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[Intervention Review]

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

Elizabeth R Moore[1], Nils Bergman[2], Gene C Anderson[3], Nancy Medley[4]

[1]School of Nursing, Vanderbilt University, Nashville, Tennessee, USA. [2]School of Child and Adolescent Health, and Department of Human Biology, University of Cape Town, Cape Town, South Africa. [3]Case Western Reserve University, Professor Emerita, University of Florida, Gainesville, FL, USA. [4]Cochrane Pregnancy and Childbirth Group, Department of Women's and Children's Health, The University of Liverpool, Liverpool, UK

Contact address: Elizabeth R Moore, School of Nursing, Vanderbilt University, 314 Godchaux Hall, 21st Avenue South, Nashville, Tennessee, 37240-0008, USA. elizabeth.moore@vanderbilt.edu.

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ABSTRACT

Background

Mother-infant separation post birth is common. In standard hospital care, newborn infants are held wrapped or dressed in their mother's arms, placed in open cribs or under radiant warmers. Skin-to-skin contact (SSC) begins ideally at birth and should last continually until the end of the first breastfeeding. SSC involves placing the dried, naked baby prone on the mother's bare chest, often covered with a warm blanket. According to mammalian neuroscience, the intimate contact inherent in this place (habitat) evokes neuro-behaviors ensuring fulfillment of basic biological needs. This time frame immediately post birth may represent a 'sensitive period' for programming future physiology and behavior.

Objectives

To assess the effects of immediate or early SSC for healthy newborn infants compared to standard contact on establishment and maintenance of breastfeeding and infant physiology.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (17 December 2015), made personal contact with trialists, consulted the bibliography on kangaroo mother care (KMC) maintained by Dr Susan Ludington, and reviewed reference lists of retrieved studies.

Selection criteria

Randomized controlled trials that compared immediate or early SSC with usual hospital care.

Data collection and analysis

Two review authors independently assessed trials for inclusion and risk of bias, extracted data and checked them for accuracy. Quality of the evidence was assessed using the GRADE approach.

Main results

We included 46 trials with 3850 women and their infants; 38 trials with 3472 women and infants contributed data to our analyses. Trials took place in 21 countries, and most recruited small samples (just 12 trials randomized more than 100 women). Eight trials included women who had SSC after cesarean birth. All infants recruited to trials were healthy, and the majority were full term. Six trials studied late preterm infants (greater than 35 weeks' gestation). No included trial met all criteria for good quality with respect to methodology and reporting; no

trial was successfully blinded, and all analyses were imprecise due to small sample size. Many analyses had statistical heterogeneity due to considerable differences between SSC and standard care control groups.

Results for women

SSC women were more likely than women with standard contact to be breastfeeding at one to four months post birth, though there was some uncertainty in this estimate due to risks of bias in included trials (average risk ratio (RR) 1.24, 95% confidence interval (CI) 1.07 to 1.43; participants = 887; studies = 14; I^2 = 41%; GRADE: *moderate quality*). SSC women also breast fed their infants longer, though data were limited (mean difference (MD) 64 days, 95% CI 37.96 to 89.50; participants = 264; studies = six; GRADE:*low quality*); this result was from a sensitivity analysis excluding one trial contributing all of the heterogeneity in the primary analysis. SSC women were probably more likely to exclusively breast feed from hospital discharge to one month post birth and from six weeks to six months post birth, though both analyses had substantial heterogeneity (from discharge average RR 1.30, 95% CI 1.12 to 1.49; participants = 711; studies = six; I^2 = 44%; GRADE: *moderate quality*; from six weeks average RR 1.50, 95% CI 1.18 to 1.90; participants = 640; studies = seven; I^2 = 62%; GRADE: *moderate quality*).

Women in the SCC group had higher mean scores for breastfeeding effectiveness, with moderate heterogeneity (IBFAT (Infant Breastfeeding Assessment Tool) score MD 2.28, 95% CI 1.41 to 3.15; participants = 384; studies = four; I^2 = 41%). SSC infants were more likely to breast feed successfully during their first feed, with high heterogeneity (average RR 1.32, 95% CI 1.04 to 1.67; participants = 575; studies = five; I^2 = 85%).

Results for infants

SSC infants had higher SCRIP (stability of the cardio-respiratory system) scores overall, suggesting better stabilization on three physiological parameters. However, there were few infants, and the clinical significance of the test was unclear because trialists reported averages of multiple time points (standardized mean difference (SMD) 1.24, 95% CI 0.76 to 1.72; participants = 81; studies = two; GRADE *low quality*). SSC infants had higher blood glucose levels (MD 10.49, 95% CI 8.39 to 12.59; participants = 144; studies = three; GRADE: *low quality*), but similar temperature to infants in standard care (MD 0.30 degree Celcius (°C) 95% CI 0.13 °C to 0.47 °C; participants = 558; studies = six; I^2 = 88%; GRADE: *low quality*).

Women and infants after cesarean birth

Women practicing SSC after cesarean birth were probably more likely to breast feed one to four months post birth and to breast feed successfully (IBFAT score), but analyses were based on just two trials and few women. Evidence was insufficient to determine whether SSC could improve breastfeeding at other times after cesarean. Single trials contributed to infant respiratory rate, maternal pain and maternal state anxiety with no power to detect group differences.

Subgroups

We found no differences for any outcome when we compared times of initiation (immediate less than 10 minutes post birth versus early 10 minutes or more post birth) or lengths of contact time (60 minutes or less contact versus more than 60 minutes contact).

Authors' conclusions

Evidence supports the use of SSC to promote breastfeeding. Studies with larger sample sizes are necessary to confirm physiological benefit for infants during transition to extra-uterine life and to establish possible dose-response effects and optimal initiation time. Methodological quality of trials remains problematic, and small trials reporting different outcomes with different scales and limited data limit our confidence in the benefits of SSC for infants. Our review included only healthy infants, which limits the range of physiological parameters observed and makes their interpretation difficult.

PLAIN LANGUAGE SUMMARY

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

What is the issue?

Babies are often separated from their mothers at birth. In standard hospital care, newborn infants can be held wrapped or dressed in their mother’s arms, placed in open cribs or under warmers. In skin-to-skin contact (SSC), the newborn infant is placed naked on the mother's bare chest at birth or soon afterwards. Immediate SSC means within 10 minutes of birth while early SSC means between 10 minutes and 24 hours after birth. We wanted to know if immediate or early SSC improved breastfeeding for mothers and babies, and improved the transition to the outside world for babies.

Why is this important?

There are well-known benefits to breastfeeding for women and their babies. We wanted to know if immediate or early SSC could improve women's chances of successfully breastfeeding. Having early contact may also help keep babies warm and calm and improve other aspects of a baby's transition to life outside the womb.

What evidence did we find?

We searched for randomized controlled studies of immediate and early SSC on 17 December 2015. We found thirty-eight studies with 3472 women that provided data for analysis. Most studies compared early SSC with standard hospital care for women with healthy full-term babies. In eight studies women gave birth by cesarean, and in six studies the babies were healthy but born preterm at 35 weeks or more. More women who had SSC with their babies were still breastfeeding at one to four months after giving birth (14 studies, 887 women, *moderate-quality evidence*). Mothers who had SSC breast fed their infants longer, too, on average over 60 days longer (six studies, 264 women, *low-quality evidence*). Babies held in SSC were more likely to have breast fed successfully during their first breast feed (five studies, 575 women). Babies held in SSC had higher blood glucose levels (three studies, 144 women, *low-quality evidence*), but similar temperature to babies with standard care (six studies, 558 women, *low-quality evidence*). We had too few babies in our included studies and the quality of the evidence was too low for us to be very confident in the results for infants.

Women giving birth by cesarean may benefit from early SSC, with more women breastfeeding successfully and still breastfeeding at one to four months (fourteen studies, 887 women, moderate-quality evidence), but there were not enough women studied for us to be confident in this result.

We found no clear benefit to immediate SSC rather than SSC after the baby had been washed and examined. Neither did we find any clear advantage of a longer duration of SSC (more than one hour) compared with less than one hour. Future trials with more women and infants may help us answer these questions with confidence.

SSC was defined in various ways and different scales and times were used to measure different outcomes. Women and staff knew they were being studied, and women in the standard care groups had varying levels of breastfeeding support. These differences lead to wide variation in the findings and a lower quality evidence. Many studies were small with less than 100 women participating.

What does this mean?

The evidence from this updated review supports using immediate or early SSC to promote breastfeeding. This is important because we know breastfeeding helps babies avoid illness and stay healthy. Women giving birth by cesarean may benefit from early SSC but we need more studies to confirm this. We still do not know whether early SSC for healthy infants helps them make the transition to the outside world more smoothly after birth, but future good quality studies may improve our understanding. Despite our concerns about the quality of the studies, and since we found no evidence of harm in any included studies, we conclude the evidence supports that early SSC should be normal practice for healthy newborns including those born by cesarean and babies born early at 35 weeks or more.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. 'Summary of findings Quality of the Evidence using GRADE

Skin-to-skin versus standard contact for healthy infants

Patient or population: mothers and their healthy newborn infants
Setting: hospital settings in Chile, Guatemala, Japan, India, Italy, UK, Germany, Nepal, Poland, USA, Sweden, South Africa, Spain, Vietnam, Taiwan, and Canada
Intervention: skin-to-skin contact
Comparison: standard contact

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with standard contact for healthy infants	Risk with Skin-to-skin contact				
Breastfeeding 1 month to 4 months post birth	Study population 541 per 1000	670 per 1000 (579 to 773)	average RR 1.24 (1.07 to 1.43)	887 (14 RCTs)	⊕⊕⊕⊖ MODERATE [1, 2, 11]	
Duration of breastfeeding in days	The mean duration of breastfeeding in days in control groups was 88 days	The mean duration of breastfeeding in days in the intervention group was 63.73 days more (37.97 days more to 89.50 days more)		264 (6 RCTs)	⊕⊕⊖⊖ LOW [4, 5]	This result is a sensitivity analysis excluding 1 trial that contributed all heterogeneity.
SCRIP score first 6 hours post birth range (0 to 6) at each time point, trials recorded multiple time points**	We could not calculate the control group mean due to different scales used in trials	The mean SCRIP score first 6 hours post birth in the intervention group was 1.24 standard deviations more (0.76 more to 1.72 more)		81 (2 RCTs)	⊕⊕⊖⊖ LOW [12, 6]	A standardized mean difference (SMD) of 1.24 represents a large effect.
Blood glucose mg/dL at 75 to 180 minutes post birth Thresholds for low glucose vary from 40 mg to 50 mg/dL	The control group mean blood glucose at 75 to 180 minutes post birth was 49.8 mg/dL	The mean blood glucose mg/dL at 75 to 180 minutes post birth in the intervention group was 10.49 mg/dL more (8.39 more to 12.59 more)		144 (3 RCTs)	⊕⊕⊖⊖ LOW [3, 4]	The mean difference (MD) of 10.49 mg/dL is clinically significant.
Infant axillary temperature (°C) 90 minutes to 2.5 hours post birth	The mean infant axillary temperature 90 minutes to 2.5 hours post birth was 36.62 °C	The mean infant axillary temperature 90 minutes to 2.5 hours post birth in the intervention group was 0.3 °C more (0.13 more to 0.47 more)		558 (6 RCTs)	⊕⊕⊖⊖ LOW [4, 7]	The mean difference (MD) of 0.3 °C temperature is not

					clinically significant.
Exclusive breastfeeding at hospital discharge to 1 month post birth	Study population		average RR 1.30 (1.12 to 1.49)	711 (6 RCTs)	⊕⊕⊕⊖ MODERATE [8, 9]
	642 per 1000	835 per 1000 (719 to 957)			
Exclusive breastfeeding 6 weeks to 6 months post birth	Study population		average RR 1.50 (1.18 to 1.90)	640 (7 RCTs)	⊕⊕⊕⊖ MODERATE [8, 10]
	519 per 1000	778 per 1000 (612 to 985)			

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).
** SCRIP - Stability of cardio-respiratory system in preterms
CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Most trials contributing data had unclear risk of bias for allocation concealment. Half had unclear sequence generation. We were unclear of the time point of data collection for 1 trial. No trial was blinded (-1).
[2] I^2 = 41% with random-effects model. Not downgraded.
[3] Estimate based on small sample size (-1).
[4] Most trials had unclear or high risk of bias for sequence generation and allocation concealment. No trial was blinded (-1).
[5] Estimate based on small sample size (-1).
[6] 1 trial had unclear risk of bias for allocation concealment. No trial contributing data were blinded (-1).
[7] I^2 = 88% with random-effects model due to 1 trial finding higher axillary temperature in the control group (-1).
[8] Several trials with unclear risk of bias for sequence generation and allocation concealment. No trial was blinded (-1).
[9] I^2 = 44% with random-effects model (not downgraded).
[10] I^2 = 62% with random-effects model (not downgraded).
[11] 2 very small trials had the most dramatic effects, and we could not rule out publication bias. The removal of these trials from the analysis does not change the overall effect or conclusions regarding the intervention. We have not downgraded for publication bias.
[12] Estimate based on small sample size. We also have some reservations regarding the trials' averaging SCRIP scores across repeated measures, as was done in both trials included in this analysis. Averaging will reduce the variability in infants' scores, reducing also the standard deviation. A smaller SD will increase the SMD, even if the actual difference between groups is not large. See http://bayesfactor.blogspot.co.uk/2016/01/averaging-can-produce-misleading.html (-1).

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-infant skin-to-skin contact (SSC). In many industrialized societies separating the newborn from its mother soon after birth has become common practice. 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

Immediate SSC is the placing of the naked baby prone on the mother's bare chest at birth and early SSC begins within the first day. In the evolutionary context, this would have been "immediate and continuous". In the context of this review, SSC is compared to all degrees of separation, from infants that are clothed but held by mother, to those in a central nursery. The clinical and nursing care does not change; SSC is regarded as the place where such care is provided. Further, although a dose-response effect has not yet been documented in randomized controlled trials (RCTs), the general consensus is that minimally, SSC should continue until the end of the first successful breastfeeding in order to show an effect and to enhance early infant self-regulation (Widstrom 2011). According to the Baby-Friendly USA Initiative criteria, Step 4, all infants should be placed in SSC with their mothers immediately post birth for at least an hour.

How the intervention might work

The rationale for SSC comes from animal studies in which some of the innate newborn behaviors that are necessary for survival are shown to be habitat or location dependent (Alberts 1994). In mammalian biology, maintenance of the maternal milieu following birth is required to elicit innate behaviors from the newborn and the mother that lead to successful breastfeeding, and thus survival. Further, maternal sensations are the triggers that ensure regulation of all aspects of neonatal physiology, including cardiorespiratory and digestive, hormonal and behavioral (Hofer 2006). Separation from this milieu is interpreted in rat studies as sudden and complete loss of such regulation (Hofer 2006), and results in immediate distress cries (Alberts 1994) and "protest-despair" behavior. Human infants placed in a cot cry 10 times more than SSC infants (Christensson 1995). Their cry is similar to the vocalizations of separated rat pups using sound spectral analysis (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 normal hippocampal development in the offspring.

Healthy, full-term infants employ a species-specific set of innate newborn 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, 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. Further evidence for a sensitive period is the activation of the olfactory cortex by colostrum, which is only present for the first day of life (Bartocci 2000). 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).

SSC is a powerful vagal stimulant, through sensory stimuli such as touch, warmth, and odor, 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). In a study of infrared thermography of the whole body during the first hour post birth, Christidis 2003 found that SSC was as effective as radiant warmers in preventing heat loss in healthy full-term infants. 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 threatening, (Graeff 1994; Porges 2007), stress mechanisms come into operation, with the focus on survival (homeostasis) rather than development (homeorhesis). The concept of allostasis takes a broader view of homeostasis and homeorhesis, being the relationship between psycho-neurohormonal responses to stress and physical and psychological manifestations of health and illness across the lifespan (McEwen 1998; Shannon 2007). Allostatic mechanisms seek to restore autonomic systems to a healthy baseline. Repeated and chronic stress imposes an ‘allostatic load’, whereby the healthy baseline can no longer be maintained, and is therefore up-regulated or adapted. The higher the allostatic load the greater the damage from stress, because allostatic load is cumulative.

Epigenetic changes probably mediate such change. In development, ‘predictive adaptive responses’ have been postulated to make early and permanent gene adaptations in many systems during sensitive periods (Gluckman 2005). In mammalian studies, maternal-infant separation is regarded as a severe form of stress, with documented epigenetic changes in stress regulation systems (Arabadzisz 2010; Sabatini 2007). The original changes in hippocampal cortisol receptors first described in rats by Meaney 2005, are now also being documented in human adults (McGowan 2009). This concept is now more broadly described in DOHaD (Developmental Origins of Health and Disease), in which early developmental plasticity impacts “long-term biological, mental, and behavioral strategies in response to local ecological and/or social conditions” (Hochberg 2011).

SSC also lowers maternal stress levels. Handlin 2009 found a dose-response relationship between the amount of SSC and maternal plasma cortisol two days post birth. A longer duration of SSC was correlated with a lower median level of cortisol (r = - 0.264, P = 0.044).

SSC induces oxytocin, which 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). In the newborn period, stimuli such as SSC, suckling and vocalizations play a role in connecting oxytocin systems to dopamine pathways, neuroimaging shows that maternal neglect is characterized by failure to make such connections (Strathearn 2011). Consistent with this, SSC outcomes for mothers suggest improved bonding/attachment (Affonso 1989); other outcomes are an 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).

Time to expulsion of the placenta was shorter (Marin 2010) (M = 409 $\pm$ 245 sec.) in mothers of SSC infants than in control mothers (M = 475 $\pm$ 277 sec., P = 0.05). With 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 a more rapid delivery of the placenta than control mothers (Marin 2010).

Why it is important to do this review

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). The updated review on kangaroo mother care (KMC), (Conde-Agudelo 2014) includes 18 randomized controlled trials (RCTs) of 2751 low birthweight infants, all less than 2500 g at birth. KMC is defined as continuous or intermittent SSC with exclusive or nearly exclusive breastfeeding and early hospital discharge but KMC is seldom practiced in its entirety. Most included studies focus on SSC as the key intervention, evidenced by exclusive breastfeeding at discharge (and other breastfeeding outcomes) being reported as outcomes rather than the intervention. KMC was associated with reductions in 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. The current WHO guidelines on newborn care “WHO recommendations on interventions to improve preterm birth outcomes” (WHO 2015) advise KMC for thermal care for preterm newborns.

In another meta-analysis of 23 studies (13 case-series, five RCT's, one cross-over and four cohort), Mori 2010 evaluated temperature, heart rate and oxygen saturation outcomes in both low and normal birthweight infants up to 28 days old; showing small changes of no clinical significance. A Cochrane review focusing on the effect of SSC on procedural pain in all neonates (Johnston 2014), including 19 RCTs and 1594 infants; concluded that SSC provides effective pain relief as measured by physiological and behavioral responses. A meta-analysis of nine RCTs and six observational studies, all from low- or middle-income settings for infants born below 2000 g focusing on mortality using primarily the GRADE tool (Lawn 2010) reported that analysis of three RCTs commencing KMC in the first week of life showed a significant reduction in neonatal mortality. A commentary on this meta-analysis points out a number of flaws (Sloan 2010), nevertheless the conclusions are in keeping with Conde-Agudelo 2014.

The possibility exists that postnatal separation of human infants from their mothers is stressful (Anderson 1995). Delivery room and postpartum hospital routines may significantly disrupt early maternal-infant interactions including breastfeeding (Anderson 2004a; Odent 2001; Winberg 1995). 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 USA by the Food and Drug Administration (FDA) in 2005 to 2007, Grummer-Strawn 2008 found that 83% of mothers initiated breastfeeding, but only 48% exclusively breast fed during their hospital stay. These innate behaviors can be disrupted by early postpartum 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 breast feed 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 post birth 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 immediate and 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. The focus of this review is on randomized controlled trials used to test the effects of immediate and early SSC. This is an update of a Cochrane review first published in 2003 and previously updated in 2007 and 2012.

OBJECTIVES

We assessed the effects of immediate or early skin-to-skin contact on healthy newborn infants and their mothers 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 included:

1. establishment and maintenance of breastfeeding/lactation;
2. infant physiology - thermoregulation, respiratory, cardiac, metabolic function, neuro behavior;
3. maternal-infant bonding/attachment.

Planned comparisons

Planned comparisons included:

1. immediate or early skin-to-skin versus standard contact for healthy infants;

2. immediate or early skin-to-skin versus standard contact for healthy infants after cesarean birth;
3. skin-to-skin versus standard contact by time of initiation;
4. and skin-to-skin versus standard contact by dose (length of contact time).

METHODS

Criteria for considering studies for this review

Types of studies

All randomized controlled trials (RCTs) in which the active encouragement of immediate or early skin-to-skin contact (SSC) between mothers and their healthy newborn infants was compared to usual hospital care. We did not include quasi-randomized trials (e.g. where assignment to groups was alternate or by day of the week, or by other non-random methods) or observational studies. We included cluster-randomized trials if these were eligible. Cross-over trials were not eligible for inclusion.

Trials reported in abstract form only were eligible for inclusion if there was sufficient information to assess the trial and include data. Abstract reports with insufficient information to assess the trial were left in Studies awaiting classification for one update cycle with a view that a full publication may clarify eligibility.

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.

Types of participants

Mothers and their healthy full-term or late preterm newborn infants (34 to less than 37 completed weeks' gestation) who had immediate or early SSC starting less than 24 hours after birth, and controls undergoing standard patterns of care. Infants eligible for our targeted trials weighed more than 2500 g, although some healthy late preterm infants weighed less and were not excluded. We excluded infants less than or equal to 1500 g because we expected that these infants did not complete at least 33 weeks' gestation. We excluded any infant admitted to the neonatal intensive care unit; eligible infants were healthy enough to stay with their mothers in the postpartum unit.

We included late preterm infants (from 34 weeks' gestation) in trials including infants of earlier gestation if we were able to separate data for the late preterm group.

We included women randomized to SSC after cesarean birth.

Types of interventions

Early SSC for term or late preterm infants can be divided into two subcategories.

(a) In 'Immediate, Birth or Very Early SSC', the infant is placed prone skin-to-skin on the mother's abdomen or chest less than 10 minutes post birth. The infant is suctioned while on the mother's abdomen or chest, if medically indicated, thoroughly dried and covered across the back with a pre-warmed 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 post birth or the first successful breastfeeding.

(b) 'Early SSC' can begin anytime between 10 minutes and 24 hours post birth. 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.

Standard contact includes a number of diverse conditions: swaddled or dressed infants held in their mothers arms or with other family; infants placed in open cribs or under radiant warmers; or infants placed in a cot in the mother's room or elsewhere without holding. No infant in the comparison arm should have SSC.

Types of outcome measures

Primary outcomes

Breastfeeding outcomes

1. Number of mothers breastfeeding (any breastfeeding) one month to four months post birth.
2. Duration of any breastfeeding in days.

Infant outcomes

1. Infant stabilization during the transition to extra-uterine life (the first six hours post birth). 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 (Bergman 2004).
2. Blood glucose levels during/after SSC compared to standard care in mg/dL 75 to 180 minutes post birth.
3. Infant thermoregulation = temperature changes during/after SSC compared to standard care (measured by axillary temperature in degree Celsius (°C) 90 minutes to 2.5 hours post birth.

Secondary outcomes

Breastfeeding outcomes (secondary)

1. Breastfeeding rates/exclusivity using the Labbok 1990; Hake-Brooks 2008 Index of Breastfeeding Status (IBS) at hospital discharge up to one month post birth. The eight patterns of IBS are ranked as 1 for exclusive and 2 for almost exclusive breastfeeding, 3 for high, 4 for medium-high, 5 for medium-low and 6 for low partial breastfeeding. Token breastfeeding is ranked 7 and weaned is ranked 8.
2. Breastfeeding rates/exclusivity (using the Labbok 1990; Hake-Brooks 2008 Index of Breastfeeding Status (IBS) six weeks to six months post birth.
3. Effective breastfeeding (Infant Breastfeeding Assessment Tool (IBFAT) (Matthews 1988; Matthews 1991) during the first feeding. The 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 to 3 on each item for a maximum total score of 12 indicating adequate suckling competence.

4. Maternal breast temperature during and after SSC - measured by an electronic thermometer positioned above the areola in a 12 o'clock position on the breast (Bystrova 2003).
5. Breast engorgement - measured by the self-reported Six Point Breast Engorgement Scale (Hill 1994) or by the mother's perception of tension/hardness in her breasts) three days post birth.

Infant outcomes (secondary)

1. Infant heart rate during/after SSC compared to standard care 75 minutes to 2 hours post birth.
2. Respiratory status - respiratory rate during/after SSC compared to standard care 75 minutes to 2 hours post birth.
3. Neonatal intensive care unit admissions.
4. Infant weight changes/rate of growth in g/kg/day (daily weight change, change in weight over days of study) (Hill 2007).
5. Length of hospital stay in hours.
6. Amount of infant crying - amount of crying in minutes during a 75- to 90-minute observation period.

Maternal outcomes

1. Maternal perceptions of bonding/connection to her infant at 12 months post birth using The Parent-Child Early Relational Assessment (PCERA). The PCERA (Clark 1985; Clark 1999) has eight sub-scales evaluating maternal and infant behavior and interaction.
2. Maternal pain four hours post cesarean birth - Possible values for the pain scale were zero to 10 with 10 being the worst pain imaginable. Pain can interfere with maternal-infant interaction.
3. Maternal sensitivity to her infant's cues using the PCERA at 12 months post birth.
4. Maternal anxiety using the state anxiety scale from the State Trait Anxiety Inventory (STAI) (Spielberger 1970) eight hours to three days post birth. The state anxiety scale is a 20-item instrument that measures how the individual feels in the present moment with a possible range of scores from 20 to 80 with higher scores indicating more anxiety.
5. Maternal parenting confidence measured at one month post birth by the Parenting Sense of Competence Scale, a 17-item scale developed by Gibaud-Wallston 1977 that assesses an individual's perceptions of their skills, knowledge, and abilities for being a good parent, their level of comfort in the parenting role, and the importance they attribute to parenting.

Search methods for identification of studies

The following methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

Electronic searches

We searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (17 December 2015).

The Register is a database containing over 22,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate Pregnancy and Childbirth's Trials Register including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link to the editorial information about the Cochrane Pregnancy and Childbirth in the Cochrane Library and select the '***Specialized Register***' section from the options on the left side of the screen.

Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains trials identified from:

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

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set which has been fully accounted for in the relevant review sections (Included studies; Excluded studies; Studies awaiting classification; Ongoing studies).

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 searched the reference lists of retrieved studies.

We did not apply any language or date restrictions.

Data collection and analysis

For methods used in the previous version of this review, *see* Moore 2012.

For this update, the following methods were used for assessing the 46 reports that were identified as a result of the updated search.

The following methods section of this review is based on a standard template used by Cochrane Pregnancy and Childbirth.

Selection of studies

Two review authors independently assessed for inclusion all the potential studies identified as a result of the search strategy. We resolved any disagreement through discussion or, if required, we consulted the third review author.

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We resolved

discrepancies through discussion or, if required, we consulted the third review author. Data were entered into Review Manager software (RevMan 2014) and checked for accuracy.

When information regarding any of the above was unclear, we planned 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). Any disagreement was resolved by discussion or by involving a third assessor.

(1) Random 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 should produce 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);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed 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);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance 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 was unlikely to affect 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.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

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 and 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 planned to re-include missing data in the analyses which we undertook.

We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomization);
- unclear risk of bias.

(5) Selective reporting (checking for 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 is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we had about other possible sources of 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 *Handbook* (Higgins 2011). With reference to (1) to (6) above, we planned to assess the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. In future updates, we will explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Assessment of the quality of the evidence using the GRADE approach

For this update we assessed the quality of the evidence using the GRADE approach as outlined in the GRADE handbook in order to assess the quality of the body of evidence relating to the following outcomes for the main comparison of SSC versus standard contact for healthy infants.

1. Breastfeeding (any breastfeeding) one month to four months post birth
2. Duration of any breastfeeding in days
3. Exclusive breastfeeding at hospital discharge to one month post birth
4. Exclusive breastfeeding six weeks to six months post birth
5. Infant stabilization (SCRIP score first six hours post birth)
6. Blood glucose mg/dL at 75 to 180 minutes post birth
7. Infant axillary temperature 90 minutes to 2.5 hours post birth

We used the GRADEpro Guideline Development Tool to import data from Review Manager 5.3 (RevMan 2014) in order to create a 'Summary of findings' table. A summary of the intervention effect and a measure of quality for each of the above outcomes was produced using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

Measures of treatment effect

Dichotomous data

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

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

Cluster-randomized trials

We included one cluster-like randomized trial in this review with methods described in 'Other unit of analysis issues' below.

If in future updates we identify more eligible cluster-randomized trials, we will include these trials in the analyses along with individually-randomized trials. We will adjust their sample sizes or standard errors using the methods described in the *Handbook* [Section 16.3.4 or 16.3.6] using an estimate of the intra cluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomized trials and individually-randomized trials, we plan to synthesize the relevant information. We will consider it reasonable to combine the results from both 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.

We will also acknowledge heterogeneity in the randomization unit and perform a sensitivity analysis to investigate the effects of the randomization unit.

Cross-over trials

Cross-over trials were not eligible for inclusion in this review.

Other unit of analysis issues

For this update, we included a trial that randomized physicians rather than women Marin 2010. This trial was previously excluded from the review due to its cluster-like design. We conducted sensitivity analyses to investigate the effects of cluster design (1.33 and 1.34). Assuming low dependence, we adjusted the sample size and event rate for the trial using a design effect of 2. Pagel 2011 offers a range of ICCs (0.01 to 0.09); a design effect of 2 uses an ICC of approximately 0.05. These adjustments did not substantially change the overall effect estimates or conclusions for our analyses 1.6 or 1.18. We therefore included unadjusted data in the meta-analyses for these outcomes. We did not adjust for cluster design for the continuous variable 1.28 maternal state anxiety; however, the data contributed by this trial are in the same direction as the other trials in the analysis, with a more conservative estimate of the intervention.

Dealing with missing data

For included studies, we noted levels of attrition. In future updates, if more eligible studies are included, we will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, analyses were carried out, 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. 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 Tau^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if an I^2 was greater than 40% and either the Tau^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity. If we identified substantial heterogeneity (above 40%), we provided possible reasons for this in the text. We also explored heterogeneity by pre-specified subgroup analysis.

Assessment of reporting biases

In future updates, if there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry 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 2014). We used fixed-effect meta-analysis for combining data where 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 of the range of possible treatment effects and we discuss the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we planned not to combine trials. Where we used random-effects analyses, the results were presented as the average treatment effect with 95% confidence intervals and the estimates of Tau^2 and I^2.

Subgroup analysis and investigation of heterogeneity

If we identified substantial heterogeneity, we considered whether an overall summary was meaningful, and if it was, we used random-effects analysis to produce it. We investigated heterogeneity using subgroup analysis.

We carried out the following subgroup analyses to explore clinical groups even where there was no heterogeneity.

1. Initiation of skin-to-skin contact: immediate (< 10 minutes from birth) versus delayed (10 minutes or more after birth) in Comparison 3
2. Dose of skin-to-skin contact: high (more than 60 minutes in the first 24 hours) versus low (60 minutes or less) in Comparison 4

The following outcomes were used in subgroup analyses.

Breastfeeding outcomes

1. Number of mothers breastfeeding (any breastfeeding) one month to four months post birth
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)

We assessed subgroup differences by interaction tests available within RevMan (RevMan 2014). We reported the results of subgroup analyses quoting the Chi^2 statistic and P value, and the interaction test I^2 value.

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 with much of the variation due to a single study. We therefore carried out sensitivity analysis excluding this study (Sosa 1976a) to examine the impact on results (1.29 and 1.30). For infant physiological outcomes, we also carried out sensitivity analysis removing Villalon 1992 to explore high levels of heterogeneity (1.31 and 1.32). Finally, we tested the impact of adjustments for cluster design for Marin 2010 as described above (1.33 and 1.34).

RESULTS

Description of studies

Results of the search

See: Figure 1.

Figure 1. 1 Study flow diagram.

For this 2016 update we assessed 41 new reports from the Pregnancy and Childbirth Group search. We located an additional trial report through our own searches (Luong 2015). From these 42 new reports we included 11 new studies. We also included one study previously excluded, so that this review includes 12 new studies (13 reports). We excluded 17 studies (19 reports). Three reports describe trials in abstract form only; we were unable to fully assess these for inclusion due to insufficient information (see Studies awaiting classification). Seven reports were additional reports for previously included studies (Bystrova 2003; Khadivzadeh 2009).

New studies found at this update

Twelve randomized controlled trials (RCTs) have been added to the review for 2016. The results from an additional report involving the data set from Bystrova 2003, and several from Khadivzadeh 2009 have been added to this update.

Included studies

Forty-six studies with 3850 mother-infant dyads met the inclusion criteria. Eight of these trials contributed no data to the review (Curry 1982; Fardig 1980; Ferber 2004; Hales 1977; Huang 2006; Kastner 2005; McClellan 1980; Svejda 1980), leaving 38 studies with 3472 infants and women for analyses. A large number of outcomes (28) have been reported in the analysis, but only 20 of these included multiple trials for pooled analysis. For many of the other

outcomes a small number of studies (two or three) contributed data.

None of the 46 studies met all of the methodological quality criteria (*see* Figure 2 and Figure 3). The total sample sizes in the studies ranged from eight to 350 mother-infant pairs, with only 12 trials each recruiting over 100 women and infant pairs. The studies represented very diverse populations in Canada, Chile, Germany, Guatemala, India, Iran, Israel, Italy, Japan, Nepal, Pakistan, Poland, Russia, South Africa, Spain, Sweden, Taiwan, Thailand, the UK, USA and Vietnam. One paper reported results for studies carried out in two different sites in Guatemala, and we have treated these as three different studies in the data analysis (Sosa 1976a; Sosa 1976b; Sosa 1976c).

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

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

For this update, we have included unpublished data or clarification from authors for the following trials (Armbrust 2016; Girish 2013; Luong 2015; Nimbalkar 2014).

Population

Most trials recruited singleton pregnancies; though this was not always stated, it was inferred through outcome data and reference to mother-infant dyad. Luong 2015 and Mahmood 2011 specifically excluded multiple births. Several trials recruited only primiparous women (Carlsson 1978; Craig 1982; Curry 1982; De Chateau 1977; Hales 1977; Khadivzadeh 2009; Nahidi 2011, all three Sosa trials, Svejda 1980; Thomson 1979). In contrast, all women in McClellan 1980 were multiparous.

All but six of the 46 studies included only healthy full-term infants. Five studies (Anderson 2003; Bergman 2004; Chwo 1999; Luong 2015; Syfrett 1993) were carried out with healthy late preterm infants who were assigned to the normal newborn nursery or neonatal unit. Nimbalkar 2014 included both term and late preterm infants, while for Luong 2015 we have included a subset of late preterm infants with low birthweight (unpublished data). Seven studies (Armbrust 2016; Beiranvand 2014; Gouchon 2010; McClellan 1980; Nasehi 2012; Nolan 2009; Norouzi 2013) were conducted with healthy mother-infant dyads after a cesarean birth. One study (Huang 2006) was conducted with hypothermic, but otherwise healthy newborns post-cesarean birth.

Interventions

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 hours of continuous SSC (Syfrett 1993); in Syfrett 1993 all dyads received 24 minutes of SSC before randomization. All dyads in Bergman 2004 also received a brief period of SSC immediately after birth. In contrast, all infants in Bystrova 2003 were immediately warmed, dried, washed and weighed before receiving control or intervention protocol. Apart from different protocols of SSC, intervention arms had different rates of compliance with the intervention (though not all trials reported this). Armbrust 2016 reported (by email) that two infants randomized to SSC did not receive this due to their need to see a neonatologist. Anderson 2003 reported that SSC mothers gave SSC 22% of the time and held their wrapped infants for 11.6% of the observation period.

For subgroup analysis we have compared trials that initiated SSC < 10 minutes post birth with trials starting SSC ≥ 10 minutes from birth. Eighteen of 38 trials contributing data to the review began SSC immediately after birth (please see Table 1). Delayed contact trials had considerable differences in timing. Many infants went to their mothers after an initial assessment that was longer than 10 minutes; exact timing was not always described. SSC dyads in the study by Shiau 1997 could not begin until four hours post birth because of hospital policy. SSC did not begin until a mean of 21.3 hours post birth in the study by Chwo 1999 of late preterm infants 34 to 36 weeks' gestational age. In 31 of the 46 studies the infants were given the opportunity to suckle during SSC but only nine studies (Beiranvand 2014; Carfoot 2004; Carfoot 2005; Girish 2013; Gouchon 2010; Khadivzadeh 2009; Mahmood 2011; Moore 2005; Srivastava 2014) 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.

We also compared trials with low (60 minutes or less SSC) or high dose (greater than 60 minutes SSC). Twenty-three of 38 trials contributing data to the review offered infants 60 minutes or less of SSC (please see Table 1).

Control groups

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 post birth and reunited 12 to 24 hours later. In Luong 2015 control infants were separated from their mothers until their discharge from the neonatal unit. 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 Marin 2010 and Punthmatharith 2001. The swaddled control infants in Khadivzadeh 2009 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, for 30 to 60 minutes in Girish 2013 and in Gouchon 2010 for a mean of 51 minutes and in Nasehi 2012, 120 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 post birth for 120 minutes but reunited with their mothers for rooming-in on the postpartum unit. In Anderson 2003 control mothers held their wrapped infants 13.9% of the time (M = 6.67 hours). Many of the trials do not report when the control mothers were reunited with their infants or the length of initial contact.

The control group in several trials received multiple interventions, including those that may interfere with breastfeeding (such as vitamin K injections and physical assessment) (Armbrust 2016; Girish 2013; Khadivzadeh 2009; Luong 2015).

Details of all included studies are set out in the Characteristics of included studies tables.

Excluded studies

Sixty-six 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 immediate or 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).

Risk of bias in included studies

Overall, no trial met all criteria for low risk of bias, due to lack of blinding in all trials. Most included studies had unclear reporting for one or more domains. Many studies also had high risk of bias for incomplete reporting of outcome data, attrition or other sources of bias, including multiple co-interventions or baseline differences in important potential or known covariates such as socio-economic status. Trials were best at reporting randomization methods, while we consider lack of blinding of outcomes assessors the highest risk of bias across included studies.

Allocation

Sequence generation

No trial was at high risk of bias due to quasi-random methods of sequence generation. In 22 of the 46 included studies trialists described clear and appropriate methods for generating the randomization sequence for an assessment of low risk of bias. For 24 studies we found insufficient information to determine if the method of sequence generation was robust before allocation of the participants to groups occurred; one of these studies used a random numbers table, but there was some confusion as to whether women could have been re-assigned (McClellan 1980).

Allocation concealment

Two studies (De Chateau 1977; McClellan 1980), we judged to be of high risk of bias for allocation concealment because the researchers used an open table of random numbers. Fourteen of 46 included studies were of low risk of bias for allocation concealment due to use of sequential, sealed envelopes or computer-numbered programs (the minimization method) (Anderson 2003; Bergman 2004; Bystrova 2003; Chwo 1999; Gouchon 2010; Mahmood 2011; Moore 2005; Nimbalkar 2014; Nolan 2009; Norouzi 2013; Punthmatharith 2001; Shiau 1997; Syfrett 1993, Thukral 2012). Randomization by minimization, clearly described by Conlon 1990 and Zeller 1997, is a method of sequential assignment into groups that reduces the amount of bias by controlling for as many known extraneous factors as possible. It produces groups that are comparable in size and distribution of potentially confounding covariates (Pocock 1975). The remaining included trials had insufficient information on allocation concealment or incomplete description of methods used - such as whether envelopes were sealed or sequentially numbered or opened consecutively. Some of these trials only reported that women were randomly assigned to groups.

Blinding

Performance bias

No trial was blinded for performance bias. Because the intervention clearly differed from the control in all trials, we have assessed all trials as of high risk of bias. We have downgraded all evidence assessed with GRADE for lack of adequate blinding of the intervention from staff and women in trials.

Most women and staff were aware of the intervention, and this awareness may have altered women's responses to questions and influenced the content and quality of care from staff. That stated, many included trials reported different scenarios where blinding of staff or women was attempted. For example, Ferber 2004 stated that the nursery staff were blind to patient group assignment. Surprisingly, several trials attempted to blind for patient performance bias. In seven older studies (Carlsson 1978; Craig 1982; Curry 1982; Ferber 2004; Kastner 2005; Svejda 1980; Thomson 1979), it was reported that the women randomized 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 the majority of studies, control for provider performance bias was difficult to determine, and certainly the risk of bias of an unblinded intervention may differ according to the outcome in question - whether physiological or self-reported. However, due to the very different protocols for intervention and control arms, we have assessed all trials as of high risk of performance bias.

Detection bias

Blinding outcome assessors to treatment group is extremely difficult for this type of intervention, and we found it hard to judge the impact of lack of blinding on particular outcomes. We assessed five trials that reported blinding of outcome assessment as of low risk of bias (Anderson 2003; Girish 2013; Norouzi 2013; Svejda 1980; Thukral 2012). In 15 trials researchers who were aware of allocation also collected outcome data; these trials were assessed as high risk of detection bias. For remaining included trials we assessed the impact of lack of blinding for detection bias as unclear, due to insufficient information or due our uncertainty regarding the impact of limited blinding of various clinical staff, data analysts or statisticians.

Incomplete outcome data

Four trials were assessed as at high risk of attrition bias due to missing data at specific time points or unclear denominators (Craig 1982; Mahmood 2011; Vaidya 2005; Villalon 1992). Several

trials (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; these and others with clear reporting on all participants were assessed as of low risk of bias. We assessed the remaining trials as unclear if denominators were unclear or not reported, or if we were unsure of the impact of incomplete or unclear follow-up at specific time points, for example.

Selective reporting

Selective reporting bias was evaluated by reviewing the outcomes listed in the Methods section of the individual trials and then examining whether data for these outcomes was reported in the Results section. We did not search for protocols but made judgements based on published reports only.

Twelve trials were assessed as at low risk of bias for selective reporting because all outcomes mentioned in the published papers were reported. We were unclear about the selective reporting of most remaining trials. There are several reasons for a judgment of unclear: we had questions about data and contacted authors; a trial reported an outcome for one treatment group and not the other; a trial reported a result in terms of statistical significance or percentages in the text without events and totals; we noted incomplete reporting of data collected at multiple time points, or finally, the trial failed to report an outcome mentioned in the methods text. We assessed the three Sosa trials as of high risk of bias due to incomplete reporting of data collected at different time points and because there were no standard deviation (SDs) reported for the mean of our primary outcome of breastfeeding duration.

Other potential sources of bias

A judgement unclear risk of 'other bias' has to do with different types of interventions and control groups (affecting generalizability of results), possible differences in important baseline characteristics between arms, and discrepancies in the published reports. The following trials were assessed as unclear for stated reasons. In several trials, women in the control arms received help with breastfeeding and lactation support (Anderson 2003; Chwo 1999; Girish 2013; Gouchon 2010; Moore 2005). Included studies Armbrust 2016, Nolan 2009, and Syfrett 1993 all had multiple co-interventions with the potential to impact on outcomes. We were unsure of the impact of possible differences in baseline characteristics in Girish 2013. Other factors noted were: whether the primary outcome of the trial targeted something different from the focus of this review and whether or not the women had analgesia.

For several trials there were factors that we felt deserved a judgement of high risk of 'other bias'. The infants in both arms of Gouchon 2010 were bathed before returning to their mother, which would impact on the temperature outcomes. For another trial, the results represent an interim analysis and this was rated as high risk of bias; Bergman 2004 had difficulty recruiting women and stopped the trial after interim analyses favored the intervention. Infants receiving SSC in Huang 2006 weighed significantly more than control infants. In the Marin 2010 trial, SCC infants weighed less than controls, and the trial report does not offer any details of adjustments made for cluster-design (randomization of pediatricians rather than women). Infants receiving the intervention in the Nolan 2009 trial had significantly higher cortisol and weighed more than control infants; further, this trial had several co-interventions. More women in the control group of Sosa 1976a had poor socio-economic status as measured with a socio-economic index score; the authors used this to explain the difference in breastfeeding status favoring the control group. Syfrett 1993 had a very small sample size that was recruited at times convenient to the investigators and multiple co-interventions.

An overall summary of risk of bias for all studies is set out in Figure 2 and 'Risk of bias' findings for individual studies are set out in Figure 3.

Effects of interventions

See: **Summary of findings for the main comparison** 'Summary of findings Quality of the Evidence using GRADE

All the studies reviewed were randomized controlled trials (RCTs).

Where multiple studies contributed outcome data, there was often considerable statistical heterogeneity noted. Where we identified statistical heterogeneity (an I^2 greater than 40%), we have drawn attention to this in the text and provided explanation. We urge caution in the interpretation of these results which show the average treatment effect. Different scales and the definition of review outcomes between trials and differences in the intervention between trials most likely contribute to the heterogeneity found in several analyses.

Comparison 1: Immediate or early skin-to-skin contact versus standard care for healthy infants

Primary outcomes - breastfeeding rates/duration

Immediate or early SSC resulted in better overall performance on several measures of breastfeeding status, although there was heterogeneity between studies. Almost all studies except Shiau 1997 and Chwo 1999 began SSC during the first hour post birth. We found few studies and limited data for many of the review outcomes.

More SSC dyads were still **breastfeeding one to four months post birth** (average risk ratio (RR) 1.24, 95% confidence interval (CI) 1.07 to 1.43; participants = 887; studies = 14; *moderate-quality evidence*). Overall, there were differences in the size of the treatment effect between studies leading to moderate heterogeneity for this outcome (Tau^2 = 0.02, P = 0.05, I^2 = 41%) (Analysis 1.1). Much of the heterogeneity was due to a single study (Sosa 1976a) where the study author speculated that variation in treatment effect was due to the particular population of women with lower socio-economic status attending one study hospital. We carried out a sensitivity analysis removing this study, which reduced statistical heterogeneity (Tau^2 = 0.00, P = 0.53, I^2 = 0%) and had little impact on the overall treatment effect; results favoring the SCC group remained (RR 1.26, 95% CI 1.14 to 1.39; participants = 827; studies = 13) (Analysis 1.28). 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 4).

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

Seven studies with 324 mother/infant pairs reported data on the **duration of breastfeeding in days**. Women randomized to SSC were probably more likely to breast feed their infants for a longer duration, though the CI for this analysis just crosses the line of no difference (mean difference (MD) 43 days, 95% CI -1.69 to 86.79; participants = 324; studies = seven; I^2 = 66%; Analysis 1.2; *low-quality evidence*). There was considerable heterogeneity for this outcome. It was clear from visual examination of the forest plot that much of the heterogeneity was due to the Sosa 1976a study where control group women breast fed their babies for a longer duration. We excluded this study in a sensitivity analysis which removed all heterogeneity; results then favored women with SSC who breast fed their infants on average 64 days longer (MD 64 days, 95% CI 37.96 to 89.50; participants = 264; studies = six; I^2 = 0%; Analysis 1.29).

Because Sosa 1976a accounted for all of the heterogeneity in our primary analysis, we have reported the results of the sensitivity analysis (Analysis 1.29) in the summary of findings, abstract and discussion of this review. We view the result of the sensitivity analysis as a truer estimate of the effect of SSC. We view all results from the Sosa trials for breastfeeding duration as of high risk of bias. No Sosa trial reported a standard deviation for the mean, and so we calculated SDs from the imprecise P values reported (as shown on the forest plot). This estimation will introduce imprecision in the effect estimate.

The first study (Sosa 1976a) (conducted at Roosevelt Hospital in 1974) was done at a charity hospital when women who moved from rural to urban areas were just beginning to deliver in a hospital; more of these poorer women who were more likely to breastfeed ended up in the control group. The socio-economic index score (includes home environment, education and income) of women in the control group was 11 and in the experimental group was 14. The women in Sosa 1976b and Sosa 1976c did not have an imbalance of socio-economic index score between the treatment and control groups.

Infant primary outcomes

Infant physiological stability in the hours following birth

Both Bergman 2004 and Luong 2015 utilized SCRIP scores (a measure of infant cardio-respiratory stability in preterm infants that evaluates infant heart rate, respiratory rate and oxygen saturation) to compare SSC in healthy late preterm SSC infants with late preterm control infants placed in a servo-controlled incubator next to their mothers (Bergman 2004) or transferred to the neonatal unit (Luong 2015). Bergman used an aggregated score with a maximum of 78 rather than the standard range of SCRIP scores of one to six for a five-minute epoch (Bergman 2004; Fischer 1998). Within the SCRIP score, infant heart rate is scored two for regular, one for a deceleration to 80 to 100 BPM and zero for a heart rate < 80 or > 200. Respiratory rate is scored two for regular, one for apnea < 10 seconds or periodic breathing, zero for apnea > than 10 seconds or tachypnea > 80 RPM. Oxygen saturation is scored two for regular > 89%, one for any fall to 80% to 89% and zero for any fall below 80.

SSC infants had higher**SCRIP scores during the first six hours post birth** suggesting better transition to extra-uterine life (stabilization), though data are very limited (standardized mean difference (SMD) 1.24, 95% CI 0.76 to 1.72; participants = 81; studies = two; Analysis 1.3; *low-quality evidence*). As a rule of thumb, an SMD of 1.24 represents a large effect. However, we are unsure of the impact of the trialists' averaging of scores at several time points, because there is some evidence to suggest that this practice can contribute to an inflated SMD (http://bayesfactor.blogspot.co.uk/2016/01/averaging-can-produce-misleading.html).

Blood glucose 75 to 90 minutes following the birth was measured in three studies with 144 infants; blood glucose was higher in SSC infants (MD 10.49 mg/dL, 95% CI 8.39 to 12.59; participants = 144; studies = three; Analysis 1.4; *low-quality evidence*). A difference of 10 mg/dL in blood glucose levels is clinically significant because symptomatic or high-risk infants may be given supplemental bottles of infant formula, a practice that can interfere with the establishment of successful breastfeeding.

Infant thermoregulation

Infant axillary temperature at 90 minutes to 2.5 hours after the birth was reported in six studies including a total of 558 dyads (Analysis 1.5). Five of the six studies found that axillary temperatures were higher in SSC infants (MD 0.30, 95% CI 0.13 to 0.47; participants = 558; studies = six; I^2 = 88%; *low-quality evidence*). A mean difference of 0.30 °C does not represent a clinically meaningful difference in temperature. All infants in this analysis had a temperature between 36.4 and 37.1 °C. Results from this meta-analysis should be interpreted with caution due to heterogeneity and studies with very small sample sizes. For Christensson 1992 and Christensson 1995, infants had SSC or were placed in a 'cot' (bassinet) next to the mother during the first 90 minutes post birth. Neither group of infants was fed. In Luong 2015 control infants were separated from their mothers and covered by a diaper, cap, socks, gloves and a blanket and placed in either a cot or an incubator. In Nimbalkar 2014 and Srivastava 2014, control infants were dressed, covered in a blanket and returned to their mothers. In Villalon 1992, control infants were clothed and taken to the nursery for four hours. In the study by Villalon 1992, 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 for this study results favored the intervention. In view of these inconsistencies, findings for Villalon 1992 are difficult to interpret. Excluding Villalon 1992 from the analysis does not substantially change the mean difference (analysis not shown).

Secondary outcomes

Breastfeeding outcomes

Six studies with 711 women reported the number **exclusively breastfeeding at hospital discharge to one month post birth**; SSC infants were more likely to be breastfeeding at that time (average RR 1.30, 95% CI 1.12 to 1.49; I^2 = 44%; *moderate-quality evidence*) (Analysis 1.6). Results from this meta-analysis should be interpreted with caution due to moderate heterogeneity for this outcome. All heterogeneity disappears when we remove the

Thukral 2012 trial, which measured exclusive breastfeeding at 48 hours post birth (analysis not shown).

Three studies with 245 women examined breastfeeding status (using the Index of Breastfeeding Status **(IBS) at one month postpartum**. The IBS (Hake-Brooks 2008; Labbok 1990) 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 subcategories. In exclusive breastfeeding, the first subcategory, the infant consumes only breast milk and no other liquid or solid food. The second is almost exclusive breastfeeding where infants are given water, juice, vitamins and minerals infrequently in addition to breast milk. Partial breastfeeding is divided into four subcategories – high, medium-high, medium-low and low. In high partial breastfeeding more than 80% of the infant's diet is composed of breast milk, in medium-high 50% to 80%, in medium-low 20% to less than 50%, and in low less than 20%. In token breastfeeding, the breast is used primarily as a source of comfort for the infant. Breastfeeding is occasional and irregular, less than 15 minutes a day. The infant is weaned when no longer receiving any breast milk. The eight patterns of IBS are ranked as one for exclusive and two for almost exclusive breastfeeding, three for high, four for medium-high, five for medium-low and six for low partial breastfeeding. Token breastfeeding is ranked seven and weaning is ranked eight. All scores were reversed for this analysis so that a higher score indicated more exclusive breastfeeding. 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 (MD 0.86, 95% CI -0.73 to 2.44; participants = 245; studies = three; I^2 = 90%; Analysis 1.8).

Different hospital care protocols for women and infants in treatment and control arms contribute to the high heterogeneity for this outcome. The mothers in the Punthmatharith 2001 study delivered in a Baby Friendly Hospital in Thailand with 24-hour rooming-in for all healthy infants. SSC began 60 minutes post birth and the infants received (M = 30 minutes) of SSC. Control mothers held their swaddled infants after the episiotomy repair. 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. There were no between-group differences in breastfeeding status in this trial. In Moore 2005, SSC infants were held a mean of 99.5 minutes and swaddled control infants a mean of 60 minutes and both groups were assisted with the first breastfeeding in the delivery room. Moore 2005 suggested that barriers to long-term breastfeeding that exist in the USA, 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 post birth. In Shiau 1997, mothers began SSC at four hours post birth and held their infants in SSC eight hours daily for three days. Control mothers began breastfeeding 24 hours post birth and they fed their infants every four hours in the nursery. In this trial there was a large difference in breastfeeding status favoring the SSC group.

More infants were **exclusively breastfeeding six weeks to six months post birth** in seven studies (n = 640) (average RR 1.50, 95% CI 1.18 to 1.90; participants = 640; studies = seven; Analysis 1.7;*moderate-quality evidence*). There was considerable heterogeneity for this outcome: Chi^2 = 15.92, P = 0.01, I^2 = 62%, so results should be interpreted with caution. Heterogeneity is likely due to the different time points at which breastfeeding was measured.

Two small studies reported no group differences in **breastfeeding at one year post birth** (RR 6.19, 95% CI 0.82 to 46.78; participants = 62; studies = two; Analysis 1.9).

Four studies with 384 women examined breastfeeding effectiveness scores and those in the SCC group had higher mean scores (**IBFAT score** MD 2.28, 95% CI 1.41 to 3.15; participants = 384; studies = four; Analysis 1.10), but there was moderate heterogeneity for this outcome: Chi^2 = 5.05, P = 0.17, I^2 = 41%. 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 to 3 on each item for a maximum total score of 12 indicating adequate suckling competence (Matthews 1988; Matthews 1991). An IBFAT > 10 is considered successful, and a 2.69 difference in score between treatment groups represents a 22% difference in score and may be clinically meaningful.

Five studies found that infants held SSC were more likely to breast feed successfully during their first feeding post birth than those who were held swaddled in blankets by their mothers. **'Successful' meant an IBFAT 10 to 12 or BAT 8 to 12,** and the mix of instruments probably contributed to the considerable variability between findings in these five studies (n = 575) (average RR 1.32, 95% CI 1.04 to 1.67; heterogeneity Tau^2 = 0.05, P < 0.00, I^2 = 85%) (Analysis 1.11).

Thukral 2012 reported similar group rates of successful breastfeeding (BAT $\geq$ 8); we did not include these data in the meta-analysis because the outcome was measured at 36 to 48 hours post birth rather than during the first breastfeeding (intervention 10/17 and controls 11/18).

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; participants = 88; studies = one) (Analysis 1.12).

Maternal breast temperature

Bystrova 2003 found higher breast temperatures and variability in temperatures 30 to 120 minutes post birth in mothers who held their infants SSC than those who were separated from their infants (MD 0.60, 95% CI 0.34 to 0.86; participants = 132; studies = one) (Analysis 1.13). Duration of SSC was 95 minutes. The researchers suggested that the variations in maternal breast temperature in the SSC group may regulate infant temperature more effectively than stable breast temperatures and help prevent neonatal hypothermia, but we do not regard such minimal difference in temperature as clinically meaningful.

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 post birth (SMD -0.41, 95% CI -0.76 to -0.06; participants = 131; studies = two; I^2 = 8%) (Analysis 1.14) (Bystrova

2003; Shiau 1997). As a rule of thumb, an SMD of 0.41 represents a moderate difference (Guyatt 2013).

Girish 2013 reported breast engorgement as a dichotomous variable, with 2/50 women in the intervention group reporting engorgement versus 1/50 in the standard care group.

Infant physiological outcomes

Infant heart rate and respiratory rate

Four studies (Christensson 1992; Mazurek 1999; Nolan 2009; Villalon 1992) obtained data on infant respiratory rate 75 minutes to two hours post birth, 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 was not clinically meaningful 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: Tau^2 = 15.26, P = 0.0005, I^2 = 87%) (Analysis 1.15). Results also favored SCC infants for respiratory rate but again these results were not clinically meaningful and there was considerable variability in findings between studies (MD -3.12 RPM, 95% CI -6.61 to 0.37; 215 infants) (heterogeneity Tau^2 = 9.24, P = 0.004, I^2 = 77%) (Analysis 1.16). Heterogeneity was mainly due to findings from the Villalon 1992 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 1992 favored the SCC groups and reduced heterogeneity, but differences were not clinically meaningful (heart rate MD -5.77, 95% CI -7.43 to -4.11; respiratory rate MD -4.76, 95% CI -6.12 to -3.41) (Analysis 1.30; Analysis 1.31).

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 airway 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; participants = 31; studies = one). The most common reasons for exceeding parameters in control infants were hypothermia, hypoglycemia, and respiratory problems (Analysis 1.17). There are too few infants in this analysis to make meaningful conclusions.

Neonatal intensive care unit (NICU) admissions

There were no differences between groups in infant admissions to the NICU (RR 0.51, 95% CI 0.20 to 1.26; participants = 305; studies = two; Analysis 1.18). Two studies with 42 infants (Chwo 1999; Syfrett 1993) examined hospital length of stay in late preterm infants 34 to 36 weeks' gestational age and found no between group differences, and there was high heterogeneity for this outcome (MD -95.30, 95% CI -368.50 to 177.89; participants = 42; studies = two; I^2 = 84%) (Analysis 1.20).

Infant body weight change

No group differences were found in infant body weight change day 14 post birth; this outcome was reported in two studies with 43 infants (MD -8.00 g, 95% CI -175.60 to 159.61) (Analysis 1.19) (Chwo 1999; Moore 2005). Infant weight change per kilogram per day was not reported in any of the included studies. Infant weight outcomes were reported in a number of different ways in the more recent trials and the data could not be added to the pre-specified weight outcomes.

Girish 2013 reported infant weight loss at three days postpartum (mean 18 g SD 6 g intervention group and mean 23 g SD 9 g in the standard care comparison group).

Thukral 2012 reported infant weight at 48 hours (intervention group 2714 g SD 220 g n = 20; control group 2574 g SD 275 g n = 21) with P value 0.11.

Srivastava 2014 reported weight loss at hospital discharge as a percentage of birthweight (intervention 4.01 % SD 2.0 n = 122 and control group 6.12 % SD 2.6 n = 118).

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; participants = 29; studies = one; Analysis 1.21). 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, 95% CI -8.98 to -7.04; participants = 44; studies = one) (Analysis 1.22).

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 group differences for maternal positive affective involvement at 12 months post birth (MD 1.90, 95% CI -1.14 to 4.94; participants = 61; studies = one) (Analysis 1.23) however, SSC dyads appeared more mutual and reciprocal (MD 1.30, 95% CI 0.24 to 2.36; participants = 61; studies = one) than those who were separated immediately post birth and later reunited for rooming-in (Analysis 1.24). The dyadic mutuality and reciprocity sub-scale of the PCERA has four items in it. Each item is scored on a five-point Likert scale with values of one to two meaning areas of concern, three some concern and four to five areas of strength; the minimum score is four and a maximum score is 20. We do not consider the MD noted for mutuality and reciprocity here to be clinically significant; the difference of 1.3 units is less than 10% of the overall possible score.

Other outcomes

Mothers who held their infants SSC indicated a strong **preference for the same type of post-delivery care** in the future (average RR 6.04, 95% CI 2.05 to 17.83; participants = 439; studies = three; I^2 = 85%) compared to those who held their infants swaddled (Analysis 1.25). However, there was high heterogeneity for this outcome.

Mothers who held their infants SSC displayed less state anxiety day three post birth, though we are unsure of the clinical meaning of this difference (SMD -0.32, 95% CI -0.59 to -0.04; participants = 390; studies = three; I^2 = 31%) (Analysis 1.26). As a rule of thumb, an SMD of 0.32 represents a small effect (Guyatt 2013). Shiau 1997 used the state anxiety scale from the State Trait Anxiety Inventory (STAI)

(Spielberger 1970). The state anxiety scale is a 20-item instrument that measures how the individual feels in the present moment and is measured on a Likert scale from one = not at all to four = very much so, with possible range from 20 to 80 and higher indicating more anxiety.

One trial could not be included in the meta-analysis of maternal state anxiety due to the direction of the scale being opposite to that of other trials. Khadivzadeh 2009 reported anxiety with their own scale (no minimum or maximum stated); a higher score meant less anxiety, and women with SSC therefore reported less anxiety (mean 28.2 SD 3.32 n = 46) than did women with standard care (26.07 SD 4.16 n = 46). We cannot interpret this result due to insufficient information in the trial report.

Parenting confidence scores were measured in a single study with data for 20 women; there was no evidence of meaningful differences between groups (MD 5.60, 95% CI -6.24 to 17.44; participants = 20; studies = one; Analysis 1.27). The Parenting Sense of Competence Scale is a 17-item scale developed by Gibaud-Wallston 1977 that assesses an individual's perceptions of their skills, knowledge, and abilities for being a good parent, their level of comfort in the parenting role, and the importance they attribute to parenting. Individuals rate their level of agreement from one (strongly disagree) to six (strongly agree) on each item. Higher scores indicate that the individuals feel more confident about their parenting abilities, with range of possible scores 17 to 102.

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 that 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.

Comparison 2: Skin-to-skin contact versus standard contact for healthy infants after cesarean birth

SSC has been widely incorporated into immediate post-delivery care following a vaginal birth in the USA. The 2013 Centers for Disease Control (CDC 2013) National Survey of Maternity Practices in Infant Nutrition and Care (nPINC) found that 72% of maternity care facilities provided SSC for at least 30 minutes following an uncomplicated vaginal delivery most of the time, up from 54% in 2011 (CDC 2013). However the figures for cesarean births are not as robust. Only 59% of facilities reported that they implemented SSC for at least 30 minutes after an uncomplicated cesarean birth most of the time in 2013, up from 43% in 2011.

A number of barriers to SSC in the operating room have been identified in the research and quality improvement literature. One of the primary concerns has been the potential for newborn hypothermia secondary to cold operating room (OR) temperatures (Brady 2014; Gouchon 2010; Mangan 2012; Smith 2008). Lack of time, staffing issues and cost concerns can prevent nursery staff from being present in the OR for an extended period to monitor these more vulnerable infants while in SSC with their mothers.

The sympathetic nervous system is not mobilized in infants born by cesarean birth in the same way that it is in vaginally delivered newborns (Hagnevik 1984) where fluid is squeezed out of the lungs during the passage through the birth canal and levels of catecholamines surge. This increases the risk of transient tachypnea of the newborn (TTNB) caused by retained lung fluid (Smith 2008). These infants are also less alert and may be less sensitive to odor cues than vaginally delivered newborns making them more susceptible to breastfeeding difficulties (Velandia 2012). Infants who are placed in SSC with their mothers immediately after an uncomplicated cesarean birth begin to breast feed a median of 117 minutes post birth, almost an hour later than vaginally delivered newborns (Velandia 2012).

Eight RCTs were found with mothers and their infants after a cesarean birth for this review (Armbrust 2016; Beiranvand 2014; Gouchon 2010; Huang 2006; McClellan 1980; Nasehi 2012; Nolan 2009; Norouzi 2013). In all the trials except Armbrust 2016, SSC began in the recovery room and in the studies that recorded when post birth the intervention began, it was around 50 minutes post birth and duration ranged from 30 to 82 minutes. SSC began in the operating room in Armbrust 2016 and there was no information in the Norouzi 2013 trial about when SSC was initiated. All these trials were conducted on women receiving regional anesthesia (epidural or spinal) except for Nasehi 2012 where the mothers received general anesthesia. All the mothers had primary planned, elective or repeat cesarean births. None of the studies were conducted with mothers receiving an emergency cesarean. All infants were full term.

There were very limited data for all review outcomes from these RCTs, and only one RCT (Armbrust 2016) was conducted in the operating room. Lack of data limits the conclusions we can make regarding SSC after cesarean birth.

Primary outcomes: breastfeeding rates/duration

Breastfeeding one month to four months post birth

Two small trials reported women receiving SSC were more likely to be breastfeeding between one and four months post birth (RR 1.22, 95% CI 1.04 to 1.44; participants = 220; studies = two; Analysis 2.1).

Exclusive breastfeeding at hospital discharge to one month post birth

One small study found no group differences in exclusive breastfeeding from hospital discharge to one month (RR 1.00, 95% CI 0.53 to 1.88; participants = 34; studies = one; Analysis 2.2).

Exclusive breastfeeding six weeks to six months post birth

There was no evidence for group differences in rates of exclusive breastfeeding from six weeks to six months, though data are limited (RR 1.16, 95% CI 0.95 to 1.43; participants = 144; studies = two; Analysis 2.3).

Secondary outcomes

Success of first breastfeeding (IBFAT score)

No evidence was found for group differences in success of first breastfeeding according to the IBFAT score, range 0 to 12, with IBFAT

> 10 interpreted as successful breastfeeding (MD 1.37, 95% CI 0.12 to 2.62; participants = 124; studies = two; Analysis 2.4). A mean difference of 1.37 represents a 11.4% difference in score.

Respiratory rate at 75 minutes - two hours post birth

One small trial reported lower respiratory rate in infants who experienced SCC, but this difference is not clinically meaningful (MD -4.48, 95% CI -9.20 to 0.24; participants = 32; studies = one; Analysis 2.5).

Maternal pain four hours post cesarean birth

Cesarean birth mothers in the SSC group reported less postoperative pain than mothers who were separated from their infants, though the CIs are wide and cross the line of no effect (MD -1.38, 95% CI -2.79 to 0.03; participants = 35; studies = one; Analysis 2.6). Possible values for the pain scale were zero to 10 with 10 being the worst pain imaginable. A mean difference of 1.38 lower represents a difference of 13.8% between treatment arms and may not be clinically meaningful.

Maternal state anxiety eight hours to three days post birth

One small trial reported no differences in women's reported anxiety (MD -2.70, 95% CI -6.06 to 0.66; participants = 60; studies = one; Analysis 2.7). Anxiety was measured through women's responses for 20 different statements, with one to four possible score for each statement (four representing highest anxiety). Total scoring for state anxiety varied from 20 to 80 and interpreted as; mild anxiety: 20 to 39, moderate:40 to 59, and severe anxiety: 60 to 80 (Norouzi 2013).

Comparison 3: Skin-to-skin versus standard contact by time of initiation

For this comparison, we analyzed trials that initiated SSC less than 10 minutes of birth versus those trials beginning SSC at 10 minutes or more after the birth.

No evidence of subgroup differences by time of initiation of SSC was found for any of the following review primary outcomes: breastfeeding one to four months post birth; duration of breastfeeding in days; infant SCRIP scores at six hours; and blood glucose). Babies with delayed SSC had higher infant axillary temperatures than those with early initiation of SSC (Test for subgroup differences: Chi^2 = 3.82, df = 1 (P = 0.05), I^2 = 73.8%). We have very little confidence in the clinical relevance of this finding. There are limited data for each subgroup, extremely high heterogeneity in one subgroup (91%), which could distort the interaction test and marginal differences in temperature observed between groups. All babies had temperatures within a normal range (36.4 °C to 37.1 °C).

Comparison 4: Skin-to-skin versus standard contact by dose (length of contact time)

For this comparison, we grouped trials that had 60 minutes or less of SSC (low dose) with trials testing more than 60 minutes of SSC (high dose). There was no evidence of subgroup differences according to high or low breastfeeding dose for any review primary outcome, including: breastfeeding one to four months post birth; duration of breastfeeding in days; infant SCRIP scores at six hours; blood glucose and infant axillary temperature.

DISCUSSION

Summary of main results

This review summarizes the results from 38 randomized controlled trials (RCTs) (3472 mother-infant pairs) that provided outcome data for analysis out of a total of 46 trials (3850 mother-infant pairs) that met our inclusion criteria. These studies were conducted in 21 countries representing both low-resource and more developed settings. Six of the 46 studies were conducted with late preterm infants and eight with women after a cesarean birth. All studies compared mother-infant skin-to-skin contact (SSC) beginning within 24 hours after birth versus standard patterns of care that did not involve SSC.

No negative outcomes associated with SSC were reported in any of the included studies except Sosa 1976a, who reported a longer duration of breastfeeding in the control group, and this finding may be due imbalances in an important covariate (socio-economic status).

Breastfeeding/lactation outcomes

Women experiencing SSC with their infants were 24% more likely to continue breastfeeding between one and four months post birth (14 trials; 887 mother-infant pairs). We graded evidence for this outcome to be of moderate quality due to unclear risk of bias for allocation concealment, lack of blinding in included trials and statistical heterogeneity with a random-effects model. We were also unsure whether the strong effects found in two small trials suggest publication bias. A GRADE of moderate quality suggests relative confidence in the finding. Future randomized trials of good quality and adequate sample size may change the results of this analysis, but we are probably near a true estimate.

There were similar positive results of SSC for our outcome of duration of breastfeeding, with similar reservations regarding the quality of the evidence. Pooled results for breastfeeding duration (seven trials; 324 mother-infant pairs) showed that women breast fed an average 43 days longer if exposed to SSC, though there was inadequate power to achieve statistical significance for this analysis. However, most of the heterogeneity in this analysis was caused by the Sosa 1976a trial and when this trial was excluded using sensitivity analysis there was no evidence of heterogeneity and results achieved statistical significance. Women who received SSC breast fed an average of 64 days longer (six trials; 264 mother/infant pairs). We have displayed the result of sensitivity analyses in our 'Summary of findings' table for the duration outcome.

Mothers who experienced SSC were also 30% more likely to be exclusively breastfeeding at hospital discharge to one month post birth (six trials; 711 participants) and 50% more likely to be exclusively breastfeeding at three to six months post birth (seven trials; 640 participants). These findings of improved breastfeeding were obtained in diverse countries and among women of low and high socio-economic class. This evidence was also found to be of moderate methodological quality due to unclear risk of bias for sequence generation, allocation concealment, lack of blinding and statistical heterogeneity.

Overall, even with the methodological inconsistencies within trials, results for breastfeeding outcomes show benefits of SSC for the first months following birth. Breastfeeding outcomes, in turn, are clinically important for maternal and infant health.

Infant physiological/behavioral outcomes

The SCRIP score as presented in Bergman 2004 is a composite measure of transition to extra-uterine life through a time-line, achieving cardiorespiratory stabilization in the first hours after birth. Individual cardiac and respiratory parameters at any particular time point do not as adequately provide a measure of stabilization. Infants whose mothers had SSC had higher SCRIP scores or better stabilization post birth. However, we have little confidence in this finding due to very limited data (two trials; 81 participants) and the possibility that the standardized mean difference (SMD) has been exaggerated by the trialists' averaging of scores over several time points. Though the evidence is weak, and derived only from late preterm infants, it is consistent with studies from mammalian biology (see Background).

Infants who experienced SSC with their mothers had higher blood glucose levels (10 mg/dL on average; three trials, 144 participants) than those exposed to standard care. The methodological quality of these trials was downgraded to low because of limitations related to small sample size and unclear risk of bias for sequence generation and allocation concealment. The assessment of blood glucose levels in term infants is controversial and recent guidelines recommend against screening of healthy newborns unless there are risk factors or clinical symptoms of hypoglycemia present (Adamkin 2011; Wight 2014). Late preterm infants are at higher risk for hypoglycemia than term infants. An arbitrary cut-off for treatment of symptomatic newborns is 40 mg/dL (Adamkin 2011), and the goal is to maintain plasma glucose between 40 mg and 50 mg/dL (Adamkin 2011; Wight 2014). A difference of 10 mg/dL in blood glucose levels is clinically significant because symptomatic or high-risk infants may be given supplemental bottles of infant formula, a practice that can interfere with the establishment of successful breastfeeding.

We did not find the mean infant axillary temperature difference of 0.3 °C (six trials; 558 participants) to be clinically meaningful. In low birthweight neonates, SSC (as in kangaroo mother care (KMC), Conde-Agudelo 2014) is associated with reduced incidence of hypothermia at discharge. Assuming maternal warming of the neonate is the biological default, it is possible that the larger infants in these studies are coping with cold stress better than smaller infants. Regardless, clinicians can be assured that infants who receive SSC are not at greater risk for hypothermia.

Adverse events

A rare adverse event occasionally associated with early SSC is sudden unexpected postnatal collapse (SUPC) of an apparently healthy infant occurring within the first two hours post birth often during the first breastfeeding attempt (Pejovic 2013). The incidence of SUPC reported in population-based studies from France, Germany and the UK ranges from 2.6 to five cases per 100,000 births and death rates from 0 to 1.1 deaths per 100,000 live births (Fleming 2012). SUPC is not an outcome analyzed in this review, but there are several studies of this issue (Dageville 2008; Fleming 2012; Pejovic 2013; Poets 2011). A neonatal clinical evaluation tool, the Respiratory, Activity, Perfusion and Position tool (RAPP) (Ludington-Hoe 2014) and a surveillance protocol (Davanzo 2015) have been developed to assist clinicians in rapidly identifying infants who are becoming unstable. Several hospitals have also developed protocols for safely providing SSC immediately after a cesarean birth (Barbero 2013; Grassley 2014; Schorn 2015).

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 Hake-Brooks 2008 (under Anderson 2003); Moore 2005; Punthmatharith 2001;and Shiau 1997 used the Index of Breastfeeding Status (Hake-Brooks 2008; 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 on breastfeeding in so far as the findings are numerous and pooled findings are 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.

Quality of the evidence

Evidence for three dichotomous breastfeeding outcomes assessed with GRADE methodology was considered to be of moderate quality. A judgement of moderate quality means that we have some confidence that our results for breastfeeding outcomes approach the true impact of SSC on breastfeeding; at the same time, we acknowledge that future trials may change these results. We assessed the breastfeeding duration outcome and all infant outcomes to be of low GRADE quality. A judgement of low quality means that we acknowledge uncertainty in results for all of these outcomes, and we anticipate that future good-quality studies may change the effect estimates presented in this review. We downgraded the evidence for all outcomes for lack of blinding in the table. Where blinding is not feasible for certain interventions, it is also acceptable not to downgrade evidence for lack of bias. Many estimates in the Summary of findings for the main comparison had inadequate sample size; many estimates also had considerable statistical heterogeneity, and all evidence suffered from risk of bias concerns in the contributing trials. There are detailed footnotes in the 'Summary of findings' table that explain our decisions.

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 such as music 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 low.

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 could 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. Several review authors have conducted trials that have been included in this review. All of these trials were assessed by another researcher, not involved in the trials.

Agreements and disagreements with other studies or reviews

The findings are in general agreement with results from other studies mentioned in this review. While we did not find a dose-response effect, in a large hospital-based cohort study (n = 21,842), Bramson 2010 demonstrated a clear dose-response effect of SSC on exclusive breastfeeding at hospital discharge. In the Bramson 2010 study there were four levels of SSC. A one- to 15-minute dose was associated with a 1.376 odds ratio (OR) of exclusive breastfeeding during hospitalization, a 16- to 30-minute dose with an OR of 1.665, a 31 to 59 minute dose with an OR of 2.357, and greater than one-hour dose with an OR of 3.145 compared to no SSC. Similar effect sizes on breastfeeding outcomes are reported in the review by Conde-Agudelo 2014 on KMC with low birthweight infants.

The data from this review are inadequate to demonstrate a dose-response effect. In our review, because of the small number of studies, we were only able to compare a low dose (defined 60 minutes or less of SSC in the first 24 hours) and a high dose (more than 60 minutes).

Data were limited in this review regarding exclusive breastfeeding after a cesarean birth. However, several quality improvement studies (Brady 2014; Crenshaw 2012; Hung 2011; Schorn 2015) have focused primarily upon exclusive breastfeeding during hospitalization. All studies except Crenshaw 2012 reported an increase in exclusive breastfeeding at hospital discharge in cesarean birth mothers post-implementation of SSC in the operating room.

Although the modality and timing of measurement of infant temperature varied between studies, minimal increases in temperature with SSC were found in this review. These results support those obtained by Mori 2010 who found a mean increase of 0.22 °C. in a meta-analysis of 21 studies of infant temperature pre-SSC compared to during the intervention. Mori 2010 also 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.

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. However, we found inadequate evidence with respect to details of SSC such as timing of initiation and dose. There was no evidence that immediate was better than delayed, however, almost all of the studies began SSC within the first hour post birth. This review does not address subsequent ongoing SSC as an intervention to support breastfeeding. It is, however, noteworthy that an intervention practiced even for a short time at birth should have measurable breastfeeding effects one to four months post birth.

Infant outcomes: Our review found evidence for a clinically meaningful increase in blood glucose in infants who received SSC. The data for all infant outcomes were limited, and we are unable to provide evidence to inform practice recommendations.

Implications for research

Current recommendations for healthy newborns are that SSC should begin as soon as possible post birth (by 10 minutes) and continue as long as possible (at least one hour) during the first 24 hours. Given the weak-to-moderate evidence for all outcomes presented here, and lack of evidence for differential effect of the timing or dosage of SSC, there is a need for larger definitive studies that make explicit SSC initiation time, frequency and duration. Techniques employed to ensure safe SSC also deserve study. More research needs to be conducted on the effects of early SSC on mothers who deliver by cesarean birth and on late preterm infants.

Breastfeeding outcomes: Clinical trials should consider the mother's prenatal breastfeeding intention (how long she planned to nurse her infant). We also need a valid measure of effective suckling at a single feeding (this may identify problems in time to minimize breastfeeding attrition (Riordan 1997)). Several potential confounding factors for breastfeeding deserve study, including the effects of assistance with the first feeding provided by an experienced nurse or midwife, the protractility of the mother's nipples or presence of a short frenulum (Dewey 2003; Geddes 2008).

Infant outcomes: rigorous and validated composite measures of physiological benefit are not yet available in the literature. This review contained only two studies (Christensson 1995, Mazurek 1999) that evaluated infant crying as an outcome. The relationship between the amount of infant crying, blood glucose and temperature needs further exploration as crying is theorized to expend calories meant for physiological adaptation. Episodes of hypoglycemia and hypothermia are also important to measure especially in the more vulnerable late preterm infants.

Attachment outcomes: improvement is needed in examining maternal attachment behaviors. Studies should consider using rigorously validated instruments.

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. 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 to increase methodological rigor, including core outcome sets where available (Anderson 2004b; Labbok 1990). The CONSORT guidelines (Moher 2001; Moher 2010) should be used to document the flow of participants through all clinical trials. Investigators should improve reporting of trial methodology and ensure reporting of outcome data is complete. Control for provider and patient performance bias may continue to be problematic for SSC trials due to requirements

for informed consent and the nature of the interventions. Outcome assessors should be blinded, however (Polit 2011).

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* Indicates the major publication for the study

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 subgroup 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 post birth for as often and as long as possible each time. At other times, mothers also held their infants wrapped in blankets.

Anderson 2003 *(Continued)*

	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 % non contact time (no hold) hours 0-48 post birth.
Outcomes	MPI measured by mean scores on the Nursing Child Assessment Satellite Training Program (NCAST) Feeding and Teaching scales at 6,12 and 18 months post birth (reported in Chiu 2009 using the same data set). Breastfeeding status (exclusivity) at hospital discharge, 6 weeks, 3, 6, 12 and 18 months post birth (reported in Hake-Brooks 2008 using the same data set).
Notes	Study was done in the USA at 2 different hospitals 1 in Cleveland, Ohio and the other in Richland, Washington. Participants were mixed parity. Subgroups: Immediate contact; high dose.

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 post birth.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Intervention not possible to blind.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The research staff involved in evaluating MPI data at 6,12 and 18 months post birth using a videotaped infant feeding and teaching session were unaware of the mother's group assignment. The nurse researcher who collected IBS scores was blind to participant group assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	At 6 months post birth, 2/15 infants were missing from the SSC group and 2/14 from the control group; at 12 months post birth 2/15 infants were missing from the SSC group and 2/14 from the control group, at 18 months post birth 3/15 infants were missing from the SSC group and 2/14 from the control group. At 3 and 6 months post birth 1/11 breastfeeding SSC infants had missing data on the IBS. At 6 weeks post birth 1/12 breastfeeding control infants had data missing on the IBS, at 3 months post birth 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 post birth. Numerical data were reported for the IBS N, n,% in each breastfeeding category at hospital discharge, 6 weeks post birth and at 3, 6,12 and 18 months post birth.

Anderson 2003 *(Continued)*

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.

Armbrust 2016

Methods	Randomized controlled trial.
Participants	205 pregnant women > 37 weeks' gestation delivering at Charite University Hospital, Berlin, Germany eligible for a primary planned cesarean section under epidural anesthesia; no bleeding disorders, no fetal anomalies, no severe maternal morbidity.
Interventions	1) SSC group N = 102 Charite cesarean section birth (CCB) – the surgical drape was lowered, the infant was "walked" out of the uterus by the obstetrician, the father given the option to cut the umbilical cord and the naked infant was examined briefly for well-being and placed on the mother's bare breast, covered by a warm blanket and allowed to remain on the mother's breast for the remainder of the surgical procedure and monitored constantly by the midwife. The baby remained on the mother's breast for 1 hour or more. Babies received the intervention only if they had an Apgar > 8. 2) Control group N = 103 standard elective cesarean section – baby was taken immediately to a neonatologist or midwife for an assessment; we have had confirmation that the control group did not receive immediate SSC.
Outcomes	The primary outcomes were satisfaction with the birth experience, breastfeeding rates and breastfeeding problems. Secondary outcomes were time of operation, maternal blood loss, SpO^2, BP, length of hospitalization, infant Apgar scores and pH values.
Notes	Subgroups: Immediate SSC; high dose.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Simple randomization.
Allocation concealment (selection bias)	Unclear risk	Closed envelope – authors do not state whether the envelopes were opaque or sequentially numbered.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Staff and women blind until day of surgery. Not possible to blind intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear; statistician blinded, but no mention of outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Low risk	10 fathers in the intervention group and 12 in the control group did not return the questionnaire. 2 infants in each group were unable to complete the intervention due to requiring care of a neonatologist.
Selective reporting (reporting bias)	Unclear risk	Apgar scores stated only as 'not statistically different' between groups; author has confirmed that the intervention was not delivered unless the baby had an Apgar > 8.

Armbrust 2016 *(Continued)*

		The published trial report states that 2 cases in each arm did not receive the intervention because the baby needed care of a neonatologist; but at the same time the report states that SSC was achieved in 72% of cases, which would mean more than 2 babies in the intervention did not receive SSC.
Other bias	Unclear risk	Women in the CCB group had higher education.

Beiranvand 2014

Methods	Randomized controlled trial. July 2011- Sept 2011, Asali Hospital, Khorramabad, western Iran.
Participants	N = 96 randomized (48 to SCC and 48 to routine care). Singleton pregnancy GA 38-42 weeks; women 18 – 40 years undergoing elective cesarean section under spinal anesthesia. Exclusion criteria for pregnant women: severe bleeding, uterine inertia, gestational diabetes, hypertension, heart disease. Infant inclusion criteria: full term; 1 and 5 min Apgar > 7; infants with high risk, abnormalities, requiring hospitalization were excluded.
Interventions	All infants were assessed and had 1-min and 5-min Apgar scores taken. 1) Intervention – In the SSC group (n = 46) the infants' temperatures were recorded immediately post birth, Apgar scores were measured and the infants were assessed, wrapped in blankets and taken to the nursery where they were measured and given their vitamin K injections. When the mothers were out of the operating room, the naked infants, except for a diaper, were positioned prone between their mother's breasts, their heads covered with a cap and back with a blanket and remained SSC for an hour. Temp measured at start, 0.5 and 1.0 hr with infrared thermometer on forehead. 2) Comparator – routine care baby dressed and placed in an incubator. Infant wrapped in blanket and taken to nursery ward, weighed and measured, vitamin K administered, then dressed and taken to mother for breastfeeding when mother was back from the operating room. Both groups taught to breast feed. IBFAT administered at first breastfeeding after this teaching.
Outcomes	Infant and maternal temperature using an infrared ray thermometer on the forehead, success of the first breastfeeding (mean IBFAT score), maternal satisfaction with SSC (11 question self-report).
Notes	Ethics approval from Lorestan University of Medical Sciences. Subgroups: delayed contact.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random numbers table.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias)	High risk	Not described; not feasible to blind intervention.

Beiranvand 2014 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data collection not blind. Data analysts blind to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 dyads in intervention group and 4 in control group excluded due to neonatal RDS.
Selective reporting (reporting bias)	Unclear risk	Stated outcomes are reported. Satisfaction scores not shown, but outcome only measured in the intervention arm.
Other bias	Low risk	No demographic differences between groups of mothers. No temperature differences between mothers before or after surgery; between infants at birth; or between operating room or wards.

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 post birth. 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 post birth. 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 post birth, SCRIP score in the 6th hour post birth.
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 minimization 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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind. 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.

Bergman 2004 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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 were based on physician assessment at the time and could not be standardized.
Incomplete outcome data (attrition bias) All outcomes	Low risk	35 randomized. 1 woman in the intervention group was excluded post randomization 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. ITT 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	High 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.

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 post birth. 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 breast fed 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 breast fed on demand. 3) Nursery group = 38 babies were clothed (swaddled or dressed) and taken to the nursery immediately post birth 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 post birth, but roomed-in with their mothers on the maternity unit and breast fed on demand.
Outcomes	Mean difference in infant axillary, interscapular, thigh temperatures and foot temperature change from 30 to 120 min post birth (Bystrova 2003). Amount of milk ingested (before and after breastfeeding infant weights), volume of supplemental feedings, number and duration of breastfeedings day 4 post birth, recovery of infant weight loss day 3-5 post birth (reported in Bystrova 2007a). Number of breastfeedings, physiological breast engorgement, feeling low/blue days 1-3 post birth, 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 post birth using the PCERA (reported in Bystrova 2009).
Notes	Study was done in St Petersburg, Russia.

Bystrova 2003 *(Continued)*

Follow-up Dumas 2012 reports: outcome – mother-infant interaction during a breastfeeding on day 4 postpartum, analysis of 151 videotaped breastfeeding sessions, the outcome assessor was blind to the group assignment of the mothers and only 1 researcher coded the videos.

An Assessment Tool for the Observation of Mother/Infant Interaction was developed for this study. It was evaluated for face and content validity as well as inter-rater reliability by experts in the field. It examined behaviors such as the mother's affective responsiveness to her infant, eye contact, stimulation of the baby, voice, patience and latch-on attempts primarily on a 5-point Likert scale from rough to soft. The researchers found that mothers in the SSC group were softer in their attempts to stimulate and latch their babies than those in the nursery separation group but had more nipple pain during latch (X^2 was the statistic).

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 conditions 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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The psychologists who evaluated videotaped mother-child interactions at 12 months post birth 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 post birth. 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 post birth (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, International Breastfeeding Journal, 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

Bystrova 2003 *(Continued)*

		results for the other composite variables were not reported but were stated as insignificant (Bystrova 2009). Additional statistical data were 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 post birth. 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 post birth (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	"The trial statistician provided a sequence of envelopes each containing the next allocation from a 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 of participants and personnel (performance bias) All outcomes	High risk	There was no blinding in this study. It is possible that the lack of blinding may have affected women's responses and behavior and that clinical care other than SSC may also have differed by randomization groups.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors were 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 post birth. 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 post birth, maternal satisfaction with care, preference for same post-delivery 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 of participants and personnel (performance bias) All outcomes	High 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 SSC may also have differed by randomization groups.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors were 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 post birth, mothers cared for infants. 2) Extended contact-old routine = kept their naked infants immediately post

Carlsson 1978 *(Continued)*

	birth for 1 hour, staff cared for infants. 3) Limited contact-old routine group = held their infants for 5 min immediately post birth, staff cared for infants.
Outcomes	Observation of maternal behavior (contact behavior and behavior not implying contact with baby) by videotape during breastfeeding on days 2 and 4 post birth.
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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind. 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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not clear whether the staff carrying out observations were aware of group allocation.
Incomplete outcome data (attrition bias) All outcomes	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. 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 of participants and personnel (performance bias) All outcomes	High risk	Women would be aware of group allocation. It is not likely that this affected outcomes such as temperature but it may have affected the baby's behavior (it appeared that mothers in the cot group were advised not to pick their babies up even if the baby was crying).
Blinding of outcome assessment (detection bias) All outcomes	High risk	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 post birth.

Christensson 1995 *(Continued)*

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 post birth.
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 of participants and personnel (performance bias) All outcomes	High 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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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 post birth. 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 post birth.
Outcomes	Infant body weight change day 14 and 28 post birth, 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

Chwo 1999 *(Continued)*

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 of participants and personnel (performance 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.
Blinding of outcome assessment (detection bias) All outcomes	High risk	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 post birth.
Notes	Study was done with low-income primapara in the USA.

Risk of bias

Bias	Authors' judgement	Support for judgement

Craig 1982 *(Continued)*

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 of participants and personnel (performance bias) All outcomes	High 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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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 post birth.
Interventions	1) Control group = held their wrapped infants for 36 min during the first hour post birth. 2) SSC group = held their infants in SSC for 35 min during the first hour post birth. 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 post birth during breastfeeding. 2) The Tennessee Self Concept measured at 2 months post birth.
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.

Curry 1982 *(Continued)*

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 of participants and personnel (performance bias) All outcomes	High risk	It was stated that mothers were not told the precise reasons for the study, although mothers would be aware of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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 post birth. The infants were placed on the breast at 10 min post birth 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 post birth.
Outcomes	Observation of mother's behavior during breastfeeding at 36 hours post birth. Mother's and infant's behavior at 3 months during free play. Breastfeeding at 3 months, 1 year post birth. 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)	Low 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".

De Chateau 1977 *(Continued)*

Allocation concealment (selection bias)	High risk	Allocation according to open list after delivery.
Blinding of participants and personnel (performance bias) All outcomes	High 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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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 blinded 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.

Fardig 1980 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	"Both the couple and their caregiver were told how the baby would be handled after delivery."
Blinding of outcome assessment (detection bias) All outcomes	High risk	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 post randomization 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 mother 15-20 min post birth, 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 post birth.
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.

Ferber 2004 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind. 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).
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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 post randomization 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.

Girish 2013

Methods	Prospective, single-blind randomized trial. Trial took place in a labor and delivery unit at a tertiary care hospital in Nagpur, India, from May - September 2011.
Participants	100 pregnant mothers were recruited for the study as soon as they were admitted in the obstetrics unit during the period May to September 2011. They were considered eligible if they consented to participate in the study, had no pre-existing medical or psychiatric illness, anticipated a spontaneous vaginal delivery, were willing to be randomized to control or intervention groups and did not have peripartum complications, which precluded immediate skin–skin contact with mother. Exclusion criteria: < 37 weeks, cesarean section, multiple pregnancy, 5-min Apgar < 7, medical complications at birth, any contra-indication to breast crawl.
Interventions	1) SSC Group n = 50 Infants were placed prone on their mother's abdomen after drying them with a towel even while the mother's episiotomy was being sutured. The infant remained skin-to-skin with the mother for 1 hour. 2) Standard care n = 50 Infants were received on a tray covered with a pre-warmed towel and moved to a baby corner for immediate care, routine examination and vitamin K injection. They were then handed over to the relatives and returned to their mother only after she was shifted to the observation room in an average time of 0.5 to 1 hour post birth.

Girish 2013 *(Continued)*

	Lactation guidance, as per the International Lactation Consultant Association guidelines, was given to all the mothers from both the groups on day 0.
Outcomes	IBFAT score on day 0 and day 3, frequency of feedings, level of breast fullness and onset of fullness, number of supplemental feedings, nipple or breast discomfort/pain while feeding, infant weight loss and support from family members (all measured on day 3 postpartum) and staff responses to a questionnaire (10-items) on the feasibility of the breast crawl.
Notes	Authors emailed 29.3 for data on breast fullness and mean weight loss on day 3 (not shown in published report); unpublished data obtained from M Girish for both outcomes.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Simple randomization.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researcher collecting data blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No attrition described, but no trial profile shown.
Selective reporting (reporting bias)	Low risk	Data for mean weight loss not shown. Breast fullness data not reported. Unpublished data obtained from author for both of these outcomes; data included in this review.
Other bias	Unclear risk	Unclear if differences in demographic characteristics were formally tested; considerably more women in the control group were of low socio-economic status and without nuclear family, but no P value in published report. We were unsure of the impact of these differences on outcome measures.

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 loco-regional 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.

Gouchon 2010 *(Continued)*

	Control: baby dressed, taken to mother's room, mother instructed on how to breast feed but she could choose whether she wanted to breast feed 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 breast feed. 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 post birth of the first breastfeeding, exclusive or prevalent breastfeeding at hospital discharge and at 3 months post birth, 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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind intervention.
Blinding of outcome assessment (detection bias) All outcomes	High risk	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 breast feed.

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 post birth, then daytime rooming-in. 2) Early contact group = 45 min of SSC immediately post birth, daytime rooming-in.

Hales 1977 *(Continued)*

	3) Delayed contact group = 45 min of SSC at 12 hours post birth, daytime rooming-in.
Outcomes	Observation of maternal affectionate, proximity maintaining and care taking behavior at 36 hours post birth.
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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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) post birth.
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 post-cesarean 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.

Huang 2006 *(Continued)*

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 post birth 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.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No information provided. Not possible to blind intervention.
Blinding of outcome assessment (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.
Other bias	High risk	Infants in the KC group weighed significantly more (30.72 $\pm$ 3.93) than those in the control group (28.08 $\pm$ 4.28) ($P < .01$).

Kastner 2005

Methods	Randomized controlled trial, no other information provided.
Participants	57 vaginally delivered mothers intending to breast feed and their healthy full-term infants.
Interventions	In the usual care condition the mother and her infant remained together for 20 min. immediately post birth. 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 post birth 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.

Kastner 2005 *(Continued)*

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 of participants and personnel (performance bias) All outcomes	High 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. Not possible to blind intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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. For other outcomes blinding unclear.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	At 3-5 days post birth, 4/31 infants were missing from the intervention group and 5/26 for the control group; at 5-6 weeks post birth 7/31 infants were missing from the intervention group and 9/26 from the control group. No reasons were provided for participant attrition. No SDs 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 2009

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 post birth. 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 post birth.
Outcomes	Duration from birth until the first breastfeeding, number of infants breastfeeding during the first 30 min. post birth, success and duration of the first breastfeeding, maternal feelings about SSC during the first 2 hours post birth.

Khadivzadeh 2009 *(Continued)*

Notes	The 2016 update identified several reports related to this previously included trial: Karimi 2014, Karimi 2014, Karimi 2012, Karimi 2013, Karimi 2014, Karimi 2012 (all listed in references). We had Bita Mesgarpour translate the Persian language reports. There was some confusion due to different denominators in some reports, but we now believe all of these reports relate to the same trial.

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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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	Unclear 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	Unclear risk	SSC infants were placed prone between their mother's breasts immediately post birth 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 breast feed.

Luong 2015

Methods	Randomized controlled trial using sealed opaque envelopes.
Participants	100 low birthweight infants (1500 to 2490 g birthweight) born at Tu Du Hospital in Ho Chi Minh City, Vietnam. Exclusion criteria: mother HIV+, Hepatitis B+, multiple births, prolonged resuscitation or severe asphyxia at birth, life-threatening disorders, severe malformation, chromosomal abnormality, neonatal convulsions, poor health of the mother. A subgroup of 50 late preterm infants (34 to 37 weeks' GA) was used for analysis from this study 24 SSC and 26 control. There were no significant between subgroup differences in maternal age, educational level, antenatal steroid use, epidural anesthesia or oxytocin in labor or infant gender, GA in weeks, birthweight, and 1-min and 5-min Apgar scores.
Interventions	In the SSC group, infants were separated from their mothers for approximately 3 mins post birth for routine procedures (height, weight, eye prophylaxis, vitamin K injection). Then they were covered by a

Luong 2015 *(Continued)*

	diaper and cap and an open vest across the back and placed on their mother's bare chest in direct SSC for the 6-hour observation period. SSC was continued uninterrupted until discharge in all but 2 dyads. Mothers were encouraged to breast feed their infants when they exhibited self-attachment behaviors. If they were unable to breast feed they were either drop fed from a syringe or gavage fed expressed breast milk or infant formula. In the control group, the infants were removed from their mothers immediately post birth for drying, suctioning, stimulation of breathing and a physical assessment. Then they were administered the same routine procedures as for the SSC group, covered by a diaper and cap, socks and gloves and with a blanket. They were transferred to the neonatal unit approximately 30 mins post birth and placed in either a cot or an incubator. The infants were either bottle or gavage fed infant formula (Similac Neosure). Mothers were reunited with their infants when they were discharged from the neonatal unit.
Outcomes	SCRIP, SCRIL score, hypothermia, blood glucose 180 and 360 mins post birth, time breastfeeding initiated, need for CPAP or ventilator support in the first 6 hours post birth, need for IV fluids in the first 6 hours post birth, oxygen use in the first 6 hours, antibiotics on admission, hospital length of stay.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomized controlled trial. States randomized using sealed, opaque envelopes prepared and shuffled by principle investigator. Performed in blocks of 20, 20 and 10.
Allocation concealment (selection bias)	Unclear risk	Does not state whether envelopes were sequentially numbered. Envelopes left in draw in birthing room and were selected by the care giver on duty.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind.
Blinding of outcome assessment (detection bias) All outcomes	High risk	States blinding of researchers collecting data was not possible.
Incomplete outcome data (attrition bias) All outcomes	Low risk	States 212 mother infant pairs were eligible to participate, 112 were excluded because research space was not available and 100 were analyzed. 50 in the SSC and 50 in the control group. The subgroup of 24 SSC and 26 control late-preterm infants was analyzed for this review.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were measured and outcome data reported.
Other bias	Unclear risk	There could be unmeasured between group differences in some characteristics in the late-preterm subgroup that could influence outcomes.

Mahmood 2011

Methods	Randomized controlled trial. November - December 2009, Islamabad, Pakistan.

Mahmood 2011 *(Continued)*

Participants	183 healthy, full-term infants and their mothers anticipating spontaneous vaginal delivery at the Department of Obstetrics of Pakistan Institute of Medical Sciences, Islamabad with intention to exclusively breast feed their infants for at least 1 month. Mothers were excluded if they had multiple pregnancy, pre-existing medical complications (diabetes, gestational diabetes, pregnancy-induced hypertension, renal failure, heart disease, psychiatric illness, etc.), severe postpartum hemorrhage, cesarean section, severely retracted/inverted nipples, or passage of meconium during labor. Infant inclusion criteria: babies who did not need resuscitation beyond oro-pharyngeal suction, Babies with gestation < 37 weeks, weight < 2500 g, signs of respiratory distress after birth, major congenital anomalies, floppiness or birth trauma were excluded.
Interventions	1) SSC infants (n = 92) were placed on their mother's abdomen immediately post birth, dried and then moved to their mother's chest between her breasts and covered with a cap and a pre-warmed sheet. SSC ended after the first feeding. 2) Infants in the control group (n = 91) were moved to the radiant warmer immediately post birth, cleaned, wrapped in pre-warmed sheets and transferred to the postpartum unit with their mothers and breastfeeding began when the mother was ready.
Outcomes	Success of the first feeding (IBFAT scores 10-12), time to initiate breastfeeding, time until effective breastfeeding (first of 3 consecutive IBFAT scores of 10-12), maternal satisfaction with care and preference for the same post-delivery care with subsequent pregnancies, breastfeeding exclusivity at 1-month post birth.
Notes	Subgroups: Immediate SSC. Low dose (duration of first feed not stated in report).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Sequence generation not described.
Allocation concealment (selection bias)	Low risk	Sealed envelopes opened sequentially; not stated if envelopes were opaque.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition for IBS at 30 days 68/80 intervention group and 67/80 control group. Unclear why data reported for 80 in each group when number randomized was 92 and 91 in treatment and controls, respectively.
Selective reporting (reporting bias)	Low risk	Not apparent.
Other bias	Low risk	No significant inter-group baseline difference was noted, except that multi-parous mothers with no previous experience of breastfeeding were more in CC group (P = 0.04).

Marin 2010

Methods	Cluster-randomized controlled trial.
Participants	350 mothers delivering vaginally at the Madrid, Spain Torrelodones Hospital were eligible to participate in the study. Inclusion criteria were healthy mothers receiving prenatal care, 35-42 weeks' gestation at delivery of a singleton infant. Exclusion criteria were fetal distress in labor, cesarean birth, positive pressure ventilation, intubation or meconium aspiration without respiratory effort. There were 6 SSC clusters with 137 women after exclusions, and 7 control clusters, also with 137 women after exclusions.
Interventions	In the SSC group, infants were placed on their mother's abdomen immediately after the cord was cut. They were dried, clothed with a diaper and cap, moved to between their mother's breasts and covered with a pre-warmed blanket. The infants remained in SSC with their mothers for 2-hours and were then removed for routine hospital procedures and then dressed and returned to their parents. In the control group, the infants were placed on an examination table after the cord was cut, dressed with a diaper and cap, wrapped in a pre-warmed blanket and returned to their parents. The infants remained with their parents for 2 hours and then removed for routine hospital procedures.
Outcomes	Infant axillary temperature 1-min and 5-min, 2-hours post birth, hypothermia in the first min post birth, time of placental delivery, maternal pain during episiotomy repair, hospital anxiety and depression, duration of exclusive or exclusive + partial breastfeeding.
Notes	We have not formally adjusted this trial for its cluster design. Pediatricians rather than women were randomized by the first letter of the surname. We have conducted sensitivity analyses for the 2 dichotomous outcomes, with no substantive changes to the effect estimates or conclusions of the analyses. We have therefore included unadjusted data.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	States pediatricians were randomized by the first letter of their surname into 1 of 2 groups SSC or control.
Allocation concealment (selection bias)	Unclear risk	Just states pediatricians were randomized, does not indicate the randomization method.
Blinding of participants and personnel (performance bias) All outcomes	High risk	States mothers were blinded to their pediatrician group (SSC or Control). Not possible to blind intervention from staff.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Pediatricians collected data on pain during episiotomy repair. No information was provided on blinding of outcome assessors for the rest of the included outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	350 mothers were eligible to participate in the study. 274 were included in data analysis (137 in the SSC and 137 in the control group, 78% of eligible participants).1-month outcome data on breastfeeding exclusivity was collected on 118 mothers in the SSC and 120 in the control group 87% of the 274 included mothers.
Selective reporting (reporting bias)	Low risk	Outcome data on infant temperature differences between groups was provided in Figure 1 but no mean (SD) temps were reported for 5-min and 2-hours post birth. Outcome data were reported on hypothermia, and BF exclusivity at

Marin 2010 *(Continued)*

		hospital discharge and 1-month post birth, as well as NICU admissions, mean time to expel the placenta, VAS score during episiotomy repair and mean anxiety and depression scores at hospital discharge.
Other bias	High risk	Infants in the SSC group weighed significantly less (3166 ± 389 g) than those in the control group (3300 ± 414 g, P < 0.007). Infants who are smaller tend to be colder than those who have more subcutaneous fat stores. The influence of this difference in weight between groups is unknown. Also the delivery room temperature in the SSC group was lower approximately 24 degrees C. than that for the control group, approximately 30 degrees C. There is no indication in the published report that the trial authors adjusted for cluster design (randomization of pediatricians rather than women).

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 post birth 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 post birth, 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 randomized groups”. Methods not described.
Allocation concealment (selection bias)	Unclear risk	Methods not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind.
Blinding of outcome assessment (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 were any missing data.

Mazurek 1999 *(Continued)*

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 post birth, 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 post birth.
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 post randomization 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 post randomization and then replaced.
Blinding of participants and personnel (performance bias) All outcomes	High 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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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.

McClellan 1980 *(Continued)*

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 post birth with effective suckling. Then mothers and infants were separated for 24 hours and infants were fed formula. After 24 hours rooming-in with every 3 hours breastfeedings. 2) Control group = first mother-infant contact 24 hours post birth then rooming-in and every 3 hours 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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind. Staff providing care would be aware of group assignment.
Blinding of outcome assessment (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. 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.

Mizuno 2004 *(Continued)*

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 post birth, 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 post birth.
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 of participants and personnel (performance bias) All outcomes	High risk	This was an unblinded study.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The chief investigator provided some of the post birth 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).

Nahidi 2011

Methods	Parallel randomized trial Taleghari hospital, Arak, Iran.
Participants	Pregnant women 19-35 year old, gestation of 37 weeks or more, without risky pregnancy/delivery; no anatomical anomaly or history of breast surgery; no contraindication to breastfeeding or skin contact to infant; no narcotic analgesic during delivery; first delivery; normal delivery without using tools. Newborn: transparent amniotic fluid; infant's weight: 2500 g or more; Apgar score: 1st min ≥ 8 and 5th min ≥ 9; lack of obvious congenital anomaly or medical problem which interfere with SSC or breast-feeding (like cardiac disease, respiratory disease and cleft palate).
Interventions	Intervention (n = 40): mother- infant SSC immediately after birth naked newborns placed prone position in mother's skin. Comparator (n = 40): routine care infants were placed in a cot under a warmer immediately after birth.
Outcomes	Limited outcome data from translation only: satisfaction with care after delivery; tendency for skin-to-skin care in next delivery.
Notes	This trial report is in Persian; our assessment and data are based on a translation.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to determine.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not reported. Not possible to blind.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition described; data for all women randomized.
Selective reporting (reporting bias)	Low risk	Data for all outcomes mentioned in text.
Other bias	Low risk	No baseline differences reported.

Nasehi 2012

Methods	Randomized controlled trial.
Participants	110 healthy full-term infants and their primiparous mothers undergoing a cesarean section with general anesthesia at Emam Khomeini Hospital in Iran.

Nasehi 2012 *(Continued)*

	Exclusion criteria: mothers with previous history of medical diseases, mental illness, below 18 years of age, substance use, infants with 5-min Apgar below 7, GA below 37 weeks, congenital anomalies, respiratory distress, low birthweight and those requiring resuscitation.
Interventions	1) SSC group n = 54 – After the mothers were transferred to the recovery room post cesarean birth, the infants were placed in "close skin contact" with their mothers and were assisted by a midwife with breastfeeding during the first 2-hours post birth. 2) Control group n = 56 – usual care was followed where the mothers were given the opportunity to breast feed after their full recovery from the cesarean birth more than 2-hours post birth.
Outcomes	Exclusive breastfeeding at 3 months post birth. At 3-month follow-up authors also asked about any infant supplementary foods, maternal nutrition and use of prescription drugs.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	States mothers were randomly allocated to groups after transfer to the recovery room; method of sequence generation not stated.
Allocation concealment (selection bias)	Unclear risk	States "predefined and closed envelopes." Does not state whether the envelopes were opaque or sequentially numbered or when they were opened.
Blinding of participants and personnel (performance bias) All outcomes	High risk	States "double blinded" but does not indicate who was blinded and not possible to blind this intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	States "double blinded" but does not indicate who was blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	States 110 mothers enrolled in the trial, 54 in the intervention group and 56 in the control group. States all mothers were contacted at 3 months post birth to evaluate whether they were exclusively breastfeeding.
Selective reporting (reporting bias)	Unclear risk	The only clinical outcome reported in this trial was exclusive breastfeeding at 3 months post birth; 3-month follow-up also included questions about any supplementary food given to infants and maternal consumption of multivitamins or prescription drugs (data not shown).
Other bias	Low risk	There were no significant between group differences in the demographic characteristics of the participants.

Nimbalkar 2014

Methods	Randomized controlled trial.
Participants	100 healthy full-term or late preterm infants mean GA 37.7 $\pm$ 1.35 weeks, birthweight 2605.6 $\pm$ 419.8 g and their mothers delivering vaginally at Shree Krishna Hospital in Karamsad, North India. Inclusion criteria: stable with birthweight $\geq$ 1800 g, vaginal delivery. Exclusion criteria: cesarean section, in need of resuscitation at birth, congenital malformations.

Nimbalkar 2014 *(Continued)*

Interventions	1) In the SSC group (n = 50), initial care was performed under a radiant warmer. SSC began 30 min. to 1-hour post birth and continued for 24 hours with a minimum of interruptions. 2) Infants in the control group (n = 50) received the same care as the SSC group except that they were dressed, head covered with a cap and back by a blanket when they were returned to their mothers. The postpartum maternity care wards were not climate controlled.
Outcomes	HR, axillary temperature, episodes of hypothermia.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was done using web based software (WINPEPI).
Allocation concealment (selection bias)	Low risk	Selection cards were sealed in opaque envelopes. Mothers signed an informed consent and then were randomized to groups.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel could not be blind to group assignment.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome data (axillary temperature, HR, episodes of hypothermia) were collected during the intervention period so the assessors could not be blind to group assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	100 infants were randomized to groups (50 in each group) and data from all infants was analyzed.
Selective reporting (reporting bias)	Low risk	No outcome data were provided for HR except to state in the abstract that the HR was normal in both groups, however, the focus of the study was on incidence of hypothermia.
Other bias	Low risk	Baseline clinical characteristics of the 2 groups (mean GA, birthweight, HR, temperature, incidence of low birthweight) were similar in the 2 groups.

Nolan 2009

Methods	Randomized controlled trial (mothers were randomly assigned to the 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 au-

Nolan 2009 *(Continued)*

	ditory 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 post birth. 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 post birth, maternal perception of childbirth.
Notes	This study took place in the USA.

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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind. The nurses who provided usual care to the control mothers were unfamiliar with the NIMS protocol.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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.

Nolan 2009 *(Continued)*

	Usual care was unstructured. The exact conditions which the NIMS protocol was being compared to are unknown.

Norouzi 2013

Methods	Randomized controlled trial.
Participants	90 pregnant women (30 SSC, 30 SSC and music, 30 usual care) scheduled for a repeat cesarean section under spinal anesthesia 20-40 years old, singleton term pregnancy Exclusion criteria: Emergency surgery, use of drugs that can lower stress levels and anxiety, a visual analogue pain scale score of ≥ 3 at the filing of the first and second State-Trait Anxiety Inventory, severe infant crying or transfer to the NICU.
Interventions	1) KC group n = 30 - room temp maintained at 26 degrees C infant placed SSC on mother's chest for 30 min and covered with mother's gown. No information about how soon post birth SSC began. A trained partner was in attendance in the room. 2) KC plus music group n = 30 - SSC plus soft instrumental music composed by Johann Sebastian Bach started immediately after SSC began using a MP3 player and continuing for 30 min. 3) Control group n = 30 - no information was provided about what happened in the control group. All women received pain relief 2 hours post-operative (pentazocine 25 mg IM).
Outcomes	Baseline maternal State Anxiety measured by the State-Trait Anxiety Inventory (20 anxiety statements) measured 2-hours post-cesarean section after receiving 25 mg pentazocine IM and pain evaluated by a visual analogue scale. Then 30 min of SSC was provided in the intervention groups. VAS plus MSA was measured again 6 hours after baseline measure.
Notes	No outcome data were provided for pain scores using the VAS. For maternal anxiety, we used continuous data from 2 of 3 trial arms: the KC only group and the Control group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	States randomly allocated into 1 of 3 groups (KC, KC + music, control) 30 mothers in each group; sequence generation not described.
Allocation concealment (selection bias)	Low risk	Cards with 3 different numbers indicating group assignment were randomly placed in opaque, sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unable to blind participants and personnel.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The baseline pre and post-intervention maternal state anxiety (MSA) and pain scores were evaluated by a co-worker who was blind to the mother's group assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	90 women were randomly allocated into 1 of 3 groups (KC, KC + music, control). 1 mother was unwilling to continue KC in the KC group. 2 infants were

Norouzi 2013 *(Continued)*

		hospitalized? (1 KC, 1 KC + music) and excluded from the study but outcome data on maternal state anxiety was obtained on all 90 women.
Selective reporting (reporting bias)	Unclear risk	No outcome data were provided for maternal pain scores although the focus of the study was on maternal state anxiety.
Other bias	Unclear risk	The 3 groups differed significantly on whether they had a wanted or unwanted pregnancy (0.025). 12/30 KC mothers, 3/30 KC + music mothers, 7/30 control mothers had an unwanted pregnancy.

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 post birth. After the cord was clamped they were shown briefly to mom and moved to a warmer. 1) SSC group = beginning 60 min post birth infants received (M = 30 min) of SSC. Mothers were encouraged to breast feed on infant demand. Infants and mothers transferred to the postpartum unit at 120 min post birth 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 breast feed 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 post birth, 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 post birth, Mother's perception of the adequacy of her milk supply, and breastfeeding status 36-48 hours and week 4 post birth, infant weight day 2 and 1 month post birth.
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 of participants and personnel (performance bias) All outcomes	High 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.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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.

Punthmatharith 2001 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	195 women were randomized and 167 remained available to follow-up. 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 post vaginal or cesarean birth.
Interventions	1) KC group = mothers began SSC at 4 hours post birth 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 post birth. Mothers fed their infants every 4 hours in the nursery.
Outcomes	1) Mean maternal state anxiety. 2) Mean score on a 6-point breast engorgement scale. 3) Chest circumference. 4) Breastfeeding status day 3 and 28 post birth. 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 of participants and personnel (performance 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.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessor not blinded.
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.

Shiau 1997 *(Continued)*

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 breast feed. 2) Control group = infants were separated from their mothers for 12 hours. All women had episiotomy (hospital routine for primiparous women). No woman had analgesia during labor.
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. We have reported on results for the Roosevelt 1 study as Sosa 1976a. This study was conducted at a charity hospital in 1974 when women who moved from rural to urban areas were just beginning to deliver in a hospital and more of these poorer women ended up in the control group and were more likely to breast feed. The socio-economic index score (includes home environment, education and income) of women in the control group was 11 and in the experimental group was 14 so the groups were unbalanced as far as socio-economic status was concerned.

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 of participants and personnel (performance bias) All outcomes	High risk	Blinding of outcome assessors is not mentioned, apart from blinding of researchers for behavior outcomes measured in a different population in a 3-armed investigation of maternal bonding. For this study staff were likely to have been aware of treatment group and may have altered other aspects of treatment.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Behavior outcomes were collected by blinded research staff; however, outcome assessors also 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.

Sosa 1976a *(Continued)*

Selective reporting (reporting bias)	High risk	No SD reported with mean breastfeeding duration. No systematic reporting of longer term outcomes for all trials collected at 3, 6, 9 and 12 months.
Other bias	High risk	More women in the control group of this trial had poor socio-economic status as measured with a socio-economic index score. The authors report a $P < 0.05$ with no further details. The authors have no evidence but guess that women in the control group for this trial were more likely to be from the countryside where breastfeeding continues for 2 years. There is no way to verify this explanation of the difference in breastfeeding status favoring the control group.

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 breast feed. 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 in 1976. We have reported on results for the Roosevelt 2 study as Sosa 1976b. All women had episiotomy (hospital routine for primiparous women). No woman had analgesia during labor. The socio-economic index in the control group was 14 and it was 12 in the experimental group so the control group had a slightly higher socio-economic status than the experimental group.

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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind. 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.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessors is not mentioned, apart from blinding of researchers for behavior outcomes measured in a different population in a 3-armed investigation of maternal bonding. For this study staff were likely to have been aware of treatment group and may have altered other aspects of treatment.
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.

Sosa 1976b *(Continued)*

Selective reporting (reporting bias)	High risk	No SD reported with mean breastfeeding duration. No systematic reporting of longer-term outcomes for all trials collected at 3, 6, 9 and 12 months.
Other bias	Unclear risk	It is not clear whether any women were still breastfeeding at the final data collection point. We were unsure of the impact of differences in socio-economic status between treatment arms. For this trial, women had higher socio-economic status in the control group.

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 breast feed. 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 in 1974. We have reported on the results of the Social Security Hospital as Sosa 1976c. All women had episiotomy (hospital routine for primiparous women). No woman had analgesia during labor. Mothers in both groups had a socio-economic index of 14 so this variable was balanced between groups in this study.

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 of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind. 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.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding of outcome assessors is not mentioned, apart from blinding of researchers for behavior outcomes measured in a different population in a 3-armed investigation of maternal bonding. For this study staff were likely to have been aware of treatment group and may have altered other aspects of treatment.
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)	High risk	No SD reported with mean breastfeeding duration. No systematic reporting of longer term outcomes for all trials collected at 3, 6, 9 and 12 months.

Sosa 1976c *(Continued)*

Other bias	Unclear risk	We were unsure of the impact of the above concerns on outcome data.

Srivastava 2014

Methods	Randomized controlled trial.
Participants	298 healthy full-term infants and their mothers delivering vaginally at a tertiary care center in Haryana, India July 2009 - July 2011. Inclusion criteria: term infant not requiring resuscitation beyond the initial steps, singleton normal delivery. Exclusion criteria: major congenital malformation.
Interventions	1) In the SSC group, the naked infants were weighed and then covered with cap on their heads and a diaper and were placed prone between their mother's bare breasts and covered with a sheet and blanket within 30 mins after birth. SSC continued for at least 2-hours. 2) In the control group infants were dried, weighed, dressed, wrapped in a sheet and blanket and placed next to their mothers. A nurse assisted the mothers in both groups with breastfeeding when the infants displayed pre-feeding behaviors.
Outcomes	Successful breastfeeding (mean IBFAT score), mother's satisfaction with breastfeeding at hospital discharge, exclusive breastfeeding on day 4 or 5 and 6-weeks post birth, infant axillary temperature after 2-hours, incidence of hypothermia, weight loss at hospital discharge, weight on day 4 or 5 and 6-weeks post birth, significant morbidity.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	States block randomization utilized each block consisting of 50 subjects; sequence generation not described.
Allocation concealment (selection bias)	Unclear risk	States sealed envelope technique utilized, does not indicate whether the envelopes were opaque or sequentially numbered.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unable to blind participants or personnel.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided about whether the outcome assessors were blind to subject group assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	298 mother-infant dyads were enrolled in this trial, 150 in the SSC group and 148 in the control group. 13 dyads in the SSC group and 19 in the control group were excluded. 15 dyads in the SSC group and 11 in the control group were lost to follow-up. 240 of 298 dyads (80.5%) completed the trial.
Selective reporting (reporting bias)	Unclear risk	Data were provided for all the pre-specified outcomes however the number of dyads analyzed in each group was not provided and some data were obtained

Srivastava 2014 *(Continued)*

		during the first breastfeeding, additional data at hospital discharge, between day 4 and 5 days post birth and 6-weeks post birth and there was 19.5% attrition at some point in this study. They do provide data for only 122 SSC mothers and 118 control mothers on parity.
Other bias	Low risk	There were no significant differences between the groups in maternal age, parity, infant birthweight and sex.

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 post birth, 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 care taking behavior during breastfeeding 36 hours post birth.
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 of participants and personnel (performance bias) All outcomes	High risk	The intervention was not explained to women but not possible to blind. 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.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	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 1993

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 post birth 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 post birth, 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 breastfeeding 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 of participants and personnel (performance 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.
Blinding of outcome assessment (detection bias) All outcomes	High risk	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 post birth, 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 post birth. Mothers were encouraged to breast feed, subsequent contact at 12-24 hours post birth, 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 post birth.
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 of participants and personnel (performance bias) All outcomes	High 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. However, not possible to blind intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	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. 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.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	34 women recruited. 4 lost to follow-up.
Selective reporting (reporting bias)	Low risk	Relevant outcomes are reported.
Other bias	Unclear risk	Little information on study methods was provided.

Thukral 2012

Methods	Randomized controlled trial.
Participants	41 healthy full-term infants and their mothers delivering vaginally at All India Institute of Medical Sciences, New Delhi, India, Aug 2008 - Sept 2009. Inclusion criteria: full term, appropriate for GA, normal delivery.

Thukral 2012 *(Continued)*

	Exclusion criteria: major congenital anomalies, infants of diabetic mothers or requiring resuscitation beyond the initial steps and/or admission to the NICU.
Interventions	1) In the SSC group n = 20 the infants were placed prone on their mother's chests immediately post birth SSC continued for 2-hours. 2) Control infants n = 21 did not receive SSC and were kept next to their mothers. Mothers in both groups received assistance with breastfeeding and did not initiate SSC after the first 2-hours.
Outcomes	Infants breastfeeding behavior 36-48 hours of age (median, IQR BAT score), Successful breastfeeding (BAT score ≥ 8) BAT is modification of the IBFAT score, exclusive breastfeeding at 48 hours and 6-weeks post birth, infant salivary cortisol at 6 hours post birth, the mothers' perception of her milk output, breast consistency, infant's weight at 48 hours, assistance required for breastfeeding, duration of feedings, infant activity during feeding.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random sequence numbers.
Allocation concealment (selection bias)	Low risk	Serially numbered, sealed and opaque envelopes. Written consent was obtained from the mothers before an anticipated vaginal delivery.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The investigators, participants and personnel were not blinded to group assignment.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	States outcome assessors who measured breastfeeding behavior were blind to group assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	41 mothers were randomized to groups 20 in the SSC group, 21 in the control group. 17 dyads in the SSC group and 18 in the control group had data available for BAT score. 20 dyads in the SSC group and 21 in the control group had outcome data available for the other outcomes except salivary cortisol where the numbers were 19 SSC, 20 control.
Selective reporting (reporting bias)	Low risk	Data were provided in Table 4 for all prespecified outcomes in this trial.
Other bias	Low risk	No significant between group differences in maternal or neonatal baseline variables.

Vaidya 2005

Methods	Randomized controlled trial.
Participants	110 healthy full-term infants and their mothers.

Vaidya 2005 *(Continued)*

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 post birth, 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 of participants and personnel (performance bias) All outcomes	High risk	Blinding was not mentioned, it is likely that all groups were aware of group assignment.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described.
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 breastfeeding 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 1992

Methods	Randomized controlled trial.
Participants	119 healthy full-term infants and their mothers.
Interventions	SSC group = babies were placed SSC on their mothers immediately post birth, 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.

Villalon 1992 *(Continued)*

Outcomes	Breastfeeding at 24 hours, hospital discharge, and 14 days post birth, maternal parenting confidence, temperature, HR, respiratory rate at 1,2,3 and 4 hours post birth 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 of participants and personnel (performance bias) All outcomes	High risk	No blinding of women or clinical staff.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding of 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
BP: blood pressure
BPM: beats per minute
CPAP: continuous positive airway pressure
GA: gestational age
HR: heart rate
IBFAT: Infant Breastfeeding Assessment Tool
IBS: Index of breastfeeding status
IM: intramuscular
IQR: interquartile range
ITT: intention-to-treat
IV: intravenous
KC: kangaroo care
M: mean
min.: minutes
MPI: mother preterm infant interaction
MSA: maternal state anxiety
NICU: neonatal intensive care unit

NIMS: Nursing Intervention to Minimize Maternal-Infant Separation
PACU: Post-Anesthesia Care Unit
PCERA: Parent-Child Early Relational Assessment
RDS: respiratory distress syndrome
SCRIP: stability of the cardio-respiratory system
SD: standard deviation
SE: standard error
SSC: skin-to-skin contact
VAS: visual analogue scale

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.
Arnon 2014	This was a cross-over trial of maternal singing during KC compared to KC alone, with stable preterm infants 32-36 weeks' GA. Cross-over trials are not eligible for inclusion in this review.
Bigelow 2012	This was an quasi-experimental study or observational study. 2 hospitals were used as study sites; mothers in 1 hospital were asked to provide daily SSC for the first month post birth, and the mothers in the control hospital were not asked to provide SSC. The information provided to the mothers in the 2 recruitment hospitals about SSC was switched half-way through the study.
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 post birth for KMC infants and 8 days post birth 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.
de Ocampo 2013	Infants in this study were stable, low birthweight infants (< 1500 g) and not eligible for our review.
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 post birth. All infants were in the NICU. Mean GA - 30.65 weeks.
Ferber 2008	This study was conducted on preterm infants in the NICU.

Study	Reason for exclusion
Filho 2015	This trial studied NICU infants with birth weight 1300 g to 1800 g, and hospitalized more than 4 days. These infants do not meet our inclusion criteria.
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 post birth.
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 $\pm$ 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 h postnatal age at study entry.
Gray 2002	Infants were between 40 and 44 h 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.
Holditch-Davis 2014	Preterm infants average GA 27 weeks in the NICU, weight approximately 1000 g, randomized to 1 of 3 groups - KC + auditory-tactile-visual-vestibular intervention, KC alone or usual care. Unclear if the intervention was delivered within 24 h of birth.
Horn 2014	This trial randomized mothers to receive forced-air-skin-surface warming during their cesarean birth and a 20-min intraoperative bonding period with their infant or passive insulation. Infants in both treatment groups were positioned on their mother's chests. The comparison group received SSC and is not eligible for our review.
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 h to 30 days of age.
Ignacio 2013	All preterm infants in this trial were being transported from the delivery room to the NICU using either KC transport or incubator transport. We are excluding NICU infants from our review (our definition of healthy is that the infants be healthy enough to remain on the postpartum unit with their mothers).
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.
Keshavarz 2010a	This is a quasi-randomised trial with the sequence generated by odd or even numbers.
Klaus 1972	The early contact in the intervention group was not skin-to-skin.

Study	Reason for exclusion
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.
Limrattamorn 2013	We have sent and email to authors for clarification, but we believe the trial compares early with late SSC, with no comparison group receiving no SSC.
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 post birth. 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.
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.
Morelius 2015	This trial included late preterm infants (32-35 weeks' GA) in the NICU.
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 h 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 post birth.
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 h post birth.
Ottaviano 1979	No mention was made regarding whether the early maternal-infant contact was skin-to-skin.
Raguindin 2015	This study looked at NICU infants < 2000 g.
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 post birth. 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 g.
Ruiz 2014	This is a cost utility analysis of KMC in Bogota, Colombia (kangaroo position, nutrition and discharge of preterm infants). This trial falls under the KMC Cochrane review conducted by the Cochrane Neonatal Group.
Saatsaz 2011	It is not clear that this is a randomised trial. All women had postpartum depression, and we were unable to determine the timing of the SSC even with translation.

Study	Reason for exclusion
Salariya 1978	No mention was made regarding whether the early maternal-infant contact was skin-to-skin.
Seeman 2015	Abstract only available. This report primarily describes a retrospective chart review (n = 138); only 10 mothers randomized to SSC in the operating room or usual care. Unclear if outcomes were analyzed separately for randomized group of 10.
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 g) in a Level III NICU.
Svensson 2013	SSC began 1-16 weeks postpartum for older infants with severe latch problems.
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 $\pm$ 2.5 weeks, control group 33.9 $\pm$ 2.7 weeks). The infants were all < 2000 g. 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.
Vendivel 2011	Abstract only available, but trial compares maternal SSC to paternal SSC rather than to usual care. There is no usual care control group.
Vesel 2013	Home visit program in Ghana to encourage mothers of low birth weight infants to practice SSC.
Wimmer-Puchinger 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 g to 1900 g) for KMC and 1471.8 g (range 930 g to 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 h 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 studies awaiting assessment *[ordered by study ID]*

Ramani 2015

Methods	Randomized controlled trial, Lusaka, Zambia. Randomized trial of SSC to prevent hypothermia in term neonates.
Participants	Term neonates (gestational age Q37 weeks) born at University Teaching Hospital.
Interventions	Randomization in 2 phases (Phase 1: birth to 1 hour, Phase 2: 1 hour to discharge). Arm 1 (n = 191 total): SSC as continuously as possible along with the WHO thermoregulation protocol as practiced (SSC group). Arm 2: (n = 192 total) the WHO thermoregulation protocol as practiced only (control group) including warm delivery rooms, immediate drying, breastfeeding, delayed bathing and weighing, appropriate bundling, mother and baby together, warm transportation, warm resuscitation, and training and awareness raising. Neonates randomized in Phase 1 were re-randomized at 1 hour for Phase 2 of the study.
Outcomes	Moderate or severe (< $36.^0$C axillary temperature) hypothermia at 1-hour post birth or hospital discharge; duration of SCC for SCC arms.
Notes	Abstract only.

Rosas 2015

Methods	Randomized controlled trial, Mexico. September and October 2012. Effect of skin-to-skin care on the success of breastfeeding exclusivity: a randomized controlled trial.
Participants	100 term infants born at a semi-urban public hospital in Mexico.
Interventions	Immediate SSC versus control (no further information).
Outcomes	Percentage of exclusive breastfeeding in the first 24 hours and at 1 week after birth. Heart rate, respiratory rate and axillary temperature stabilization during the first hour after birth.
Notes	Abstract only. Data reported for 70 infants.

Tateoka 2014

Methods	Randomized controlled trial, Japan. Effect of early mother–child contact immediately after birth on delivery stress state.
Participants	n = 46 primiparous mothers and their infants.

Tateoka 2014 *(Continued)*

Interventions	Immediate postpartum contact versus no immediate postpartum contact (no further information).
Outcomes	Delivery stress state of first-time mothers. Physical and psychological stresses were evaluated by salivary cortisol and saliva (CgA) from the participants in the 2 groups at 60 and 120 minutes after birth. Reported also: intrapartum hemorrhage, mean delivery time as baseline.
Notes	Abstract only.

SSC: skin-to-skin contact
SCRIL score: Stability of the Cardio-respiratory System for Late Preterm Infants
WHO: World Health Organization

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

Keshavarz 2010b

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; we are unsure if this is the same as our excluded Keshavarz 2010 or not.

DATA AND ANALYSES

Comparison 1. Immediate or Early skin-to-skin versus standard contact for healthy infants

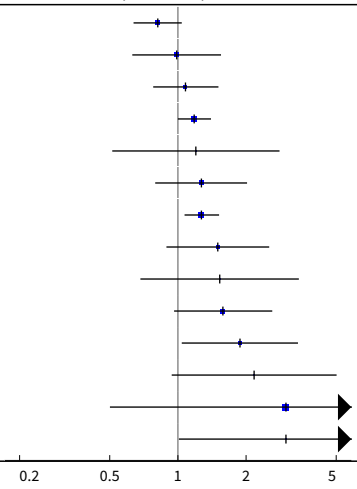
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Breastfeeding 1 month to 4 months post birth	14	887	Risk Ratio (M-H, Random, 95% CI)	1.24 [1.07, 1.43]
2 Duration of breastfeeding in days	7	324	Mean Difference (IV, Random, 95% CI)	42.55 [-1.69, 86.79]
3 SCRIP score first 6 hours post birth	2	81	Std. Mean Difference (IV, Random, 95% CI)	1.24 [0.76, 1.72]
4 Blood glucose mg/dL at 75-180 minutes post birth	3	144	Mean Difference (IV, Fixed, 95% CI)	10.49 [8.39, 12.59]

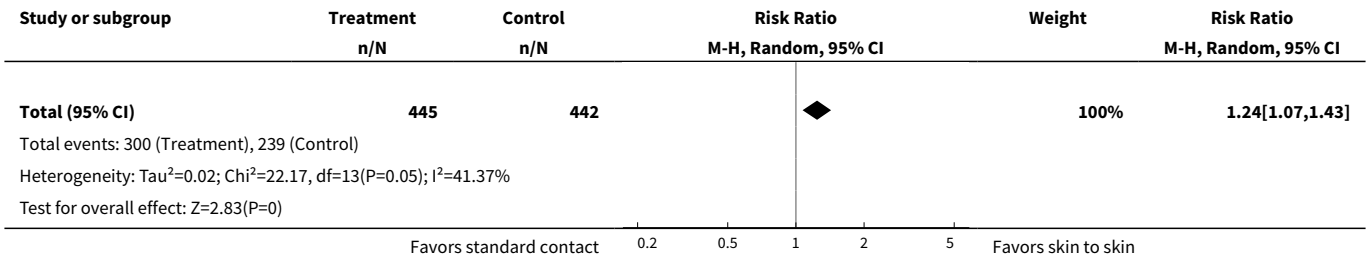
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Infant axillary temperature 90 minutes to 2.5 hours post birth	6	558	Mean Difference (IV, Random, 95% CI)	0.30 [0.13, 0.47]
6 Exclusive breastfeeding at hospital discharge to 1 month post birth	6	711	Risk Ratio (M-H, Random, 95% CI)	1.30 [1.12, 1.49]
7 Exclusive breastfeeding 6 weeks to 6 months post birth	7	640	Risk Ratio (M-H, Random, 95% CI)	1.50 [1.18, 1.90]
8 Breastfeeding status day 28 to 1 month post birth	3	245	Mean Difference (IV, Random, 95% CI)	0.86 [-0.73, 2.44]
9 Breastfeeding 1 year post birth	2	62	Risk Ratio (M-H, Fixed, 95% CI)	6.19 [0.82, 46.78]
10 Success of the first breastfeeding (IBFAT score)	4	384	Mean Difference (IV, Random, 95% CI)	2.28 [1.41, 3.15]
11 Successful first breastfeeding (IBFAT score 10-12 or BAT score 8-12)	5	575	Risk Ratio (M-H, Random, 95% CI)	1.32 [1.04, 1.67]
12 Suckled during the first 2 hours post birth	1	88	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.83, 1.35]
13 Mean variation in maternal breast temp. 30-120 minutes post birth	1	132	Mean Difference (IV, Fixed, 95% CI)	0.60 [0.34, 0.86]
14 Breast engorgement - pain, tension, hardness 3 days post birth	2	131	Std. Mean Difference (IV, Fixed, 95% CI)	-0.41 [-0.76, -0.06]
15 Heart rate 75 minutes to 2 hours post birth	3	183	Mean Difference (IV, Random, 95% CI)	-3.05 [-7.84, 1.75]
16 Respiratory rate 75 minutes - 2 hours post birth	4	215	Mean Difference (IV, Random, 95% CI)	-3.12 [-6.61, 0.37]
17 Infant did not exceed parameters for stability	1	31	Risk Ratio (M-H, Fixed, 95% CI)	10.83 [1.63, 72.02]
18 Transferred to the neonatal intensive care unit	2	305	Risk Ratio (M-H, Fixed, 95% CI)	0.51 [0.20, 1.26]
19 Infant body weight change (grams) day 14 post birth	2	43	Mean Difference (IV, Fixed, 95% CI)	-6.00 [-175.60, 159.61]
20 Infant hospital length of stay in hours	2	42	Mean Difference (IV, Random, 95% CI)	-95.30 [-368.50, 177.89]
21 Not crying for > 1 minute during 90 minutes	1	29	Risk Ratio (M-H, Fixed, 95% CI)	12.86 [1.91, 86.44]
22 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]
23 PCERA Maternal positive affective involvement and responsiveness 12 months post birth	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
24 PCERA Dydadic mutuality and reciprocity 12 months post birth	1	61	Mean Difference (IV, Fixed, 95% CI)	1.30 [0.24, 2.36]
25 Mother's most certain preference for same postdelivery care in the future	3	439	Risk Ratio (M-H, Random, 95% CI)	6.04 [2.05, 17.83]
26 Maternal state anxiety 8 hours to 3 days post birth	3	390	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-0.59, -0.04]
27 Maternal parenting confidence at 1 month post birth	1	20	Mean Difference (IV, Fixed, 95% CI)	5.60 [-6.24, 17.44]
28 Breastfeeding 1 month to 4 months post birth: Sensitivity analysis	13	827	Risk Ratio (M-H, Random, 95% CI)	1.26 [1.14, 1.39]
29 Duration of breastfeeding in days: Sensitivity analysis	6	264	Mean Difference (IV, Random, 95% CI)	63.73 [37.96, 89.50]
30 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]
31 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]
32 Exclusive bf discharge - Marin 2010 sensitivity analysis	6	592	Risk Ratio (M-H, Random, 95% CI)	1.30 [1.12, 1.52]
33 NICU admission - Marin 2010 sensitivity analysis	2	167	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.21, 2.02]

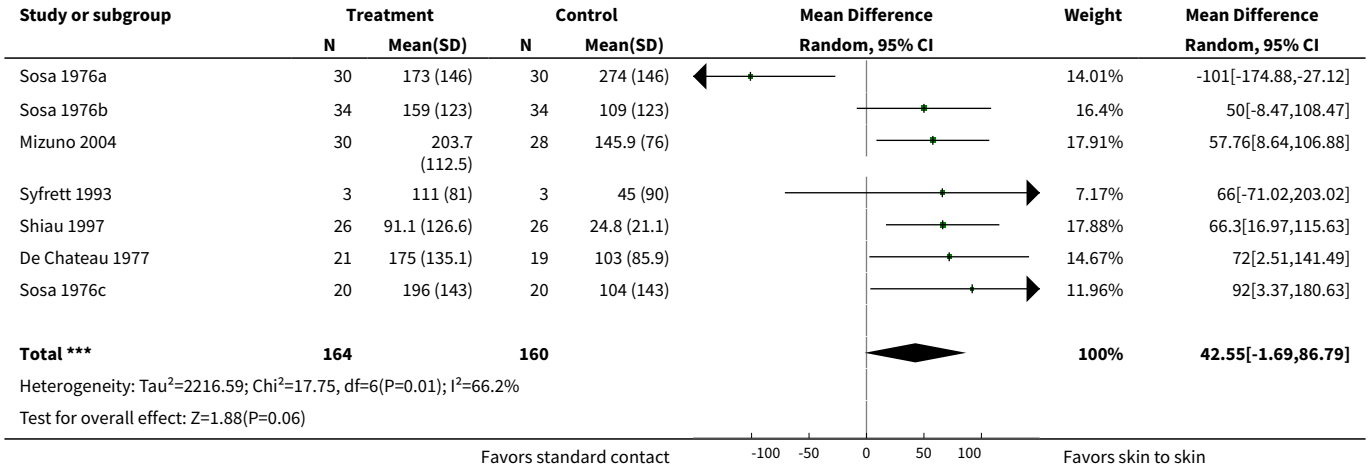
Analysis 1.1. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 1 Breastfeeding 1 month to 4 months post birth.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Sosa 1976a	22/30	27/30		13.74%	0.81[0.64,1.04]
Carlsson 1978	12/17	10/14		7.17%	0.99[0.63,1.55]
Carfoot 2005	42/97	40/100		10.48%	1.08[0.78,1.51]
Armbrust 2016	75/92	64/93		17.35%	1.18[1,1.4]
Carfoot 2004	7/14	5/12		2.63%	1.2[0.51,2.81]
Sosa 1976b	19/32	15/32		6.85%	1.27[0.79,2.02]
Vaidya 2005	42/44	36/48		16.99%	1.27[1.07,1.52]
Nolan 2009	16/20	8/15		5.84%	1.5[0.89,2.53]
Anderson 2003	7/11	5/12		2.89%	1.53[0.68,3.42]
Shiau 1997	19/28	12/28		6.26%	1.58[0.96,2.61]
Sosa 1976c	15/20	8/20		4.8%	1.88[1.04,3.39]
De Chateau 1977	12/21	5/19		2.69%	2.17[0.94,5.02]
Syfrett 1993	3/4	1/4		0.65%	3[0.5,17.95]
Thomson 1979	9/15	3/15		1.67%	3[1.01,8.95]

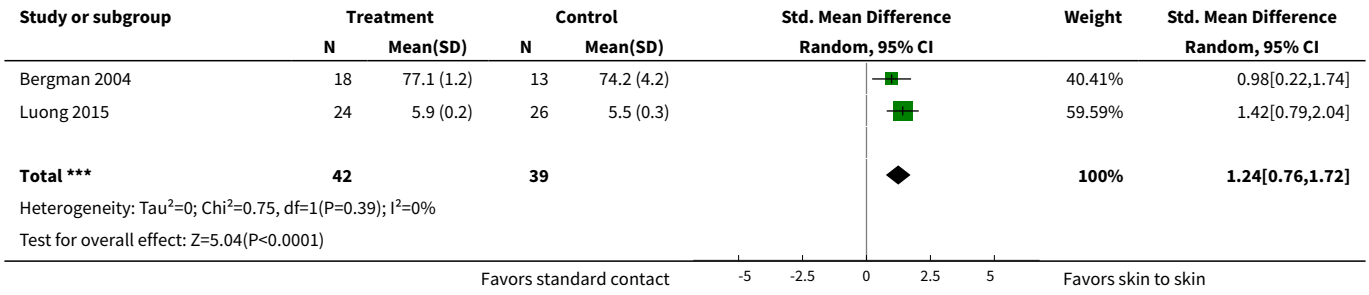




Analysis 1.2. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 2 Duration of breastfeeding in days.

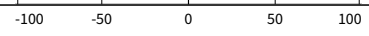


Analysis 1.3. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 3 SCRIP score first 6 hours post birth.



Analysis 1.4. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 4 Blood glucose mg/dL at 75-180 minutes post birth.

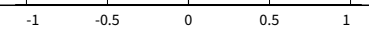
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Christensson 1992	25	57.6 (12.7)	25	46.5 (12.9)		8.71%	11.07[3.97,18.17]
Luong 2015	24	62.5 (12.6)	26	53.2 (18.7)		5.7%	9.3[0.52,18.08]
Mazurek 1999	22	60.1 (4.2)	22	49.6 (3.4)		85.59%	10.51[8.24,12.78]
Total ***	**71**		**73**			**100%**	**10.49[8.39,12.59]**
Heterogeneity: Tau^2=0; Chi^2=0.1, df=2(P=0.95); I^2=0%							
Test for overall effect: Z=9.81(P<0.0001)							



Favors standard contact — Favors skin to skin

Analysis 1.5. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 5 Infant axillary temperature 90 minutes to 2.5 hours post birth.

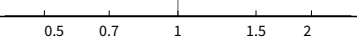
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Christensson 1992	25	37.1 (0.3)	25	36.7 (0.4)		15.77%	0.4[0.19,0.61]
Christensson 1995	14	36.9 (0.4)	15	36.4 (0.5)		11.54%	0.5[0.17,0.83]
Luong 2015	24	36.6 (0.3)	26	36 (0.4)		16.01%	0.6[0.4,0.8]
Nimbalkar 2014	50	37.1 (0.3)	50	36.8 (0.4)		18.32%	0.3[0.17,0.43]
Srivastava 2014	122	37 (0.2)	118	36.7 (0.3)		20.28%	0.23[0.18,0.28]
Villalon 1992	44	37 (0.3)	45	37.1 (0.4)		18.08%	-0.1[-0.24,0.04]
Total ***	**279**		**279**			**100%**	**0.3[0.13,0.47]**
Heterogeneity: Tau^2=0.04; Chi^2=40.47, df=5(P<0.0001); I^2=87.64%							
Test for overall effect: Z=3.51(P=0)							



Favors standard contact — Favors skin to skin

Analysis 1.6. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 6 Exclusive breastfeeding at hospital discharge to 1 month post birth.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Anderson 2003	8/11	9/12		7.16%	0.97[0.6,1.58]
Gouchon 2010	9/17	9/17		4.53%	1[0.53,1.88]
Mahmood 2011	56/68	39/67		20.6%	1.41[1.12,1.78]
Marin 2010	100/118	84/120		31.35%	1.21[1.05,1.39]
Srivastava 2014	105/122	79/118		30.6%	1.29[1.11,1.49]
Thukral 2012	19/20	8/21		5.75%	2.49[1.43,4.34]
Total (95% CI)	**356**	**355**		**100%**	**1.3[1.12,1.49]**
Total events: 297 (Treatment), 228 (Control)					
Heterogeneity: Tau^2=0.01; Chi^2=8.87, df=5(P=0.11); I^2=43.6%					
Test for overall effect: Z=3.56(P=0)					



Favours standard contact — Favours skin to skin

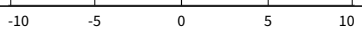
Analysis 1.7. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 7 Exclusive breastfeeding 6 weeks to 6 months post birth.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Anderson 2003	2/11	1/12		1.07%	2.18[0.23,20.84]
Gouchon 2010	8/17	5/17		5.77%	1.6[0.66,3.91]
Nasehi 2012	45/54	42/56		25.53%	1.11[0.92,1.35]
Nimbalkar 2014	27/50	20/50		15.5%	1.35[0.88,2.07]
Srivastava 2014	104/122	75/118		27.11%	1.34[1.15,1.57]
Thukral 2012	18/20	6/21		8.54%	3.15[1.58,6.29]
Vaidya 2005	34/44	18/48		16.47%	2.06[1.38,3.07]
Total (95% CI)	**318**	**322**		**100%**	**1.5[1.18,1.9]**
Total events: 238 (Treatment), 167 (Control)					
Heterogeneity: Tau^2=0.05; Chi^2=15.92, df=6(P=0.01); I^2=62.32%					
Test for overall effect: Z=3.34(P=0)					

Favors standard contact — Favors skin to skin

Analysis 1.8. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 8 Breastfeeding status day 28 to 1 month post birth.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Moore 2005	10	6.5 (1.1)	10	5.9 (2.2)		28.33%	0.6[-0.94,2.14]
Punthmatharith 2001	83	5.3 (1.1)	86	5.4 (1.1)		37.93%	-0.11[-0.44,0.22]
Shiau 1997	28	6.2 (2.1)	28	4 (1.6)		33.74%	2.16[1.19,3.13]
Total ***	**121**		**124**			**100%**	**0.86[-0.73,2.44]**
Heterogeneity: Tau^2=1.7; Chi^2=19.32, df=2(P<0.0001); I^2=89.65%							
Test for overall effect: Z=1.06(P=0.29)							



Favors standard contact — Favors skin to skin

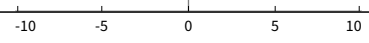
Analysis 1.9. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 9 Breastfeeding 1 year post birth.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
De Chateau 1977	3/16	0/15		45.95%	6.59[0.37,117.77]
Shiau 1997	4/19	0/12		54.05%	5.85[0.34,99.83]
Total (95% CI)	**35**	**27**		**100%**	**6.19[0.82,46.78]**
Total events: 7 (Treatment), 0 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0, df=1(P=0.95); I^2=0%					
Test for overall effect: Z=1.77(P=0.08)					

Favors standard contact — Favors skin to skin

Analysis 1.10. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 10 Success of the first breastfeeding (IBFAT score).

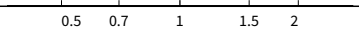
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Beiranvand 2014	46	8.8 (3.6)	44	7.3 (3.5)		22.12%	1.51[0.04,2.98]
Gouchon 2010	17	9.2 (3.8)	17	8.2 (3.2)		11.13%	1[-1.36,3.36]
Moore 2005	10	8.7 (2.1)	10	6.3 (2.6)		13.76%	2.4[0.33,4.47]
Srivastava 2014	122	9.6 (1.1)	118	6.7 (1.9)		52.99%	2.84[2.44,3.24]
Total * **	**195**		**189**			**100%**	**2.28[1.41,3.15]**
Heterogeneity: Tau²=0.33; Chi²=5.05, df=3(P=0.17); I²=40.63%							
Test for overall effect: Z=5.12(P<0.0001)							



Favors standard contact — Favors skin to skin

Analysis 1.11. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 11 Successful first breastfeeding (IBFAT score 10-12 or BAT score 8-12).

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Carfoot 2004	13/13	8/13		14.66%	1.59[1.03,2.45]
Carfoot 2005	89/98	82/99		27.07%	1.1[0.98,1.22]
Girish 2013	48/50	46/50		27.35%	1.04[0.94,1.15]
Khadivzadeh 2009	28/47	16/45		13.85%	1.68[1.06,2.65]
Mahmood 2011	47/80	26/80		17.08%	1.81[1.25,2.6]
Total (95% CI)	**288**	**287**		**100%**	**1.32[1.04,1.67]**
Total events: 225 (Treatment), 178 (Control)					
Heterogeneity: Tau²=0.05; Chi²=26.79, df=4(P<0.0001); I²=85.07%					
Test for overall effect: Z=2.29(P=0.02)					



Favors standard contact — Favors skin to skin

Analysis 1.12. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 12 Suckled during the first 2 hours post birth.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Bystrova 2003	34/44	32/44		100%	1.06[0.83,1.35]
Total (95% CI)	**44**	**44**		**100%**	**1.06[0.83,1.35]**
Total events: 34 (Treatment), 32 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.49(P=0.62)					

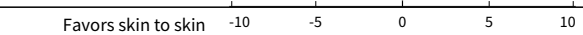
Favours standard contact — Favours skin to skin

Analysis 1.13. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 13 Mean variation in maternal breast temp. 30-120 minutes post birth.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Bystrova 2003	44	1.3 (0.8)	88	0.7 (0.5)		100%	0.6[0.34,0.86]
Total ***	**44**		**88**			**100%**	**0.6[0.34,0.86]**
Heterogeneity: Not applicable							
Test for overall effect: Z=4.46(P<0.0001)							

Analysis 1.14. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 14 Breast engorgement - pain, tension, hardness 3 days post birth.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Bystrova 2003	37	2.6 (0.6)	38	2.7 (0.6)		58.31%	-0.26[-0.71,0.2]
Shiau 1997	28	3 (1.2)	28	3.8 (1.3)		41.69%	-0.63[-1.17,-0.09]
Total ***	**65**		**66**			**100%**	**-0.41[-0.76,-0.06]**
Heterogeneity: Tau^2=0; Chi^2=1.09, df=1(P=0.3); I^2=8.06%							
Test for overall effect: Z=2.33(P=0.02)							

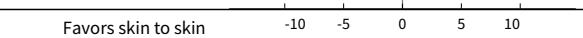


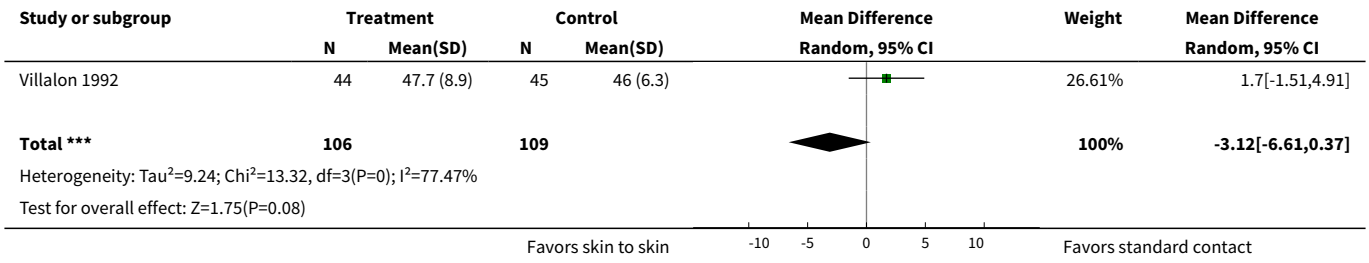
Analysis 1.15. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 15 Heart rate 75 minutes to 2 hours post birth.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Christensson 1992	25	136.6 (6.9)	25	140.7 (9)		29.34%	-4.1[-8.55,0.35]
Mazurek 1999	22	134.1 (3)	22	140.1 (3.1)		37.2%	-6.04[-7.83,-4.25]
Villalon 1992	44	144.4 (7.3)	45	143.2 (8)		33.46%	1.2[-1.98,4.38]
Total ***	**91**		**92**			**100%**	**-3.05[-7.84,1.75]**
Heterogeneity: Tau^2=15.26; Chi^2=15.12, df=2(P=0); I^2=86.77%							
Test for overall effect: Z=1.25(P=0.21)							

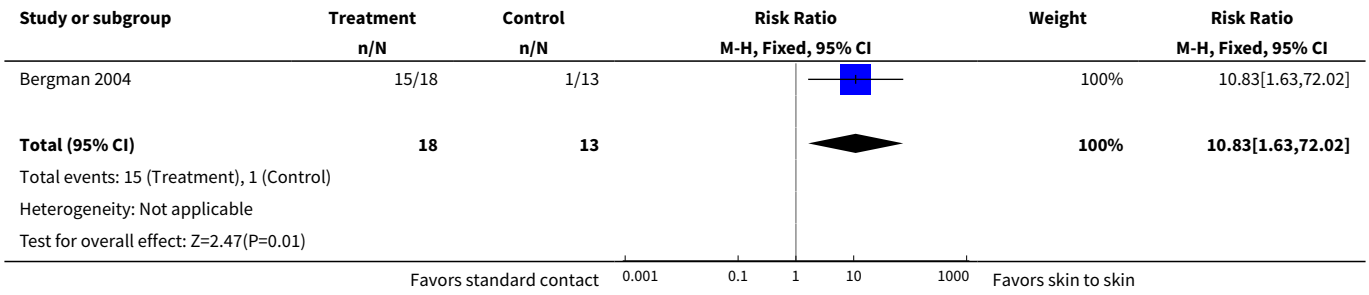
Analysis 1.16. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 16 Respiratory rate 75 minutes - 2 hours post birth.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Christensson 1992	25	44.3 (7.9)	25	49.8 (10.2)		19.96%	-5.5[-10.56,-0.44]
Mazurek 1999	22	45 (2)	22	49.7 (2.9)		32.35%	-4.73[-6.21,-3.25]
Nolan 2009	15	46.9 (5.7)	17	51.4 (7.9)		21.08%	-4.48[-9.2,0.24]

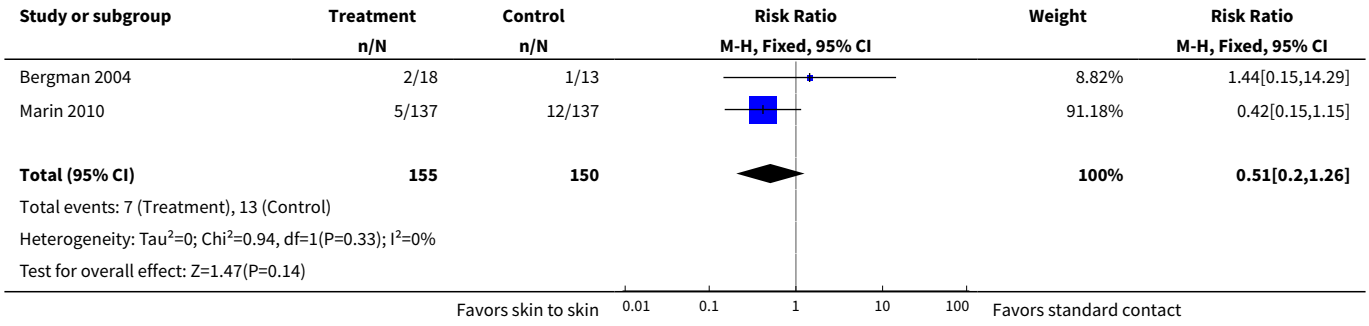




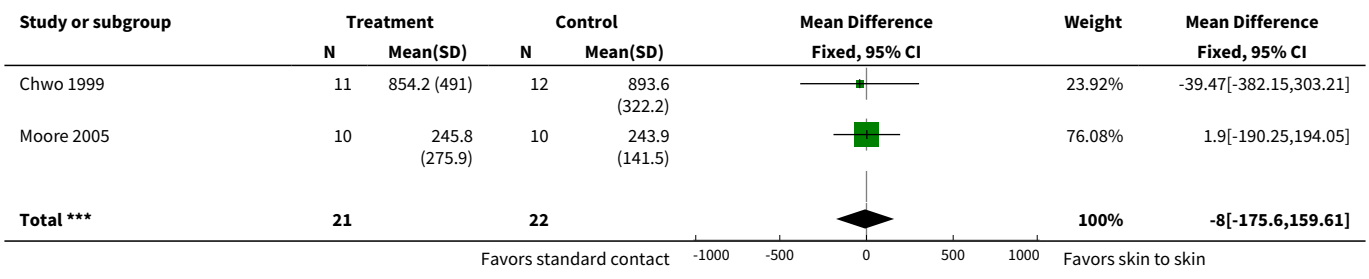
Analysis 1.17. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 17 Infant did not exceed parameters for stability.

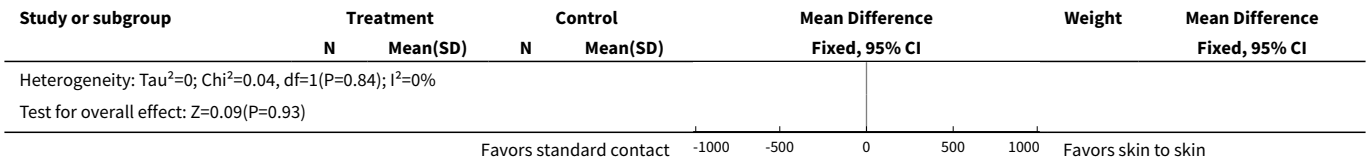


Analysis 1.18. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 18 Transferred to the neonatal intensive care unit.

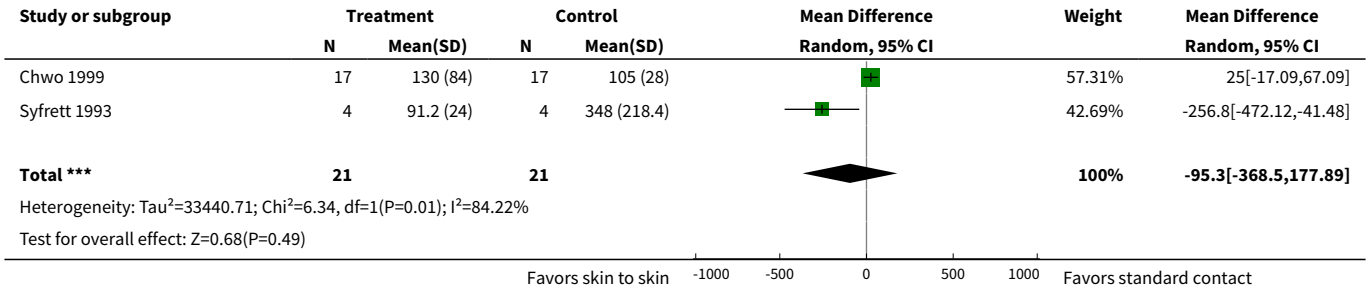


Analysis 1.19. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 19 Infant body weight change (grams) day 14 post birth.

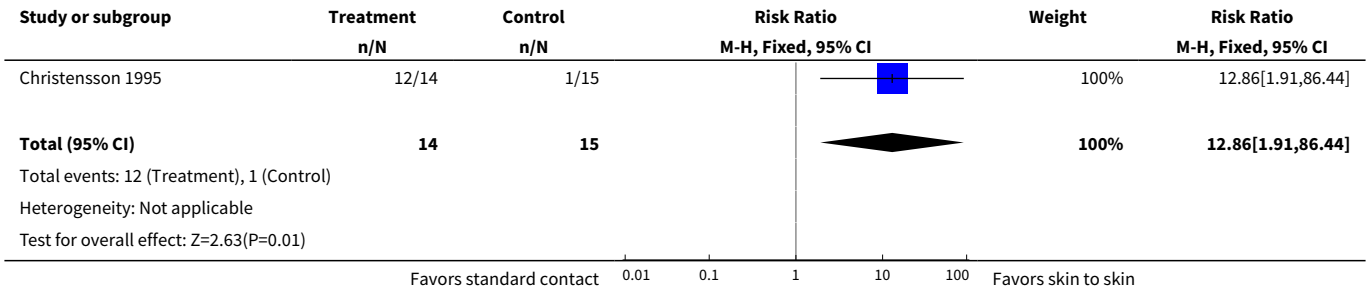




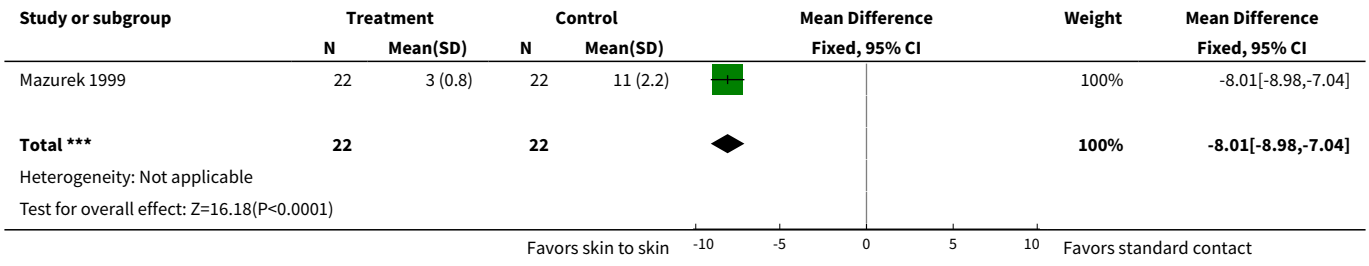
Analysis 1.20. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 20 Infant hospital length of stay in hours.



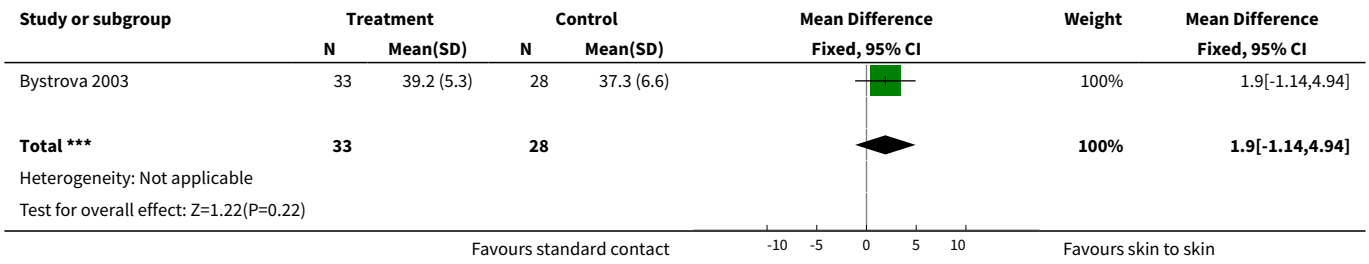
Analysis 1.21. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 21 Not crying for > 1 minute during 90 minutes.



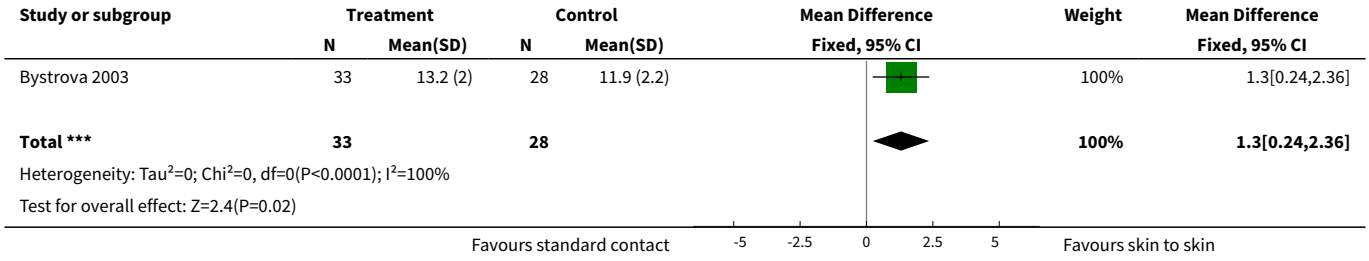
Analysis 1.22. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 22 Amount of crying in minutes during a 75-minute observation period.



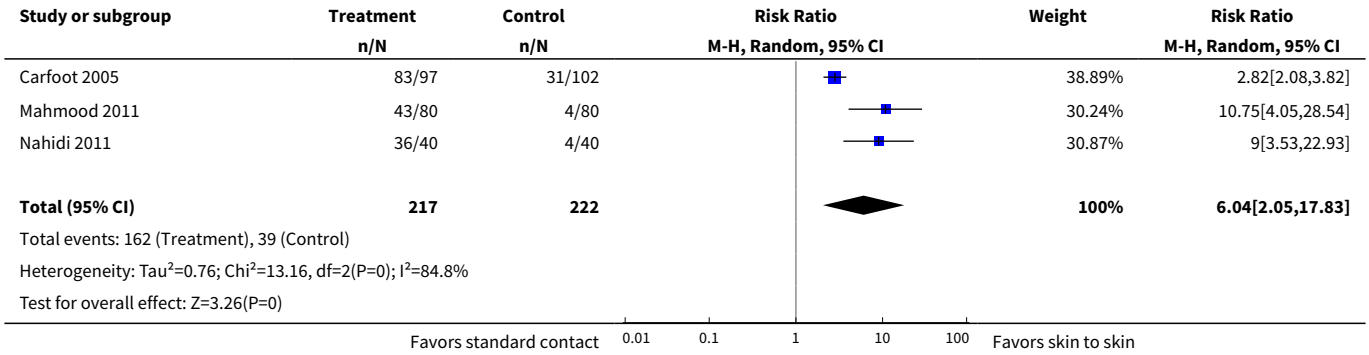
Analysis 1.23. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 23 PCERA Maternal positive affective involvement and responsiveness 12 months post birth.



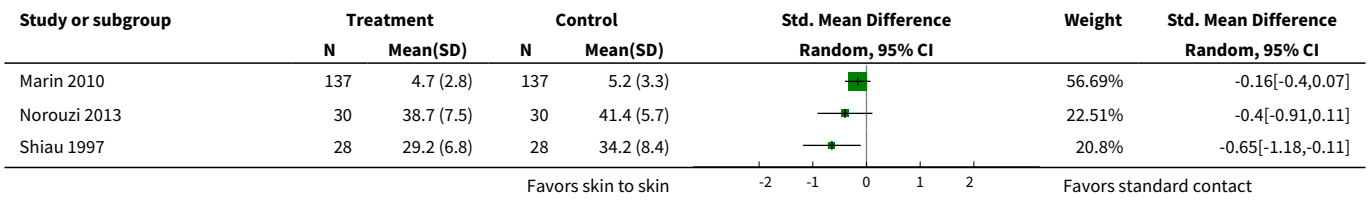
Analysis 1.24. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 24 PCERA Dydadic mutuality and reciprocity 12 months post birth.

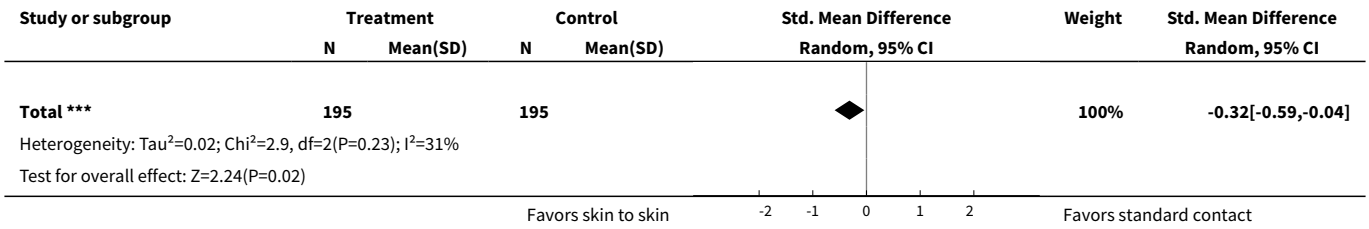


Analysis 1.25. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 25 Mother's most certain preference for same postdelivery care in the future.

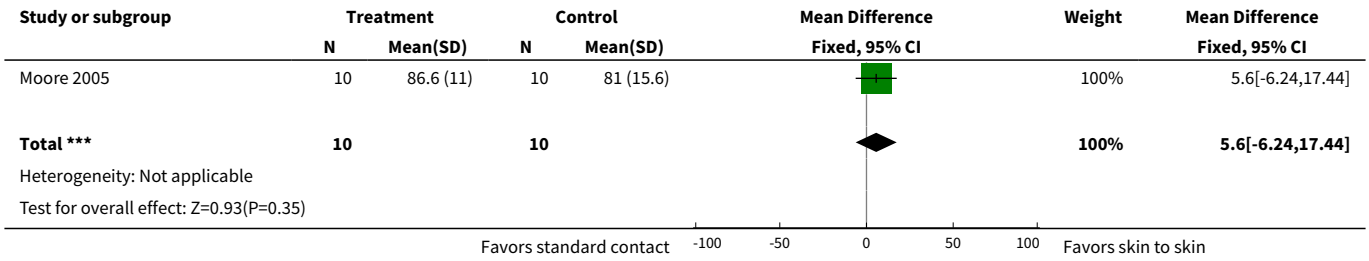


Analysis 1.26. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 26 Maternal state anxiety 8 hours to 3 days post birth.

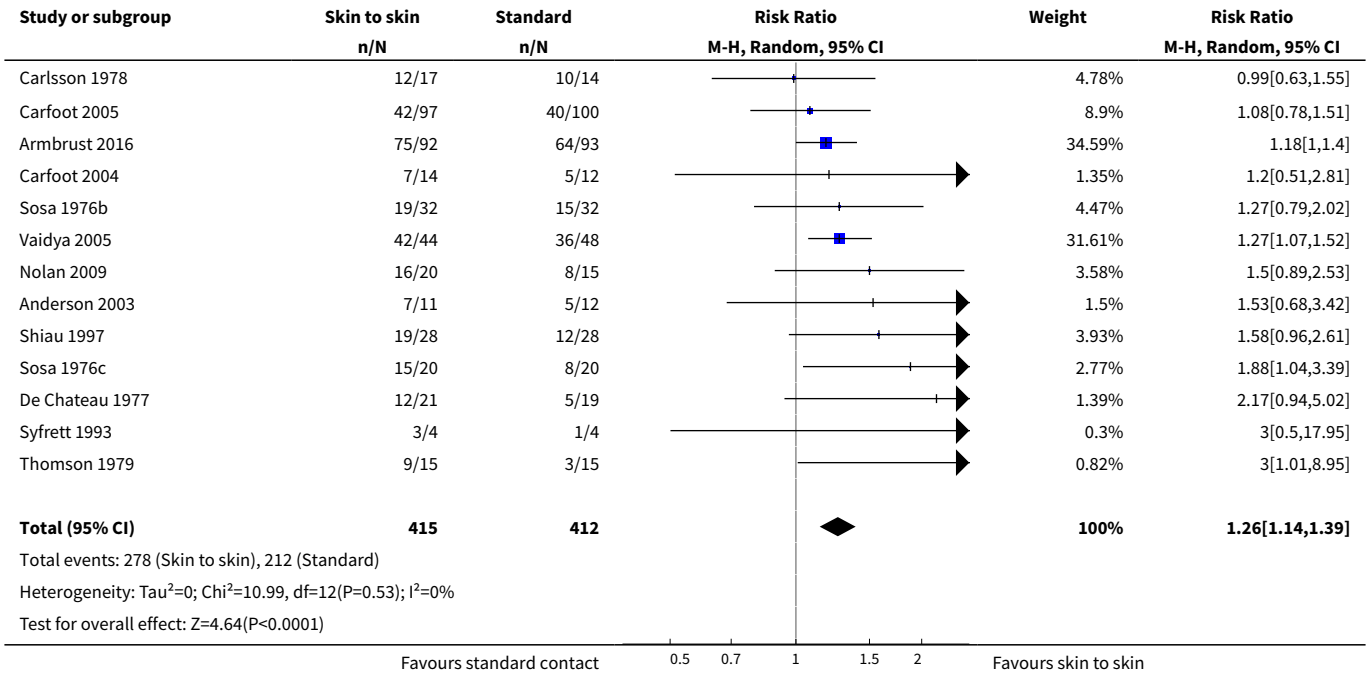




Analysis 1.27. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 27 Maternal parenting confidence at 1 month post birth.



Analysis 1.28. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 28 Breastfeeding 1 month to 4 months post birth: Sensitivity analysis.

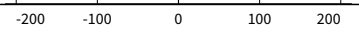


Analysis 1.29. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 29 Duration of breastfeeding in days: Sensitivity analysis.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
De Chateau 1977	21	175 (135.1)	19	103 (85.9)		13.75%	72[2.51,141.49]
Mizuno 2004	30	203.7 (112.5)	28	145.9 (76)		27.53%	57.76[8.64,106.88]
Shiau 1997	26	91.1 (126.6)	26	24.8 (21.1)		27.29%	66.3[16.97,115.63]
Sosa 1976b	34	159 (123)	34	109 (123)		19.43%	50[-8.47,108.47]
Sosa 1976c	20	196 (143)	20	104 (143)		8.46%	92[3.37,180.63]
Syfrett 1993	3	111 (81)	3	45 (90)		3.54%	66[-71.02,203.02]
Total * **	**134**		**130**			**100%**	**63.73[37.96,89.5]**

Heterogeneity: Tau^2=0; Chi^2=0.73, df=5(P=0.98); I^2=0%

Test for overall effect: Z=4.85(P<0.0001)



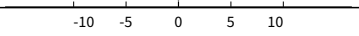
Favours standard contact — Favours skin to skin

Analysis 1.30. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 30 Heart rate 75 minutes to 2 hrs post birth: Sensitivity analysis.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Christensson 1992	25	136.6 (6.9)	25	140.7 (9)		13.96%	-4.1[-8.55,0.35]
Mazurek 1999	22	134.1 (3)	22	140.1 (3.1)		86.04%	-6.04[-7.83,-4.25]
Total * **	**47**		**47**			**100%**	**-5.77[-7.43,-4.11]**

Heterogeneity: Tau^2=0; Chi^2=0.63, df=1(P=0.43); I^2=0%

Test for overall effect: Z=6.81(P<0.0001)



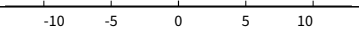
Favours skin to skin — Favours standard contact

Analysis 1.31. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 31 Respiratory rate 75 minutes to 2 hours post birth: Sensitivity analysis.

Study or subgroup	Experimental N	Experimental Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
Christensson 1992	25	44.3 (7.9)	25	49.8 (10.2)		7.2%	-5.5[-10.56,-0.44]
Mazurek 1999	22	45 (2)	22	49.7 (2.9)		84.55%	-4.73[-6.21,-3.25]
Nolan 2009	15	46.9 (5.7)	17	51.4 (7.9)		8.25%	-4.48[-9.2,0.24]
Total * **	**62**		**64**			**100%**	**-4.76[-6.12,-3.41]**

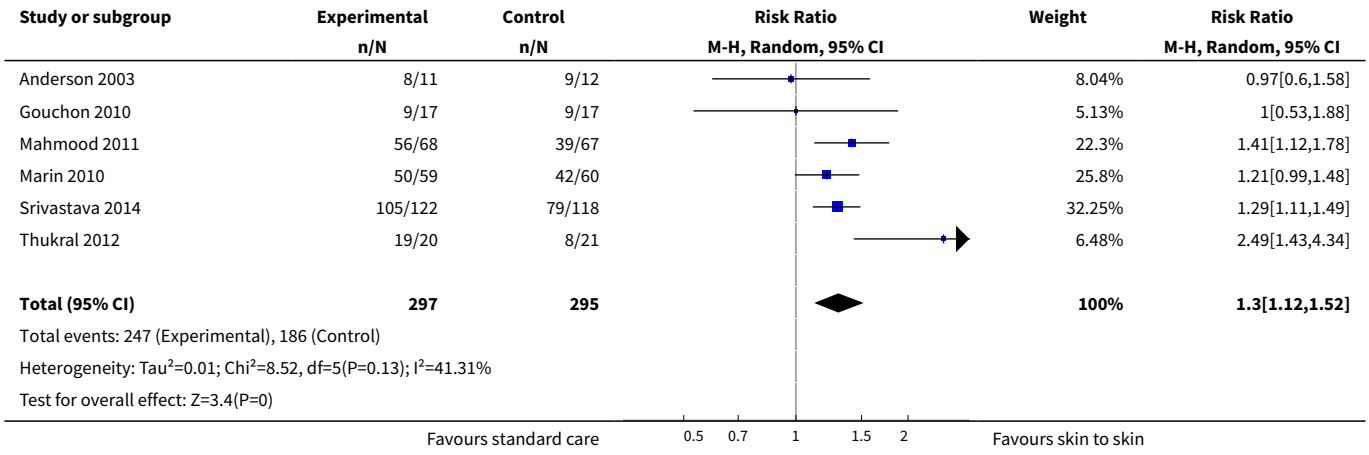
Heterogeneity: Tau^2=0; Chi^2=0.1, df=2(P=0.95); I^2=0%

Test for overall effect: Z=6.88(P<0.0001)

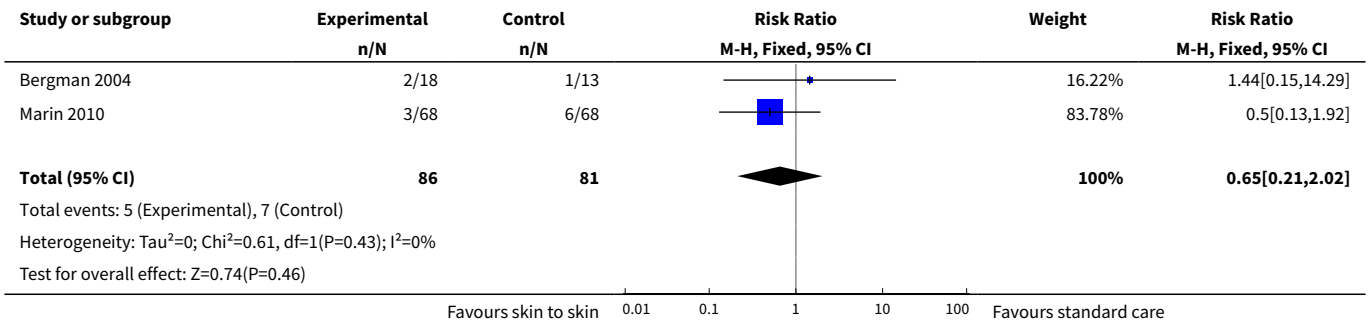


Favours skin to skin — Favours standard contact

Analysis 1.32. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 32 Exclusive bf discharge - Marin 2010 sensitivity analysis.



Analysis 1.33. Comparison 1 Immediate or Early skin-to-skin versus standard contact for healthy infants, Outcome 33 NICU admission - Marin 2010 sensitivity analysis.

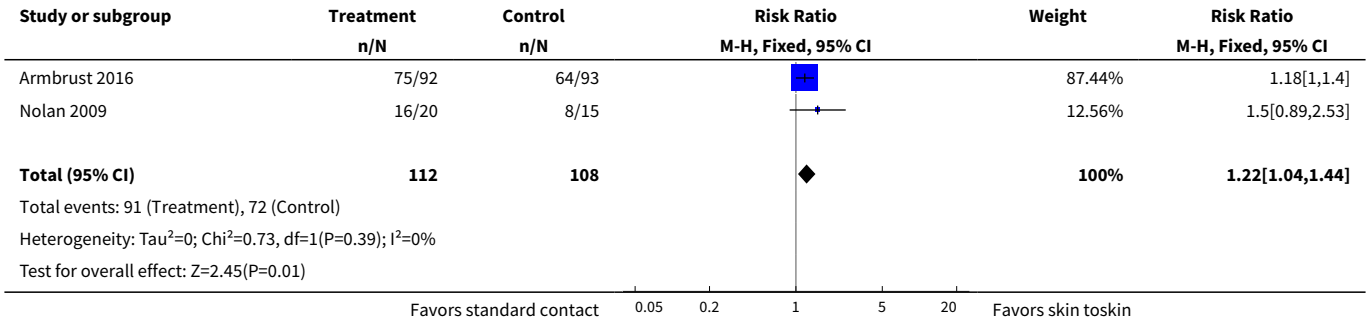


Comparison 2. Immediate or Early skin-to-skin versus standard contact for healthy infants after cesarean birth

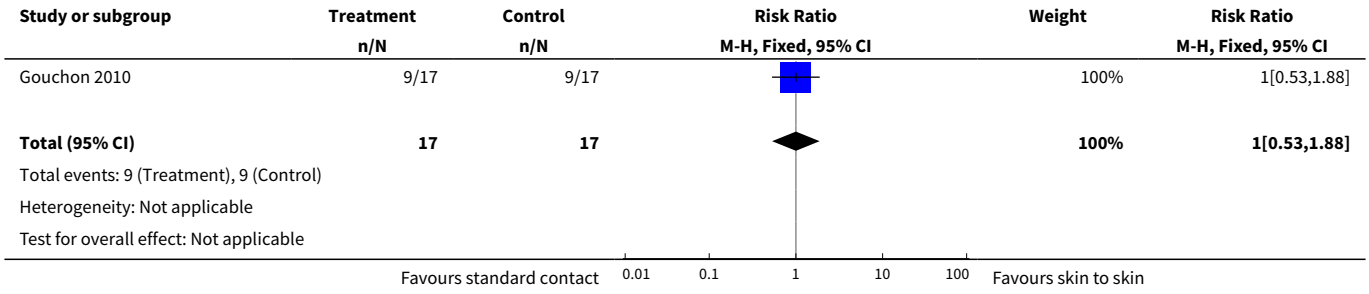
Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Breastfeeding 1 month to 4 months post birth	2	220	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [1.04, 1.44]
2 Exclusive breastfeeding at hospital discharge to 1 month post birth	1	34	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.53, 1.88]
3 Exclusive breastfeeding 6 weeks to 6 months post birth	2	144	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.95, 1.43]
4 Success of the first breastfeeding (IBFAT score)	2	124	Mean Difference (IV, Fixed, 95% CI)	1.37 [0.12, 2.62]
5 Respiratory rate 75 minutes - 2 hours post birth	1	32	Mean Difference (IV, Random, 95% CI)	-4.48 [-9.20, 0.24]

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
6 Maternal pain 4 hours post-cesarean birth	1	35	Mean Difference (IV, Fixed, 95% CI)	-1.38 [-2.79, 0.03]
7 Maternal state anxiety 8 hours to 3 days post birth	1	60	Mean Difference (IV, Fixed, 95% CI)	-2.70 [-6.06, 0.66]

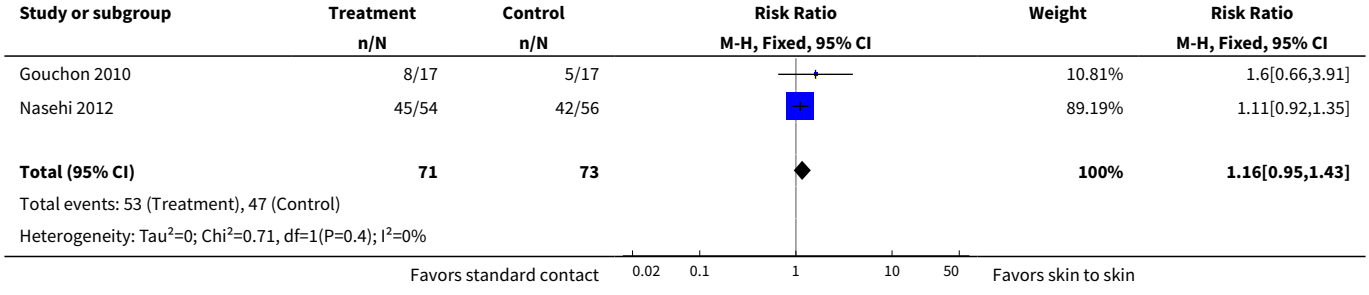
Analysis 2.1. Comparison 2 Immediate or Early skin-to-skin versus standard contact for healthy infants after cesarean birth, Outcome 1 Breastfeeding 1 month to 4 months post birth.

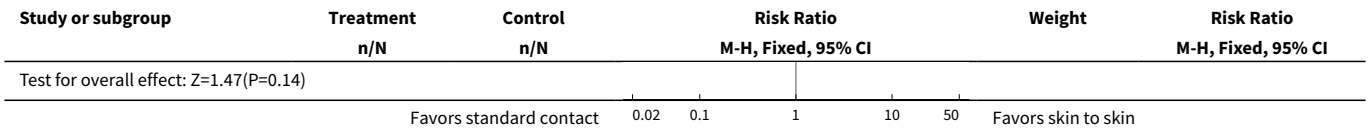


Analysis 2.2. Comparison 2 Immediate or Early skin-to-skin versus standard contact for healthy infants after cesarean birth, Outcome 2 Exclusive breastfeeding at hospital discharge to 1 month post birth.

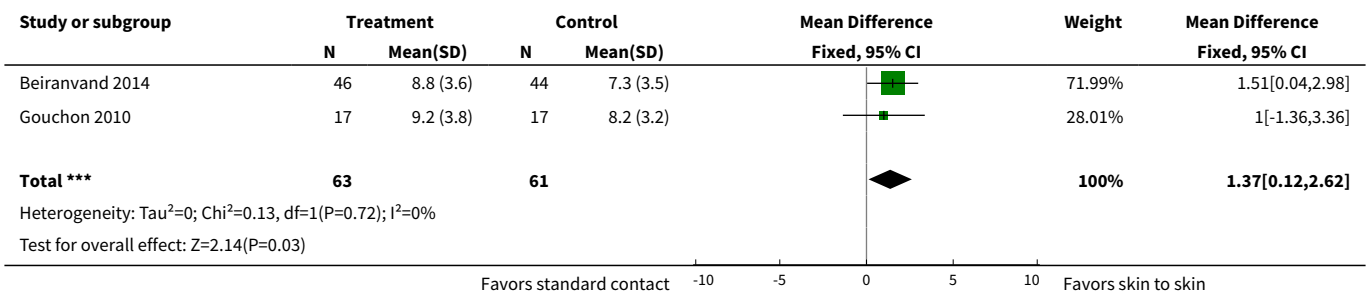


Analysis 2.3. Comparison 2 Immediate or Early skin-to-skin versus standard contact for healthy infants after cesarean birth, Outcome 3 Exclusive breastfeeding 6 weeks to 6 months post birth.

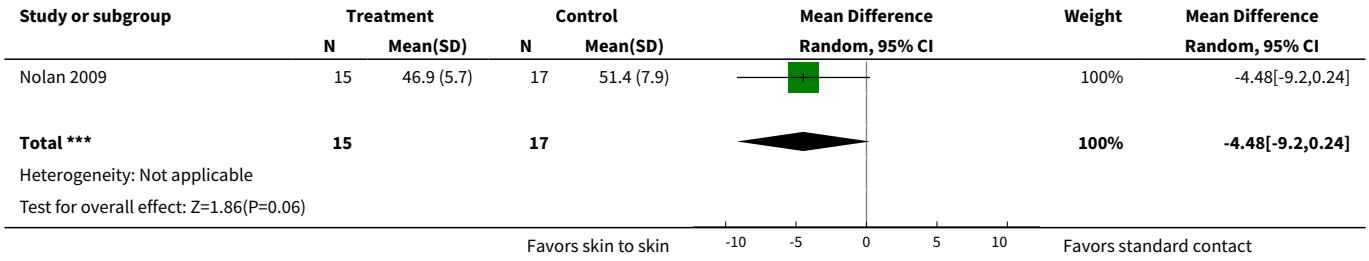




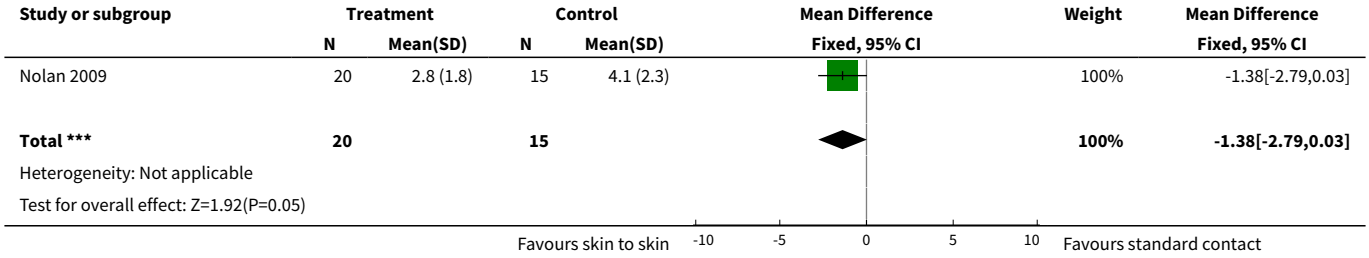
Analysis 2.4. Comparison 2 Immediate or Early skin-to-skin versus standard contact for healthy infants after cesarean birth, Outcome 4 Success of the first breastfeeding (IBFAT score).



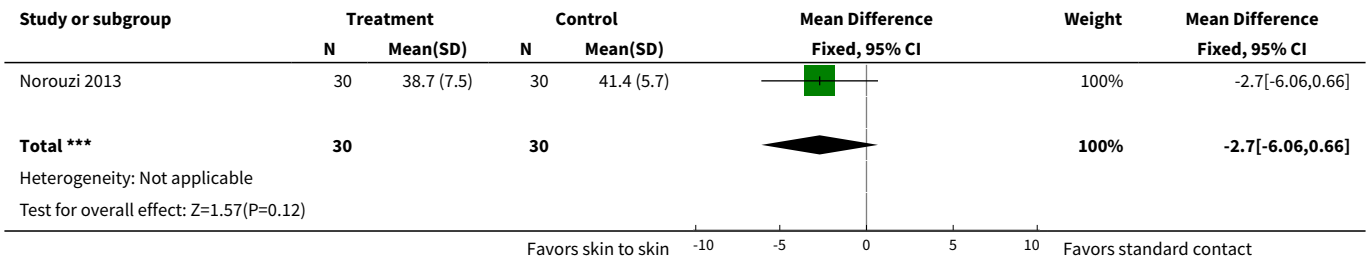
Analysis 2.5. Comparison 2 Immediate or Early skin-to-skin versus standard contact for healthy infants after cesarean birth, Outcome 5 Respiratory rate 75 minutes - 2 hours post birth.



Analysis 2.6. Comparison 2 Immediate or Early skin-to-skin versus standard contact for healthy infants after cesarean birth, Outcome 6 Maternal pain 4 hours post-cesarean birth.



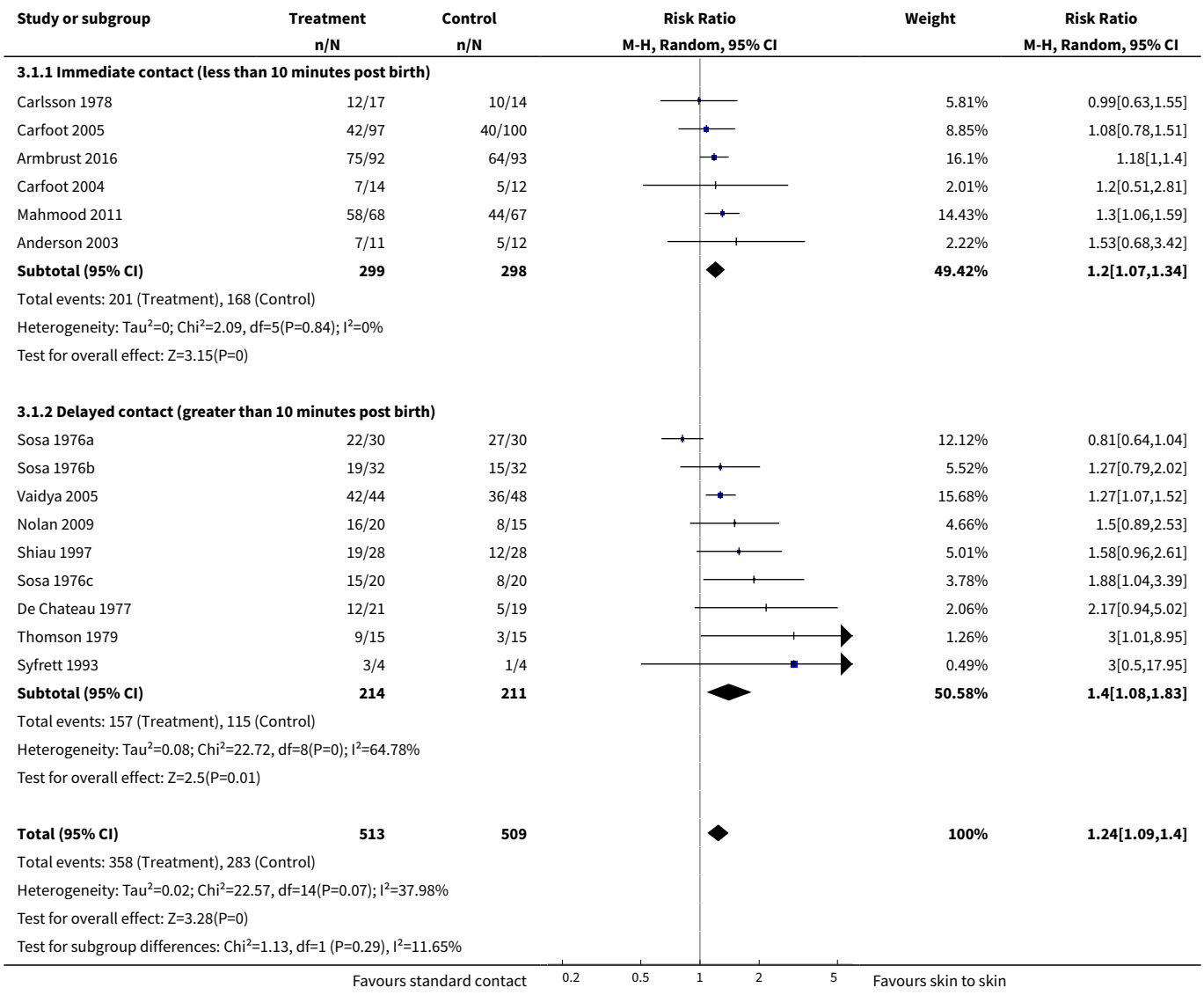
Analysis 2.7. Comparison 2 Immediate or Early skin-to-skin versus standard contact for healthy infants after cesarean birth, Outcome 7 Maternal state anxiety 8 hours to 3 days post birth.



Comparison 3. Skin-to-skin versus standard contact by time of initiation

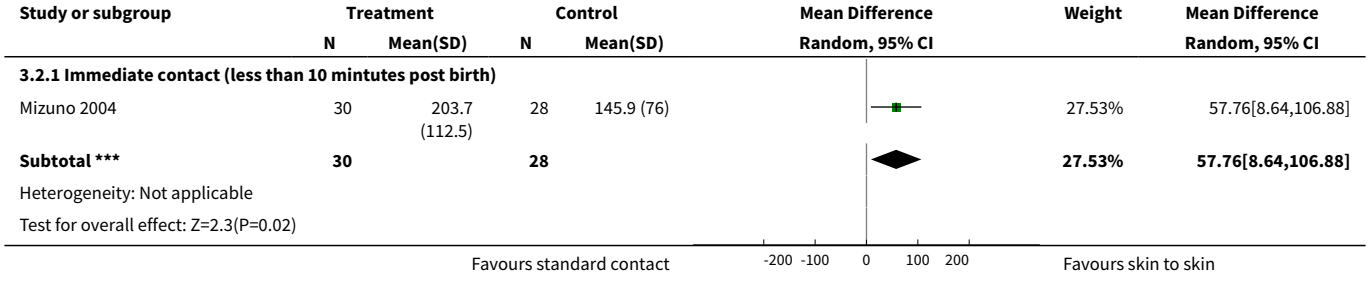
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Breastfeeding 1 month to 4 months post birth	15	1022	Risk Ratio (M-H, Random, 95% CI)	1.24 [1.09, 1.40]
1.1 Immediate contact (less than 10 minutes post birth)	6	597	Risk Ratio (M-H, Random, 95% CI)	1.20 [1.07, 1.34]
1.2 Delayed contact (greater than 10 minutes post birth)	9	425	Risk Ratio (M-H, Random, 95% CI)	1.40 [1.08, 1.83]
2 Duration of breastfeeding in days	6	264	Mean Difference (IV, Random, 95% CI)	63.73 [37.96, 89.50]
2.1 Immediate contact (less than 10 mintutes post birth)	1	58	Mean Difference (IV, Random, 95% CI)	57.76 [8.64, 106.88]
2.2 Delayed contact (greater than 10 minutes post birth)	5	206	Mean Difference (IV, Random, 95% CI)	66.00 [35.72, 96.27]
3 SCRIP score first 6 hours post birth	1	31	Mean Difference (IV, Fixed, 95% CI)	2.88 [0.53, 5.23]
3.1 Immediate contact (less than 10 minutes post birth)	1	31	Mean Difference (IV, Fixed, 95% CI)	2.88 [0.53, 5.23]
4 Blood glucose mg/dL at 75-90 minutes post birth	2	94	Mean Difference (IV, Fixed, 95% CI)	10.56 [8.40, 12.72]
4.1 Immediate contact (less than 10 minutes post birth)	2	94	Mean Difference (IV, Fixed, 95% CI)	10.56 [8.40, 12.72]
5 Infant axillary temperature 90 minutes to 2.5 hours post birth	5	508	Mean Difference (IV, Fixed, 95% CI)	0.21 [0.16, 0.25]
5.1 Immediate contact (less than 10 minutes post birth)	3	168	Mean Difference (IV, Fixed, 95% CI)	0.11 [-0.00, 0.22]
5.2 Delayed contact (more than 10 minutes post birth)	2	340	Mean Difference (IV, Fixed, 95% CI)	0.23 [0.18, 0.28]

Analysis 3.1. Comparison 3 Skin-to-skin versus standard contact by time of initiation, Outcome 1 Breastfeeding 1 month to 4 months post birth.

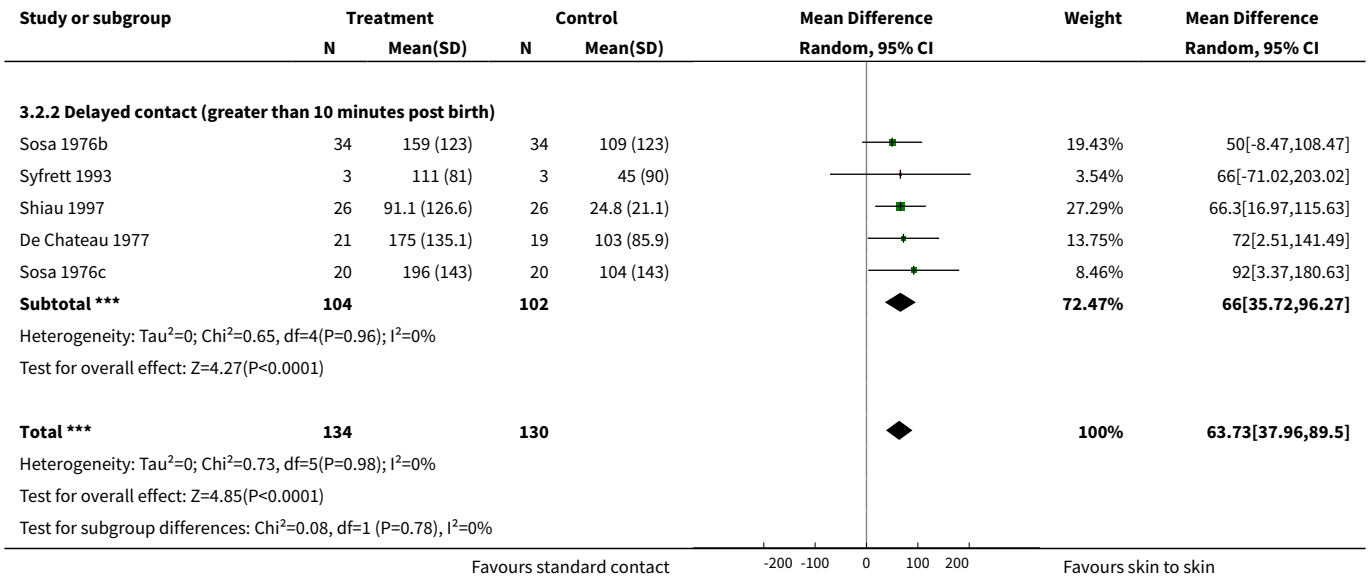


Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
3.1.1 Immediate contact (less than 10 minutes post birth)					
Carlsson 1978	12/17	10/14		5.81%	0.99[0.63,1.55]
Carfoot 2005	42/97	40/100		8.85%	1.08[0.78,1.51]
Armbrust 2016	75/92	64/93		16.1%	1.18[1,1.4]
Carfoot 2004	7/14	5/12		2.01%	1.2[0.51,2.81]
Mahmood 2011	58/68	44/67		14.43%	1.3[1.06,1.59]
Anderson 2003	7/11	5/12		2.22%	1.53[0.68,3.42]
Subtotal (95% CI)	**299**	**298**		**49.42%**	**1.2[1.07,1.34]**
Total events: 201 (Treatment), 168 (Control)					
Heterogeneity: Tau^2=0; Chi^2=2.09, df=5(P=0.84); I^2=0%					
Test for overall effect: Z=3.15(P=0)					
3.1.2 Delayed contact (greater than 10 minutes post birth)					
Sosa 1976a	22/30	27/30		12.12%	0.81[0.64,1.04]
Sosa 1976b	19/32	15/32		5.52%	1.27[0.79,2.02]
Vaidya 2005	42/44	36/48		15.68%	1.27[1.07,1.52]
Nolan 2009	16/20	8/15		4.66%	1.5[0.89,2.53]
Shiau 1997	19/28	12/28		5.01%	1.58[0.96,2.61]
Sosa 1976c	15/20	8/20		3.78%	1.88[1.04,3.39]
De Chateau 1977	12/21	5/19		2.06%	2.17[0.94,5.02]
Thomson 1979	9/15	3/15		1.26%	3[1.01,8.95]
Syfrett 1993	3/4	1/4		0.49%	3[0.5,17.95]
Subtotal (95% CI)	**214**	**211**		**50.58%**	**1.4[1.08,1.83]**
Total events: 157 (Treatment), 115 (Control)					
Heterogeneity: Tau^2=0.08; Chi^2=22.72, df=8(P=0); I^2=64.78%					
Test for overall effect: Z=2.5(P=0.01)					
Total (95% CI)	**513**	**509**		**100%**	**1.24[1.09,1.4]**
Total events: 358 (Treatment), 283 (Control)					
Heterogeneity: Tau^2=0.02; Chi^2=22.57, df=14(P=0.07); I^2=37.98%					
Test for overall effect: Z=3.28(P=0)					
Test for subgroup differences: Chi^2=1.13, df=1 (P=0.29), I^2=11.65%					

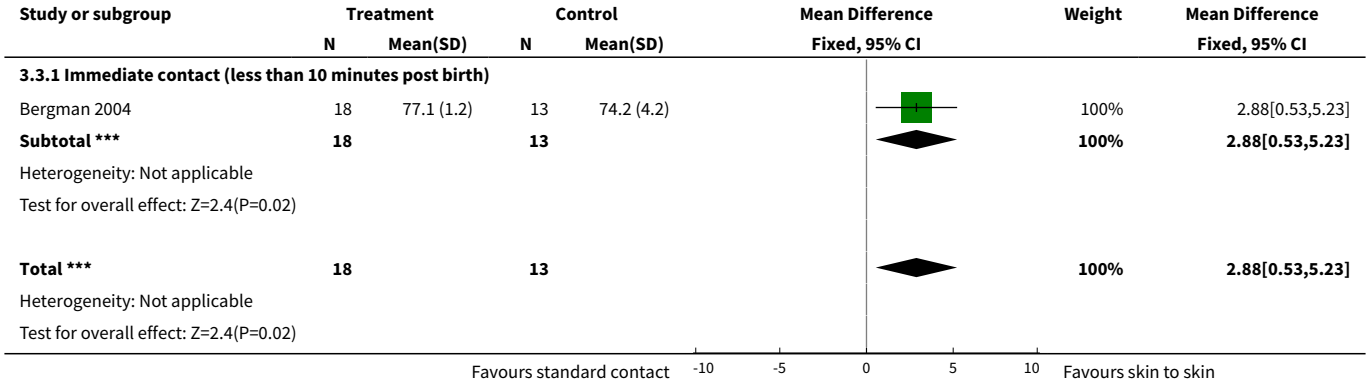
Analysis 3.2. Comparison 3 Skin-to-skin versus standard contact by time of initiation, Outcome 2 Duration of breastfeeding in days.



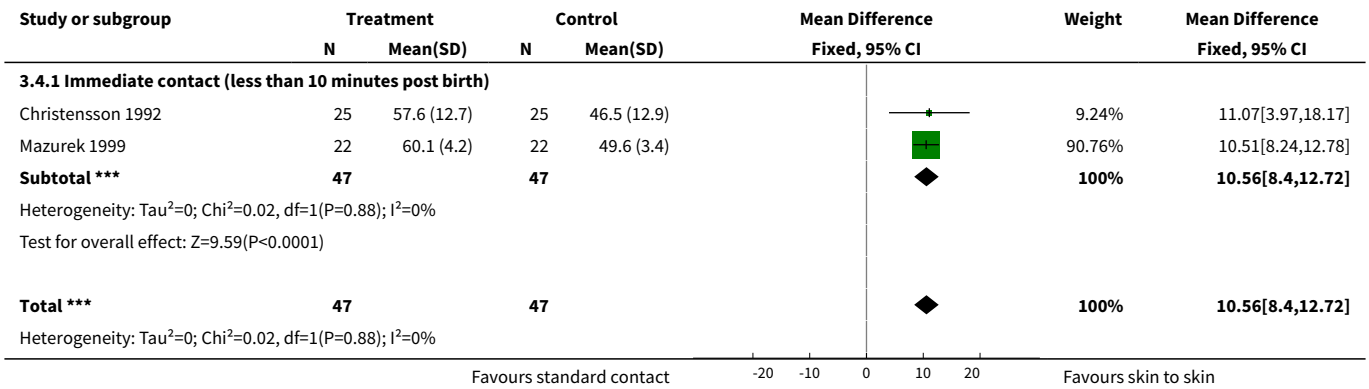
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
3.2.1 Immediate contact (less than 10 mintutes post birth)							
Mizuno 2004	30	203.7 (112.5)	28	145.9 (76)		27.53%	57.76[8.64,106.88]
Subtotal ***	**30**		**28**			**27.53%**	**57.76[8.64,106.88]**
Heterogeneity: Not applicable							
Test for overall effect: Z=2.3(P=0.02)							

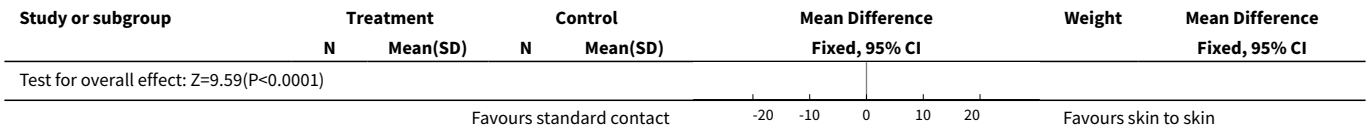


Analysis 3.3. Comparison 3 Skin-to-skin versus standard contact by time of initiation, Outcome 3 SCRIP score first 6 hours post birth.

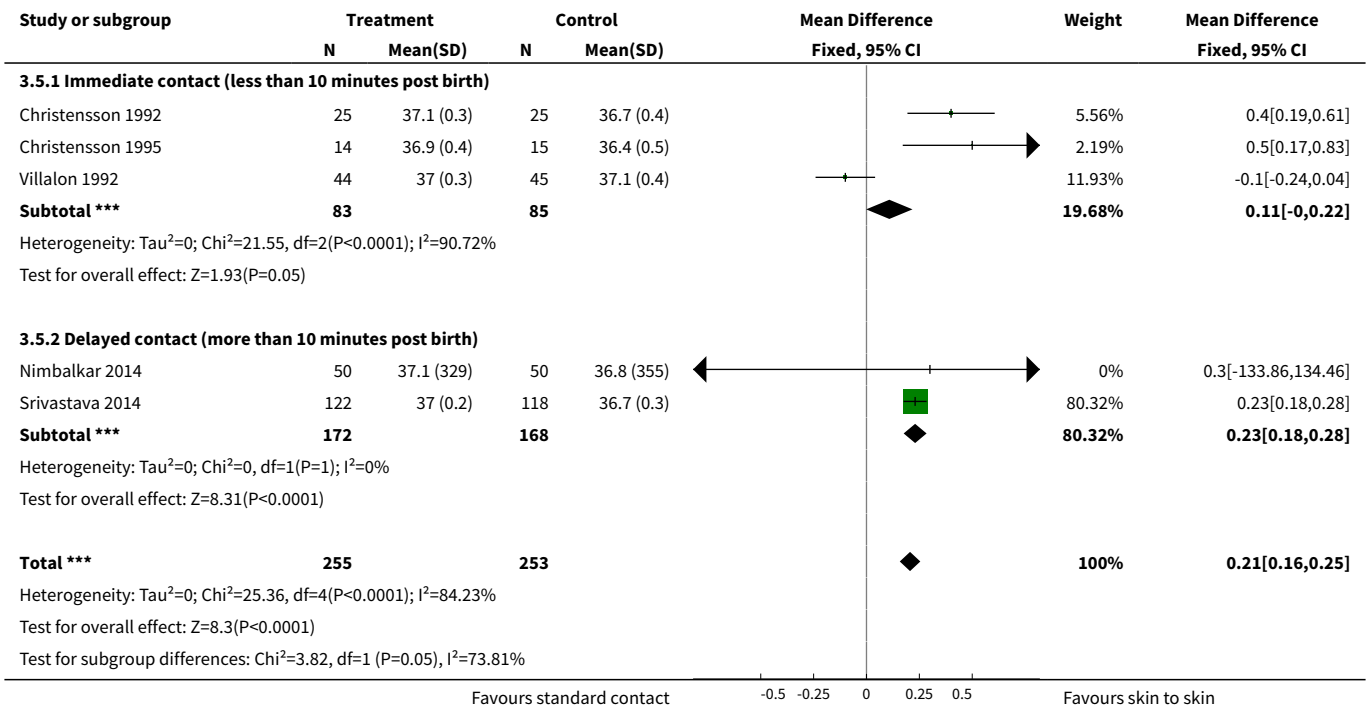


Analysis 3.4. Comparison 3 Skin-to-skin versus standard contact by time of initiation, Outcome 4 Blood glucose mg/dL at 75-90 minutes post birth.





Analysis 3.5. Comparison 3 Skin-to-skin versus standard contact by time of initiation, Outcome 5 Infant axillary temperature 90 minutes to 2.5 hours post birth.



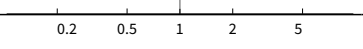
Comparison 4. Skin-to-skin versus standard contact by dosage (length of contact time)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Breastfeeding 1 month to 4 months post birth	15	1022	Risk Ratio (M-H, Random, 95% CI)	1.24 [1.09, 1.40]
1.1 Low dose (60 minutes or less)	10	724	Risk Ratio (M-H, Random, 95% CI)	1.23 [1.04, 1.46]
1.2 High dose (more than 60 minutes)	5	298	Risk Ratio (M-H, Random, 95% CI)	1.24 [1.06, 1.44]
2 Duration of breastfeeding in days	6	264	Mean Difference (IV, Random, 95% CI)	63.73 [37.96, 89.50]
2.1 Low dose (60 minutes or less)	3	148	Mean Difference (IV, Random, 95% CI)	65.80 [25.86, 105.74]
2.2 High dose (more than 60 minutes)	3	116	Mean Difference (IV, Random, 95% CI)	62.25 [28.52, 95.99]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3 SCRIP score first 6 hours post birth	1	31	Mean Difference (IV, Fixed, 95% CI)	2.88 [0.53, 5.23]
3.1 High dose (more than 60 minutes)	1	31	Mean Difference (IV, Fixed, 95% CI)	2.88 [0.53, 5.23]
4 Blood glucose mg/dL at 75-90 minutes post birth	2	94	Mean Difference (IV, Fixed, 95% CI)	10.56 [8.40, 12.72]
4.1 High dose (more than 60 minutes)	2	94	Mean Difference (IV, Fixed, 95% CI)	10.56 [8.40, 12.72]
5 Infant axillary temperature 90 minutes to 2.5 hours post birth	5	508	Mean Difference (IV, Fixed, 95% CI)	0.21 [0.16, 0.25]
5.1 High dose (more than 60 minutes)	5	508	Mean Difference (IV, Fixed, 95% CI)	0.21 [0.16, 0.25]

Analysis 4.1. Comparison 4 Skin-to-skin versus standard contact by dosage (length of contact time), Outcome 1 Breastfeeding 1 month to 4 months post birth.

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
4.1.1 Low dose (60 minutes or less)					
Sosa 1976a	22/30	27/30		12.12%	0.81[0.64,1.04]
Carlsson 1978	12/17	10/14		5.81%	0.99[0.63,1.55]
Carfoot 2005	42/97	40/100		8.85%	1.08[0.78,1.51]
Sosa 1976b	19/32	15/32		5.52%	1.27[0.79,2.02]
Vaidya 2005	42/44	36/48		15.68%	1.27[1.07,1.52]
Mahmood 2011	58/68	44/67		14.43%	1.3[1.06,1.59]
Nolan 2009	16/20	8/15		4.66%	1.5[0.89,2.53]
Sosa 1976c	15/20	8/20		3.78%	1.88[1.04,3.39]
De Chateau 1977	12/21	5/19		2.06%	2.17[0.94,5.02]
Thomson 1979	9/15	3/15		1.26%	3[1.01,8.95]
Subtotal (95% CI)	**364**	**360**		**74.17%**	**1.23[1.04,1.46]**
Total events: 247 (Treatment), 196 (Control)					
Heterogeneity: Tau^2=0.03; Chi^2=19.83, df=9(P=0.02); I^2=54.61%					
Test for overall effect: Z=2.35(P=0.02)					
4.1.2 High dose (more than 60 minutes)					
Armbrust 2016	75/92	64/93		16.1%	1.18[1,1.4]
Carfoot 2004	7/14	5/12		2.01%	1.2[0.51,2.81]
Anderson 2003	7/11	5/12		2.22%	1.53[0.68,3.42]
Shiau 1997	19/28	12/28		5.01%	1.58[0.96,2.61]
Syfrett 1993	3/4	1/4		0.49%	3[0.5,17.95]
Subtotal (95% CI)	**149**	**149**		**25.83%**	**1.24[1.06,1.44]**
Total events: 111 (Treatment), 87 (Control)					
Heterogeneity: Tau^2=0; Chi^2=2.6, df=4(P=0.63); I^2=0%					
Test for overall effect: Z=2.73(P=0.01)					
Total (95% CI)	**513**	**509**		**100%**	**1.24[1.09,1.4]**
Total events: 358 (Treatment), 283 (Control)					



Favours standard contact

Favours skin to skin

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Heterogeneity: Tau²=0.02; Chi²=22.57, df=14(P=0.07); I²=37.98%					
Test for overall effect: Z=3.28(P=0)					
Test for subgroup differences: Chi²=0, df=1 (P=0.96), I²=0%					

Favours standard contact 0.2 0.5 1 2 5 Favours skin to skin

Analysis 4.2. Comparison 4 Skin-to-skin versus standard contact by dosage (length of contact time), Outcome 2 Duration of breastfeeding in days.

Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.2.1 Low dose (60 minutes or less)							
Sosa 1976b	34	159 (123)	34	109 (123)		19.43%	50[-8.47,108.47]
De Chateau 1977	21	175 (135.1)	19	103 (85.9)		13.75%	72[2.51,141.49]
Sosa 1976c	20	196 (143)	20	104 (143)		8.46%	92[3.37,180.63]
Subtotal ***	**75**		**73**			**41.64%**	**65.8[25.86,105.74]**
Heterogeneity: Tau²=0; Chi²=0.65, df=2(P=0.72); I²=0%							
Test for overall effect: Z=3.23(P=0)							
4.2.2 High dose (more than 60 minutes)							
Mizuno 2004	30	203.7 (112.5)	28	145.9 (76)		27.53%	57.76[8.64,106.88]
Syfrett 1993	3	111 (81)	3	45 (90)		3.54%	66[-71.02,203.02]
Shiau 1997	26	91.1 (126.6)	26	24.8 (21.1)		27.29%	66.3[16.97,115.63]
Subtotal ***	**59**		**57**			**58.36%**	**62.25[28.52,95.99]**
Heterogeneity: Tau²=0; Chi²=0.06, df=2(P=0.97); I²=0%							
Test for overall effect: Z=3.62(P=0)							
Total ***	**134**		**130**			**100%**	**63.73[37.96,89.5]**
Heterogeneity: Tau²=0; Chi²=0.73, df=5(P=0.98); I²=0%							
Test for overall effect: Z=4.85(P<0.0001)							
Test for subgroup differences: Chi²=0.02, df=1 (P=0.89), I²=0%							

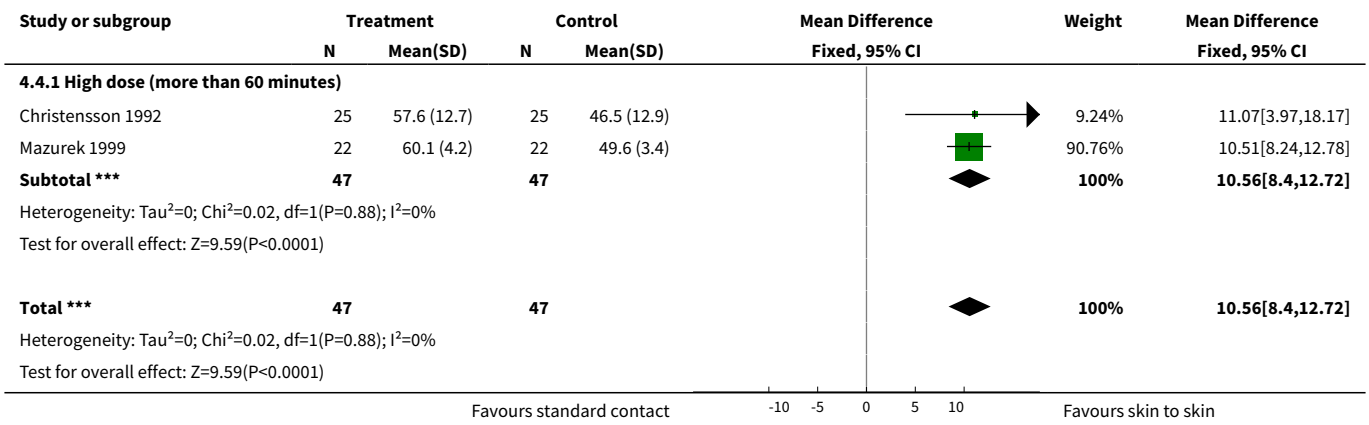
Favours standard contact -400 -200 0 200 400 Favours skin to skin

Analysis 4.3. Comparison 4 Skin-to-skin versus standard contact by dosage (length of contact time), Outcome 3 SCRIP score first 6 hours post birth.

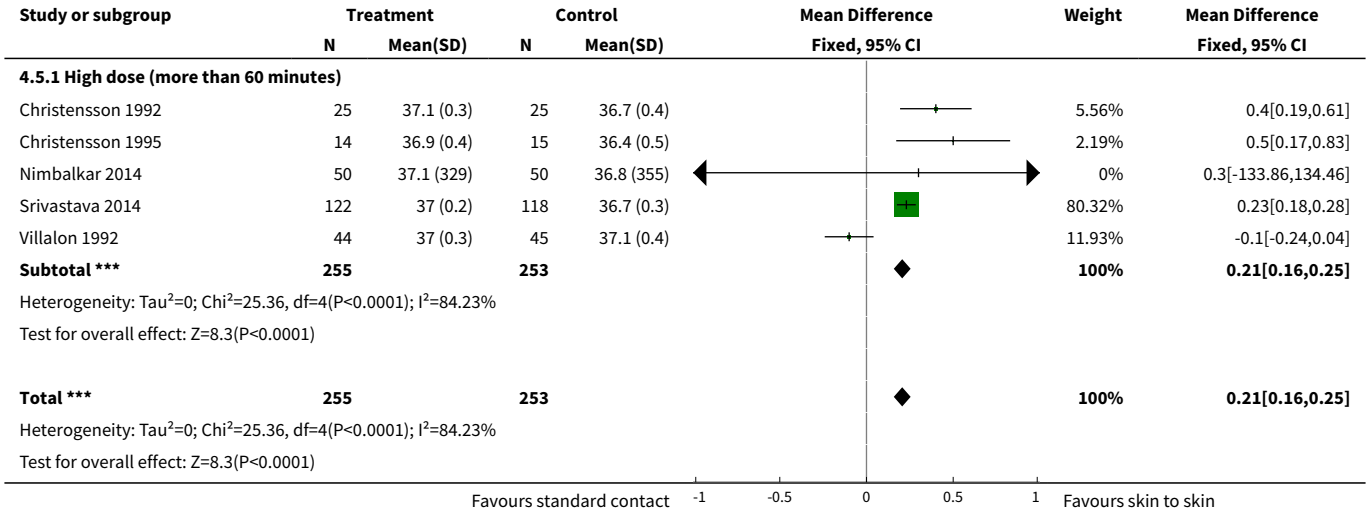
Study or subgroup	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
4.3.1 High dose (more than 60 minutes)							
Bergman 2004	18	77.1 (1.2)	13	74.2 (4.2)		100%	2.88[0.53,5.23]
Subtotal ***	**18**		**13**			**100%**	**2.88[0.53,5.23]**
Heterogeneity: Not applicable							
Test for overall effect: Z=2.4(P=0.02)							
Total ***	**18**		**13**			**100%**	**2.88[0.53,5.23]**
Heterogeneity: Not applicable							
Test for overall effect: Z=2.4(P=0.02)							

Favours standard contact -10 -5 0 5 10 Favours skin to skin

Analysis 4.4. Comparison 4 Skin-to-skin versus standard contact by dosage (length of contact time), Outcome 4 Blood glucose mg/dL at 75-90 minutes post birth.



Analysis 4.5. Comparison 4 Skin-to-skin versus standard contact by dosage (length of contact time), Outcome 5 Infant axillary temperature 90 minutes to 2.5 hours post birth.



ADDITIONAL TABLES

Table 1. SSC Timing and Dosage

Trial	Immediate (< 10 min) or Delayed SSC (> 10 min)[1]	Low dose (< 60 min) or High dose (> 60 min)
Anderson 2003	I	H

Table 1. SSC Timing and Dosage *(Continued)*

Armbrust 2016	I	H
Beiranvand 2014	D	L
Bergman 2004	I	H
Bystrova 2003	D	H
Carfoot 2004	I	H
Carfoot 2005	I	L
Carlsson 1978	I	L
Christensson 1992	I	H
Christensson 1995	I	H
Chwo 1999	D	H
Craig 1982	D	L
De Chateau 1977	D	L
Girish 2013	I	L
Gouchon 2010	D	H
Khadivzadeh 2009	I	H
Luong 2015	I	H
Mahmood 2011	I	L
Marin 2010	I	H
Mazurek 1999	I	H
Mizuno 2004	I	H
Moore 2005	I	H
Nahidi 2011	I	Not stated
Nasehi 2012	D	H
Nimbalkar 2014	D	H
Nolan 2009	D	L
Norouzi 2013	not stated	L
Punthmatharith 2001	D	L
Shiau 1997	D	H

Table 1. SSC Timing and Dosage *(Continued)*

Sosa 1976a	D	L
Sosa 1976b	D	L
Sosa 1976c	D	L
Srivastava 2014	not stated	H
Syfrett 1993	D	H
Thomson 1979	D	H
Thukral 2012	D	L
Vaidya 2005	D	L
Villalon 1992	I	H

1. I = immediate; D = delayed; L = low; H = high.

APPENDICES

Appendix 1. The International Network for Kangaroo Mother Care

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

WHAT'S NEW

Date	Event	Description
17 December 2015	New citation required but conclusions have not changed	Skin-to-skin contact improves breastfeeding in the first months post birth, but limited data and the methodological quality of trials restrict our confidence in findings for infant outcomes. There are no changes to the conclusions from the previous review.
17 December 2015	New search has been performed	We added 12 new studies in this update (Armbrust 2016; Beiranvand 2014; Girish 2013; Luong 2015; Mahmood 2011; Marin 2010; Nahidi 2011; Nasehi 2012; Nimbalkar 2014; Norouzi 2013; Srivastava 2014; Thukral 2012). We added a comparison for women who had a cesarean birth and subgroups exploring dose and time of skin-to-skin initiation.

HISTORY

Protocol first published: Issue 1, 2002
Review first published: Issue 2, 2003

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.

Date	Event	Description
		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.
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.

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. Nancy Medley contributed to study assessment, analysis and drafting text.

DECLARATIONS OF INTEREST

Dr Anderson, Dr Bergman and Dr Moore have conducted trials that have been included in this review.

Anderson 2003 was conducted by Dr Anderson. Chwo 1999, Punthmatharith 2001, Shiau 1997 and Syfrett 1993 were conducted by students of Dr Anderson's at Case Western Reserve University. Risk of bias for all these trials was assessed by T Dowswell, Research Associate, Cochrane Pregnancy and Childbirth, Dr Moore and Dr Bergman.

Dr Bergman conducted Bergman 2004 and was a consultant for Luong 2015. T Dowswell, Dr Anderson and Dr Moore evaluated Bergman 2004 for Risk of Bias and N Medley, Research Associate, Cochrane Pregnancy and Childbirth, Dr Anderson and Dr Moore evaluated Luong 2015 for risk of bias. Dr Bergman has received lecture fees for teaching and demonstrating on Skin-to-Skin Contact theory and techniques, and produces promotional products for sale. Further, he has participated on a South African patent in the name of the University of Cape Town for a neonatal autonomic nervous system monitoring device. He is an active trialist working on skin-to-skin contact for low birth weight newborns.

Dr Moore conducted Moore 2005 while a student of Dr Anderson's at Vanderbilt University. Moore 2005 was evaluated for risk of bias by T Dowswell and Dr Bergman.

Nancy Medley's work was financially supported by the University of Liverpool's Harris-Wellbeing of Women Preterm Birth Centre research award and by a grant to University of Liverpool from the World Health Organization.

SOURCES OF SUPPORT

Internal sources

- None, Other.

External sources

- Evidence and Programme Guidance Unit, Department of Nutrition for Health and Development, World Health Organization, Switzerland.
- Harris-Wellbeing of Women Preterm Birth Centre, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For previous updates we revised the protocol, modified outcomes and updated methods. At a previous update we also decided to exclude quasi-randomized trials.

For the 2016 update we have made the following changes to review methods.

1. Cluster-randomized trials are now eligible for inclusion.
2. Trials of SSC after cesarean birth were eligible for inclusion.
3. We have clarified our definition of standard care to say that no infant in the comparison arms should have SSC.
4. We have clarified our eligibility criteria for types of participants. We included healthy term and healthy late preterm babies. Late preterm infants were those > 33 weeks' gestation. We excluded any infants < 1500 g or any infants requiring NICU care.
5. We have revised our subgroup analysis of clinical groups to compare the following: timing of initiation - immediate contact (< 10 minutes) versus delayed contact (≥ 10 minutes post birth), and dose – high dose (> 60 minutes) versus low dose (60 minutes or less).
6. The definition of outcome from Analysis 1.6 has been changed from exclusive breastfeeding at hospital discharge to exclusive breastfeeding at hospital discharge to one month post birth.
7. The definition of outcome from Analysis 1.26 has been changed from maternal state anxiety three days post birth to maternal state anxiety eight hours to three days post birth.
8. The definition of outcome from Analysis 1.7 of exclusive breastfeeding up to three to six months post birth has been changed to exclusive breastfeeding six weeks to six months post birth.

INDEX TERMS

Medical Subject Headings (MeSH)

*Breast Feeding [statistics & numerical data]; *Object Attachment; *Skin Physiological Phenomena; Kangaroo-Mother Care Method [*methods]; Mother-Child Relations; Mothers; Randomized Controlled Trials as Topic; Touch [*physiology]

MeSH check words

Female; Humans; Infant; Infant, Newborn