The theory of allostasis is the relationship between psycho-neurohormonal responses to stress and physical and psychological manifestations of health and illness (McEwen 1998; Shannon 2007).

Allostasis is necessary, and it can be viewed as beneficial, because its goal is to bring aberrant physiology closer to normal; however, an allostatic response comes with a physiological cost referred to as allostatic load. The higher the allostatic load the greater the damage from stress, because allostatic load is cumulative. SSC also lowers maternal stress levels. Handlin 2009 found a dose-response relationship between the amount of SSC and maternal plasma cortisol two days postbirth. A longer duration of SSC was correlated with a lower median level of cortisol ($r = -0.264$, $P = 0.044$).

Oxytocin antagonizes the flight-fight effect, decreasing maternal anxiety and increasing calmness and social responsiveness (Uvnas-Moberg 2005). During the early hours after birth, oxytocin may also enhance parenting behaviors (Uvnas-Moberg 1998; Winberg 2005). SSC outcomes for mothers suggest improved bonding/attachment (Affonso 1989); other outcomes are increased sense of mastery and self-enhancement, resulting in increased confidence. Sense of mastery and confidence are relevant outcomes because they predict breastfeeding duration (Dennis 1999). Women with low breastfeeding confidence have three times the risk of early weaning (O'Campo 1992) and low confidence is also associated with perceived insufficient milk supply (Hill 1996).

Marin 2010 found that time to expulsion of the placenta was shorter ($M = 409 \pm 245$ sec.) in mothers of SSC infants than in control mothers ($M = 475 \pm 277$ sec., $P = 0.05$). When SSC on the mother's abdomen, the infant's knees and legs press into her abdomen in a massaging manner which would logically induce uterine contractions and thereby reduce risk of postpartum hemorrhage. Mothers who experience SSC have reduced bleeding (Dordevic 2008) and more rapid delivery of the placenta (Marin 2010).

In previous meta-analyses with full term infants, early contact was associated with continued breastfeeding (Bernard-Bonnin 1989; Inch 1989; Perez-Escamilla 1994). Just altering hospital routines can increase breastfeeding levels in the developed world (Rogers 1997). Conde-Agudelo 2011 conducted a Cochrane review of 16 randomized clinical trials of kangaroo mother care (KMC), a strategy of continuous or intermittent SSC with exclusive or nearly exclusive breastfeeding and early hospital discharge of infants less than 2500 g at birth in settings with limited resources. KMC was associated with reductions in several clinically important adverse infant outcomes, including mortality at hospital discharge and at latest follow-up, nosocomial infection/sepsis at hospital discharge and severe infection/sepsis at latest follow-up, hypothermia and hospital length of stay. SSC mothers were more satisfied with the method of care, and more likely to be exclusively breastfeeding at hospital discharge. In another meta-analysis of 24 studies (13 case-series, five RCT's, one cross-over and four cohort), Mori 2010 evaluated outcomes in both low and normal birthweight infants up to 28 days old. Infant body temperature increased 0.22 °C during and 0.14 °C after SSC ($P < 0.001$, 21 studies); heart rate increased 2.04 beats per minute (bpm) during ($P = 0.05$) and decreased 0.07 bpm after SSC ($P = 0.95$, 12 studies); oxygen saturation decreased 0.60% (three/fifths of 1%) during ($P = 0.01$) and 0.48% (essentially one-half of 1%) after SSC ($P = 0.06$, 10 studies). These decreases in oxygen saturation are too small to be of clinical significance.

Why it is important to do this review

Separation of mothers from their newborn infants at birth has become standard practice, despite mounting evidence that this may have harmful effects. However, delivery room and postpartum hospital routines may significantly disrupt early maternal-infant interactions including breastfeeding (Anderson 2004a; Odent 2001; Winberg 1995). The possibility exists that postnatal separation of human infants from their mothers is stressful (Anderson 1995) and might result in harmful effects that persist across the lifespan, if the studies with laboratory animals cited earlier hold true for humans. This possibility needs careful

evaluation using the allostatic theoretical framework (McEwen 1998) as well as new epigenetic findings (Meaney 2005).

A concurrent widespread decline in breastfeeding is of major public health concern. Although more women are initiating breastfeeding, fewer are breastfeeding exclusively. Using data from the Infant Feeding Practices Study II conducted in the United States by the Food and Drug Administration in 2005 to 2007, Grummer-Strawn 2008 found that 83% of mothers initiated breastfeeding, but only 48% exclusively breastfed during their hospital stay. These innate behaviors can be disrupted by early post-partum hospital routines as shown experimentally by Widstrom 1990 and in descriptive studies by Gomez 1998; Jansson 1995 and Righard 1990. Gomez 1998 found that infants were eight times more likely to breastfeed spontaneously if they spent more than 50 minutes in SSC with their mothers immediately after birth, and concluded that the dose of SSC might be an essential component regarding breastfeeding success. Bramson 2010 showed a clear dose-response relationship between SSC in the first three hours postbirth and exclusive breastfeeding at discharge in a large (N = 21,842 mothers) hospital-based cohort study, (odds ratio (OR) for exclusive breastfeeding = 1.665 if in SSC for 16 to 30 minutes, and OR = 3.145 for more than 60 minutes of SSC).

The purpose of this review is to examine the available evidence of the effects of early SSC on breastfeeding exclusivity and duration and other outcomes in mothers and their healthy full term and late preterm newborn infants. Although our intent is to examine all clinically important outcomes, breastfeeding is the predominant outcome investigated so far in healthy newborns. Hence, our emphasis is on breastfeeding, although we also will examine maternal-infant physiology and behavior. Because the focus of this review is on mothers and their healthy infants, potential effects of early SSC on father-infant attachment and also the resistance of staff to this intervention are beyond the scope of this review. Maternal feelings about early SSC and satisfaction with the birth experience are important and relevant but require more qualitative methods. The focus of this review is on randomized controlled trials used to test the effects of early SSC. This is an update of a Cochrane review first published in 2003 and previously updated in 2007.

OBJECTIVES

To assess the effects of early skin-to-skin contact for healthy newborn infants compared to standard contact (infants held swaddled or dressed in their mothers arms, placed in open cribs or under radiant warmers).

The three main outcome categories include:

- **a.** establishment and maintenance of breastfeeding/lactation;
- **b.** infant physiology - thermoregulation, respiratory, cardiac, metabolic function, neurobehavior;
- **c.** maternal-infant bonding/attachment.

METHODS

Criteria for considering studies for this review

Types of studies—All randomized controlled trials in which the active encouragement of early skin-to-skin contact (SSC) between mothers and their healthy newborn infants was compared to usual hospital care. We have not included quasi-randomized trials (e.g. where assignment to groups was alternate or by day of the week, or by other non-random methods).

Types of participants—Mothers and their healthy full term or late preterm newborn infants (34 to less than 37 completed weeks' gestation) having early SSC starting less than 24 hours after birth, and controls undergoing standard patterns of care.

Types of interventions—Early SSC for term or late preterm infants can be divided into several subcategories.

a. In 'birth SSC', the infant is placed prone skin-to-skin on the mother's abdomen or chest during the first minute postbirth. The infant is suctioned while on the mother's abdomen or chest, if medically indicated, thoroughly dried and covered across the back with a prewarmed blanket. To prevent heat loss, the infant's head may be covered with a dry cap that is replaced when it becomes damp. Ideally, all other interventions are delayed until at least the end of the first hour postbirth or the first successful breastfeeding.

b. In 'very early SSC', beginning approximately 30 to 40 minutes postbirth, the naked infant, with or without a cap, is placed prone on the mother's bare chest. A blanket is placed across the infant's back.

c. 'Early SSC' can begin anytime between one and 24 hours postbirth. The baby is naked (with or without a diaper and cap) and is placed prone on the mother's bare chest between the breasts. The mother may wear a blouse or shirt that opens in front, or a hospital gown worn backwards, and the baby is placed inside the gown so that only the head is exposed. What the mother wears and how the baby is kept warm and what is placed across the baby's back may vary. What is most important is that the mother and baby are in direct ventral-to-ventral SSC and the infant is kept dry and warm.

In the future these groups may be analyzed separately. However, at present, not enough studies are available for subgroup analysis. Standard contact includes a number of diverse conditions, infants held swaddled or dressed in their mothers arms, or infants placed in open cribs or under radiant warmers in the mother's room or elsewhere with no holding allowed.

Types of outcome measures

Primary outcomes

Breastfeeding outcomes:

1. Number of mothers breastfeeding (any breastfeeding) one month to four months postbirth
2. Duration of breastfeeding

Infant outcomes:

1. Infant stabilization during the transition to extra-uterine life Measured by the SCRIP score (e.g. stability of the cardio-respiratory system - a composite score of heart rate, respiratory status and arterial hemoglobin oxygen saturation (SaO2), range of scores = 0-6 (Fischer 1998)
2. Blood glucose levels during/after SSC compared to standard care
3. Infant thermoregulation = temperature changes during/ after SSC compared to standard care (measured by axillary temperature)

Secondary outcomes

Breastfeeding outcomes (secondary):

1. Effective breastfeeding (Infant Breastfeeding Assessment Tool (IBFAT) (Matthews 1988; Matthews 1991)
2. Breastfeeding rates/exclusivity (using either the Labbok 1990 Index of Breastfeeding Status or the Thulier 2010 five-point scale) at hospital discharge up to two weeks postbirth
3. Breastfeeding rates/exclusivity (using either the Labbok 1990 Index of Breastfeeding Status or the Thulier 2010 five-point scale) three to six months postbirth
4. Maternal breast temperature during and after SSC
5. Breast engorgement

Infant outcomes (secondary):

1. Infant heart rate during/after SSC compared to standard care
2. Respiratory status - respiratory rate during/after SSC compared to standard care
3. Neonatal intensive care unit admissions
4. Infant weight changes/rate of growth in gm/kg/day (daily weight change, change in weight over days of study) (Hill 2007)
5. Length of hospital stay
6. Duration of infant crying

Maternal outcomes:

1. Maternal perceptions of bonding/connection to her infant
2. Maternal pain post cesarean
3. Maternal sensitivity to her infant's cues
4. Maternal anxiety
5. Maternal parenting confidence

Search methods for identification of studies

Electronic searches—We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (30 November 2011).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the

current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

Searching other resources—The first three review authors have been active trialists in this area and have personal contact with many groups in this field including the International Network for Kangaroo Mother Care, based in Trieste (*see* Appendix 1).

We did not apply any language restrictions.

Data collection and analysis

For the methods used when assessing the trials identified in the previous version of this review, *see* Appendix 2.

For this update we used the following methods when assessing the reports identified by the updated search.

Selection of studies—Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. First, we screened titles and abstracts of all the retrieved studies. Two review authors independently assessed full text articles for inclusion in the review. We resolved any disagreement through discussion or, if required, we consulted a third individual. We have listed studies that did not meet the inclusion criteria for the review in the Characteristics of excluded studies tables along with the reasons for their exclusion.

Data extraction and management—We designed a form to extract data. For eligible studies, at least two review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted a third person. We entered data into Review Manager software (RevMan 2011) and checked for accuracy.

When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies—Two review authors independently assessed risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). We resolved any disagreement by discussion or by involving a third assessor. We used the electronic 'Risk of bias' form in RevMan 2011 to describe study methodological quality.The following criteria were assessed.

(1) Sequence generation (checking for possible selection bias): We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it produced comparable groups.

We assessed the method as:

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

- risk of bias unclear.

(2) Allocation concealment (checking for possible selection bias): We described for each included study the method used to conceal the allocation sequence and determined whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

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

(3) Blinding (checking for possible performance and detection bias): We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results. We assessed blinding separately for different outcomes or classes of outcomes. We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel;
- low, high or unclear risk of bias for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations): We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomized 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 could be supplied by the trial authors, we re-included missing data in the analyses. We assessed methods as:

- low risk of bias where loss was low and was balanced across groups;
- high risk of bias where attrition was high or unbalanced across groups;
- unclear risk of bias.

(5) Selective reporting bias: We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

- low risk of bias (where it was clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review had been reported);
- high risk of bias (where not all the study's prespecified outcomes had been reported; one or more reported primary outcomes were not prespecified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported);

- unclear risk of bias.

(6) Other sources of bias: We described for each included study any important concerns we had about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- low, high or unclear risk of other bias.

(7) Overall risk of bias: We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it is likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analysis.

Measures of treatment effect

Dichotomous data: For dichotomous data, we have presented results as summary risk ratio with 95% confidence intervals.

Continuous data: For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We used the standardized mean difference to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues—The unit of analysis was the healthy newborn infant receiving SSC or standard care.

We did not identify any cluster-randomized trials in this version of the review. If we identify such trials in future updates we will include them in the review along with individually randomized trials.

To take account of design effect, provided sufficient information is available, we will adjust the sample sizes and event rates from cluster-randomized studies using the methods described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011). We will use an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), or from another source. If ICCs from other sources are used, we will report this and will conduct sensitivity analyses to investigate the effect of variation in the ICC.

We will consider that it is reasonable to combine the results from both individually and cluster-randomized trials if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomization unit is considered to be unlikely.

Dealing with missing data—For included studies, we noted levels of attrition and have described in the Characteristics of included studies tables the levels of loss to follow up at each data collection point.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomized to each group in the analyses, and all participants were analyzed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome

in each trial was the number randomized minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity—We assessed statistical heterogeneity in each meta-analysis using the I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if either I^2 was greater than 40% or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases—If there were 10 or more studies in the meta-analysis we planned to investigate reporting biases (such as publication bias) using funnel plots. In this version of the review insufficient studies contributed data to allow us to carry out this analysis for all but one of the outcomes. In future updates, if more studies become available we will assess funnel plot asymmetry visually, and will use formal tests for funnel plot asymmetry. For continuous outcomes, we will use the test proposed by Egger 1997, and for dichotomous outcomes, we will use the test proposed by Harbord 2006. If asymmetry is detected in any of these tests or is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis—We carried out statistical analysis using the Review Manager software (RevMan 2011). We used fixed-effect meta-analysis for combining data when it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and we have discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials.

If we used random-effects analyses, the results have been presented as the average treatment effect with its 95% confidence interval, along with estimates of I^2.

Subgroup analysis and investigation of heterogeneity—For primary outcomes we planned subgroup analysis by:

1. gestational age at birth; infants born at term (greater than 37 weeks) versus later preterm (greater than 34 to 37 weeks);
2. type of SSC (at birth, very early SSC, and early SSC).

We planned to assess differences between subgroups by using the interaction tests available in RevMan 2011. In this version of the review insufficient studies contributed data to allow us to carry out the planned analysis. In future updates, as more data become available, we hope to be able to look for possible differences between subgroups.

Sensitivity analysis—We planned to carry out sensitivity analysis to look at whether the methodological quality of studies had an impact on results; however, none of the included studies met all criteria for low risk of bias and we therefore did not carry out this analysis in this version of the review. In view of the mixed methodological quality of trials we advise caution in the interpretation of results. For our two primary outcomes there were high levels of heterogeneity; much of the variation was due to a single study; we therefore carried out sensitivity analysis excluding this study from the analysis to examine the impact on results

(Sosa 1976a). For infant physiological outcomes, we also carried out sensitivity analysis to explore high levels of heterogeneity.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

Included studies: Thirty-four studies with 2177 mother-infant dyads met the inclusion criteria. None of the 34 studies met all of the methodological quality criteria (*see* Figure 1 and Figure 2). The total sample sizes in the studies ranged from eight to 204 mother-infant pairs. The studies represented very diverse populations in Canada, Chile, Germany, Guatemala, Iran, Israel, Italy, Japan, Nepal, Poland, Russia, South Africa, Spain, Sweden, Taiwan, Thailand, the United Kingdom, and the United States. All but four of the 34 studies included only healthy full term infants. Four studies (Anderson 2003; Bergman 2004; Chwo 1999; Syfrett 1996) were done with healthy late preterm infants who were assigned to the normal newborn nursery. Three studies (Gouchon 2010; McClellan 1980; Nolan 2009) were conducted with mothers scheduled for repeat cesarean birth using regional anesthesia. One study (Huang 2006) was conducted with hypothermic, but otherwise healthy, newborns postcesarean birth with spinal anesthesia. One paper reported results for studies carried out in three different sites and we have treated these as three different studies in the data and analysis (Sosa 1976a; Sosa 1976b; Sosa 1976c). A large number of outcomes (31) have been reported in the analysis, but only 15 included multiple trials and for many of the other outcomes only a relatively small number of studies (two or three) contributed data. Four of the 34 included studies did not report data on our prespecified primary and secondary outcomes and data from these studies have not been included in the analysis (Curry 1982; Fardig 1980; Ferber 2004; Hales 1977). Details of all included studies are set out in the Characteristics of included studies tables.

The characteristics of the intervention varied greatly between studies. Duration of skin-to-skin (SSC) ranged from approximately 15 minutes (De Chateau 1977; Svejda 1980; Thomson 1979; Vaidya 2005) to a mean of 37 of 48 hours (84%) of continuous SSC (Syfrett 1996); in this study all dyads received 24 minutes of SSC before randomization. Hake-Brooks 2003 (under Anderson 2003) reported that SSC mothers gave SSC 22% of the time and held their wrapped infants for 11.6% of the observation period. Although SSC began by 0 to 15 minutes postbirth in 18 of the 34 studies, the SSC dyads in the study by Shiau 1997 could not begin until four hours postbirth because of hospital policy. SSC did not begin until a mean of 21.3 hours postbirth in the study by Chwo 1999 of late preterm infants 34 to 36 weeks' gestational age. In 22 of the 34 studies the infants were given the opportunity to suckle during SSC but only five studies (Carfoot 2004; Carfoot 2005; Gouchon 2010; Khadivzadeh 2008; Moore 2005) documented the success of the first breastfeeding using a validated instrument, the Infant Breastfeeding Assessment Tool. The amount of assistance the mothers received with breastfeeding during SSC was unclear in many of the research reports.

Substantial differences were found between studies in the amount of separation that occurred in the control group. In eight studies (Chwo 1999; Hales 1977; Huang 2006; Mizuno 2004; Shiau 1997; Sosa 1976a; Sosa 1976b; Sosa 1976c), infants were removed from their mothers immediately postbirth and reunited 12 to 24 hours later. In five studies (Carlsson 1978; Craig 1982; Gouchon 2010; Svejda 1980; Thomson 1979), the mothers held

their swaddled infants for about five minutes soon after birth and then were separated from their infants. Control mothers held their swaddled infants six times for 60 minutes in Chwo 1999, 20 minutes in Kastner 2005, 60 minutes in Moore 2005 and for two hours in the recovery room in Punthmatharith 2001. The swaddled control infants in Khadivzadeh 2008 were reunited with their mothers after the episiotomy repair. Control infants in Nolan 2009 were separated from their mothers for a mean of 21 minutes and in Gouchon 2010 for a mean of 51 minutes post-cesarean birth. There were four groups in the study by Bystrova 2003; an SSC group, a mother's arms group where the infants were held swaddled or dressed, a nursery group and a reunion group where the infants were taken to the nursery immediately postbirth for 120 minutes but reunited with their mothers for rooming-in on the postpartum unit. In Hake-Brooks 2003 (under Anderson 2003) control mothers held their wrapped infants 13.9% of the time (M = 6.67 hours).

Excluded studies: Fifty studies were assessed and excluded from the review. The primary reason for exclusion was that the investigators did not state that the infants in the intervention group received early SSC with their mothers. When the information in the research report was unclear, where possible we contacted the investigators, to determine whether the early contact was indeed skin-to-skin (*see* the table of Characteristics of excluded studies).

New studies found at this update: Five randomized controlled trials have been added to the review. Two of the new studies (Gouchon 2010; Nolan 2009) were conducted with mothers scheduled for repeat cesarean birth using regional anesthesia. One study (Huang 2006) was conducted with hypothermic, but otherwise healthy, newborns post-cesarean birth with spinal anesthesia. The results from four additional reports involving the data set from Bystrova 2003, two additional reports from Anderson 2003 and one additional report from Bergman 2004 have been added to this update.

Risk of bias in included studies

Allocation—The overall methodological quality of the included studies was mixed and many studies did not provide clear information on the way the that the randomization sequence was generated, or on the methods used to conceal group allocation at the point of randomization. In 18 of the 34 studies the way the randomization sequence was produced was not clearly described and in 22 of the 34 studies, not enough information was provided to determine if the method of random assignment was robust before allocation of the participants to groups occurred. In two studies (De Chateau 1977; McClellan 1980), allocation concealment was at high risk of bias because the researchers used an open table of random numbers. In seven studies (Anderson 2003; Bergman 2004; Chwo 1999; Moore 2005; Punthmatharith 2001; Shiau 1997; Syfrett 1996), allocation concealment was controlled by using a computer program to assign women to groups (the minimization method). Although the Syfrett 1996 study was small (n = 8), the recruiter was naive to the minimization method of random assignment. In 12 studies (Carlsson 1978; Christensson 1992; Christensson 1995; Hales 1977; Kastner 2005; Khadivzadeh 2008; Mazurek 1999; Mizuno 2004; Svejda 1980; Thomson 1979; Vaidya 2005; Villalon 1993), the researchers indicated that women were randomly assigned to groups but no further information was provided about the randomization method. In eight studies (Bystrova 2003; Carfoot 2004; Craig 1982; Curry 1982; Nolan 2009; Sosa 1976a; Sosa 1976b; Sosa 1976c), sealed envelopes were used but the investigators do not state whether the envelopes were sequentially numbered, although Bystrova 2003 noted that the envelopes were opened consecutively.

Blinding—Blinding women, clinical staff and outcome assessors to treatment group is extremely difficult for this type of intervention, and we found it difficult to judge the impact of lack of blinding on particular outcomes. We have provided a single assessment for performance blinding and detection bias for these studies taking into account both the information provided by investigators, and our assessments of the potential impact of lack of blinding on the particular outcomes measured (i.e. we considered for example, that lack of blinding may have had more impact on outcomes where unblinded outcome assessors observed maternal behavior and less impact on laboratory investigations). In 28 studies we rated the impact of lack of blinding as unclear; in studies where an unblinded investigator provided clinical care for the treatment group and also collected outcome data, we assessed that results may have been more susceptible to observer bias. In the Characteristics of included studies tables we have described for each study any attempts investigators made to blind women, staff and outcome observers.

None of the research reports stated that the delivery and postpartum staff were unaware of the group assignment of the mothers. Ferber 2004, however, stated that the nursery staff were blind to patient group assignment. Therefore, in the majority of studies control for provider performance bias was difficult to determine. In the 10 studies that evaluated infant physiological outcomes (Bergman 2004; Bystrova 2003; Christensson 1992; Fardig 1980; Gouchon 2010; Huang 2006; Mazurek 1999; Nolan 2009; Syfrett 1996; Villalon 1993), however, patient or provider performance bias may not be as significant an issue as it might be with maternal attachment and breastfeeding outcomes. Surprisingly, there was more effort made to control for patient performance bias than for provider performance bias. In seven studies (Carlsson 1978; Craig 1982; Curry 1982; Ferber 2004; Kastner 2005; Svejda 1980; Thomson 1979), it was reported that the women were not aware that they were receiving an experimental treatment and/or they were not informed about the true purpose of the study. Adequate control for patient performance is problematic in the more recent studies because of Institutional Review Board requirements that investigators disclose the true purpose of the study or the experimental conditions, or both. In 14 of the 34 studies, outcome assessors (whenever possible) were reported to be unaware of the woman's group assignment. In several studies, when infant physiological or crying data were obtained by observation during SSC (Bergman 2004; Bystrova 2003; Christensson 1992; Christensson 1995; Fardig 1980; Gouchon 2010; Huang 2006; Mazurek 1999; Syfrett 1996; Villalon 1993), the outcome assessors could not be masked.

Incomplete outcome data—In all but one study (Carlsson 1978), outcome data were either obtained on all the enrolled women or reasons were provided for women who withdrew or had to be withdrawn. Six investigators (Anderson 2003; Bergman 2004; Bystrova 2003; Carfoot 2005; Gouchon 2010; Moore 2005), utilized the Consort Guidelines (Moher 2001; Moher 2010) to document the flow of participants through their clinical trial.

An overall summary of risk of bias for all studies is set out in Figure 1 and 'Risk of bias' findings for individual studies are set out in Figure 2.

Effects of interventions

All the studies reviewed were randomized controlled trials. Most of our primary and secondary outcomes were measured in only one or two studies and where more studies contributed data there was some heterogeneity between trials. Where we identified moderate or high statistical heterogeneity (I^2 greater than 40%), we have drawn attention to this in the text and would urge caution in the interpretation of these results which show the average treatment effect.

Primary outcomes - breastfeeding rates/duration—Early SSC resulted in better overall performance on several measures of breastfeeding status, although there was heterogeneity between studies.

More SSC dyads were still breastfeeding one to four months postbirth (average risk ratio (RR) 1.27, 95% confidence interval (CI) 1.06 to 1.53). This meta-analysis included 13 studies and involved 702 mother-infant pairs. In 11 of the 13 studies, SSC dyads were more likely to be breastfeeding at one to four months postbirth, although the difference reached statistical significance in only two studies (Sosa 1976c; Thomson 1979). Overall, there were differences in the size of the treatment effect between studies leading to moderate heterogeneity for this outcome ($T^2 = 0.04$, P = 0.03, $I^2 = 47\%$) (Analysis 1.1). Much of the heterogeneity was due to a single study (Sosa 1976a) (the study author speculated that variation in treatment effect was due to the particular population attending the study hospital). We carried out a sensitivity analysis removing this study from the analysis; when this study was excluded there was no evidence of statistical heterogeneity ($T^2 = 0.00$, P = 0.52, $I^2 = 0\%$) and removing this study had very little impact on the overall treatment effect; the difference between groups favoring the SCC group remained statistically significant (RR 1.31, 95% CI 1.16 to 1.48) (Analysis 1.31). As sufficient studies contributed data to this outcome, we generated a funnel plot to explore whether there was any obvious small study effect; Visual examination of the forest and funnel plots suggested that there was a greater treatment effect associated with smaller studies and this may indicate possible publication bias (Figure 3).

Seven studies with 324 mother/infant pairs reported data on the duration of breastfeeding in days. Six of the seven studies (De Chateau 1977; Mizuno 2004; Shiau 1997; Sosa 1976b; Sosa 1976c; Svejda 1980) found a longer duration of breastfeeding in the SSC dyads (mean difference (MD) 42.55 days, 95% CI −1.69 to 86.79). However, overall, the difference between groups did not reach statistical significance. Results from this meta-analysis should be interpreted with caution; there was considerable heterogeneity for this outcome and some of the findings are from studies with very small sample sizes, and although mean duration of breastfeeding was reported this may not have been an appropriate measure in studies where the distribution of scores was unlikely to have been normal (heterogeneity: $T^2 = 2216$, P = 0.007, $I^2 = 66\%$) (Analysis 1.2). Again, it was clear from visual examination of the forest plot that much of the heterogeneity was due to the Sosa 1976a study. Sensitivity analysis excluding this study removed heterogeneity ($I^2 = 0\%$) and the difference between groups was statistically significant with breastfeeding duration increased by an average of 64 days in the SSC group (MD 63.73, 95% CI 37.96 to 89.5) (Analysis 1.32).

Infant primary outcomes

Infant physiological stability in the hours following birth: Bergman 2004 utilized SCRIP scores (a measure of infant cardio-respiratory stability in preterm infants that evaluates infant heart rate, respiratory rate and oxygen saturation) (Fischer 1998) to compare SSC in healthy late preterm 31 SSC infants (mean gestational age (GA) = 34.2 weeks) with 13 late preterm control infants (mean GA = 35.3 weeks) placed in a servo-controlled incubator next to their mothers. SSC infants had higher SCRIP scores during the first six hours postbirth, indicating better stabilization (MD 2.88, 95% CI 0.53 to 5.23) (Analysis 1.3). A subset of infants below 1800 grams birthweight also demonstrated better stabilization (MD 4.92, 95% CI −1.67 to 11.51) but this result did not reach statistical significance (Analysis 1.4).

Blood glucose 75 to 90 minutes following the birth was measured in two studies with 94 infants; blood glucose was higher in SSC infants (MD 10.56 mg/dL, 95% CI 8.40 to 12.72) and this result was statistically significant (Analysis 1.5).

Infant thermoregulation: Infant axillary temperature at 90 minutes to two hours after the birth was reported in three studies including a total of 168 dyads. In the studies by Christensson 1992 and Christensson 1995, infants had SSC or were placed in a 'cot' (bassinet) next to the mother during the first 90 minutes postbirth. Neither group of infants was fed. In Villalon 1993 control infants were taken to the nursery. Due to heterogeneity between studies we did not combine results in meta-analysis but results for the individual studies are set out in Analysis 1.6. In the Christensson 1992 and Christensson 1995 studies, results favored the SCC group (RR 0.40, 95% CI 0.19 to 0.61, and RR 0.50, 95% CI 0.17 to 0.83 respectively) whereas in the study by Villalon 1993 temperatures were on average slightly higher for the control group at this time point (RR −0.10, 95% −0.24 to 0.04) (although at other time points reported results favored the intervention group and therefore, in view of these inconsistencies findings for this study, are difficult to interpret).

Secondary outcomes

Breastfeeding outcomes: Two studies with 57 women reported the number exclusively breastfeeding at hospital discharge; there was no evidence of a difference between groups receiving SSC compared with routine care (RR 0.99, 95% CI 0.66 to 1.47) (Analysis 1.7).

Three studies with 245 women examined breastfeeding status (using the Index of breastfeeding status (IBS) at one month postpartum. The IBS is a single item indicator and consists of three major levels of breastfeeding exclusivity -- full, partial, and token breastfeeding. Full breastfeeding is divided into two sub-categories exclusive and almost exclusive. In almost exclusive breastfeeding, the infant is given water, juice, vitamins and minerals infrequently in addition to breast-milk. Partial breastfeeding is divided into three sub-categories - high, medium and low. Token breastfeeding is occasional and irregular, less than 15 minutes a day.There was no clear evidence of differences between groups for this outcome, and results varied considerably between studies therefore the overall average treatment effect should be interpreted with caution (mean difference (MD) 0.86, 95% CI −0.73 to 2.44) (heterogeneity: $T^2 = 1.70$, $P < 0.0001$, $I^2 = 90\%$) (Analysis 1.8).

More infants were exclusively breastfeeding up to three to six months postbirth in three studies (n = 149) (RR 1.97, 95% CI 1.37 to 2.83) (Analysis 1.9).

Two studies reported breastfeeding at one year postbirth.There were no statistically significant differences between groups (RR 6.91, 95% CI 0.82 to 46.78) (Analysis 1.10).

Two studies with 54 women examined breastfeeding effectiveness scores and those in the SCC group had higher mean scores (MD in IBFAT scores 1.79, 95% CI 0.24 to 3.35) (Analysis 1.11). The Infant Breastfeeding Assessment Tool (IBFAT) evaluates four parameters of infant suckling competence infant state of arousal or readiness to feed; rooting reflex; latch-on; and suckling pattern.The infant can receive a score of 0-3 on each item for a maximum total score of 12 indicating adequate suckling competence (Matthews 1988; Matthews 1991) .

Carfoot 2004, Carfoot 2005 and Khadivzadeh 2008 found that infants held SSC were slightly more likely to breastfeed successfully during their first feeding postbirth than those who were held swaddled in blankets by their mothers, although he evidence of a difference between groups was not statistically significant and there was considerable variability between findings in these three studies (n = 315) (average RR 1.36, 95% CI 0.95 to 1.95; heterogeneity $T^2 = 0.07$, $P = 0.03$, $I^2 = 72\%$) (Analysis 1.12). These findings were obtained using a modification of the IBFAT.

In a single study with data for 88 women, Bystrova 2003 reported the number of infants that suckled within two hours of the birth; there was no clear evidence of differences between groups (RR 1.06, 95% CI 0.83 to 1.35) (Analysis 1.13).

Maternal breast temperature: Bystrova 2003 found significant between group differences in the mean variation in breast temperature 30 to 120 minutes postbirth as measured by the interquartile range between mothers who held their infants SSC and those who were separated from their infants (MD 0.60, 95% CI 0.34 to 0.86) (Analysis 1.14). Duration of SSC was 95 minutes. The researchers suggested that these variations in maternal breast temperature in the SSC group may regulate infant temperature more effectively than stable breast temperatures and help prevent neonatal hypothermia.

Breast problems: Breast engorgement pain (measured by the self-reported Six Point Breast Engorgement Scale (Hill 1994) or by the mother's perception of tension/hardness in her breasts) was less for SSC than non-SSC mothers on day three postbirth (standardized mean difference (SMD) −0.41, 95% CI −0.76 to −0.06) (Analysis 1.15) (Bystrova 2003; Shiau 1997).

Infant physiological outcomes

Infant heart rate and respiratory rate: Four studies (Christensson 1992; Mazurek 1999; Nolan 2009; Villalon 1993) obtained data on infant respiratory rate 75 minutes to two hours postbirth. and three studies obtained data on infant heart rate. SSC infants had a lower mean heart rate than control infants who were separated from their mothers although the evidence of a difference between groups did not reach statistical significance and there was high heterogeneity for this outcome (MD −3.05 beats per minute (BPM), 95% CI −7.84 to 1.75; 183 infants); (heterogeneity: $T^2 = 15.26$, P = 0.0005, I^2 87%) (Analysis 1.16). Results also favored SCC infants for respiratory rate but again these results did not reach statistical significance and there was considerable variability in findings between studies (MD −3.12 RPM, 95% CI −6.61 to 0.37; 215 infants) (heterogeneity $T^2 = 9.24$, P = 0.004, $I^2 = 77\%$) (Analysis 1.17). Heterogeneity was mainly due to findings from the Villalon 1993 study; as stated above, findings at different time points varied considerably in this study. We carried out sensitivity analysis where results for this study were excluded; for both heart rate and respiratory rate, removal of findings for Villalon 1993 resulted in statistically significant findings favoring the SCC groups and there was no longer any evidence of between study heterogeneity (heart rate MD −5.77, 95% CI −7.46 to −4.11; respiratory rate MD −4.76, 95% CI −6.12 to 3.41) (Analysis 1.33; Analysis 1.34).

Bergman 2004 compared the number of infants in the two groups who did not exceed physiological parameters for stability requiring medical attention. The five parameters were infant skin temperature less than 35.5 °C on two consecutive occasions, heart rate less than 100 or more than 180 BPM on two consecutive occasions, apnea more than 20 seconds, oxygen saturation less than 87% on two consecutive occasions, blood glucose less than 2.6 mmol/L and FIO2 up to 0.6 with continuous positive airways pressure (CPAP) up to 5 cm of water pressure. Fifteen of the 18 SSC and one of the 13 control infants did not exceed parameters (RR 10.83, 95% CI 1.63 to 72.02). The most common reasons for exceeding parameters in control infants were hypothermia, hypoglycemia, and respiratory problems (Analysis 1.18).

Neonatal intensive care unit (NICU) admissions: There were no significant differences between groups in infant admissions to the NICU in Bergman 2004. Two SSC infants and one control infant required CPAP and they were transferred to the NICU (RR 1.44, 95% CI 0.15 to 14.29) (Analysis 1.19).Two studies with 42 infants (Chwo 1999; Syfrett 1996)

examined hospital length of stay in late preterm infants 34 to 36 weeks' GA and found no significant between group differences and there was high heterogeneity for this outcome (MD −95.30 hours, 95% CI −368.50 to 177.89) (Analysis 1.22).

Infant body weight change: No statistically significant differences were found in infant body weight change day 14 postbirth; this outcome was reported in two studies with 43 infants (MD −8.00 grams, 95% CI −175.60 to 159.61) (Analysis 1.20) (Chwo 1999; Moore 2005). Infant weigh change per kilogram per day was not reported in any of the included studies.

Infant crying/behavior: Christensson 1995 found that 12 of the 14 SSC infants cried no more than one minute during the 90-minute observation compared with only one of the 15 control infants (RR 12.86, 95% CI 1.91 to 86.44) (Analysis 1.23). Mazurek 1999 found that SSC infants cried for a shorter length of time during a 75-minute observation period than control infants (MD −8.01 minutes, 95% CI −8.98 to −7.04) (Analysis 1.24).

Maternal Outcomes

Maternal-infant bonding: Bystrova 2003 used The Parent-Child Early Relational Assessment (PCERA) in a study with data for 61 women.The PCERA (Clark 1985; Clark 1999) has eight sub-scales evaluating maternal and infant behavior and interaction. Bystrova 2003 found no evidence of significant between group differences for maternal positive affective involvement at 12 months postbirth (MD 1.90, 95% CI −1.14 to 4.94) (Analysis 1.25) however, SSC dyads appeared more mutual and reciprocal (MD 1.30, 95% CI 0.24 to 2.36) than those who were separated immediately postbirth and later reunited for rooming-in (Analysis 1.26). Bigelow 2010 under Bergman 2004 found significant effects of SSC during the first 24 hours postbirth on maternal sensitivity to her infant's behavioral cues, which demonstrated a dose-response effect. However it was a small sub-sample (12 of 31 randomized), and the effect was related to the 24-hour dose, with participants randomized to the control condition later receiving SSC, hence excluded from this review.

Other outcomes: Cesarean birth mothers in the SSC group also reported less postoperative pain than mothers who were separated from their infants (MD −1.38, 95% CI −2.79 to 0.03) (Analysis 1.27) (Nolan 2009). Mothers who held their infants SSC indicated a strong preference for the same type of postdelivery care in the future (86%) whereas only 30% of mothers who held their infants swaddled indicated that they would most certainly prefer this type of care in the future (RR 2.82, 95% CI 2.08 to 3.82) (Analysis 1.28) (Carfoot 2005). Mothers who held their infants SSC displayed less state anxiety day three postbirth (MD −5.00, 95% CI −9.00 to −1.00) (Analysis 1.29). Parenting confidence scores were measured in a single study with data for 20 women; there was no evidence of significant differences between groups (MD 5.60, 95% CI −6.24 to 17.44) (Moore 2005) at one month postbirth between mothers who held their infants SSC or swaddled (Analysis 1.30).

Non-prespecified outcomes: A large number of additional outcomes were measured in the included studies. Most of these outcomes were measured in single studies The clinical importance of results for many such outcomes is difficult to determine. Outcomes which appeared similar were measured in a range of different ways, in addition, many outcomes were reported at different or multiple time points and results may not have been consistent within or between studies. Non-prespecified outcomes reported include observed mother and infant behavior during the first few hours after birth, outcomes relating to breastfeeding (e.g. duration of first feed and number of breastfeeding problems) and a range of outcomes relating to mother-child interaction.

DISCUSSION

Summary of main results

The results of this review demonstrated a statistically significant positive effect of skin-to-skin contact (SSC) on the following primary outcomes: breastfeeding one month to four months postbirth, SCRIP score first six hours postbirth, and blood glucose mg/ dL at 75 to 90 minutes postbirth, We did not identify significant between group differences in duration of breastfeeding, and results relating to infant axillary temperature at 90 minutes to two hours postbirth were difficult to interpret due to high heterogeneity.

We found a statistically significant and positive effect of SSC on the following secondary outcomes: success of the first breastfeeding (IBFAT score), mean variation in maternal breast temperature 30 to 120 minutes postbirth, infant did not exceed physiological parameters for stability, number of babies not crying for more than one minute during a 90-minute observation, amount of crying in minutes during a 75-minute observation period and PCERA dyadic mutuality and reciprocity 12 months postbirth. We did not identify significant between group differences in successful first breastfeeding (IBFAT score 10 to 12 or BAT score 8 to 12), infant heart rate 75 minutes to two hours postbirth, infant respiratory rate 75 minutes to two hours postbirth, infant body weight change (grams) day 14 postbirth, transfers to the neonatal intensive care unit, infant hospital length of stay in hours, or PCERA maternal positive affective involvement and responsiveness 12 months postbirth.

No negative outcomes associated with SSC were reported in any of the studies except Sosa 1976a, who reported a longer duration of breastfeeding in the control group.

In summation, the totality of significant outcomes relating to breastfeeding, infant physiology and maternal neurobehavior supports the use of SSC in the early period after birth. However, this overall finding should be treated with some caution: for many outcomes only one or two studies contributed data, and for those outcomes where several studies were combined in meta-analysis there was considerable heterogeneity between individual studies. At the same time, some of those results that did not reach statistical significance were derived from small studies which did not have the statistical power to demonstrate differences between groups.

Breastfeeding/lactation outcomes—Only two breastfeeding meta-analyses contained more that three studies. Thirteen studies (702 infants) reported breastfeeding rates between one and four months postbirth (Analysis 1.1) demonstrating that mothers in the SSC group were more likely to be breastfeeding than those in the control group. The only other outcome with more than three studies (seven studies, 324 infants) was breastfeeding duration (Analysis 1.2). Infants in the SSC group breastfed an average of 42.55 days longer than control infants and when a study with inconsistent results was removed from the analysis the difference between groups was statistically significant. Evidence for breastfeeding exclusivity was conflicting, being no different at hospital discharge (Analysis 1.7, 2 studies) but significantly greater at three to six months postbirth (Analysis 1.9, three studies).The findings of improved breastfeeding for the two largest meta-analyses in this review were obtained in diverse countries and among women of low and high socio-economic class.

Results for IBFAT scores for the first breastfeeding postbirth were conflicting with one meta-analysis which treated this outcome as a dichotomous variable (Analysis 1.12) demonstrating no significant between group differences and another meta-analysis which used interval level data (Analysis 1.11) finding a significant effect of early SSC. Moore

2005 also found that SSC and the mother's nipple protractility contributed equally to the variance in infant IBFAT scores.The mother's nipple protractility was important in relation to the infant's ability to establish competent suckling. Dewey 2003 reported that suboptimal breastfeeding behavior during the first 24 hours postbirth was associated with the mother's flat or inverted nipples (RR 1.56). These infants were also 2.6 times more likely to have excessive weight loss.

Timing of when this outcome is measured may be critical because most healthy full term infants spontaneously grasp the nipple and begin to suckle by approximately 55 minutes postbirth. During the first 30 minutes, they may only lick the nipple. Widstrom 2011 found that some infants may take up to 45 minutes to latch after crawling towards and reaching the nipple and recommended that this process should not be disturbed or forced. Also, the intervention will be more successful if a clinician reassures the mother that healthy full term babies are able to crawl to the breast and begin to nurse on their own without assistance when they are ready. After the first two hours postbirth, infants often become sleepy and difficult to arouse.

Babies breastfed more successfully during SSC immediately postbirth than if they were held swaddled in blankets, probably because of the extra tactile, odor, and thermal cues provided by SSC, but this result did not translate into significantly more mothers breastfeeding at one to four months postbirth in two studies by the same investigator (Carfoot 2004; Carfoot 2005). Carfoot 2005 stated that barriers to long-term breastfeeding, such as returning to work, and breastfeeding problems contributed to the minimal effect that early SSC had on this outcome. Early SSC appears to have less of an effect on breastfeeding exclusivity or duration in studies where control infants are held swaddled by their mothers or placed swaddled or clothed on their mother's naked chest and given the opportunity to breastfeed soon after birth than in studies where control infants are separated from their mothers for 12 to 24 hours immediately postbirth. Given the strong evidence of the negative impact of early mother-infant separation, it is noteworthy that in some hospitals usual care still includes this practice for healthy full term newborns (Mizuno 2004).

Moore 2005 suggested that barriers to long-term breastfeeding that exist in the United States, especially the customary absence of, or very brief, paid maternity leave, attenuated the effectiveness of early SSC on breastfeeding status day 28 to one month postbirth (Analysis 1.8). The mothers in Punthmatharith 2001 delivered in a Baby Friendly Hospital in Thailand with 24-hour rooming-in. Control infants were cup fed if they needed supplementation. In addition, most of the SSC took place in extremely warm, un-air conditioned eight-bed postpartum rooms with frequent visitors so that contextual issues, such as body warmth and modesty, may have changed SSC desirability and also effectiveness.

Such factors as room temperature, lack of privacy, modesty, overcrowding, supplemental bottle or pacifier use, and 24-hour rooming-in may play a role in the effectiveness of SSC. Early SSC may not have as strong an effect on long-term breastfeeding in countries with a widespread bottle feeding culture compared to countries with cultures that are supportive of breastfeeding. In the studies by Carfoot 2004, Carfoot 2005, and Moore 2005, mothers in the control group received extra assistance with breastfeeding, which is not always available with usual hospital care. In Moore 2005, the investigator was an experienced lactation consultant who assisted mothers in both groups with initiating breastfeeding. In Carfoot 2005, the midwife usually provided breastfeeding assistance, but if she was unavailable, the research assistant often provided help with breastfeeding. More definitive results might have been obtained if the control groups received only usual hospital care.

Infant physiological/behavioral outcomes—The between-group differences in SCRIP scores and maintenance of physiological parameters in late preterm infants is certainly clinically significant, especially given the fact that SSC was compared with a servo-controlled incubator. The clinical significance of some of the other physiological outcomes for healthy full term infants is debatable. Full term infants in the SSC group were less than one degree warmer than control infants. Their heart rate was three BPM slower and their respiratory rate was three breaths less per minute, on average. However, their blood glucose was 10.56 mg/ dL higher, a significant finding.The results suggest that early SSC is a safe intervention for healthy infants and that it may increase cardio-respiratory stability, thermal stability, and blood glucose in late preterm infants. Lagercrantz 1986 and Lagercrantz 1996 found that newborn infants experience a catecholamine surge after vaginal birth, caused by compression of the fetal head and intermittent hypoxia during contractions. This response is felt to aid in adaptation to the extrauterine environment immediately postbirth by causing an increase in infant level of alertness, lung compliance, blood glucose, body temperature, and shunting of blood to the vital organs. However, this response may become maladaptive if allowed to continue.These findings correlate accurately with findings predicted from mammalian research on separation in the newborn period. The neurobehavioral stabilization achieved in SSC correlates in mammalian studies with a parasympathetically mediated allostasis, the purpose of which is growth and development. The stabilization achieved in the separated state is mediated by a sympathetically driven defense program, whose purpose is primarily to survive the period of separation. In so far as the differences observed corroborate the findings from mammalian research, they can be considered clinically significant.

The large between-group difference in the amount of crying is certainly clinically significant. Anderson 1989 proposed an evidence-based rationale that maternal-infant separation is associated with excessive infant crying and can be harmful because crying re-establishes portions of the fetal circulation. Each cry cycle causes a bolus of desaturated venous blood to shunt through the foramen ovale into the systemic circulation instead of the lungs, creating hypoxemia. This may result in delayed closure of the foramen ovale or explain the approximately 20% incidence in apparently normal adults of a permanently patent foramen ovale (estimates in numerous recent studies range from 15% to 35% (Del Sette 1998). Anderson 1989 further proposed that crying wastes calories meant for growth, and causes increased and fluctuating cerebral blood flow, cerebral blood flow velocity, and intracranial pressure, thereby increasing the risk of intraventricular hemorrhage in preterm infants. Consequences for healthy full term infants are unknown, but may be similar and correlated with gestational age.

Maternal bonding/attachment: The results of this analysis indicate that SSC may affect maternal attachment behaviors, although the results are mixed. A dose-response relationship may exist as well.

Bystrova 2003 found significant between group differences on two of the eight subscales of the PCERA at 12 months postbirth. The effects of rooming-in on these outcomes did not compensate for a short (120 minutes) period of separation.

These findings would make sense from the perspective of programming (Lucas 2005) and early evolution, where human mothers would be expected to form a rapid attachment to their infants to protect them from predators and to provide the high level of parental care necessary for such physiologically immature newborns. However, it is important to document how many infants in the SSC group breastfed and how effectively they nursed. Breastfeeding during SSC stimulates the secretion of hormones such as oxytocin that promote maternal attachment and prolactin which promotes lactation and, at least in rodents,

maternal behavior. Breastfeeding has been considered an integral part of the intervention in Kangaroo Mother Care research in low- and middle-income countries. In this review, breastfeeding has been considered an outcome and SSC the habitat that elicits this outcome. However, mothers would logically nurse their infants soon after birth in early human evolution. Early and effective breastfeeding while in SSC may increase the strength of this intervention with respect to maternal attachment behaviors.

Overall completeness and applicability of evidence

The available evidence does address the review question, but seldom abides by any clear definition of acceptable public health breastfeeding outcomes. Only Anderson 2003; Moore 2005; Punthmatharith 2001; and Shiau 1997 used breastfeeding status (Labbok 1990) to measure the degree of breastfeeding exclusivity. In all the other studies, breastfeeding was considered a dichotomous variable. The infant was either breastfeeding (yes/no) or exclusively breastfeeding (yes/no). Further, the actual intervention in terms of timing and duration of SSC was highly variable, and at times very short. Despite this, the evidence is fairly consistent in supporting the effect of SSC in so far as the findings are numerous and pooled findings were consistently in favor of SSC and show moderate effects. However, for many outcomes findings were from individual studies: the variety of outcomes measured and the lack of consistency in the way outcomes were measured meant that meta-analysis was not appropriate.

The high levels of heterogeneity between studies could possibly reflect bias with selective outcome reporting, with data reported on the basis of post-hoc observations rather than predefined public health outcomes. Another possible source of bias concerns the quality of breastfeeding support provided, and whether this was controlled for adequately between groups. In some instances, co-interventions were added to SSC that make it difficult to disentangle the effects of SSC from the other interventions.

The variability in outcomes reported, instruments used, context, and timing made it difficult to combine many of the attachment outcomes for meta-analysis. Because of these methodological limitations, the overall quality of the evidence is again considered moderate.

Quality of the evidence

The presently available evidence has a number of limitations.

(1) Design limitations—All studies were randomized controlled trials. However, the methodological quality of trials was mixed. Overall, the quality of reporting on study methods was poor. For the majority of trials we did not have sufficient information on the methods used to carry out randomization to allow us to assess whether findings were at high risk of bias. A particular problem in all of the included studies was the lack of blinding. SSC cannot be implemented masked, but the assessment of physiologic changes or outcomes can often be carried out by individuals masked to allocation but overall it is very difficult to judge the impact of lack of blinding or only partial blinding on findings. It is possible that differences in the care women received in SSC and control groups were not confined to whether or not they had early SSC. In some studies the staff providing care to the two groups were different, and in these cases it is possible that the overall care experience for women in different arms of trials was not the same, and it may be that aspects of care other than, or in addition to, SSC led to reported differences between groups. This may have been compounded by the fact that in some studies the same staff delivering interventions also measured outcomes. Outcomes such as observed maternal and infant behavior may have been susceptible to detection bias. The impact of lack of blinding may have been less for some of the outcomes measured, for example, some infant physiological outcomes however,

even outcomes such as infant temperature may be affected by bias in staff collecting outcome data.

(2) Outcome variability—Meta-analysis was limited in this review, due to the numerous outcomes and the limited number of randomized trials that could be included for each outcome. Although many of the studies measured broadly similar outcomes, the outcomes were too dissimilar to be included in a meta-analysis. In some studies, means were reported without standard deviations, or exact P values, or both. The context, the instruments used, and the timing of the measurement of attachment and temperature outcomes varied greatly among studies. Breastfeeding was measured as a dichotomous variable in some studies or as an interval level measure of breastfeeding exclusivity in four. Modality for measurement of temperature outcomes varied between studies. These contextual and measurement differences should be noted when considering the results of the review.

Potential biases in the review process

We are aware that the review process may be affected by bias; and we attempted to minimize bias in a number of ways. At least two review authors independently assessed study eligibility, carried out data extraction, and assessed risk of bias. However, some aspects of the review process involve subjective judgements: assessing risk of bias in included studies, for example, is not an exact science, and it is possible that a different review team may have reached different conclusions about the quality of the evidence. We have attempted to explain our decisions regarding study quality in the 'Risk of bias' tables. We have also provided details about the participants and interventions in individual studies and we would encourage readers to interpret results in the light of the information set out in the Characteristics of included studies tables.

Agreements and disagreements with other studies or reviews

The findings are in general agreement with results from other studies mentioned in this review notably Bramson 2010. This large hospital-based study (n = 21,842) demonstrated a clear dose-response effect on exclusive breastfeeding at hospital discharge. The data from this review, although suggestive, are inadequate to demonstrate a dose-response effect. Although the modality and timing of measurement of infant temperature varied between studies, this review found minimal increases in temperature with SSC although the results were often not statistically significant. These results support those obtained Mori 2010 who found a mean increase of 0.22 degrees C. in a meta-analysis of 21 studies of infant temperature pre SSC compared with during the intervention. Mori 2010 found an increase in infant heart rate of 2.04 BPM in a meta-analysis of 12 studies of preterm infants pre versus during SSC. The process of transferring a preterm infant from a radiant warmer or isolette to SSC and back again can be somewhat stressful and may account for these findings. The length of SSC in some of the included studies was very short, 15 minutes in one study, 30 minutes in another. This review found a decrease in infant heart rate of 3.05 in between group comparisons of early SSC with usual care. However, the findings were not clinically significant. We assess the methodological quality of the evidence as moderate because these studies have the same limitations as those with breastfeeding outcomes; small samples, varied contexts and heterogenous outcomes.

AUTHORS' CONCLUSIONS

Implications for practice

Breastfeeding outcomes—this review does provide evidence to support current practices as recommended by the UNICEF endorsed Baby Friendly Hospital Initiative, in which SSC is encouraged for the first hour after birth. There is, however, inadequate

evidence with respect to details such as timing of initiation, dose of skin-to-skin contact (SSC) and technique. This review does not address subsequent ongoing SSC as an intervention to support breastfeeding. It is, however, noteworthy that an intervention practiced for a short time at birth should have measurable breastfeeding effects one to four months postbirth.

Infant outcomes—the significant increase in blood glucose, and maintenance of infant temperature in the neutral thermal range are both clinically important, and lend support to current American Academy of Pediatrics recommendations for the use of SSC in the first hour after birth (American Academy of Pediatrics 2005). Clearly there is a relationship between improved breastfeeding and higher blood glucose. In terms of evolutionary biology, and mammalian studies, this higher value may in fact be the norm, and a lowering may reflect the autonomic nervous system evoking a separation distress response, consuming excess calories (Christensson 1995). This is further supported by the significantly increased crying seen in separation versus SSC (three studies). The decreased crying is in itself clinically important for other reasons as described in the background (Ludington-Hoe 2002). Late-preterm infants are at increased risk for hypoglycemia and hypothermia which can worsen any symptoms of respiratory distress (Raju 2006).

The SCRIP score attempts to provide a composite measure of cardiorespiratory stability. Only one study reported this, with significant benefit in favor of SSC, providing further support for the use of early SSC. While differences in particular cardiorespiratory outcomes are evident, these are open to different interpretations, and mean little without a sense of trend and direction in terms of stabilization and physiological self-regulation.

Although a number of the infant physiological outcomes, (except SCRIP scores, blood glucose, infant crying, and maintenance of physiological parameters), demonstrated little or no clinically significant differences with or without SSC, no negative short- or long-term effects were found. Based on the available evidence, SSC appears to have some clinical benefit, especially for temperature and cardio-respiratory stability in late preterm infants.

Attachment outcomes—despite the variability in dose and timing of the intervention, there is at least a small effect on several dimensions of maternal neurobehavior in relation to her infant. This is consistent with evolutionary biology theory, in which infant survival depended on an immediate care-giving imperative. There is no benefit shown in any study from infants being separated.

The main results of the meta-analysis, and from the single studies, indicate that SSC appears to have a positive effect on breastfeeding one to four months postbirth, blood glucose, infant crying and on infant temperature stability. These benefits of early SSC can be discussed with mothers and their partners during prenatal visits and mothers can be encouraged to incorporate early SSC into their birth plans.The timing of the intervention may be important, because most infants are very alert in the first two hours postbirth and, if undisturbed and unmedicated, will self-attach to the nipple, and do so correctly, at approximately 55 minutes postbirth. However, Widstrom 2011 noted that it may take some infants up to 45 minutes to latch after they reach the mother’s nipple.The temperature of a healthy newly delivered infant will remain in a safe range, provided ventral-to-ventral SSC is uninterrupted; the infant is thoroughly dried and covered across the back with a prewarmed blanket; and the head is covered with a dry cap that is replaced if it becomes damp. These practices need to be incorporated into hospital routines along with the stipulation that mothers and newborn infants should not be left alone and unattended by medical personnel in the delivery or recovery room during this transitional period (Dageville 2008).

Implications for research

Interpreting the findings of this review was hampered by the large number of outcomes reported in included studies and inconsistency in the way outcomes were measured. We have reported results for 31 pre-specified outcomes, however, the included studies reported many other outcomes, measured in different ways, reported at different (and sometimes multiple) time points. This lack of consistency was a particular problem for outcomes relating to mother and infant behavior and mother-infant interaction.

Breastfeeding outcomes—suggestions for improvement of clinical trials examining early skin-to-skin contact (SSC) and breastfeeding outcomes include the following. The mother's prenatal breastfeeding intention (how long she planned to nurse her infant) was not controlled in any study except Punthmatharith 2001 and Moore 2005. Only Carfoot 2004; Carfoot 2005; Gouchon 2010; Khadivzadeh 2008 and Moore 2005 evaluated the success of the first breastfeeding in both the SSC and control groups using a published breastfeeding observation instrument, the IBFAT. A valid measure of effective suckling at a single feeding remains elusive (Riordan 1997) and is needed to identify problems in time to minimize breastfeeding attrition; this would be a major contribution to the field. It remains difficult to disentangle the effects of early SSC from the effects of assistance provided by an experienced nurse with the first breastfeeding. The protractility of the mother's nipples is a potential confounding factor that could influence breastfeeding outcomes Dewey 2003 and should be measured in future studies that evaluate breastfeeding and infant suckling patterns. The use of SSC to facilitate breastfeeding for mothers who are having breastfeeding difficulties requires further evaluation. Future research should use standardized public health measures, such as the Index of Breastfeeding Status (IBS) rather than, or in addition to, measuring breastfeeding as a dichotomous variable.

Infant outcomes—rigorous and validated composite measures of physiological benefit are not yet available in the literature. Until better and validated scores or measures for stabilization are presented, we recommend the use of the SCRIP score as a primary outcome measure in studies on early SSC. There is also a clear need for dose-response studies: the intervention of SSC is applied in small doses in many studies. As described in the introduction, in animal studies, the dose of separation is accurately measured and correlated with harmful effects (Poletto 2006; Ziabreva 2003). Further, it is possible that the physiological benefit demonstrated is only as lasting as the actual intervention; therefore, clinical benefit may require prolonged or continuous use of SSC.

Attachment outcomes—improvement is needed in examining maternal attachment behaviors. These studies are all weakened by the lack of consistency in the measurement of these variables. Each research team appeared to have its own ideas about how to operationally define attachment behavior. More recent studies (Anderson 2003; Bystrova 2003) have begun to use more rigorously validated instruments such as the NCAST feeding and teaching scales and the PCERA. No information was provided in the research reports about how many infants successfully breastfed in either group using a validated measurement instrument such as the IBFAT.

Future investigations are recommended because the methodological quality of the included studies is marginally adequate, the characteristics of the SSC and control conditions are diverse, and many outcome measures are difficult to combine. Only four studies (Anderson 2003; Bergman 2004; Chwo 1999; Syfrett 1996) examined the effects of early SSC on late preterm infants who were judged healthy enough to remain on the postpartum ward. The effects of this intervention may be different in this more vulnerable population, and more research is definitely indicated. More research needs to be conducted on the effects of early

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SSC on mothers who deliver by cesarean birth. To facilitate meta-analysis of the data, future research in this area should involve outcome measures consistent with the best measures used in previous studies or measures developed recently to increase methodological rigor (Anderson 2004b; Labbok 1990). The CONSORT guidelines (Moher 2001; Moher 2010) should be used to document the flow of participants through all clinical trials. Studies should make explicit SSC initiation time, frequency and duration to investigate a possible dose-response relationship.

To improve the methodological quality and reporting in similar clinical trials would be relatively easy. Investigators can provide more details in research reports regarding the method and timing of random assignment, allocation concealment scheme, measures used to control for selection bias, context, timing, and modality of outcome measurements, and means and standard deviations for the interval or ratio level outcome variables examined. However, control for provider and patient performance bias may continue to be problematic, because Institutional Review Boards now require investigators to disclose the purpose of their study to potential participants so they can be informed when they consent to random assignment. Labor and delivery room staff often ask for group assignment of women before delivery so that they will know how to manage the infant immediately postbirth. Outcome assessors should be blinded, however, if at all possible (Polit 2011). Speaking more generally, recommendations by Thomson 1984 provide guidelines for well-controlled clinical trials that remain important to this day.

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Appendix 1: The International Network for Kangaroo Mother Care

The International Network maintains a bibliography of all the research articles published on KangarooMother Care. The bibliography is available from Dr Susan Ludington - Susan.ludington@.case.edu

Appendix 2: Methods used to assess trials included in previous versions of this review

Each study that we identified as a result of the search strategy was evaluated independently for inclusion in the review by two review authors. We rejected trials without a concurrent

control group (e.g. those with historical controls). We included relatively high quality quasi-randomized studies in the review. If the assignment to groups appeared to create equivalent groups, then the study was included even if a truly random process was not used for group assignment. For example, if women were alternately assigned to treatment and control groups and there was no reason to think that this should result in nonequivalent groups, that study was included. On the other hand, if assignment to groups was based on woman or provider preference, the study was excluded. Studies conducted by each of the three authors were reviewed for inclusion by the other two authors and a consensus was reached regarding inclusion of these studies in the review. Methods used for generation of the randomization sequence were described for each trial.

Each identified trial was assessed for methodological quality with respect to (1) selection bias, (2) attrition bias, and (3) performance bias. We assigned a quality score for each trial, using the following criteria.

(1) Selection bias (allocation concealment)

- **A.** Adequate concealment of allocation: centralized randomization, sequentially-numbered, sealed opaque envelopes, computerized minimization technique;
- **B.** unclear whether adequate concealment of allocation: sealed envelopes but not sequentially numbered or opaque, a trial in which description suggests adequate concealment but other features suspicious, e.g. markedly different treatment and control groups, stated random but unable to obtain further details;
- **C.** inadequate concealment of allocation: any allocation procedure transparent before assignment, such as open list of random-number tables, use of case record numbers, dates of birth or days of the week.

(2) Attrition bias

We assessed completeness to follow up using the following criteria: complete follow up of all study participants/reasons given for attrition/NSD between participants who terminated their involvement in the study and those who remained enrolled (yes/no/unclear).

(3) Performance bias

We assessed blinding using the following criteria:

- **A.** blinding of participants (yes/no/unclear);
- **B.** blinding of caregiver (yes/no/unclear);
- **C.** blinding of outcome assessment (yes/no/unclear).

We designed a form to extract data. Several review authors extracted data and assessed the methodological quality of each study independently and compared results. Disagreements about study inclusion and methodological quality were resolved through discussion until a consensus was reached. We reviewed the inclusion criteria and therapeutic interventions for each trial to see how they differed between trials. We examined the outcomes in each trial to see how comparable they were between studies. We contacted investigators (if possible) to obtain information about any missing data. For categorical data, we made 2 × 2 tables from each trial for each important outcome, and used odds ratios with 95% CI in the meta-analysis. For continuous variables, we calculated weighted mean differences with 95% CI. We used standardized mean differences to combine trials that used different scales to measure the same outcome. We used fixed-effect meta-analysis for combining data in the

absence of significant heterogeneity. We used random-effects meta-analysis for trials with significant heterogeneity identified by using the I^2 statistic. We were unable to explore heterogeneity using subgroup analysis or sensitivity analysis because there were not enough clinical trials included for the heterogeneous outcomes.

CHARACTERISTICS OF STUDIES

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

Anderson 2003

Methods	Randomized controlled trial (computerized minimization technique)
Participants	91 healthy preterm infants 32-36 weeks' gestation and their mothers. Only data from the 31 infants on the postpartum unit were included in the analysis; the 60 NICU infants were excluded. Mean GA of the included infants was 35.6 weeks. There were no significant between group differences in socio- demographic or medical characteristics in this sub-group of infants except 5-min Apgar scores. The mean 5-min Apgar score was 9.0 in the SSC group and 8.5 in the control group
Interventions	1) SSC group = diaper clad infants placed prone and SSC between their mother's breasts as soon as possible for as long as possible postbirth. Along with SSC, mothers also held their infants wrapped in blankets. 2) Control group = infants kept warm in incubators, warmer beds, bassinets or held wrapped in blankets Process outcomes include mean % contact time during hours 0-48 spent in SSC or wrapped holding by mother, father or others and mean % noncontact time (no hold) hours 0-48 postbirth
Outcomes	Mother preterm infant interaction (MPI) measured by mean scores on the Nursing Child Assessment Satellite Training Program (NCAST) Feeding and Teaching scales at 6, 12 and 18 months postbirth (reported in Chiu 2009 using the same data set). Breastfeeding status (exclusivity) at hospital discharge, 6 weeks, 3, 6, 12 and 18 months postbirth (reported in Hake-Brooks 2008 using the same data set)
Notes	Study was done in the USA at 2 different hospitals 1 on Cleveland, Ohio and the other in Richland, Washington. Participants were mixed parity

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomization was by a computerized minimization program.
Allocation concealment (selection bias)	Low risk	Sealed, sequentially numbered opaque envelopes containing the next group assignment were used for the first 10 participants to prevent selection bias. The rest of the participants were assigned to groups using the minimization technique. Informed consent was obtained during early labor Mother-infant dyads were randomly assigned to groups immediately postbirth
Blinding (performance bias and detection bias) All outcomes	Low risk	The research staff involved in evaluating MPI data at 6,12 and 18 months postbirth using a videotaped infant feeding and teaching session were unaware of the mother's group assignment The nurse researcher who collected Index of Breastfeeding Status (IBS) scores was blind to participant group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	At 6 months postbirth, 2/15 infants were missing from the SSC group and 2/14 from the control group; at 12 months postbirth 2/15 infants were missing from the SSC group and 2/14 from the control group, at 18 months postbirth 3/15 infants were missing from the SSC group and 2/14 from the control group. At 3 and 6 months postbirth 1/11 breastfeeding SSC infants had missing data on the IBS. At 6 weeks postbirth 1/12 breastfeeding control infants had data missing on the IBS, at 3 months postbirth 3/12 infants had missing data
Selective reporting (reporting bias)	Low risk	Numerical data (M,SD) were reported by group assignment for the NCAST feeding scales at 6 and 12 months, and the NCAST teaching scales at 6, 12 and 18 months postbirth Numerical data were reported for the IBS N,n,% in each breastfeeding category at hospital discharge, 6 weeks postbirth and at 3,6,12 and 18 months postbirth

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Other bias	Unclear risk	In the SSC group the nurse researchers provided breastfeeding assistance with the initial feedings. The control mothers received standard hospital care. Lactation consultants provided breastfeeding assistance if the mother requested help and if they were available

Bergman 2004

Methods	Randomized controlled trial (computerized minimization technique)
Participants	35 healthy late preterm infants and their mothers. Mean GA SSC group 34.2 weeks, control group 35.3 weeks
Interventions	All infants had a brief period of SSC immediately postbirth. 1) SSC group = after the 5-min Apgar the naked infant was secured to their mother's chest by a towel. A shirt with long ties was placed around the mother's waist to secure the baby below. The dyad was transferred to the observation area of the neonatal unit at 60 min postbirth. SSC was continuous for at least 6 hours 2) Control group = after the 5-min Apgar the infant was transferred to an incubator which remained with the mother in the delivery room for 60 min. At 1 hour the infant in the incubator was transferred to the observation area of the neonatal unit
Outcomes	Transfers to NICU, exceeded parameters −temp < 35.5, HR < 100 >180 BPM, Apnea > 20s, O2 sat < 89%, blood glucose < 2.6, SCRIP score during the first 6 hours postbirth, SCRIP score in the 6th hour postbirth
Notes	Study was done with indigent participants in 2 secondary level referral hospitals in Cape Town, South Africa

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"computerized minimisation method". Range of factors taken into account in the minimization process in an attempt to reduce confounding
Allocation concealment (selection bias)	Low risk	Computerized method of allocation following ascertainment of eligibility (5-min Apgar score) by nurse researcher present at delivery or by mobile phone.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Women and staff present during intervention would be aware of allocation but, it is not clear whether this was likely to have had an impact on most of the types of outcomes measured and there was an attempt to standardize other aspects of care. The nurse carrying out randomization was involved in other aspects of care such as breastfeeding instruction. For many outcomes reported (physiological measurements) most were continuously recorded on monitors and unlikely to have been subject to bias. Clinical decisions re admission to NICU could not be standardized
Incomplete outcome data (attrition bias) All outcomes	Low risk	35 randomized.1 woman in the intervention group was excluded postrandomization as she was no longer eligible. The remaining 34 remained available for the primary outcome (NICU admission) and the remaining 31 were followed up for 6 hour measurements. Intention-to-treat analysis for primary outcome
Selective reporting (reporting bias)	Unclear risk	Not apparent, although risk of bias was carried out using published study report
Other bias	Unclear risk	The initial power calculation suggested a sample size of 64 and the investigators planned to recruit 100 women. There were logistical difficulties in recruitment that may have led to selection biases and this may reduce the generalizability of findings. The 2 study groups were of different sizes; this occurred by chance. Difficulties in recruitment led to interim analysis and as results favored the intervention group, the study was discontinued Baseline imbalance: not apparent.

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Bystrova 2003

Methods	Randomized controlled trial (envelope with group assignment)
Participants	176 healthy full term infants and their mothers were divided into 4 treatment groups
Interventions	All infants were immediately placed under a radiant warmer, dried, washed, weighed, given eye prophylaxis and cord care during the first 22 min postbirth. 1) SSC group = 37 babies were placed prone and SSC on mother's bare chest for approximately 90 min and then roomed-in (swaddled or dressed) on the maternity ward and breastfed on demand. 2) Mother's arms group = 40 babies were clothed (swaddled or dressed) and placed prone on their mother's bare chest. for approximately 90 min and then roomed-in on the maternity ward and breastfed on demand. 3) Nursery group = 38 babies were clothed (swaddled or dressed) and taken to the nursery immediately postbirth and remained there while their mothers were on the maternity ward except for breastfeeding 7 times a day. 4) Reunion Group = 38 babies were clothed (swaddled or dressed) and taken to the nursery immediately postbirth, but roomed-in with their mothers on the maternity unit and breastfed on demand
Outcomes	Mean difference in infant axillary, interscapular, thigh temperatures and foot temperature change from 30 to 120 min postbirth (Bystrova 2003). Amount of milk ingested (before and after breastfeeding infant weights), volume of supplemental feedings, number and duration of breastfeedings day 4 postbirth, recovery of infant weight loss day 3-5 postbirth (reported in Bystrova 2007a). Number of breastfeedings, physiological breast engorgement, feeling low/blue days 1-3 postbirth, duration of nearly exclusive breastfeeding (reported in Bystrova 2007b).Maternal breast and axillary temperature, (reported in Bystrova 2007c). Assessment of mother-child interaction at 12 months postbirth using the Parent-Child Early Relational Assessment (PCERA) (reported in Bystrova 2009).
Notes	Study was done in St Petersburg, Russia.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	An experimental 2 factor design (baby's location, apparel) was used. The randomization sequence was blocked for time and parity. Randomization to the 8 treatment combinations occurred in blocks of 8 mothers independent of the other blocks and separated by parity
Allocation concealment (selection bias)	Low risk	Informed consent was obtained during labor. Random assignment occurred immediately after birth. Sealed, numbered, opaque envelopes were opened sequentially. The research report stated that "both the researchers and the recruited women were blind to the task"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	The psychologists who evaluated videotaped mother-child interactions at 12 months postbirth using the PCERA were blind to group assignment. The videotaping was also performed by a psychologist who was blind to group assignment. No information was provided about whether the researchers who evaluated the other outcomes in these research reports were blind to group assignment. The evaluators of some of the outcomes, for example, infant temperatures taken during SSC, could not be blind to group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	176 mothers were randomly assigned to the 4 main treatment groups. 23 mothers were excluded during their stay on the maternity ward for various reasons which were listed in the research report. There were no significant between group differences in background variables between the 23 mothers who were excluded and the 153 who remained in the study. 9 mothers were lost to follow-up at 1 year. Reasons for their exclusion were provided. An additional 20 mother-infant pairs were excluded from the PCERA assessments 12 months postbirth. Reasons for their exclusion were provided
Selective reporting (reporting bias)	Low risk	Numerical data were provided for all outcomes except recovery of infant weight loss day 3-5 postbirth (Bystrova 2007a) however, between the 4 groups, differences were reported to be insignificant. The results of the statistical tests and P values were reported for all outcomes in Bystrova, IBJ, 2007). However, the M, SE was used instead of M, SD for the descriptive statistics. Data for the mean maternal axillary and breast temperatures were plotted on a graph for the 7 time points for data collection in Bystrova 2007c. The SE rather than the SD was used as the measure of dispersion. Data for the infant's foot and axillary temperatures were recorded in Bystrova 2003. Results of the statistical tests for the SSC group compared with the other groups were provided for 2/8 of the PCERA composite variables, child disregulation and irritability and dyadic mutuality and reciprocity. The results for the other composite variables

		were not reported but were stated as insignificant (Bystrova 2009). Additional statistical data was obtained from the researchers
Other bias	Unclear risk	Data were reported using “per protocol” rather than “intention to treat” analysis

Carfoot 2004

Methods	Randomized controlled trial (sealed envelopes).
Participants	26 healthy full term infants > 36 weeks’ gestation and their mothers
Interventions	1) SSC group = mothers given infants to hold prone between their breasts and covered with a warm blanket as soon as possible postbirth. Midwives assisted with the 1st breastfeeding. 2) Control group = babies dried, wrapped in a towel and handed to mom or dad. Midwives assisted with the 1st breastfeeding
Outcomes	Success of the 1st breastfeeding (BAT score 8-12), type of feeding at 4 months postbirth (exclusive breastfeeding, mixed feedings, artificial feedings)
Notes	Study was done in Cheshire, UK.

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomization list.
Allocation concealment (selection bias)	Unclear risk	Sequence of sealed envelopes (not clear if opaque) and not clear whether the envelopes were numbered and opened in sequence.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	There was no blinding in this study. It is possible that the lack of blinding may have affected women’s responses and behavior, that clinical care other than skin to skin contact may also have differed by randomization groups and outcome assessors would be aware of allocation during the first feed (observed) and this may have affected their observations
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Pilot study including 26 mother infant pairs looking at study feasibility (data on review outcomes not reported).
Selective reporting (reporting bias)	Unclear risk	Assessment from published study report only.
Other bias	Low risk	Other bias not apparent.

Carfoot 2005

Methods	Randomized controlled trial (sequence of sealed envelopes containing next allocation from a computer-generated randomization list)
Participants	204 healthy full term infants > 36 weeks’ gestation and their mothers
Interventions	1) SSC group = mothers given naked infants to hold prone between their breasts and covered with a warm blanket as soon as possible postbirth. Midwives assisted with the 1st breastfeeding. 2) Control group = babies dried, wrapped in a towel and handed to mom or dad. Midwives assisted with the 1st breastfeeding
Outcomes	Success of the 1st breastfeeding (BAT score 8-12), success of a subsequent breastfeeding, mean temperature 1 hour postbirth, maternal satisfaction with care, preference for same postdelivery care in the future, type of feeding at 4 months (exclusive, partial breast, formula feeding)

Notes	Study was done in Cheshire, UK.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomization list.
Allocation concealment (selection bias)	Unclear risk	Sequence of sealed envelopes (not clear if opaque) and not clear whether the envelopes were numbered and opened in sequence.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	There was no blinding in this study. It is possible that the lack of blinding may have affected women's responses and behavior, that clinical care other than skin to skin contact may also have differed by randomization groups and outcome assessors would be aware of allocation during the first feed (observed) and this may have affected their observations
Incomplete outcome data (attrition bias) All outcomes	Low risk	325 women initially approached and 244 agreed to take part (75%). 204 women randomized data and 197 observed at 1st data collection point (with analysis according to randomization group) and data available for 197 women at 4 month follow-up
Selective reporting (reporting bias)	Unclear risk	Assessment from published study report only.
Other bias	Low risk	Other bias not apparent. Baseline characteristics appeared similar.

Carlsson 1978

Methods	Randomized controlled trial.
Participants	62 healthy, full term infants. The mothers were randomized into 1 of 3 groups before delivery
Interventions	1) Extended contact-new routine group = kept their naked infants for 1 hour immediately postbirth, mothers cared for infants. 2) Extended contact-old routine = kept their naked infants immediately postbirth for 1 hour, staff cared for infants. 3) Limited contact-old routine group = held their infants for 5min immediately postbirth, staff cared for infants
Outcomes	Observation of maternal behavior (contact behavior and behavior not implying contact with baby) by videotape during breastfeeding on day 2 and 4 postbirth
Notes	Study was done with middle-income primipara in Sweden.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method used to generate the randomization sequence were not described. The study involved "randomly selected" women who were "randomly assigned" to 1 of the 3 study groups
Allocation concealment (selection bias)	Unclear risk	The method used to conceal group allocation at the point of randomization was not described.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	It was stated that participants "were unaware of the purposes of the study". However, presumably women would be aware that they were being observed when they were feeding their babies. Clinical staff caring for women may have been aware of early contact and it was not clear whether the staff carrying out observations were aware of group allocation
Incomplete outcome data	Unclear risk	62 women were randomized. 50 were available for follow up (81%) and full observational data were available for 46 (74%). Loss appeared to be reasonably balanced across groups.

(attrition bias) All outcomes		12/62 women lost to follow up and there were further missing data
Selective reporting (reporting bias)	Unclear risk	Although observation methods were described it is not clear what the main study outcome means (frequency of mother/infant contact/not contact during breast or bottle feeding) . The frequencies were presented as means with SEs. The average number of observation points during a feed would be approximately 100, but the mean figures are closer to 200 so it seems more than 1 behavior was noted in each observation period. However, it was stated that if the same behavior (which may have been a contact behavior) occurred more than once in any observation period it was only recorded once. It is possible therefore that continuous high contact behavior was rated as being of lower contact value than rapidly changing behaviors Several results were not presented according to randomization group and results were difficult to interpret.
Other bias	Unclear risk	Baseline imbalance not apparent. Other: Results were difficult to interpret and 2 groups that received different treatments were merged for some results but not others

Christensson 1992

Methods	Randomized controlled trial.
Participants	50 full term infants and their mothers randomized after the delivery
Interventions	a) 80 min of SSC with the mother, b) 80 min in a cot.
Outcomes	Axillary, thigh, and interscapular temperatures. Duration of crying. Blood glucose, base excess, respiratory rate, HR after 90 min
Notes	Study was done in Madrid, Spain.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Methods to generate the allocation sequence were not described.
Allocation concealment (selection bias)	Unclear risk	Very little information on study methods. Described as "allocated randomly"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Women would be aware of group allocation. It is not likely that this affected outcomes such as temperature but it may have affected baby behavior (it appeared that mothers in the cot group were advised not to pick their babies up even if the baby was crying) Clinical staff and observers were not blind to group allocation. It is difficult to know whether this had any effect on temperature recording. The observation of crying may have been affected by knowledge of group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	It appeared that all women randomized were followed up, randomization seemed to occur before delivery and it appeared that no women were excluded following randomization (as they became ineligible due to complications in labor, etc)
Selective reporting (reporting bias)	Unclear risk	Difficult to assess without access to study protocol. Multiple observation points means that results for temperature are difficult to interpret. Results for crying are also difficult to interpret as mothers in the cot group were discouraged from picking up their babies during the observation period even if they were crying.
Other bias	Unclear risk	No power calculations reported. Baseline characteristics in the 2 groups appeared similar. Very little information was provided on study methods

Christensson 1995

Methods	Randomized controlled trial.
Participants	44 full term infants and their mothers immediately postbirth
Interventions	Group a) 76-85 min of SSC with the mother, b) infant in a cot for 76-85 min, c) infant in a cot for 35 min then SSC for 45 min
Outcomes	Duration of crying, axillary temperature 90 min postbirth.
Notes	Study was done in Madrid, Spain.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described "allocated randomly".
Allocation concealment (selection bias)	Unclear risk	Not described (allocation was before delivery but women and staff were not informed of the allocation until after delivery)
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Participants and staff were not blinded. It is not clear whether knowledge of allocation would have affected maternal behavior and responses (for those in the "cot" group, women were asked not to move the baby). Staff providing care may have altered other aspects of care. Outcome assessors were blinded (blind assessment of audiotapes - although presumably they would also hear the mother and other noise so may have been able to ascertain group assignment)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Due to mechanical failures there were missing data for the primary outcome.44 women were randomized and audiotape data were available for 33 (75%)
Selective reporting (reporting bias)	Unclear risk	Assessed from published study report.
Other bias	Unclear risk	Describe any baseline in balance: Not apparent, but sample size was small so imbalances between groups although not statistically significant may have been important (e.g. cot group 7/14 primips, s to s 5/15 primips)

Chwo 1999

Methods	Randomized controlled trial (computerized minimization technique)
Participants	34 healthy late preterm infants 34-36 weeks' gestation and their mothers
Interventions	1) SSC group = SSC and on cue self-regulatory feedings during 6 1-hour feeding periods beginning M = 21 hours postbirth. The infant, in a small diaper, was placed on the ventral surface of their mother's torso. 2) Control group = infants held wrapped in blankets during 6 1-hour feeding periods beginning M = 23 hours postbirth
Outcomes	Infant body weight change day 14 and 28 postbirth, length of stay in the hospital, tympanic temperature change and variability, behavioral state inactive awake, drowsy, crying during feedings
Notes	Study was done in a teaching hospital near Taipei, Taiwan.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated minimization process with stratification for gender, birthweight, mode of delivery and parity

Allocation concealment (selection bias)	Low risk	Computerised allocation. Not clear how the process was carried out at the point of group allocation
Blinding (performance bias and detection bias) All outcomes	High risk	Women in both the control and intervention did not receive usual care and would likely to have been aware of group assignment. Staff providing care and breastfeeding advice also collected outcome data. This may have had an impact on some outcomes - particularly the observation of infant behavior
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	34 women followed up in hospital by day 14 23 infants available to follow up and 26 on day 28
Selective reporting (reporting bias)	Unclear risk	Assessment carried out using published study report only.
Other bias	Unclear risk	The intervention may not be generalizable to other babies in the same study setting. The intervention was described as KC but infants were not in SSC until 4 hours after the birth, then contact was for 1 hour at 4-hourly intervals at specified feeding times for 6 feeds. Control infants were offered the same contact but babies were in blankets, both groups were given advice and support from the observer. It was not clear how much time infants spent feeding during the observation period Groups were reported to be similar at baseline.

Craig 1982

Methods	Randomized controlled trial (sealed envelopes prepared using a table of random numbers by gender)
Participants	60 healthy full term infants and their mothers.
Interventions	1) Control group = mothers held their wrapped infants for 3 min then contact at feedings every 4 hours. 2) Early SSC group = infants were placed in SSC on their mother's chests for 54 min then contact at feedings every 4 hours
Outcomes	1) Neonatal Perception Inventory. 2) Interview of mother's experiences during pregnancy, delivery, 1st postpartum month. 3) Questions about infant behavior during a home visit at 1 month postbirth
Notes	Study was done with low-income primapara in the USA.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Table of random numbers.
Allocation concealment (selection bias)	Unclear risk	"sealed envelopes" (not clear if opaque and used in sequential order or if any envelopes were discarded) "Separate envelopes were prepared for male and female infants to insure a comparable sex distribution in each contact group"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	"Mothers given extra contact were not aware that their care differed from that given to other patients". "Patients were told that the investigators wished to study maternal-infant relationships during the first postpartum month." Staff caring for women would be aware of group assignment during the early postpartum period. The principal investigator recruited mothers and collected most of the outcome data. An attempt was made to check whether the data collected by this investigator and another researcher; there was no evidence of bias.
Incomplete outcome data (attrition bias) All outcomes	High risk	There was serious attrition and missing data at some data collection points. 60 women were recruited; outcome data at 1 month were available for 49 (81.7%). Loss was reported to be balanced between groups. 24 of the sample (40%) completed a behavioral record.

Selective reporting (reporting bias)	Unclear risk	Data reported as in introduction, but not clear if other data collected. (Assessment from published paper only.)
Other bias	Unclear risk	Baseline imbalance not apparent. Some results were difficult to interpret. It appeared that mean scores had been calculated from a 4-point category measure

Curry 1982

Methods	Randomized controlled trial (sealed envelopes).
Participants	20 healthy full term infants randomized during the first hour postbirth
Interventions	1) Control group = held their wrapped infants for 36 min during the first hour postbirth. 2) SSC group = held their infants in SSC for 35 min during the first hour postbirth. Both groups had 12 hours of rooming-in during the day
Outcomes	1) 7 maternal attachment behaviors (en face, kiss, hold, encompass, close contact and smile at) measured at 36 hours and 3 months postbirth during breastfeeding. 2) The Tennessee Self Concept measured at 2 months postbirth
Notes	Study was done with well-educated, married, middle-income, Caucasian, breastfeeding primipara in the USA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	In batches of 10, 5 envelopes each contained control or intervention allocations
Allocation concealment (selection bias)	Unclear risk	Dark brown envelopes containing allocations were shuffled and an envelope selected. When 10 envelopes had been used a further 10 were prepared, then 1 of each allocation for last 2 random assignments
Blinding (performance bias and detection bias) All outcomes	Unclear risk	It was stated that mothers were not told the precise reasons for the study, although mothers would be aware of the intervention. The staff taking infant temperatures during the intervention period would be aware of allocation. It was stated that the investigators collecting outcome data at 36 hours and at 3 months was not aware of group, although mothers may have revealed this during interviews
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	56 women were recruited, but at the point of randomization only 20 women remained. Only women delivering while the researcher was on the premises were included. Not clear exactly when randomization occurred
Selective reporting (reporting bias)	Unclear risk	Used observation as main outcome which is difficult to interpret. Results reported as mean occurrence of attachment behaviors, it is not clear whether the same mother could exhibit lots of behaviors. Mean number of behaviors during the same length of observation period appeared considerably less at 3 months follow-up compared with 36 hrs.
Other bias	Unclear risk	Baseline imbalance not clear, small sample size. Less than half of the eligible sample was recruited.

De Chateau 1977

Methods	Randomized controlled trial (open random numbers table).
Participants	62 healthy full term infants and their mothers. Group 1 primiparous mothers and their infants n = 22. Group 2 primiparous mothers and their infants n = 20. Group 3 multiparous mothers and their infants n = 20

Interventions	Group 1: 15-20 min of SSC during the first hour postbirth. The infants were placed on the breast at 10 min postbirth and assisted by the midwives with breastfeeding. Groups 2 and 3 = routine care. The dressed babies were placed in a crib at the mother's bedside or in her bed at 10 min postbirth
Outcomes	Observation of mother's behavior during breastfeeding at 36 hours postbirth. Mother's and infant's behavior at 3 months during free play. Breastfeeding at 3 months, 1 year postbirth. Mother's and infant's behavior during a physical exam and infant development at 12 months
Notes	Study was done with middle-income women in Sweden. 2-arm trial with individual randomization (a 3rd group of women (multips) were also included as a comparison group in 1 of the reports but this group was not randomly allocated and is not included in the analyses)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"Immediately after delivery, the midwife or auxiliary compared the number on the mother's record with a coincidence table… placed in an office outside the delivery room - the primiparous mothers were randomly assigned"
Allocation concealment (selection bias)	High risk	Allocation according to open list after delivery.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	It appeared that women were not aware that the intervention was part of a study, they were told that the observation was to examine mother infant behavior during breastfeeding. Staff providing care would be aware of the allocation. It was stated that observation was carried out by staff who "did not know to which group the mother-infant pairs belonged". It was not clear whether other data were collected by blind observers
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	42 women were randomized. 1 woman from the intervention group was not observed at 36 hours. At 1 year follow up there were 33 remaining; of the 9 lost to follow up, 5 were described as belonging to the "lowest socioeconomic category". There were some further missing data
Selective reporting (reporting bias)	Unclear risk	Data collected by observation difficult to interpret. It appeared that women could contribute different numbers of observations to mean scores.
Other bias	Unclear risk	No baseline imbalance apparent. There was some discrepancy between results in the text and tables in 1 of the papers. Denominators for some outcomes were not clear

Fardig 1980

Methods	Randomized controlled trial (blind drawing of 1 of 3 numbers with replacement)
Participants	51 uncomplicated infants with gestation 38-42 weeks, birthweight of at least 2500 g, normal labor and delivery and normal Apgar score
Interventions	Group 1 infants were suctioned, dried under a radiant heater for 5 min and then placed naked on the mother's bare chest for 25 min. The infant's back was then covered with 2 cotton blankets. Group 2 infants were placed naked directly on the mother's chest for 28 min after the umbilical cord was cut. Group 3 infants were placed under a radiant warmer without being placed on the mother's chest
Outcomes	Skin temperature measured on the infant's left side every 3 min for 45 min. Rectal temperature at 21 and 45 min. Outcomes were the number of infants with skin or rectal temperature in the neutral range at 21 or 45 min
Notes	Study was done in the USA.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Drawing numbers.

Allocation concealment (selection bias)	Unclear risk	Women were "randomly assigned to either the control group or to 1 of the experimental groups by blind drawing of 1 of 3 numbers, with replacement." This suggests that group allocation could be changed by the investigator
Blinding (performance bias and detection bias) All outcomes	High risk	"Both the couple and their caregiver were told how the baby would be handled after delivery." Researcher collecting outcome data would also be aware of group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Describe any loss of participants to follow-up at each data collection point: It appeared that all women were accounted for at each data collection point. It was not clear if there was any missing data
Selective reporting (reporting bias)	Unclear risk	Most outcomes appear to have been reported
Other bias	Unclear risk	Authors reported that there were no significant differences between groups for a number of variables but the data were not shown. It was not clear how many of those eligible were approached to take part or whether recruitment only occurred at particular times (e.g. was the same researcher available at night and weekend) nor whether women who had long labors remained in the study. It is not clear whether women were excluded postrandomization if there was any intrapartum problem

Ferber 2004

Methods	Randomized controlled trial (table of random numbers).
Participants	42 healthy full term infants 38-42 weeks' gestation and their mothers
Interventions	All newborns were placed on mother's chest for 5-10 min, then dried, weighed and dressed. 1) SSC group = infants brought back to mom 15-20 min postbirth, undressed, placed SSC between the mother's breasts and covered with blankets for 60 min. Then the infants were taken to the newborn nursery for 4 hours of observation. 2) Control infants were taken to the newborn nursery, placed under a warmer for 5-10 min, swaddled and laid in a bassinet. They were brought back to their mothers at 5 hours postbirth
Outcomes	Optimal respirations, motor disorganization, visceral stress response, optimal flexed movements, extension movements, facial movements, sleep state, drowsy, fussy and crying states, positive attention signs, negative attention signs
Notes	Study was done in Haifa, Israel with primarily middle- to upper-middle class European, African and Arab mothers

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number tables, the sequence was generated by a different person from the 1 carrying out recruitment and group assignment
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	It was stated that mothers were not aware of group assignment as mothers in each group were kept separate (it was not clear how the study was described to mothers or how consent was obtained). Those staff caring for mothers after the birth would be aware of group assignment and other aspects of care may have differed. It was stated that staff in the newborn nursery (where outcomes were assessed) were blind to group assignment but it was not clear how effective this blinding would be as babies in the control and intervention arms were admitted at different times after birth (and this would be stated on notes). It was stated that outcome assessment was done by blind observers, it was not clear whether attempted blinding was successful

Incomplete outcome data (attrition bias) All outcomes	Low risk	Randomization was carried out at the start of labor. 50 women were randomized and there were 3 postrandomization exclusions from the control group as women became ineligible. It was not clear whether there were any missing data
Selective reporting (reporting bias)	Unclear risk	Assessment from published report.
Other bias	Unclear risk	No significant differences between groups at baseline on the variables measured, although there were a greater proportion of female children in the control group (63% vs 48%) (it is not clear whether this would be likely to be associated with any between group differences) Other: it was not clear whether possible confounding factors were taken into account. The main outcome was infant sleep and movement. This is likely to have been affected by the use of systemic opioid analgesia during labor . It was not clear whether any women had received opioids.

Gouchon 2010

Methods	Randomized controlled trial (a computer-generated a randomization list). Mothers were randomized using opaque, sealed envelopes containing the group allocation
Participants	34 Italian women scheduled for elective cesarean delivery using locoregional anesthesia recruited from the maternity ward of Pinerolo Hospital, Turin, Italy and their healthy full term infants
Interventions	Both groups: physical assessment, Apgar score, infants dried, wrapped in towel, handed to mother for brief contact and transported to neonatal ward in an incubator for inspection, bath, weight. Mother to OB ward Control: baby dressed, taken to mother's room, mother instructed on how to breastfeed but she could choose whether she wanted to breastfeed or not. Mom could keep baby in her bed, in a crib or in the nursery during the 2-hour observation period SSC: same treatment as control, but not dressed; fitted with disposable diaper, cap and wrapped in a warm cloth; placed on mother's skin between breasts, left covered with cloth, bed sheet, and blanket for approximately 2 hours. Mother instructed about how to breastfeed Mean duration of SSC was 82.9 + 45.9 min.
Outcomes	Newborn skin temperature using an infrared ray thermometer on the forehead, effectiveness of the first breastfeeding, min postbirth of the first breastfeeding, exclusive or prevalent breastfeeding at hospital discharge and at 3 months postbirth, infant crying and maternal satisfaction with SSC
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	States mothers were randomized using a computer-generated randomization list
Allocation concealment (selection bias)	Low risk	States opaque, sealed envelopes containing the next allocation were used. The mothers were recruited prenatally, the envelopes were opened by the nurse on the day of surgery
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No information provided. IBFAT scores and infant temperatures were obtained while the infants were held either SSC or dressed so the outcome assessors could not be blind to group assignment for these outcomes
Incomplete outcome data (attrition bias) All outcomes	Low risk	36 women were randomized, 2 women did not receive their assigned intervention and there were no losses to follow-up. Reasons were provided for why the 2 mothers did not receive their allocated intervention. Data were analyzed on 17 mothers in the SSC group and 17 in the control group
Selective reporting (reporting bias)	Low risk	All outcomes were listed under the aims of the study. Numerical results for all outcomes, except infant crying were reported

Other bias	High risk	Infants in both groups were bathed in the neonatal ward before being returned to their mothers. Bathing (as well as SSC) would influence the temperature outcomes. Mothers in both groups were instructed about how to breastfeed

Hales 1977

Methods	Randomized controlled trial.
Participants	60 healthy full term infants randomized into 3 groups.
Interventions	1) Control group = glance at babies immediately after delivery, swaddled infants brought to bedside at 12 hours postbirth, then daytime rooming-in. 2) Early contact group = 45 min of SSC immediately postbirth, daytime rooming-in. 3) Delayed contact group = 45 min of SSC at 12 hours postbirth, daytime rooming-in
Outcomes	Observation of maternal affectionate, proximity maintaining and caretaking behavior at 36 hours postbirth
Notes	Study was done with low-income, urban, breastfeeding primipara in Guatemala city

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Twenty mothers were randomly assigned to each of three groups"
Allocation concealment (selection bias)	Unclear risk	"Twenty mothers were randomly assigned to each of three groups"
Blinding (performance bias and detection bias) All outcomes	Unclear risk	It was not clear whether the lack of blinding would affect maternal or clinician behavior. It was stated that observation of maternal behavior was carried out by an investigator who was not aware of group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	60 mothers were randomized and followed up at 36 hours. It appeared that all women were accounted for, although denominators were not provided in the results tables.
Selective reporting (reporting bias)	Unclear risk	Assessment from brief study report.
Other bias	Unclear risk	There was little information on study methods. It was stated that groups were comparable at baseline although it appeared that groups were not balanced in terms of infant sex; in the 2 intervention groups 14/20 and 13/20 babies were female compared with 7/20 in the control group

Huang 2006

Methods	Randomized controlled trial, states random digit table on page 43
Participants	78 mothers who had spinal anesthesia for cesarean birth and their full term infants who were hypothermic (body temperature < 36.5 °C) postbirth
Interventions	Control group = infants received routine care while under a radiant warmer KC group = infants were placed skin-to-skin between their mother's breasts after the mothers felt comfortable approximately 50 min postcesarean birth and covered with blankets. The duration of KC was 30 min. The infant's rectal temperature was taken after 30 min of KC and then every hour until the temperature was back to normal. If the rectal temperature was < 36.5, the infant was placed under a radiant warmer. The researchers did not state how many KC infants had rectal temperatures < 36.5 at the end of the intervention

Outcomes	The infant's rectal temperature was taken 30 min after KC started or after radiant warmer care. Infant temperature was recorded hourly starting 1 hour until 6 hours postbirth and was plotted on a graph. The number and % of infants in each group who reached normal body temperature after 4 hours was listed
Notes	Study was conducted in Taiwan.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Abstract states "randomized control trial." States random digit table on page 43
Allocation concealment (selection bias)	Unclear risk	No information provided other than random digit table.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	86 mothers agreed to participate in the study but data were analyzed for only 78 infants. 2 mothers withdrew because they were tired. 4 mothers felt cold and began to shiver. The other 2 mothers exhibited tachypnea. It was not clear which of these mothers were in the KC and control groups
Selective reporting (reporting bias)	Unclear risk	Data collected on the % of infants in each group who achieved normal body temperature (36.5 °C.) after 1-6 hours and plotted on a graph, numerical data provided for only hour 4

Kastner 2005

Methods	Randomized controlled trial, no other information provided.
Participants	57 vaginally delivered mothers intending to breastfeed and their healthy full term infants
Interventions	In the usual care condition the mother and her infant remained together for 20 min. immediately postbirth. Then they were separated for routine infant care (weighing, measuring). Next the infant was dressed and returned to the mother for the first breastfeeding In the SSC group the mother and infant spent the first hour postbirth alone and undisturbed as much as possible
Outcomes	4 mother-child relationship scales (maternal physical contact, maternal speech/verbal communication, maternal breastfeeding, child to mother contact), infant attempts to reach the breast and grasp the nipple independently. 3 additional scales evaluating maternal fatigue and anxiety, partner support, maternal medication administration
Notes	Study was conducted in Munich, Germany.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Summary states that the study was "prospective and randomized." No further information provided
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding (performance bias and detection bias)	Low risk	Mothers were told that the study involved "observation of healthy newborns and their behavior in the first hour after childbirth as well as their further development in the early weeks of the child's life," not the true purpose of the study

All outcomes		The 2 outcome assessors who evaluated the video recordings were “blind to the group division of the mother-child pairs,” according to the research report
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	At 3-5 days postbirth, 4/31 infants were missing from the intervention group and 5/26 for the control group; at 5-6 weeks postbirth 7/31 infants were missing from the intervention group and 9/26 from the control group. No reasons were provided for participant attrition No standard deviations were reported for mean outcome data on scales 1-4
Selective reporting (reporting bias)	Unclear risk	No numerical data were reported for scales 5-7 although the results were stated as insignificant
Other bias	Unclear risk	The researchers acknowledge that video recording is a “disturbance” to the mother. The amount that video recording might have altered the mother’s behavior is unknown

Khadivzadeh 2008

Methods	Randomized controlled trial. The randomization method was not described
Participants	92 primigravid mothers and their healthy full term infants delivering at Om-ol-banin Hospital in Mashhad, Iran
Interventions	Control: the infant was shown briefly to the mother before being placed under a radiant warmer for routine care (physical assessment, vitamin K injection). The infant was then given to the mother wrapped in a blanket after the perineal or episiotomy repair and the mother was encouraged to start breastfeeding SSC: the infant was placed prone between mother’s breasts skin-to-skin immediately postbirth. The infant’s head was covered with a hat, and the back with a warm blanket. The infant was moved next to the breast and the mother was encouraged to start breastfeeding as soon as the infant displayed prefeeding behaviors. The Apgar score was assessed during SSC; all routine care was delayed until the infant was 2 hours postbirth
Outcomes	Duration from birth until the first breastfeeding, number of infants breastfeeding during the first 30 min. postbirth, success and duration of the first breastfeeding, maternal feelings about SSC during the first 2 hours postbirth
Notes	

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	States randomized controlled trial at the beginning of the Methods section. No further information provided
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No information provided. However, IBFAT scores were obtained during the first breastfeeding when the infants were either SSC or wrapped in a blanket so the outcome assessors could not be blind to group assignment for this outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	The trial included 92 mothers and their infants, 47 received SSC and 45 received routine care. Data were analyzed on all the participants
Selective reporting (reporting bias)	Unclear risk	Numerical data were reported for all the outcomes identified in the results section Data were also collected on maternal attachment and anxiety, results were reported elsewhere

Other bias	High risk	SSC infants were placed prone between their mother's breasts immediately postbirth and then left undisturbed. The control infants received a number of co-interventions (physical assessment, vitamin K injection) which could have been disruptive to their ability to breastfeed

Mazurek 1999

Methods	Randomized controlled trial.
Participants	66 healthy full term infants and their mothers (mean GA 39 weeks)
Interventions	After birth all infants were dried, cord blood PH was drawn and measurements were taken. 1) SSC group = the infant was placed in their mother's arms SSC 6-8 min postbirth and both were covered with a sheet. SSC continued for 75 min. 2) Mother's arms group = the infant was wrapped in a blanket and given to the mother to hold for 75 min. 3) Control group = the infant was wrapped and kept at a distance from their mother in the same room
Outcomes	Crying time, blood glucose, HR and respiratory rate at 75 min postbirth, blood PH, skin thigh temperature
Notes	Study was done in Warsaw, Poland.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Women were divided into "three randomised groups". Methods not described
Allocation concealment (selection bias)	Unclear risk	Methods not described.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	There was no mention of blinding and some of the outcomes (infant crying behavior) and temperature may have been susceptible to observer bias. Other outcomes may not have been affected by lack of blinding (arterial blood gases)
Incomplete outcome data (attrition bias) All outcomes	Low risk	66 women were randomized and all appeared to be accounted for in the results and analyses; the period of follow-up was short (75 min). It was not clear whether there was any missing data.
Selective reporting (reporting bias)	Unclear risk	Large number of data collection points and measures. Assessment from published report only
Other bias	Unclear risk	Baseline imbalance not apparent. There was little information on study methods. Assessment of risk of bias was from abstract and translation notes (original paper not in English)

McClellan 1980

Methods	Randomized controlled trial (table of random numbers).
Participants	40 healthy full term infants born by repeat cesarean section (spinal anesthesia)
Interventions	1) Control group = visual contact < 5 min, holding the swaddled infant for 10-20 min in the nursery during the first 12 hours postbirth, then rooming-in. 2) Early contact group = visual contact for 5 to 15 min, SSC for the first hour in the recovery room, then rooming-in

Outcomes	1) Neonatal Perception Inventory. 2) Postnatal research inventory. 3) Observation of maternal behavior. All variables measured on postpartum day 1 or 2 and 28-32 days postbirth
Notes	Study was done with middle-income, multipara in the USA.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated that a table of random numbers was used to ensure "no systematic bias" but then went on to say that "if the woman did not meet the characteristics of the population, she was replaced by the next woman who qualified, until there were 20 mothers in each group" It was not clear at what point randomization occurred or how many women were randomized and excluded postrandomization and then replaced
Allocation concealment (selection bias)	High risk	Women were "randomly assigned", "if the woman did not meet the characteristics of the population, she was replaced by the next woman who qualified, until there were 20 mothers in each group" It was not clear at what point randomization occurred or how many women were randomized and excluded postrandomization and then replaced
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Women would be aware of which group they were in and would be aware of observations. Clinical staff would be aware of group assignment. It was stated that the nurses carrying out observations were unaware of group assignment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	It was not clear how many women were randomized and then later excluded and replaced. 40 women received the intervention and all seemed to be accounted for in the analysis. It was not clear if there was any missing data.
Selective reporting (reporting bias)	Unclear risk	All outcomes specified in the introduction were reported on, it is not clear if other outcomes were measured, we did not have access to the study protocol.
Other bias	Unclear risk	Groups appeared similar at baseline. It was not clear what the mean scores reported represented, e.g. a mean mother and infant behavior score (from observation) - whether a higher score was more positive or what was being recorded. The measure is referenced but without knowing how scoring works it is not easy to interpret the results

Mizuno 2004

Methods	Randomized controlled trial.
Participants	60 healthy full term infants > 37 weeks' gestation and their mothers
Interventions	1) SSC group = extensive SSC (M = 63.7 min) immediately postbirth with effective suckling. Then mothers and infants were separated for 24 hours and infants were fed formula. After 24 hours rooming-in with q3hr breastfeedings. 2) Control group = first mother-infant contact 24 hours postbirth then rooming-in and q3hr breastfeedings. Midwives assisted both groups with the first breastfeeding
Outcomes	Frequency of mouthing movements with exposure to own mother's milk, another mother's milk, formula, orange juice, distilled water at 1 and 4 days of age. Difference in frequency of mouthing movements between mother's milk and another mother's milk at 1 and 4 days of age, duration of breastfeeding
Notes	Study was done in Chiba, Japan.

Risk of bias

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Unclear risk	Randomization process was not described.
Allocation concealment (selection bias)	Unclear risk	“randomly assigned”.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Main outcome was baby reaction to various odor stimuli, it is unlikely that lack of maternal blinding would have affected this. Staff providing care would be aware of group assignment and it was not clear whether those carrying out infant observations were aware of group assignment, it was stated that interviewers collecting longer term breastfeeding outcome data were blind to group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	60 women were included, 30 in each group, 2 women were lost from the control group. Denominators were not provided on tables or figures, so it was not clear how many women were followed up after hospital discharge
Selective reporting (reporting bias)	Unclear risk	Assessment carried out from published report. The validity of the main outcome measure and the method of observing infant response were not clear.
Other bias	Unclear risk	No baseline imbalance between groups reported.

Moore 2005

Methods	Randomized controlled trial (computerized minimization technique)
Participants	20 healthy full term infants > 37 weeks’ gestation and their mothers
Interventions	1) SSC group = infant placed prone SSC on mothers abdomen. Baby moved to warmer after cord cut. Then infant placed prone on mother’s bare chest between breasts. Moved to cross cradle nursing position when infant displayed early hunger cues (M = 99.5 min of SSC) Breastfeeding assistance provided by researcher. 2) Control group = infant shown briefly to mother and moved to warmer. Then infant swaddled in blankets and held by mother. Moved to cross cradle nursing position when infant displayed early hunger cues. Breastfeeding assistance provided by researcher
Outcomes	Success of the 1st breastfeeding, time of effective breastfeeding, body weight change day 14 postbirth, number of breastfeeding problems in the 1st postpartum month, mother’s perception of the adequacy of her milk supply, maternal parenting confidence, breastfeeding status 1 month postbirth
Notes	Study was done in the USA with primarily Caucasian, married, college-educated primipara

Risk of bias

Bias	**Authors’ judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated minimization process.
Allocation concealment (selection bias)	Low risk	Assignment by computer minimization process.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	This was an unblinded study. Participants were aware of group assignment. The chief investigator provided some of the postbirth care (including help with breastfeeding) and collected some of the outcome data
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 of the 23 women randomized were followed up.
Selective reporting (reporting bias)	Unclear risk	All outcomes appear to have been reported. Assessment from published trial report

Other bias	Low risk	Groups appeared similar at baseline (randomization by minimization technique)

Nolan 2009

Methods	Randomized controlled trial (mothers were randomly assigned to the Nursing Intervention to Minimize Maternal-Infant Separation (NIMS) or control group by a coin flip)
Participants	50 women scheduled for a repeat cesarean delivery with regional anesthesia and their healthy full term infants
Interventions	Control: standard/usual postoperative OB care was unstructured. The mothers typically had brief physical or no contact with their infants until they were admitted to the obstetric postanesthesia care unit. Breastfeeding was sometimes included. SSC was not routinely encouraged in the PACU Intervention: a minimum of 10-15 min of SSC was offered in the PACU as part of a NIMS protocol which included a number of co-interventions such as intra-/postoperative environmental manipulation to maintain a maternal-infant spatial distance of less than 8ft. with uninterrupted maternal visual and auditory contact, en face presentation at birth, and intraoperative cheek-to-cheek contact for a minimum of 3 min. The NIMS intraoperative protocol could be considered a sensory intervention which is a preamble to SSC in a situation where it is impossible to implement SSC immediately postbirth The mean duration of SSC was 33 + 13 min.
Outcomes	Maternal pain, anxiety, infant respiratory rate, temperature, salivary cortisol, breastfeeding initiation in the PACU, breastfeeding at hospital discharge and at 4 weeks postbirth, maternal perception of childbirth
Notes	This study took place in the US.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Mothers were randomly assigned to the NIMS or control group by a coin flip
Allocation concealment (selection bias)	Low risk	The researchers obtained informed consent from interested mothers when they arrived on the obstetrics ward and then randomly assigned the mothers to groups by a coin flip
Blinding (performance bias and detection bias) All outcomes	Unclear risk	The nurses who provided usual care to the control mothers were unfamiliar with the NIMS protocol No information was provided about whether the research nurse who conducted the medical record reviews, and obtained salivary cortisol samples was blind to participant group assignment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	72 mothers were recruited to participate in the study. 23% of the mothers did not receive their assigned intervention for various reasons such as unplanned general anesthesia, infant medical complications, staffing issues. There were 25 mother infant pairs in each group. 30% (n = 15) of the mothers has some missing pain scores. The number of missing pain scores did not differ significantly between groups. 30% (n = 15) of the infants had some missing temperature and salivary cortisol data. More infants in the NIMS group had missing salivary cortisol data. The number of missing infant temperature data did not differ significantly between groups. 36% (n = 18) of the infants had missing respiratory rate data. The amount of missing respiratory data did not differ significantly between groups
Selective reporting (reporting bias)	Low risk	Numerical data were provided for all outcomes.
Other bias	High risk	This study was included with considerable caution due to the following issues Infants in the SSC group weighed significantly more (3585.40 + 546.5 g) than those in the control group (3299.60 + 374.7 g) (P < .04). On admission to the PACU, before SSC was initiated, infants in the NIMS group had significantly higher salivary cortisol levels (M = 3.27 + 1.43) than infants in the control group (M = 1.90 + 0.72).

	There were a number of co-interventions in this study. Therefore, it is impossible to disentangle the effects of SSC from those of the other interventions Usual care was unstructured. The exact conditions which the NIMS protocol was being compared to are unknown.

Punthmatharith 2001

Methods	Randomized controlled trial (computerized minimization technique)
Participants	196 healthy full term 37-42 weeks' gestation infants and their mothers
Interventions	All infants received standard care for the 1st 30-60 min postbirth. After the cord was clamped they were shown briefly to mom and moved to a warmer. 1) SSC group = beginning 60 min postbirth infants received (M = 30 min) of SSC. Mothers were encouraged to breastfeed on infant demand. Infants and mothers transferred to the postpartum unit at 120 min postbirth for 24 hour rooming-in. Mothers encouraged to provide SSC 15-30 min before each breastfeeding. No other fluids given to infants. 2) Control group = swaddled infant given to mom after episiotomy repair and they were transferred together to the recovery room for 2 hours, then to postpartum for 24 hour rooming-in. Mothers encouraged to breastfeed on infant demand. Cup feeding was encouraged if the infant required supplementation
Outcomes	Observation of maternal affectionate behaviors during a breastfeeding at 36-48 hours postbirth, 4 subscales of the maternal-infant bonding questionnaire (attention/connection to the infant, preparation for nurturing the infant, role of mother, breastfeeding the infant) at 36-48 hours and week 4 postbirth, Mother's perception of the adequacy of her milk supply, and breastfeeding status 36-48 hours and week 4 postbirth, infant weight day 2 and 1 month postbirth
Notes	Study was done in a Baby Friendly Hospital in Songkhla, Thailand

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sequence generation was by computerized minimization method with stratification for 10 factors including parity, age, SES, medication, ward, planned duration of breastfeeding, previous breastfeeding, experience, infant weight and sex
Allocation concealment (selection bias)	Low risk	Computerized minimization method but no clear description of what happened at the point of randomization
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Mothers would be aware of group assignment and it was stated that because of lack of privacy and cultural factors mothers might feel reluctant to accept the intervention. It was not clear whether there was an attempt to blind staff or outcome assessors and the impact of lack of blinding is not clear
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	195 women were randomized and 167 remained available to followup. Loss was balanced across groups
Selective reporting (reporting bias)	Unclear risk	Assessment from unpublished thesis.
Other bias	Low risk	Groups appeared comparable at baseline (stratified). Recruitment was at convenient times, so the sample may not have been representative of the population

Shiau 1997

Methods	Randomized controlled trial (computerized minimization technique)

Participants	58 healthy full term infants and their mothers randomized into 1 of 2 groups 0-4 hours postvaginal or cesarean birth
Interventions	1) KC group = mothers began SSC at 4 hours postbirth and held their infants in SSC 8 hours daily for 3 days. Breastfeeding based on infant hunger cues during the day and every 4 hours at night. 2) Control group = began breastfeeding 24 hours postbirth. Mothers fed their infants every 4 hours in the nursery
Outcomes	1) Mean maternal state anxiety. 2) Mean score on 6 point breast engorgement scale. 3) Chest circumference. 4) Breastfeeding status day 3 and 28 postbirth. 5) Breast milk maturation. 6) Breastfeeding duration
Notes	Study was done with married primipara and multipara in Taiwan. The researcher provided all nursing care to the SSC group during the day

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	By computerized minimization technique taking account of gestational and maternal age, infant sex, type of birth, maternal education and previous BF experience
Allocation concealment (selection bias)	Low risk	Computerized assignment.
Blinding (performance bias and detection bias) All outcomes	High risk	There was no blinding in this study and care for the intervention group was provided by the investigator who also gave advice on breastfeeding and collected outcome data. The control group received care from different staff. It is likely that other aspects of care as well as SSC would be different between the 2 groups
Incomplete outcome data (attrition bias) All outcomes	Low risk	58 mother infant pairs were randomized and all were accounted for in the analyses although there was some missing data for some outcomes.
Selective reporting (reporting bias)	Unclear risk	Assessment from unpublished dissertation.
Other bias	Unclear risk	No baseline imbalance apparent. The fact that care for the intervention and control groups was provided by different staff may be a serious source of bias in this study

Sosa 1976a

Methods	Randomized controlled trial (random numbers in sealed envelopes)
Participants	60 healthy full term infants and their mothers randomized immediately after delivery
Interventions	1) Experimental group = mothers held their infants in SSC for 45 min after the episiotomy repair. They were encouraged to breastfeed. 2) Control group = infants were separated from their mothers for 12 hours
Outcomes	1) Mean duration of breastfeeding. 2) Episodes of illness, growth and development, mortality
Notes	Study was done with poor, urban primipara from the marginal area of Guatemala city

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Assignment of mother-infant pairs…. was made from random numbers.."
Allocation concealment (selection bias)	Unclear risk	Allocations were concealed in sealed envelopes which were opened immediately after delivery

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Attempts to blind mothers, staff and outcome assessors were not mentioned. Mothers would be aware of allocation, staff were also likely to have been aware of treatment group and may have altered other aspects of treatment and outcome assessors accompanied the mothers home from hospital so may well have been aware of group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	60 women. Denominators for longer tem outcomes were not specified so it is not clear how many women remained available to follow-up at each data collection point
Selective reporting (reporting bias)	Unclear risk	Assessment made from published reports only. In this study the intervention appeared to have a negative effect on breastfeeding duration this was explained by possibly different populations in the control and intervention groups (although randomization should have controlled for this).
Other bias	Unclear risk	There was some imbalance in the socioeconomic background of women although this was not consistent across study sites Little information was provided on study methods. Women were followed up for 9 months or 1 year. Duration of breastfeeding was an outcome. It is not clear whether any women were still breastfeeding at the final data collection point. No SDs were provided for continuous variables so some findings were difficult to interpret

Sosa 1976b

Methods	Randomized controlled trial (random numbers in sealed envelopes)
Participants	68 healthy full term infants and their mothers randomized immediately after delivery
Interventions	1) Experimental group = mothers held their infants in SSC for 45 min after the episiotomy repair. They were encouraged to breastfeed. 2) Control group = infants were separated from their mothers for 12 hours
Outcomes	1) Mean duration of breastfeeding. 2) Episodes of illness, growth and development, mortality
Notes	Study was done with poor, urban primipara from the marginal area of Guatemala city

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Assignment of mother-infant pairs…. was made from random numbers.."
Allocation concealment (selection bias)	Unclear risk	Allocations were concealed in sealed envelopes which were opened immediately after delivery
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Attempts to blind mothers, staff and outcome assessors were not mentioned. Mothers would be aware of allocation, staff were also likely to have been aware of treatment group and may have altered other aspects of treatment and outcome assessors accompanied the mothers home from hospital so may well have been aware of group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	68 women. Denominators for longer tem outcomes were not specified so it is not clear how many women remained available to follow-up at each data collection point
Selective reporting (reporting bias)	Unclear risk	Assessment made from published reports only.
Other bias	Unclear risk	There was some imbalance in the socioeconomic background of women although this was not consistent across study sites Little information was provided on study methods. Women were followed up for 9 months or 1 year. Duration of breastfeeding was an outcome. It is not clear whether any women were still breastfeeding at the final data collection point. No SDs were

	provided for continuous variables so some findings were difficult to interpret

Sosa 1976c

Methods	Randomized controlled trial (random numbers in sealed envelopes)
Participants	40 healthy full term infants and their mothers randomized immediately after delivery
Interventions	1) Experimental group = mothers held their infants in SSC for 45 min after the episiotomy repair. They were encouraged to breastfeed. 2) Control group = infants were separated from their mothers for 24 hours
Outcomes	1) Mean duration of breastfeeding. 2) Episodes of illness, growth and development, mortality
Notes	Study was done with poor, urban primipara from the marginal area of Guatemala city

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Assignment of mother-infant pairs…. was made from random numbers.."
Allocation concealment (selection bias)	Unclear risk	Allocations were concealed in sealed envelopes which were opened immediately after delivery
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Attempts to blind mothers, staff and outcome assessors were not mentioned. Mothers would be aware of allocation, staff were also likely to have been aware of treatment group and may have altered other aspects of treatment and outcome assessors accompanied the mothers home from hospital so may well have been aware of group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	40 women. Denominators for longer tem outcomes were not specified so it is not clear how many women remained available to follow-up at each data collection point
Selective reporting (reporting bias)	Unclear risk	Assessment made from published reports only.
Other bias	Unclear risk	There was some imbalance in the socioeconomic background of women although this was not consistent across study sites Little information was provided on study methods. Women were followed up for 9 months or 1 year. Duration of breastfeeding was an outcome. It is not clear whether any women were still breastfeeding at the final data collection point. No SDs were provided for continuous variables so some findings were difficult to interpret

Svejda 1980

Methods	Randomized controlled trial.
Participants	30 healthy full term infants and their mothers.
Interventions	1) Control group = held their wrapped infants briefly (< 5 min) during transfer, then 30 min of contact at feedings every 4 hours. 2) Extra contact group = SSC for 15 min beginning 25 min postbirth, then the gowned mothers held their nude infants for 45 min in their rooms, 90 min of contact every 4 hours for feedings
Outcomes	Videotaped affectionate and proximity - maintaining behavior in interaction with the infant, affectionate and caretaking behavior during breastfeeding 36 hours postbirth
Notes	Study was done with middle-income, primipara in the USA.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Very little information about study methods provided. Method of sequence generation not described
Allocation concealment (selection bias)	Unclear risk	"mothers were randomly assigned". Method not described.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	The intervention was not explained to women. Staff providing care would be aware of group assignment. There was an attempt to check that the duration of time nurses spent with women was not greater for the intervention group. Outcome data were derived from observations of videotapes with maternal behavior coded by researchers who were described as being blind to group assignments; inter-rater reliability was checked
Incomplete outcome data (attrition bias) All outcomes	Low risk	All women were included in the analyses.
Selective reporting (reporting bias)	Unclear risk	It was not clear how scores from observations were calculated and whether women could contribute different numbers of observations.
Other bias	Unclear risk	It was stated that the 2 groups were comparable at baseline. Very little information was provided on study methods

Syfrett 1996

Methods	Randomized controlled trial (computerized minimization technique)
Participants	8 healthy late preterm infants 34-36 weeks' gestation, average for GA, Apgars 7 or more, and their mothers
Interventions	1) Control group = 24 min of SSC during the first hour postbirth before randomization to radiant warmer for 3 hours, double wrapped in open bassinet for 3 hours then demand feeding and continuous rooming-in if stable. 2) KC group = 40 min of SSC during the first hour postbirth, transferred to nursery for admission procedures, then continuous SSC (mean 37 hours) and breastfeeding on demand
Outcomes	Temperature, temperature variability, breastfeedings/day, bottle-feedings (ml/day), IV fluids (ml/day), weight loss (g/hr), birthweight lost (%), number of heel sticks, length of stay (total days), breastfeeding duration
Notes	Study was done in the USA. All nursing care in the KC group was done by the researchers

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"random assignment…. was done using the minimization technique". The randomization sequence took account of a relatively large number of stratifying variable and the eventual sample size was only 8 women. (Stratification by GA, race, sex, induction or augmentation, intrapartum analgesia/anesthesia, maternal magnesium sulphate and previous breast feeding experience
Allocation concealment (selection bias)	Low risk	Randomization was carried out 1 hour after birth at admission to the newborn nursery. 1 of the investigators revealed the next allocation in the randomization sequence
Blinding (performance bias and detection bias) All outcomes	High risk	This study was at high risk of bias due to the lack of blinding. It was stated that control group women may have been dissatisfied knowing that the intervention group were given more infant contact. The control group and the intervention group were cared for by different staff. The control group received routine care while the intervention groups received special care from the investigators - which included advice on breastfeeding and 5 min pager access to staff as well as advice on SSC. The same nurse investigators also collected outcome data for the SSC group

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	8 infants were involved in this study and all but 1 were followed up for a year
Selective reporting (reporting bias)	Unclear risk	Assessment from unpublished thesis. The recruitment, intervention and data collection were carried out by the same (unblinded) investigators
Other bias	High risk	This study had a very small sample size that was recruited at times convenient to the investigators over a 10 month period. It is not clear that the sample was representative of the population from which it was drawn. The intervention was delivered by the investigators and included changes to aspects of care other than SSC (e.g. breastfeeding advice). It is difficult to separate the effects of the intervention from the effects of other elements within the package of care

Thomson 1979

Methods	Randomized controlled trial.
Participants	34 healthy full term infants and their mothers.
Interventions	1) Control group = held their wrapped infants briefly (< 5 min), subsequent contact at 12-24 hours postbirth, then contact every 4 hours for feedings during the day. 2) Early contact group = held infant in SSC for 15-20 min starting 15-30 min postbirth. Mothers were encouraged to breastfeed, subsequent contact at 12-24 hours postbirth, then contact every 4 hours for feedings during the day
Outcomes	1) Happy maternal reaction to birth. 2) Breastfeeding at hospital discharge. 3) Successful breastfeeding 2 months postbirth
Notes	Study was done with married, primipara in Canada.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The randomization process was not described "the observer randomly assigned the mother-infant pair to a control or to an early-contact group"
Allocation concealment (selection bias)	Unclear risk	The process was not described.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Women were not told about the study intervention but told that the study was about infant nutrition. It was stated that only delivery room staff caring for women were aware of group assignments, staff thereafter were not made aware of allocation. The person carrying out the randomization also collected delivery room data, but staff collecting other outcome data were described as blind although women may have revealed group status
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	34 women recruited. 4 lost to follow up.
Selective reporting (reporting bias)	Unclear risk	1 outcome "Happy maternal reaction to the infant" was assessed by an observer that had carried out the randomization and remained in the delivery room during the intervention.
Other bias	Unclear risk	Little information on study methods was provided.

Vaidya 2005

Methods	Randomized controlled trial.

Participants	110 healthy full term infants and their mothers.
Interventions	1) SSC group = the naked infant was placed on the mother's naked chest for 10-15 min within 1 hour of birth. 2) Control group = after immediate newborn care the infants were dressed and given to their mothers or visitors. Both groups were encouraged to initiate breastfeeding
Outcomes	Exclusive breastfeeding up to 2-4 and 4-6 months postbirth, started other feedings before 2 months of age
Notes	Study was done in Kathmandu, Nepal.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"…some mother-baby pairs were selected randomly and after taking verbal consent were allowed to have skin-to-skin contact…. In the remaining control group, babies after immediate newborn care were dressed as usual"
Allocation concealment (selection bias)	Unclear risk	There was little information about study methods and the method of randomization was not described clearly
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Blinding was not mentioned, it is likely that all groups were aware of group assignment
Incomplete outcome data (attrition bias) All outcomes	High risk	It was stated that 110 women were included in the study and 92 were followed up, the reasons for loss to follow up were not stated. It was not clear where the numbers of women lost to follow up were the same in the control and intervention groups. There was some discrepancy in numbers in different tables; in a table setting out duration of breast feeding by mode of delivery only 60 women were accounted for
Selective reporting (reporting bias)	Unclear risk	Assessment from published study report.
Other bias	Unclear risk	The sample was not described and it was not clear whether the 2 groups were balanced in terms of parity, mode of delivery, and other potentially important variables Very little information about study methods was provided.

Villalon 1993

Methods	Randomized controlled trial.
Participants	119 healthy full term infants and their mothers.
Interventions	SSC Group = babies were placed SSC on their mothers immediately postbirth, then dried and given medications. Diapered infants were then placed between their mother's breasts and covered with a blanket. Breastfeeding was initiated or attempted. Babies stayed in contact with their mothers for most of the following 4 hours. Control group = babies were dried, given medications, clothed and taken to the nursery for 4 hours
Outcomes	Breastfeeding at 24 hours, hospital discharge, and 14 days postbirth, maternal parenting confidence, temperature, HR, respiratory rate at 1,2,3 and 4 hours postbirth in a subset of 92 infants
Notes	Study was done in Coyhaique, Chile. All mothers were Hispanic with mixed parity and education. Temperature, HR and respiratory rate data were obtained from a subset of 96 infants

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The randomization process was not described.

Allocation concealment (selection bias)	Unclear risk	The randomization process was not described.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No blinding of women, clinical staff or observers and outcomes susceptible to response and observer bias
Incomplete outcome data (attrition bias) All outcomes	High risk	Describe any loss of participants to follow-up at each data collection point: 119 women randomized. It appeared that outcome data were available for all women at 24 hours. However, at 14 days data were only available for 65 (54%) of the randomized sample (loss was balanced across groups). There was no ITT analysis for outcomes at 14 days.
Selective reporting (reporting bias)	Unclear risk	Assessment made from translation notes from published article (protocol not available).
Other bias	Unclear risk	Baseline imbalance not apparent. Other: risk of bias assessment from translation notes.

BAT: Breastfeeding Assessment Tool

BPM: beats per minute

GA: gestational age

HR: heart rate

IBFAT: Infant Breastfeeding Assessment Tool

IBS: Index of breastfeeding status

ITT: intention-to-treat

IV: intravenous

KC: kangaroo care

M: mean

min.: minutes

MPI: Mother preterm infant interaction

NICU: neonatal intensive care unit

NIMS: Nursing Intervention to Minimize Maternal-Infant Separation

PACU: Post-Anesthesia Care Unit

PCERA: Parent-Child Early Relational Assessment

q3hr: every 3 hours

SAT: saturation

SCRIP: stability of the cardio-respiratory system

SD: standard deviation

SE: standard error

SSC: skin-to-skin contact

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

Study	Reason for exclusion
Abdel Razek 2009	This quasi-experimental study was conducted in 2 maternal and child health centers in Jordan. The study was conducted on infants receiving immunization injections during their first year of life

Ali 1981	No mention was made regarding whether the early maternal-infant contact was skin-to-skin
Anisfeld 1983	This study was a quasi-randomized trial. Group assignment was by day of the week
Castral 2008	This study took place with stable preterm infants (at least 30 weeks' GA) during a heel lance procedure. All of the infants were located in the intermediary neonatal care unit; 62% of these infants had been transferred from the NICU. Mean birthweight was 1748.8 g for the SSC infants and 1846.2 g for the control group
Cattaneo 1998	This was not a study of early KMC. The median age of enrolment in the study was 10 days postbirth for KMC infants and 8 days postbirth for CMC infants
Christensson 1998	Infants in the control and intervention groups were hypothermic and admitted to the NICU before the study began
Darmstadt 2006	This was not a study of early SSC. The intervention was a community mobilization and behavior change communication program aimed at increasing the acceptability of skin-to-skin care for mothers who deliver at home in rural Uttar Pradesch, India
Durand 1997	Not a randomized trial, participants self-selected into the experimental or control group based on their desire to breast or bottle feed
Erlandsson 2007	This was a study of skin-to-skin care with the father after cesarean birth
Feldman 2003	Study was not an RCT. KC infants were recruited at 1 hospital and control infants from another hospital. Infants were cared for concurrently at the 2 hospitals. Families were recruited to participate several days to several weeks postbirth. All infants were in the NICU. Mean GA - 30.65 weeks
Ferber 2008	This study was conducted on preterm infants in the NICU.
Gardner 1979	No information was provided about whether infants were randomized to SSC (group 1) or standard care in a Kreisselman warmer bed (group 2). No means and standard deviations were provided for the outcome variable rectal temperature at 17 min postbirth
Gathwala 2008	This was a study of KMC for preterm and low birthweight infants in the NICU. KMC was initiated at a mean age of 1.72 + 0.45 days of age.
Gomes-Pedro 1984	The early contact in the intervention group was not skin-to-skin
Gray 2000	This was not a study of early SSC. Infants were between 33 and 55 hours postnatal age at study entry
Gray 2002	Infants were between 40 and 44 hours postnatal age at study entry
Grossman 1981	A questionable quasi-randomization procedure was used - the experimental treatment and time are confounded. No mention was made regarding whether the early contact was skin-to-skin
Hill 1979	The study was described as "experimental" with 50 infants per group but the author does not state that infants were randomized to groups. Study compared swaddled holding (not SSC) by the mother or father to a heated transporter
Ibe 2004	In the KMC group, infants were dressed in cotton vests and caps and placed between their mother's breasts. The study was not an RCT - infants served as their own controls and alternated between KMC and incubator care. Infants were recruited between 24 hours to 30 days of age
Johanson 1992	In the KC group "the baby was placed under the mother's clothes on her chest. If the clothing alone was considered insufficient, the baby was swaddled in 1 of the labor room blankets and then kept immediately against the mother" (p 860). The full term data were not reported separately; instead they were combined with preterm data in the analyses
Johnson 1976	No mention was made regarding whether the early maternal-infant contact was skin-to-skin
Kadam 2005	Study was conducted in a level 3 NICU in Mumbai, mean age of the infants at enrolment was 3.2 days, range 1-8 days, mean GA of the KC infants was 33.3 weeks
Karlsson 1996	Not a randomized trial; a descriptive study.
Klaus 1972	The early contact in the intervention group was not skin-to-skin
Kontos 1978	This study was not a randomized trial. Mothers who chose to room in and those who did not were alternately assigned to early SSC or usual care. No means or standard deviations were provided for the attachment summary score or individual attachment behaviors
Lindenberg 1990	No mention was made regarding whether the early maternal-infant contact was skin-to-skin

Ludington-Hoe 2004	This was not a study of early SSC. SSC began M =17.82 days postbirth. All infants were in the NICU
Ludington-Hoe 2006	This study was conducted on preterm infants (mean GA 30.8 + 1.4 weeks SSC group, 30.8 + 1.1 weeks control group) in the NICU. Mean age at the time of the study was 11.6 + 5.1 days SSC group, 12.0 + 12 days control group.
Marin 2010	The pediatricians, rather than the mothers, were randomly assigned to whether or not they would provide early SSC immediately postbirth
Mikiel-Kostyra 2002	In this study infants were not randomly assigned to groups. Information on the care of 11,973 newborn infants from birth to hospital discharge was collected in 427 maternity wards using a standardized questionnaire. Then a subset of 9612 newborns was created. Then 1923 participants (20% of the subset) were randomly selected by systematic sampling of every 5th case to complete a follow-up questionnaire
Miles 2006	This study was conducted on preterm infants < 32 weeks' GA in 2 NICUs
Nagai 2010	This study was excluded as both groups received SSC in a setting where SSC had already been introduced as standard care; earlier and later SSC were compared. It was intended that the "early" SSC group would begin SSC within 24 hours of the "later" SSC group. In fact there was considerable overlap between the 2 groups and results are difficult to interpret
Neu 2010	This was not a study of early SSC. It is a study of preterm birth (mean GA at birth 33 weeks) in NICU. Women were recruited to participate within 1 month of the birth
Ohgi 2002	This was a non-randomized intervention study of infants who received KC compared to a historical comparison group of infants who did not receive KC. Also KC was initiated 1-3 days postbirth
Okan 2010	This was not a study of early SSC. The infant's mean postnatal age at the time of the intervention hypothesized to decrease pain from a heel lance procedure was 33.1 + 5 hours postbirth.
Ottaviano 1979	No mention was made regarding whether the early maternal-infant contact was skin-to-skin
Ramanathan 2001	This study took place in the NICU. Mean GA of the infants was 31.5 weeks
Roberts 2000	This was not a study of early KMC. SSC was started median = 11.8 days postbirth. Median GA was 30.4 weeks in the KMC group; 30.9 weeks in the control group
Rojas 2001	This was a study of preterm infants who were < 1500 grams.
Salariya 1978	No mention was made regarding whether the early maternal-infant contact was skin-to-skin
Sloan 2008	This was a study of community-based KMC in rural Bangladesh. Half of 42 unions in 2 Bangladesh divisions were randomly assigned to community-based KMC
Suman 2008	This study enrolled low birthweight infants (< 2000 grams) in a Level III NICU
Taylor 1979	The early contact in the intervention group was not skin-to-skin
Taylor 1985	The early contact in the intervention groups was not skin-to-skin
Taylor 1986	Not a randomized trial, a descriptive study. The early contact in the intervention group was not skin-to-skin
Tessier 2009	This study was conducted with preterm infants (mean GA KMC group 33.6 + 2.5 weeks, control group 33. 9 + 2.7 weeks). The infants were all < 2000 grams. The median age for study eligibility was 4 days in the KMC group and 3 days in the control group
Thukral 2010	Not enough information was provided in the research abstract to be able to evaluate the study for methodological quality
Velandia 2010	In this study all infants received early SSC; following cesarean SSC with mothers was compared with SSC with fathers
Wimmer 1982	No standard deviations provided for breastfeeding duration.
Worku 2005	This was not a study of late preterm infants. The mean GA was 32.45 weeks KMC and 31.59 weeks CMC infants. The mean birthweight was 1514.8 g (range 1000-1900 g) for KMC and 1471.8 g (range 930-1900 g) for CMC infants. 58% of the KMC and 52% of CMC infants were on IV fluids and 34% of the KMC and 37% of the CMC infants were on oxygen through nasopharyngeal catheter. In addition, these infants experienced significant morbidity; 22.5% of the KMC infants and 38% of the CMC infants died during the study period. Infants were randomly assigned using a list of random numbers to conventional care (n = 61, overhead lamp warmers or a heated room, oxygen therapy, breast, tube, cup or mixed feedings) or early KMC (n = 62) starting during the first 24 hours of life (mean age 10 h KMC, 9.8 CMC)

CMC: conventional method of care

GA: gestational age

h: hour

KC: kangaroo care

KMC: kangaroo mother care

min: minutes

NICU: neonatal intensive care unit

RCT: randomized controlled trial

SSC: skin-to-skin contact

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

Keshavarz 2010

Trial name or title	Skin to skin contact with or without music and maternal state anxiety
Methods	Randomized (single blind) trial.
Participants	Healthy Iranian women 20-40 years with term, singleton pregnancy with cesarean section under spinal anesthesia. No history of neonatal death
Interventions	Skin to skin contact for 30 minutes with music.
Outcomes	Maternal state anxiety.
Starting date	July 2009.
Contact information	Maryam Keshavarz keshavarz@iums.ac.ir m-keshir@yahoo.com
Notes	Information from a trial registration.

DATA AND ANALYSES

Comparison 1
Skin-to-skin versus standard contact healthy infants

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Breastfeeding 1 month to 4 months postbirth	13	702	Risk Ratio (M-H, Random, 95% CI)	1.27 [1.06, 1.53]
2 Duration of breastfeeding in days	7	324	Mean Difference (IV, Random, 95% CI)	42.55 [−1.69, 86.79]
3 SCRIP score first 6 hours postbirth	1	31	Mean Difference (IV, Fixed, 95% CI)	2.88 [0.53, 5.23]
4 SCRIP score first 6 hours in newborns below 1800 g birthweight	1	13	Mean Difference (IV, Fixed, 95% CI)	4.92 [−1.67, 11.51]
5 Blood glucose mg/dL and mmol/L at 75-90 minutes postbirth	2	94	Mean Difference (IV, Fixed, 95% CI)	10.56 [8.40, 12.72]
6 Infant axillary temperature 90 minutes to 2 hours postbirth	3		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7 Exclusive breastfeeding at hospital discharge	2	57	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.66, 1.47]
8 Breastfeeding status day 28 to 1 month postbirth	3	245	Mean Difference (IV, Random, 95% CI)	0.86 [−0.73, 2.44]
9 Exclusive breastfeeding up to 3-6 months postbirth	3	149	Risk Ratio (M-H, Fixed, 95% CI)	1.97 [1.37, 2.83]
10 Breastfeeding 1 year postbirth	2	62	Risk Ratio (M-H, Fixed, 95% CI)	6.19 [0.82, 46.78]
11 Success of the first breastfeeding (IBFAT score)	2	54	Mean Difference (IV, Fixed, 95% CI)	1.79 [0.24, 3.35]
12 Successful first breastfeeding (IBFAT score 10-12 or BAT score 8-12)	3	315	Risk Ratio (M-H, Random, 95% CI)	1.36 [0.95, 1.95]
13 Suckled during the first 2 hours postbirth	1	88	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.83, 1.35]
14 Mean variation in maternal breast temp. 30-120 minutes postbirth	1	132	Mean Difference (IV, Fixed, 95% CI)	0.60 [0.34, 0.86]
15 Breast engorgement - pain, tension, hardness 3 days postbirth	2	131	Std. Mean Difference (IV, Fixed, 95% CI)	−0.41 [−0.76, −0.06]
16 Heart rate 75 minutes to 2 hours postbirth	3	183	Mean Difference (IV, Random, 95% CI)	−3.05 [−7.84, 1.75]
17 Respiratory rate 75 minutes - 2 hours postbirth	4	215	Mean Difference (IV, Random, 95% CI)	−3.12 [−6.61, 0.37]
18 Infant did not exceed parameters for stability	1	31	Risk Ratio (M-H, Fixed, 95% CI)	10.83 [1.63, 72.02]
19 Transferred to the neonatal intensive care unit	1	31	Risk Ratio (M-H, Fixed, 95% CI)	1.44 [0.15, 14.29]
20 Infant body weight change (grams) day 14 postbirth	2	43	Mean Difference (IV, Fixed, 95% CI)	−6.00 [−175.60, 159.
21 Infant weight gain per kilogram per day (in grams)	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
22 Infant hospital length of stay in hours	2	42	Mean Difference (IV, Random, 95% CI)	−95.30 [−368.50, 177.89]
23 Not crying for > 1 minute during 90 minutes	1	29	Risk Ratio (M-H, Fixed, 95% CI)	12.86 [1.91, 86.44]
24 Amount of crying in minutes during a 75-minute observation period	1	44	Mean Difference (IV, Fixed, 95% CI)	−8.01 [−8.98, −7.04]
25 PCERA Maternal positive affective involvement and	1	61	Mean Difference (IV, Fixed, 95% CI)	1.90 [−1.14, 4.94]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
responsiveness 12 months postbirth				
26 PCERA Dydadic mutuality and reciprocity 12 months postbirth	1	61	Mean Difference (IV, Fixed, 95% CI)	1.30 [0.24, 2.36]
27 Maternal pain 4 hours postcesarean birth	1	35	Mean Difference (IV, Fixed, 95% CI)	−1.38 [−2.79, 0.03]
28 Mother's most certain preference for same postdelivery care in the future	1	199	Risk Ratio (M-H, Fixed, 95% CI)	2.82 [2.08, 3.82]
29 Maternal state anxiety day 3 postbirth	1	56	Mean Difference (IV, Fixed, 95% CI)	−5.00 [−9.00, 1.00]
30 Maternal parenting confidence at 1 month postbirth	1	20	Mean Difference (IV, Fixed, 95% CI)	5.60 [−6.24, 17.44]
31 Breastfeeding 1 month to 4 months post birth: Sensitivity analysis	12	642	Risk Ratio (M-H, Random, 95% CI)	1.31 [1.16, 1.48]
32 Duration of breastfeeding in days: Sensitivity analysis	6	264	Mean Difference (IV, Random, 95% CI)	63.73 [37.96, 89.50]
33 Heart rate 75 minutes to 2 hrs post birth: Sensitivity analysis	2	94	Mean Difference (IV, Fixed, 95% CI)	−5.77 [−7.43, −4.11]
34 Respiratory rate 75 minutes to 2 hours post birth: Sensitivity analysis	3	126	Mean Difference (IV, Fixed, 95% CI)	−4.76 [−6.12, −3.41]

WHAT'S NEW

Last assessed as up-to-date: 15 March 2012.

Date	Event	Description
7 March 2012	New search has been performed	The search was updated to 30 November 2011 and, as a result, five randomized controlled trials have been added to the review. Two of the new studies (Gouchon 2010; Nolan 2009) were conducted with mothers scheduled for repeat cesarean birth using regional anesthesia. One study (Huang 2006) was conducted with hypothermic, but otherwise healthy, newborns postcesarean birth with spinal anesthesia. The results from four additional reports involving the data set from Bystrova 2003, two additional reports from Anderson 2003 and one additional report from Bergman 2004 have been added to this update. In this update we have used new methods and have modified outcomes. One trial previously included has now been excluded because quasi-randomized trials are no longer included (Anisfeld 1983).
30 September 2011	New citation required but conclusions have not changed	New author helped to update this review.

HISTORY

Protocol first published: Issue 1, 2002

Review first published: Issue 2, 2003

Date	Event	Description
8 May 2008	Amended	Converted to new review format.
3 April 2007	New search has been performed	The search was updated to August 2006, as a result of which 17 studies have been added to the review along with 23 clinical outcomes. Additional breastfeeding outcomes include: exclusive breastfeeding up to four to six months postbirth; starting other feedings before the infant is two months of age; success of the first breastfeeding; time to effective breastfeeding; number of breastfeeding problems; frequency of infant mouthing movements with exposure to mother's own milk; and infant body weight change. New outcomes related to maternal feelings and attitudes include: preference for the same postdelivery care in the future; perceptions of the adequacy of her milk supply; self-confidence about her child care ability; and parenting confidence. Three studies with late preterm infants who were healthy enough to remain with their mothers on the postpartum unit and between 34 to 37 weeks' gestational age have been added to this review. Additional outcomes related to these infants include: SCRIP scores; number of infants who did not exceed physiological parameters; transfers to the neonatal intensive care unit; and hospital length of stay. A new outcome related to infant behavior is optimal flexed movements. Two outcomes have also been added evaluating maternal attachment: mean % of maternal contact time and maternal perceptions of bonding/connection to her infant. Although 23 outcomes have been added, there are no significant changes from the conclusions of the previous review
3 April 2007	New citation required but conclusions have not changed	This review has been substantially updated.

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* *Indicates the major publication for the study*

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PLAIN LANGUAGE SUMMARY

Early skin-to-skin contact for mothers and their healthy newborn infants

Skin-to-skin contact between a mother and her baby at birth reduces crying, and helps the mother to breastfeed successfully.

In many cultures, babies are generally cradled naked on their mother's bare chest at birth. Historically, this was necessary for the baby's survival. In recent times, in some societies such as in industrialized countries more babies are born in hospital, and as part of usual hospital care babies are often separated and swaddled or dressed before being given to their mothers. It has been suggested that hospital routines may significantly disrupt early mother and baby interactions and have harmful effects. This review was done to see if there was any impact of early skin-to-skin contact between the mother and her newborn baby on infant health, behavior, and breastfeeding.

The review included 34 randomized studies involving 2177 mothers and their babies. It showed that babies exposed to skin-to-skin contact interacted more with their mothers and cried less than babies receiving usual hospital care. Mothers were more likely to breastfeed in the first one to four months, and tended to breastfeed longer, if they had early skin-to-skin contact with their babies. Babies were possibly more likely to have a good early relationship with their mothers but this was difficult to measure. The overall methodological quality of trials was mixed. There was variation in how the intervention was implemented, including the time of skin-to-skin contact started after the birth and how long it lasted, the outcomes looked at and how they were measured. No clear negative outcomes were reported in association with skin-to-skin contact.

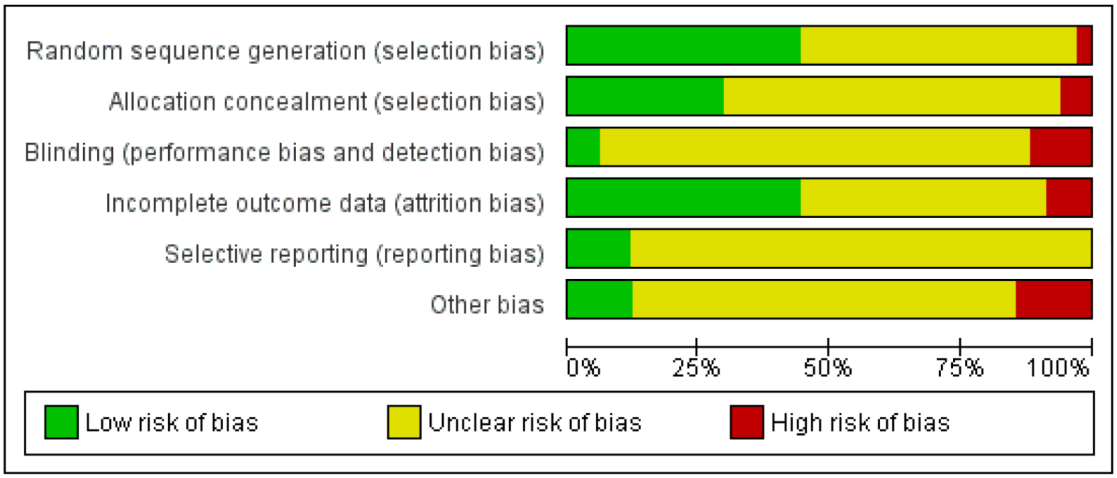

Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

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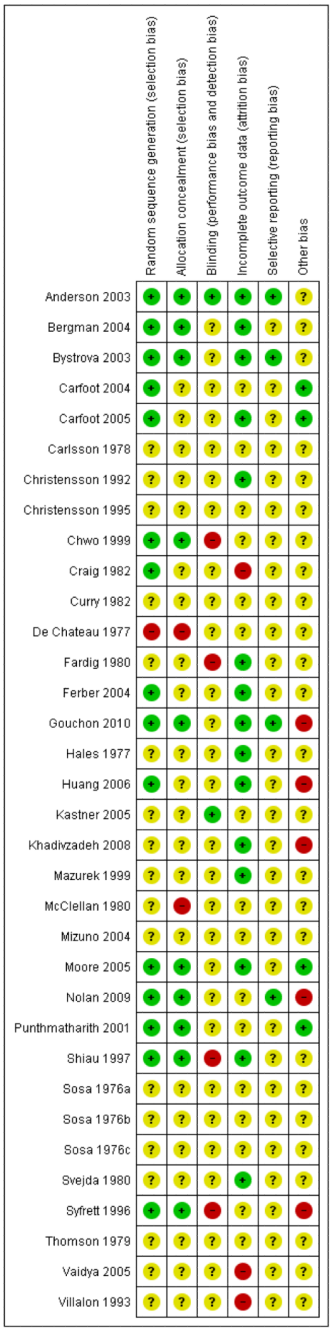

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

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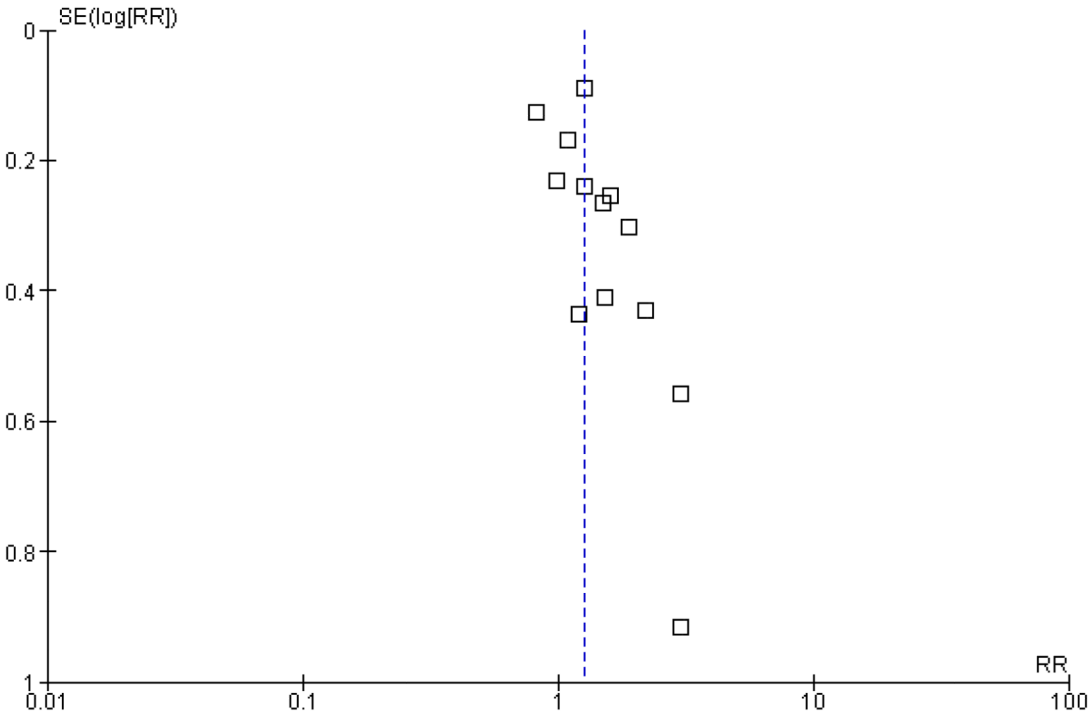

Figure 3. Funnel plot of comparison: 1 Skin-to-skin versus standard contact healthy infants, outcome: 1.1 Breastfeeding 1 month to 4 months postbirth.

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