Health Technology Assessment 2009; Vol. 13: No. 40

Appendices

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Breastfeeding promotion for infants in neonatal units: a systematic review and economic analysis

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August 2009
DOI: 10.3310/hta13400

Health Technology Assessment
NIHR HTA programme
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Appendix 3

Pre-screen form – effectiveness review

1. DESIGN

Is this an evaluation of effectiveness of an intervention (SRs, RCTs, other study designs will be considered, case studies will not be included in the review)	No	Yes	?
	go to 5	go to 2	go to 2

2. PARTICIPANTS

Are participants babies who are NOT both term and healthy[a], i.e. babies who need special care[b] ? (e.g. preterm, growth-restricted and sick neonates, multiples, babies requiring surgery and babies with feeding problems, hypoglycaemia and jaundice)	No	Yes	?
	go to 5	go to 3	go to 3

a There may be studies of babies who have particular illnesses (e.g. cardiac) who have not been on NICU (they may have been on e.g. a specialised neonatal cardiac unit). At the trawling stage we will not exclude these studies – later we may decide to include only the ones where the baby was admitted to SCBU.
b We expect the babies in included studies will have been admitted to SCBU, but we will include studies about babies who needed special care and received (the intervention of) care on e.g. a transitional care ward.

3. INTERVENTIONS

Does the intervention[c] specifically address[d] breastfeeding/feeding with breastmilk in SCBU/NICUs?	No	Yes	?
	go to 5	go to 4	go to 4

c A list of interventions from Table 1 of the final version of the protocol appears on the reverse of this sheet.
d Exclude (and mark as background) studies that evaluate:
- the effectiveness of breastmilk on clinical outcomes (e.g. studies of associations between breastmilk consumption and the incidence of necrotising enterocolitis)
- the nutritional content of formula and breastmilk fortifiers
- the establishment and maintenance of milk banking will not be included in the review (include studies of availability of a milk bank/donor milk, see list over).

4. OUTCOMES

Are breastfeeding/breastmilk-related outcomes reported, e.g. breastmilk composition and volume, licking mother's nipple/ tasting dripped breastmilk, number of sucks, initiation of breastfeeding, any breastfeeding, exclusive breastfeeding, and rates of breastfeeding at discharge and beyond?	No	Yes	?
	go to 5	go to 5	go to 5

5. DECISIONS

If any 1–4 No – enter no (exclude)
If all 1–4 Yes – enter yes (paper to be ordered for data extraction)
If any 1–4 ? – enter ? (reviewer 1 and 2 discuss, involve reviewer 3 if no agreement)
Possible background papers – enter bg

6. REFERENCE *list checked* *yes/no*

Citations to follow up:

Interventions (from Table 1 of final version of protocol)

Interventions to deliver breastmilk to babies:

Methods of feeding (tube, cup, spoon, supplementer, bottle, nipple shields)

Interventions that may affect breastfeeding behaviour:

Pacifiers (or non-nutritive sucking): with and without use of breastmilk to taste
Timing feeds according to cues/baby's state

Interventions to support adequate nutritional intake (e.g. fat, protein) from breastmilk:

Creamatocrits
Hindmilk vs foremilk
Morning expression vs later expression

Interventions involving physical contact:

Skin-to-skin contact (mother and father)
Kangaroo mother contact

Interventions involving access to and caring for the baby:

Enabling mother to stay with and/or care for the baby (including rooming-in or 24-hour visitation)
Involving family in aspects of baby care including feeding by tube/cup, etc.

Interventions involving breastfeeding education and/or support:

Breastfeeding education to parents and families
Breastfeeding support by the fathers/families
Support from peers and/or professionals (antenatally and postnatally)

Interventions involving other aspects of organisation of care:

Facilities for expression and storage
Availability of milk bank/donor milk (not running of a milk bank)
Feeding policies
Policies for handling and testing breastmilk
Early discharge
Staffing levels and organisation

Interventions that affect breastmilk expression:

Methods of breastmilk expression
Teaching and support of breast expression
Galactagogues

Interventions involving staff training:

Staff training in breastfeeding support and in prescribing of drugs for breastfeeding women
Staff training in baby weight gain

Appendix 4

Data extraction tables for included studies

Appendix 4.1: Effectiveness review

TABLE 26 *Blaymore Bier 1996*[115]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Blaymore Bier 1996 USA (Rhode Island) **Research aim** To evaluate the effect of maternal–infant skin-to-skin contact (SSC) vs standard contact (SC) on very low birthweight infants' physiological profile, maternal milk production and duration of breastfeeding **Study design** Randomised controlled trial **Method of group allocation** Randomised by blindly picking a precoded label from a bin. Siblings were placed in same group – not clear if randomly allocated **Unit of allocation** Mother-infant dyads **Unit of analysis** Mother-infant dyads or infant depending on outcome	**Selection** Fifty consecutive mother-infant dyads who met inclusion criteria from 3643 infants admitted to special care nursery during period 22 September 1993 to 14 November 1995 **Inclusion criteria** *Mothers* Expressing breastmilk Planning to breastfeed *Infants* Birthweight less than 1500 g **Exclusion criteria** *Mothers* History of drug use, mental illness, HIV infection or receiving any medications contraindicative to breastfeeding *Infants* Positive screen for cocaine or other illicit drugs or showing drug withdrawal symptoms at birth	Mother-infant dyads SSC: $n = 21$ SC: $n = 20$ Infants SSC: $n = 25$ SC: $n = 25$ *Mothers* Mean [SD] (range) age (years) SSC: 29 [5] (20–37) SC: 30 [6] (17–38) Mean [SD] (range) socioeconomic status (Hollingshead score) SSC: 45 [14] (19–66) SC: 47 [15] (27–66) Previous live births SSC: 10 (48%) SC: 7 (35%) Previous experience in breastfeeding SSC: 8 (38%) SC: 6 (30%) *Infants* Mean weeks [SD] (range) gestational age SSC: 28 [2] (24–33) SC: 27 [2] (24–33) Mean birthweight [SD] (range) (g)	**I: $n = 21$** Skin-to-skin care (SSC) Infant held upright between the mother's breasts. Infant clothed only in a diaper and hat and mother and infant covered with a blanket. SSC took place for 10 minutes per weekday for a maximum of 10 days **C: $n = 20$** Standard contact (SC) Infant held cradled in mother's arms. Infant fully clothed and wrapped in a blanket. SC was observed for 10 minutes per weekday for a maximum of 10 days. **Both groups** Study protocol began when enrolled infants considered medically stable to be held, i.e. not ventilator dependent, no chest tubes and not requiring continuous positive airway pressure (CPAP). During the study, mother-infant dyads were observed as detailed above until bottle and breastfeedings were initiated (i.e. all infants were gavage fed during the study)	**Statistical techniques** Unpaired *t*-test for baseline characteristics, analysis of variance for physiological data and chi-squared analysis for duration of breastfeeding data at discreet points in time **Breastfeeding/breastmilk-related outcomes** *Milk production* No difference in mean daily maternal milk expression by mothers of singleton infants during the 10-day period was noted between the groups *Duration of breastfeeding for singleton mother-infant dyads* Breastfeeding at: / SSC ($n = 21$) / SC ($n = 18$) Discharge $p < 0.05$ / 19 / 11 One month $p < 0.01$ / 10 / 2 6 months / 20% / 10% *(n not reported for either group)*	41 mother-infant dyads were randomised (SSC 21, SC 20), comprising a total of 50 infants (25 per group) Total of four losses, all from SC group. Two mothers wanted to move to SSC so were excluded (including one mother of twins) and two mothers didn't want to hold their infants each day. These mothers did participate in follow-up resulting in data for 18/20 SC group Numbers remaining in the study after 1 month not reported	Data were not analysed using intention-to-treat model

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation Not calculated **Outcome measures** Maternal milk production Breastfeeding at discharge and 1 & 6 month(s) after discharge Rate of infant weight gain Infant oxygen saturation, respiratory rate, heart rate and temperature maintenance Length of hospital stay Length of days in incubator		SSC: 993 [275] (520–1470) SC: 942 [322] (350–1475) Mean days intubated [SD] (range) SSC 7 [10] (0–36) SC 8 [10] (0–42) Mean days oxygen requirement [SD] (range) SSC: 27 [29] (0–93) SC: 34 [28] (0–91) Number (%) with necrotising enterocolitis before the intervention SSC: 6 (24) SC: 2(8) Number (%) with sepsis before the intervention SSC: 3 (12) SC: 0 (0) No episodes of NEC or sepsis after sessions began **Group comparability** No significant differences between the groups were found in mother or infant characteristics	**Data collection** Maternal and neonatal characteristics were prospectively recorded. Mothers recorded the amount of milk they expressed daily. Duration of breastfeeding was monitored by face-to-face follow-up during infants' stay in special care nursery and by telephone follow-up at 1, 3 and 6 months after discharge. Clinical outcomes were recorded each minute for 10 minutes of the 10 holding sessions and reported graphically in the paper	*Duration of breastfeeding for multiple mother-infant dyads* Breastfeeding at: / SSC ($n = 3$) / SC ($n = 4$) Discharge / 3 / 2 1 month / 1 / 0 6 months / 0 / 0 **Clinical/health outcomes** *Infant weight gain, mean [SD], g/d* SSC (n = 25) / SC (n = 25) 26 [6] / 25 [5] Mean oxygen saturation was reported as higher during SSC than SC ($p < 0.001$) Episodes of oxygen desaturation to < 90% occurred in 191/1716 (11%) recordings during SSC compared with 319/1334 (24%) recordings during SC ($p < 0.001$) Respiratory rate, heart rate and temperature were similar in both groups		

continued

TABLE 26 *Blaymore Bier 1996[115] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
				Process outcomes SSC ($n = 25$) / SC ($n = 25$) *Mean chronological age when study observations began* 29 days / 30 days *Mean gestational age when observations began* 32 weeks / 31 weeks *Mean [SD] days hospitalised* 69 [25] / 73 [22] *Mean [SD] days in incubator* 55 [24] / 59 [23] No statistically significant differences found **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported		

I, intervention group, skin-to-skin care (SSC); C, control group, standard contact (SC).

DOI: 10.3310/hta13400

TABLE 27 *Boo 2007*[41]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Boo 2007 Malaysia (Kuala Lumpar) **Research aim** To compare the weight gain, head growth and breastfeeding rates in very low birthweight infants with or without exposure to short duration of skin-to-skin contact (STSC) while in a NICU **Study design** Randomised controlled trial **Method of group allocation** Stratified by multiplicity of pregnancy and birthweight prior to randomisation using serially numbered sealed envelopes prepared in blocks of eight **Unit of allocation** Infant **Unit of analysis** Infant	**Selection** Eligible infants admitted to NICU of a major teaching hospital (Hospital Universiti Kebangsaan Malaysia) from 1 January 2002 to 30 October 2004 **Inclusion criteria** *Infants* Birthweight less than 1501 g Stable and adapted to extrauterine life including: • able to tolerate at least 50% of required feed volume enterally • with or without nasal continuous positive airway pressure (CPAP) ventilatory support **Exclusion criteria** *Infants* Lethal or major malformations Severe perinatal asphyxia with evidence of hypoxic ischaemic encephalopathy Transfer to another hospital	**STSC; SC; *p*** (*n* = 64); (*n* = 62) *Mothers* Mean [SD] age (years) 30.2 [2.9]; 31.1 [5.2]; NS Mean years education (%) 13.0 [2.9]; 12.1 [1.7]; 0.04 Household income/ month (RM) (%) < 2501 22 (34); 19 (31); NS Parity > 2 (%) 5 (8); 7 (11); NS Malay ethnic group (%) 40 (63); 34 (55); NS Infants at enrolment Mean postmenstrual age [SD] in days 246 [15]; 240 [15]; 0.02 Mean bodyweight [SD] (g) 1515 [120]; 1492 [128]; NS Mean head circumference [SD]/cm 29.3[1.4]; 29.1[2.1]; NS Multiples (%) Twins: 12 (19); 8(13); NS Triplets: 3 (5); 6 (10); NS	**I: *n* = 64** Skin-to-skin contact (STSC) plus standard care below STSC took place in infant's cubicle with drawn curtain for at least 1 hour daily. Parents sat on sofa and wore front opening clothing. Mother removed bra, infants wore nappy and bonnet. Infant held upright between the breasts, covered with thermal blanket. If infant showed signs of searching for food, mother offered her breast. Infant's vital signs monitored throughout. STSC terminated if severe adverse event occurred and resumed when stabilised. Parents were trained in STSC by a researcher using written instructions and photographs	**Statistical techniques** Unpaired Student's *t* test, Mann–Whitney *U* test, chi-squared or Fisher's exact test and linear regression **Breastfeeding/ breastmilk-related outcomes** STSC (*n* = 64) | SC (*n* = 62) | *p* *On EBM or any breastmilk between enrolment and discharge:* 21 (33%) | 6 (10%) | 0.0002 *Breastfeeding on discharge:* 19 (30%) | 9 (15%) | 0.004 **Clinical/health outcomes** STSC (*n* = 64) | SC (*n* = 62) | *p* *Developed sepsis* 2 (3%) | 1 (1.6%) | 1.0 *Developed NEC* 0 | 0 | *Mean [SD] increase in head circumference (cm/week):* 1.0 [0.3] | 0.7 [0.3] | < 0.0001	128 of 225 eligible infants randomised (STSC *n* = 65) (SC *n* = 63) One infant per group died between randomisation and before start of study Data from remaining 126 infants reported	Data were analysed using intention-to-treat model Census of study unit (2000) showed 30% breastfeeding rate among VLBW infants Authors note although infants in SC group weighed significantly more than STSC infants, they also stayed significantly longer in hospital after recruitment (p. 835) Logistic regression found only significant predictors of successful breastfeeding at discharge were infants receiving EBM at enrolment (adjusted OR: 4.1; 95% CI: 1.4–11.7; *p* = 0.009) or receiving EBM during intervention period (adjusted OR: 8.3; 95% CI 2.8–24.4; *p* < 0.0001)

continued

TABLE 27 *Boo 2007[141] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation Minimal sample of 47 infants per group to detect a between-group difference of breastfeeding rate of 25% with 95% level of confidence and a power of 80%. Minimal sample of 13 infants per group to detect a difference of 5 g/day of weight gain **Outcome measures** Weight gain Head circumference Breastfeeding at discharge	*Parents (STSC group)* Refusal to participate in study or STSC	On expressed breastmilk (EBM) or any breastmilk (%) 20 (31); 13 (21); NS **Group comparability** Significant differences between the groups were found in maternal education and infants' postmenstrual age	**C: *n* = 62** Standard care (SC) Each infant was nursed in own cubicle with curtain at open end. On admission, mother was taught techniques for hand washing, handling their infants and expressing breastmilk **Both groups** Infants' well-being reported weekly to parents by researcher. Mother counselled regularly on importance of providing EBM. Infants ≥ 1750 g with good sucking reflex started on oral feeds Mothers encouraged to breastfeed 2–2½ hourly	*Mean [SD] head circumference at discharge (cm):* 31.5 [1.4] | 31.5 [1.6] | 0.9 *Mean [SD] weight gain (g/day):* 28.3 [11.3] | 27.5 [9.0] | 0.6 *Weight at discharge (g) median (IQR):* 1878 (160) | 1993 (452) | 0.001 **Process outcomes** STSC (*n* = 64) | SC (*n* = 62) | *p* *Received human milk fortifier (between enrolment and discharge):* 5 (8%) | 3 (5%) | 0.7 *Mean days postmenstrual age at discharge [SD]:* 253 [21] | 263 [16] | 1.0 *Median (IQR) days duration of hospital stay postrecruitment:* 13.5 [11.5] | 22.5 [14.0] | < 0.0001		Authors acknowledge study limitations including differences in some characteristics at baseline, failure to obtain consent from controls and lack of blinding

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
			Data collection Infants weighed naked using a calibrated, digital weighing scale by nurse in-charge each morning before first feed. Head circumferences measured weekly with disposable paper tapes. Nurses blind to aims or design of study. Clinical problems diagnosed using laboratory tests	*STSC infants received from a parent:* Mean [SD] days 10 [5.6] Median hours/day (IQR) 1 (0) Mean [SD] total hours 11.3 [5.9] **Psychosocial outcomes** Eight STSC infants received STSC on < 50% of postrecruitment hospital stay. Mothers' reasons: • too frightened to handle infants ($n = 3$) • unable to visit regularly ($n = 4$) • afraid STSC would prevent infant gaining weight ($n = 1$) **Cost-effectiveness outcomes** Not reported		

I, intervention group, skin-to-skin contact (STSC); C, control group, standard care (SC); IQR, interquartile range.

TABLE 28 *Cattaneo 1998*[131]

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Cattaneo 1998 Ethiopia (Addis Ababa) Indonesia (Yogyakarta) Mexico (Merida) **Research aim** To explore the effectiveness, safety, feasibility, acceptability and costs of kangaroo mother care (KMC) in low-income countries **Study design** Multi-centre randomised controlled trial **Method of group allocation** List of random numbers. In Yogyakarta, carried out in blocks of six and stratified by weight	**Selection** Eligible infants admitted to one major hospital in each of the three sites over an approximate 12-month period between August 1995 and September 1996 **Inclusion criteria** *Infants* Birthweight 1000–1999 g Any gestational age Not on oxygen or i.v. fluids Some ability to feed No visible major malformation Mother present and willing to collaborate **Exclusion criteria** *Infants* Multiple births not excluded unless twins randomly assigned to different groups In practice, eligible twins were enrolled only if the sibling died	KMC; C (*n* = 149); (*n* = 136) *Addis Ababa* (*n* = 50); (*n* = 50); *p* GA; < 32 weeks; (%) 6 (32); 6 (12); 0.02 *Yogyakarta* (*n* = 52); (*n* = 54) Exclusive breastfeeding at enrolment (%) 45 (87); 33 (61); 0.003 *Merida* Primiparas (%) 27 (57); 9 (28%); 0.01 *Overall* Exclusive breastfeeding at enrolment (%) 100 (67%); 75 (55); 0.04 No other significant differences between KMC and C	***I: n = 146*** Kangaroo mother care (KMC) defined as early, prolonged and continuous skin-to-skin contact between a mother and her infant, both in hospital and after discharge, until at least the 40th week of postnatal gestational age Infant stayed in 4-bed rooms with their mothers, skin-to-skin between breasts, wearing nappy and hat, and backs covered with mother's clothes, all day and night, for an average of 20 hours/day, including when mother asleep. Occasionally replaced for a few hours by another person, usually father. For absences < 1 hour, baby left on mother's bed, covered with a blanket. Mothers encouraged to continue KMC after discharge	**Statistical techniques** All data analysed in Trieste using ANOVA, chi-squared, *t* and Kruskal–Wallis tests, stratifying by site, gender, birthweight and socioeconomic variables **Breastfeeding/breastmilk-related outcomes**[a] *Exclusive breastfeeding at discharge (%):* KMC: Addis Ababa 40/48 (83); Yogyakarta 51/52 (98); Merida 37/46 (80); Overall 128/146 (88) C: Addis Ababa 40/47 (85); Yogyakarta 48/54 (89); Merida 5/32 (15); Overall 93/133 (70) Merida, $p = 0.00001$; not significant for Addis Ababa or Yogyakarta $p = 0.0003$ (see Additional comments) **Clinical/health outcomes** *Episodes of severe disease (/1000* infants/day) KMC: Addis Ababa 6 (12.0); Yogyakarta 7 (8.1); Merida 1 (1.6); Overall 14 (7.1) C: Addis Ababa 6 (9.4); Yogyakarta 18 (15.8); Merida 1 (2.2); Overall 25 (11.2)	285 of 463 eligible infants randomised (KMC *n* = 149; C *n* = 136) Six infants died after enrolment (three from each group) *KMC* 129/146 (88%) attended first visit 93/146 (64%) attended fourth visit *C* 112/133 (84%) attended first visit 82/133 (62%) attended fourth visit Authors state relative loss to follow-up was the same by group and by site	Data were not analysed using intention-to-treat model Authors note the many differences between the sites make overall comparison between the KMC and C groups problematic. Authors warn their results should not be interpreted without continuous reference to the specific findings of each site. For example: exclusive breastfeeding significantly higher in

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of allocation Infant **Unit of analysis** Infant **Sample size calculation** Not calculated. Aimed to randomise approximately 100 infants of low birthweight per site **Outcome measures** Exclusive breastfeeding at discharge Predefined serious illness Hypo- and hyperthermia Weight gain Mothers' views Adequacy and availability of structures/staff Costs		*Overall* **KMC; C** *(n = 149); (n = 136)* Born in same hospital 102 (68%); 85 (63) Caesarean section 45 (30%); 34 (25%) *Primiparas* 85 (57%); 67 (49%) *Mean birthweight (g) [SD]* 1622 [239]; 1638 [247] *Mean gestational age (weeks) [SD]* 33.7 [2.5]; 34/9 [2.2] *Gestational age < 32 weeks* 24 (16%); 14(10%) *Exclusive breastfeeding at admission* 63 (48%); 49 (40%) *Median days old at enrolment (range)* 10 (1–30); 8 (1–40) *Mean grams weight at enrolment [SD]* 1584 [223]; 1574 [251]	***C: n = 133*** Control, standard care *Addis Ababa* Infants in open cribs in a warm room (possibility of rewarming in a bulb-heated cot). All mothers stayed in hospital, in separate rooms with access for breastfeeding *Yogyakarta* Infants Infants in incubators. All mothers stayed in hospital, in separate rooms with access for breastfeeding *Merida* Infants in incubators. Mothers not allowed to stay or to visit at night, could visit any time during the day **Data collection** Six tools: a form to record data for each admission, a form for follow-up, two semistructured questionnaires for interviews with mothers and staff, a monthly record of observed constraints, and a monthly form for costs. Tools were tested, standardised and translated into local languages.	*Episodes of hypothermia[b] (/100 infants/day)* KMC: C Addis Ababa: 119 (23.7): 158 (24.8) Yogyakarta: 12 (1.4): 26 (2.3) Merida: 82 (13.5): 141 (31.5) Merida, $p = 0.00001$; among sites, $p = 0.000001$ Overall: 213 (10.8): 325 (14.6) $p = 0.0005$ (see Additional comments) *Episodes of hyperthermia[c] (/100 infants/day)* KMC: C Addis Ababa: 0 (0): 1 (1.6) Yogyakarta: 1 (1.2): 10 (8.8) Merida: 0 (0): 1 (2.2) Yogyakarta, $p = 0.02$ Overall: 1 (0.5): 12 (5.4) $p = 0.004$ (see Additional comments) *Mean daily weight gain (g) [SD]* KMC: C Addis Ababa: 17.9 (13.4): 13.4 (10.6) Yogyakarta: 25.6 (11.7): 21.4 (11.9) Merida: 20.1 (8.7): 18.0 (13.9) Among sites, $p = 0.00003$ Overall: 21 (11.8): 17.7 (12.4) $p = 0.001$ (see Additional comments)		Merida where exclusive breastfeeding at enrolment was also significantly higher among KMC group compared to C group

continued

TABLE 28 *Cattaneo 1998[131] (continued)*

<table>
<tr><th>Study details</th><th>Participant selection and inclusion/exclusion criteria</th><th>Baseline characteristics of participants</th><th>Intervention details</th><th>Results</th><th>Withdrawals</th><th>Additional comments</th></tr>
<tr><td></td><td></td><td>Group comparability
No differences between the groups in maternal age, reproductive history, education or social/ economic conditions</td><td>The principal investigator in each site was in charge of monitoring the quality of data collection. Qualitative data from the two questionnaires was coded before data entering. Staff interviews were conducted during the second half of the study among 45% of the professional staff engaged in the study, proportionally distributed across the sites including 15 doctors, 31 nurses and 3 others</td><td>
<table>
<tr><td colspan="3">Mean weight gain during study (g) [SD]</td></tr>
<tr><td></td><td>KMC</td><td>C</td></tr>
<tr><td>Addis Ababa</td><td>166 (137)</td><td>154 (121)</td></tr>
<tr><td>Yogyakarta</td><td>367 (173)</td><td>395 (262)</td></tr>
<tr><td>Merida</td><td>259 (200)</td><td>286 (218)</td></tr>
<tr><td>Among sites, $p = 0.000001$</td><td></td><td></td></tr>
<tr><td>Overall</td><td>267 (190)</td><td>284 (234)</td></tr>
<tr><td colspan="3">Mean weight gain at discharge (g) [SD]</td></tr>
<tr><td></td><td>KMC</td><td>C</td></tr>
<tr><td>Addis Ababa</td><td>1645 (204)</td><td>1615 (223)</td></tr>
<tr><td>Yogyakarta</td><td>2039 (140)</td><td>2049 (158)</td></tr>
<tr><td>Merida</td><td>1852 (52)</td><td>1886 (83)</td></tr>
<tr><td colspan="3">Merida, $p = 0.04$; among sites, $p = 0.000001$</td></tr>
<tr><td>Overall</td><td>1848 (220)</td><td>1851 (257)</td></tr>
<tr><td colspan="3">Process outcomes</td></tr>
<tr><td colspan="3">Median length of stay (days) after enrolment (range)</td></tr>
<tr><td></td><td>KMC</td><td>C</td></tr>
<tr><td>Addis Ababa</td><td>9 (3–31)</td><td>11 (2–39)</td></tr>
<tr><td>Yogyakarta</td><td>13 (2–85)</td><td>18 (3–60)</td></tr>
<tr><td>Merida</td><td>10 (2–41)</td><td>12 (2–39)</td></tr>
<tr><td>Among sites, $p = 0.000001$</td><td></td><td></td></tr>
<tr><td>Overall</td><td>11 (2–85)</td><td>13 (2–60)</td></tr>
<tr><td colspan="3">$p = 0.003$ (see Additional comments)</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments

Mean age (days) at discharge (range)		
	KMC	C
Addis Ababa	17 (6–78)	20 (7–65)
Yogyakarta	21.5 (8–97)	25 (8–74)
Merida	27.5 (9–56)	24 (3–51)
Among sites, $p = 0.003$		
Overall	21 (6–97)	23 (3–74)
Psychosocial outcomes		
Mothers happy with assignment (%)		
	KMC	C
Addis Ababa	44/50 (88)	23/50 (46)
Yogyakarta	48/52 (92)	54/54 (100)
Merida	38/41 (93)	21/22 (96)
Yogyakarta, $p = 0.000008$; among sites, $p = 0.002$		
Overall	130/143 (91)	98/126 (78)
$p = 0.003$		
Mothers would prefer the other assignment (%)		
	KMC	C
Addis Ababa	9/50 (18)	34/50 (68)
Yogyakarta	1/52 (2)	1/54 (2)
Merida	1/41 (2)	15/22 (68)
Merida, $p = 0.0000001$; among sites, $p = 0.0000001$		
Overall	11/143 (8)	50/126 (40)
$p = 0.0000001$ (see Additional comments)		

continued

TABLE 28 *Cattaneo 1998[131] (continued)*

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
				Staff views 92% considered KMC as safe 90% found mothers were comfortable with KMC 69% found mothers were comfortable with standard care (control) When asked whether they would prefer KMC or CMC if they had a low birthweight infant, 100% chose KMC in Addis Ababa and Merida compared with 41% in Yogyakarta where 6% chose standard care and 47% were uncertain **Cost-effectiveness outcomes** *Running costs (US$)* Average monthly salaries (US$) Doctors 250 Nurses 96 Other staff 55 Electricity and maintenance costs much higher in standard care. Food for mothers and laundry were more expensive for KMC than C group		

	KMC	C
Salaries	11,788	29,888
Other items	7501	9876

I, intervention group, kangaroo mother care (KMC); C, control group, standard care.
a In this study, breastfeeding included feeding from the breast and feeding with expressed breastmilk, always exclusively. The WHO definition for exclusive breastfeeding was used: WHO. Indicators for assessing breastfeeding practices. Division of Diarrhoeal and Acute Respiratory Disease Control (WHO/CDD/SER/91.14). Geneva: WHO; 1991.
b Hypothermia: $< 36.0^{\circ}C$ without other cause; axillary temperature taken twice a day with low-reading thermometer.
c Hyperthermia: $> 38.5^{\circ}C$ without other cause; axillary temperature taken twice a day with low-reading thermometer.

TABLE 29 *Charpak 1997[107] and 2001[108]*

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Charpak 1997 Colombia (Bogotá) Follow-up after term to one year of corrected age is reported in Charpak 2001 **Research aim** To evaluate the effect of the three components of Rey-Martinez KMC (position, feeding policy and discharge policy) on a range of outcomes for LBW infants in the first year of life **Study design** Randomised controlled trial **Method of group allocation** Random numbers list (permutations of 16) Stratified block randomisation by weight	**Selection** Infants with birthweight/weight at transfer ≤2000 g being cared for at Clínica San Pedro Claver, a tertiary care obstetric facility with 13,500–15,000 live births per year **Inclusion criteria** Infants eligible for KMC, i.e.: • had overcome major adaptation problems to extrauterine life • had received proper treatment for infection or concomitant condition • sucked and swallowed properly • had achieved positive weight gain regardless of actual weight or gestational age	*Mothers* I (KMC); C (controls) Mean age in years 27.3; 27.4 Stable couples 83%; 86% Education: • elementary school or less 22%; 22% • secondary school 56%; 56% • post-secondary school 22%; 22% Employment: • office work 11%; 13% • physical labour 33%; 30% • housewife 35%; 38% • other 21%; 19%	Prior to randomisation, some infants ≤2000 g were admitted to NICU and some were placed in a crib in the mother's hospital room All were assessed for eligibility for the trial (on NICU/before mother and infant discharge, respectively) Randomisation took place once the attending physician decided the infant was eligible ***I: n = 382*** KMC infants were discharged, regardless of weight or gestational age, to another hospital (Clínica del Nino) with their mothers immediately after randomisation, for programme of ambulatory adaptation to KMC Mothers and infants could stay at the programme as long as necessary to demonstrate appropriate adaptation	**Statistical techniques** Chi-squared and Fisher exact tests; *t* tests or non-parametric tests; ANOVA/ANCOVA and regression **Breastfeeding/breastmilk-related outcomes** *Exclusive breastfeeding at term* I: 159/343 (46.4%) C: 145/320 (45.3%) *Partial breastfeeding at term* I: 177/343 (51.6%) C: 151/320 (47.2%) *Only formula at term* I: 7/343 (2%) C: 24/320 (7.5%) $p < 0.05$ *Duration of any breastfeeding to 1 year* More babies in KMC were breastfed to 3 months corrected age	777 infants were randomised 31 were withdrawn (I = 14, C = 17) because evidence of severe neurological problems or intrauterine infection emerged No mothers assigned to KMC refused to participate 746 entered the study (I = 382, C = 364) Complete follow-up data for 679 (91%) at term (40–41 weeks post-conception age)	All subjects were analysed according to allocated group, regardless of compliance with treatment or contamination of the intervention Consent was postrandomisation for the KMC group only, to avoid contamination bias from parents asking for KMC (early discharge) Ethics committee approval for not seeking consent from the control group was given because the control group received usual care Funded jointly by Instituto de Seguros Sociales de Colombia and the World Laboratory (ONG, Lausanne, Switzerland, Project Number MCD13)

Age (months)	KMC (%)	Control (%)	*p*
Term	98.0	93.3	0.001
3	81.7	75.3	0.05
6	51.6	48.2	NS
9	36.3	34.8	NS
12	19.7	22.2	NS

continued

TABLE 29 *Charpak 1997[107] and 2001[108] (continued)*

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of allocation Product of each delivery (twins and triplets allocated to same group) **Unit of analysis** Infant **Sample size calculation** Based on previous work showing a death rate among eligible infants under traditional care of ~7%, to detect a twofold increase in the risk of dying ($\alpha = 0.05$, two-tailed test, power 80%) 215 per group **Outcome measures** Primary: mortality, growth Secondary: length of stay, infections, any and exclusive breastfeeding	Also: Mother or relative in same household willing to care for a premature infant and comply with 1-year follow-up schedule Twins and triplets were included **Exclusion criteria** Referred to another institution Plans to leave Bogotá Life-threatening or major malformations Early-detected major conditions arising from perinatal problems (e.g. severe hypoxic-ischaemic encephalopathy, pulmonary hypertension) Parental/family refusal to comply with the follow-up programme For KMC group, refusal to comply with the specifics of the intervention	Median per capita monthly income (Colombian pesos, 1994) Col$70,000; Col$70,000 Distribution of sociodemographic variables noted to reflect the composition and characteristics of the population served by the Social Security in Bogotá Mothers' usual weight (kg; mean ± SD) 54 ± 6.9; 53.7 ± 7.8 Mothers' height (cm; mean ± SD) 158 ± 7; 157 ± 6.5 Primiparas 145 (38%); 138 (38%) Multiple births 79 (21%); 57(16%) Caesarean births 264 (69%); 246 (67%) Postpartum hospital stay, median days minimum–maximum 3 (0–11); 3 (0–11) The high rate of pathological conditions such as pre-eclampsia (38%) during pregnancy and the high rate of caesarean births in both groups reflect the fact that the study population was the high-risk segment of deliveries at the study hospital	Infants spent 24 hours per day in an upright position, in skin-to-skin contact, and attached to the mother's chest Infants to remain in kangaroo position until they demonstrate discomfort by pushing out limbs, crying and fussing when mothers try to return them to the upright position Infants to be breastfed regularly Premature formula used to guarantee adequate weight gain if necessary **C: *n* = 364** Control group infants remained in incubator care at the Clínica San Pedro Claver until able to regulate temperature and reached weight 1700 g Parents' access to infants was severely restricted at the time of the study **Post-discharge** from their respective hospitals, both groups had access to the same follow-up care	**Clinical/health outcomes** *Deaths between eligibility and term* I: 6/364 (1.6%) C: 10/345 (2.9%) Not statistically significant RR = 0.59 (95% CI: 0.22–1.6) *During follow-up to 12 months:* I: 11/350 deaths (3.1%) C: 19/343 deaths (5.5%) Not statistically significant *Mean [SD] weight at term (g)* I: 2814 [541] vs 2803 [509] Similar to term newborn infants in Bogotá (2600 m above sea level) Growth indices were almost identical in the two groups *Head circumference* Larger for KMC infants (as proportion of expected circumference at 12 months corrected age) than control group infants ($p = 0.06$ before adjustment in linear regression analysis and $p = 0.014$ after) *Infectious episodes between eligibility and term* I: 49 (14%) vs C: 44 (14%), $p = 0.25$ *Infections not requiring readmission* I: 6.7% vs C: 2.8%, $p = 0.019$ *Readmissions for infections* I: 7.6% vs C: 11% $p = 0.17$		

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
		Infants *I (n = 382); C (n = 364)* Weight at birth g (mean ± SD) 1750 ± 261; 1735 ± 256 Distribution of weight at birth, number of infants (%) ≤1200 g: 26 (6.8); 22(6) 1201–1500 g: 56 (14.7); 58 (16) 1501–-1800 g: 147 (38.5); 124 (34) 1801–12,000 g: 153 (40); 60 (44) Gestational age (weeks; mean ± SD) 33.6 ± 2.5; 33.9 ± 2.7 Distribution of gestational age at birth (weeks; number, % of infants) ≤32: 137 (36); 109 (30) 33–34: 112 (29); 97 (26) 35–36: 83 (22); 106 (29) ≥37: 50 (13); 52 (14) Infants never admitted to neonatal unit 132 (35%); 155 (42.5%) Infants never admitted to neonatal intensive care unit (NICU)	**Data collection** Interviews with mothers Clinical records	*Infectious episodes between term and 1 year* Overall frequency of infections to 12 months in KMC and CMC groups was similar, with no differences between the groups in cumulative frequency of mild/moderate infections (requiring ambulatory use of antibiotics) or severe infections (requiring hospitalisation) *Psychomotor development to 1 year* No difference was found between the two groups in the proportions of infants with cerebral palsy, psychomotor delay, or visual or hearing impairment The only factor associated with an increased risk of cerebral palsy was the total number of days spent in NICU – authors note this reflects the severity of the infant's initial condition **Process outcomes** CMC infants had more paediatrician visits during their (longer than KMC) hospital stay and KMC infants had more ambulatory clinic visits after their (earlier than CMC) primary discharge Number of readmissions after primary discharge was similar in the two groups Total length of hospital stay from eligibility to 12 months corrected age shorter for KMC infants, particularly for those with birthweight < 1500 g **Psychosocial outcomes** Not reported		

continued

TABLE 29 *Charpak 1997[107] and 2001[108] (continued)*

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
		321 (84%); 311 (85.4%) Days on NICU for those admitted; median (range) 8 (2–44); 6 (1–34) Infants never in ventilator 330 (87%); 332 (91%) Days ventilation for those ever ventilated; median (range) 4 (1–19); 4.5 (1–11) **Group comparability** The only differences noted between the groups was in the number of multiple births (22 more in the KMC group, significance not reported) and number of infants never admitted to neonatal unit (greater in the control group (I: 35% vs C: 42.5%, $p < 0.05$)		**Cost-effectiveness outcomes** After adjusting for weight at eligibility there was an average saving of 1.1 days in total hospital stay from eligibility to term in the KMC group The saving in hospital stay was related to birthweight *Hospital stay from eligibility to term; mean (range) [number of infants]* Birthweight ≤1200 g I: 8.6 (0–28) [23] C: 14.84 (3–26) [19] Birthweight 1800–2000 g I: 2.86 (0–36) [137] C: 2.77 (0–34) [139] Authors state savings in hospital stay persist up to 12 months of corrected age		

I, intervention group, kangaroo mother care (KMC); C, control group, traditional care.

DOI: 10.3310/hta13400

TABLE 30 *Kadam 2005*[118]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Kadam 2005 India (Mumbai) **Research aim** What are the effects of kangaroo mother care (KMC) compared with conventional care (CC) on physiological parameters and is KMC acceptable to parents? **Study design** Pilot study for a randomised controlled trial **Method of group allocation** Sealed envelope method. No further details **Unit of allocation** Infant **Unit of analysis** Infant Mother for psychosocial outcomes	**Selection** Infants who met inclusion criteria in a major tertiary care centre in Mumbai between 1 November 2000 and 31 October 2001 **Inclusion criteria** *Infants* Birthweight less than 1800 g Stable cardiopulmonary status in air Apgar score of 7 at 5 minutes On breastfeeds or spoon *wati* feeds with expressed breastmilk **Exclusion criteria** *Infants* Sick and unstable infants Major congenital malformation Refusal of parental consent	KMC: $n = 44$ CC: $n = 45$ *Infants* Mean gestational age (weeks) [SD] KMC: 33.3 [2.1] CC: 34.0 [1.7] Mean birthweight (g) [SD] KMC: 1467 [228] CC: 1461 [217] Mean length (cm) [SD] KMC: 39.9 [1.4] CC: 40.0 [2.6] Mean head circumference (cm) [SD] KMC: 28.0 [1.4] CC: 28.6 [1.7] *Mothers* Not reported No significant differences between the groups were found in infant characteristics	**I: *n = 44*** **Kangaroo mother care (KMC)** Infants placed between mothers' breasts in vertical position supported by a cloth *'dupatta'*, with mothers sitting in a semireclining position. KMC for at least 1 hour each episode and continued for as long as comfortable. KMC was discontinued if baby demonstrated discomfort (crying, pushing out legs) or mother uncomfortable. Infants who developed clinical problems were transferred to CMC and after stabilisation, transferred back to KMC **C: *n = 45*** **Conventional care (CC)** Infants managed under radiant warmers **Both groups** Mothers allowed to enter and handle, change and breastfeed their infants at any hour of the day. Infants discharged following:	**Statistical techniques** Unpaired, two-tailed *t* test on means in KMC and CC for respiratory rate, temperature and oxygen saturation Infants: KMC ($n = 44$) | CC ($n = 45$) | *p* **Breastfeeding/breastmilk-related outcomes** *Mean days old when started breastfeeding [SD]* 4.7 [3.3] | 5.6 [3.9] | NS **Clinical/health outcomes** *Deaths* 1 (sepsis) | 1 (NEC) | NS *Sepsis* 6 | 8 | NS *Apnoea (with sepsis)* 6 (3) | 8 (4) | NS *Episodes of hypothermia* 10 | 21 | < 0.01 *Episodes of hyperthermia* 13 | 15 | NS *Oxygen saturation* 95.7 ± 1.1 | 94.8 ± 0.7 | < 0.01 *Respiratory rates* 36.2 ± 3.3 | 40.7 ± 2.9 | < 0.01	A total of 21/110 infants excluded on defined criteria. 89 infants randomised (KMC 44; CC 45) No withdrawals Numbers of mothers or numbers completing interview are not reported	Data were analysed using intention-to-treat model Background breastfeeding rates not reported All infants in this study received 100% human breastmilk Researchers note their rate of transfer of KMC infants into CC (34.1%) was higher than that reported by Cattaneo 1998 (13.4%). They attribute this to their lower median age of enrolment (3.2 days) [2.8] compared with 10 days [1–74]

continued

TABLE 30 *Kadam 2005[118] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation Not calculated **Outcome measures** Mean days old when started breastfeeding Deaths Episodes of sepsis, apnoea, hypothermia (36°C) and hyperthermia (38°C) Oxygen saturation Respiratory rates Length of hospital stay Mean weight at discharge Mothers' views			recorded weight gain for 3+ consecutive days; maintaining temperature without warmer; feeding well; mother confident about care of infant at home **Data collection** Gestational age assessed by Ballard's score within 24 hours, weighed immediately after birth, length measured at 24 hours with an infantometer, head circumference measured at 48 hours with a non-stretchable cloth tape, all by same single observer. Infants continuously monitored for oxygen saturation and heart rate by pulse oximeter. Respiratory rates counted hourly, axillary temperature taken hourly for 3 minutes (during KMC period for KMC). Interview of KMC mothers using semistructured questionnaire at end of study to assess views	**Process outcomes** *Mean duration of KMC contact (hours/day) [SD]:* 9.8 [3.7] *Transfers from KMC to CC:* 15/44 (34.1%) (range 1–6 days) *Reasons for transfer:* Sepsis (2); apnoea (3); jaundice (6) Sepsis and apnoea (3); sepsis and jaundice (1) *Mean age of enrolment (days) (range)* 3.2 (1.8) (not reported by group) *Mean days before discharge [SD]* 8.5 [4.4] | 9.3 [4.5] | NS *Hospital stay* Reported as shorter in KMC but not statistically significant ($p = 0.47$) *Mean weight at discharge (g) [SD]* 1494 [211] | 1462 [205] | NS **Psychosocial outcomes (KMC mothers)** 86% happy with KMC 14% preferred CC *Do you feel comfortable when giving KMC?* Yes: 79% *Reasons for not:* pain, stress of labour *Will you continue giving KMC at home?* Yes: 73% *Does your husband agree with KMC?* Agree: 64% **Cost-effectiveness outcomes** Not reported		

I, intervention group, kangaroo mother care (KMC); C, control group, conventional care (CC); NEC, necrotising enterocolitis.

DOI: 10.3310/hta13400

TABLE 31 *Roberts 2000*[129]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Roberts 2000 Australia (Darwin, Northern Territory) **Research aim** To compare kangaroo mother care with conventional cuddling care in premature and small for gestational age (SGA) infants **Study design** Randomised controlled trial **Method of group allocation** Randomised by means of envelopes that contained the group assignment, stratified by gender **Unit of allocation** Mother-infant pairs	**Selection** Infants in the NICU at the Royal Darwin Hospital and the nursery at the Darwin Private Hospital **Inclusion criteria** *Parents* • English-speaking • Resident in the Darwin area • Willing to cuddle their infant for at least 2 hours per day, 5 days a week for a maximum of 4 weeks *Infants* • Born ≥ 30 weeks' gestation/corrected age, with Apgar ≥5 • Medically stable • Stable temperature ≥24 hours • Extubated ≥48 hours • No crib or headbox oxygen ≥24 hours	KMC ($n = 16$) CCC ($n = 14$) *Mothers* Mean [SD] maternal age (years) KMC: 26 [6] CCC: 28 [6] Mean [SD] parity KMC: 1.6 [0.9] CCC:1.5 [0.9] *Infants* Mean weeks [SD] gestational age KMC: 31.7 [3.1] CCC: 31.2 [2.4] Mean birthweight [SD] (g) KMC: 1562 [465] CCC: 1482 [409] Mean [SD] weight at enrolment (g) KMC: 1687 [418] CCC: 1693 [212] No significant differences between the groups were found in mother or infant characteristics	**I: *n = 16*** Kangaroo mother care (KMC) Skin-to-skin contact during cuddling Infant dressed only in a diaper (smaller infants also wore a bonnet) Infant near-naked at or between mother's breasts Covered with a light blanket KMC was done in private, in a comfortable chair that allowed rocking **C: *n = 14*** Conventional cuddling care (CCC) Infants wore normal clothing and were covered with a light blanket during cuddling The only difference between the groups was that infants in the KMC group had skin-to-skin contact with the mother, whereas infants in the CCC group had contact only through clothing	**Statistical techniques** Two-tailed independent *t* tests; one-tailed *t* tests, Mann–Whitney *U* and chi-squared; paired *t* tests **Breastfeeding/breastmilk-related outcomes** *Duration of breastfeeding* Breastfeeding at: KMC ($n = 16$) / CCC ($n = 14$) Discharge: 10 / 11 6 weeks: 9 / 6 3 months: 7 / 5 6 months: 4 / 4 **Clinical/health outcomes** *Infant weight gain* Both groups gained a mean of 23 [SD 7] g/day in hospital. No significant differences in weight gain were found between the groups at 6 weeks, 3 or 6 months KMC: 6 weeks: 52 ± 24 g/day 3 months: 39 ± 12 g/day 6 months: 30 ± 6 g/day CCC: 6 weeks: 55 ± 15 g/day 3 months: 42 ± 10 g/day 6 months: 30 ± 6 g/day	30 mother-infant pairs were randomised (KMC 16, CCC 14) After the first 11 cuddling episodes, 20 mother-infant pairs remained in the study Numbers remaining in the study at other data collection points not reported Withdrawals not reported by group	Data were not analysed using intention-to-treat model The paper mentions mothers and parents; it is not clear whether or how fathers were involved in the study Funding assistance came from the Northern Territory University and the Australian Nurse-Teachers' Society

continued

TABLE 31 *Roberts 2000[129] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of analysis Group, individual **Sample size calculation** Not reported **Outcome measures** Infant weight gain Temperature maintenance during KMC and CCC **Length of hospital stay** Breastfeeding duration Maternal stress and confidence	• Infants having nasal continuous positive airway pressure (CPAP), or a nasal cannula delivering oxygen at < 2 l/min were eligible • Infants with episodes of apnoea or bradycardia requiring only mild stimulation were eligible • Infants with an intravenous infusion were eligible • Infants receiving medications that did not maintain systemic function (i.e. no inotropes) were eligible		**Data collection** • Length of cuddling episodes • Infant temperature before and after each cuddling episode • Infants routinely weighed twice per week in NICU and at well-baby clinic visits postdischarge • Parental Stressor Scale-NICU (PSS-NICU) for maternal stress levels, shortly before infant's discharge • Parental Expectations Survey (PES) for mothers' perceptions of their competence, 6 weeks after discharge	*Infant temperature maintenance (first 11 KMC/ CCC episodes)* In both groups for all 11 episodes, temperatures remained stable or rose by 0.1 to 0.2°C, with no significant difference in temperature gain found between the groups for any episode Mean temperature before KMC or CCC for both groups 36.7 ± 0.1°C After KMC or CCC for both groups 36.9 ± 0.2°C **Process outcomes** *Mean hours cuddling per day [SD]* KMC: 1.6 [0.9] CCC: 1.8 [0.9] *Length of hospital stay* KMC: 48 ± 28 days CCC: 46 ± 19 days		

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
	• Nasogastric or oral feeds 1–4 hourly • Being nursed in an open crib or incubator **Exclusion criteria** *Mothers* • History of drug use *Infants* • Congenital abnormality • Central nervous system impairment • Receiving inotrope medications • Phototherapy in the previous 24 hours • Infants who had been resuscitated		• Researchers contacted mothers at 6 months to ask if they were still breastfeeding	**Psychosocial outcomes** *Maternal stress* The mothers expressed moderate to very stressful responses on all four subscales (nursery environment, infant appearance, relationship with the infant, staff behaviour and communication). Scores were not significantly different between the groups *Maternal confidence* For the whole group all items had a mean score (≥ 7.5) indicating a high level of confidence among parents in their parenting abilities. Scores were not significantly different between the groups **Cost-effectiveness outcomes** Not reported		

I, intervention group, kangaroo mother care; C, control group, conventional cuddling care.

TABLE 32 *Rojas 2003*[121]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Rojas 2003 USA (Connecticut) **Research aim** To determine whether infants receiving skin-to-skin care (SSC) grew more rapidly and had a shorter duration of hospital stay than infants held in a traditional way (TH) **Study design** Randomised controlled trial **Method of group allocation** Numbered and sealed opaque envelopes previously prepared using random number table **Unit of allocation** Infant **Unit of analysis** Infant	**Selection** Consecutively born preterm infants at Yale New Haven Hospital who met criteria from 31 August 1995 to 19 April 1998 **Inclusion criteria** *Infants* Gestational age of 32 weeks or less Birthweight of 1500 g or less Minimal ventilatory support (peak airway pressure < 8 cmH_2O and F_iO_2 < 40% or extubated on nasal continuous positive airway pressure or nasal canula) Haemodynamically stable **Exclusion criteria** *Infants* Clinical evidence of perinatal asphyxia Potential transfer within first month of life	*Infants* *SSC (n = 33); TH (n = 27); p* [SD] where reported Mean birthweight (g) 906 [245]; 939 [230]; 0.3 Mean birth length (cm) 35.3 [3.0]; 35.0 [3.5]; 0.8 Mean birth head circumference (cm) 24.7 [2.0]; 24.9 [2.3]; 0.7 Mean weight at study entry (g) 1021 [268]; 1002 [219]; 0.4 Mean gestational age at birth (weeks) 26.6 [2.3]; 27.2 [2.3]; 0.1 Mean corrected age at entry (weeks) 29.4 [2.0]; 29.8 [2.3]; 0.2 Apgar ≤3 at 5 minutes age 2/32 (6%); 1/27 (4%); 0.6 Ventilated > 3 days 24/33 (73%); 18/27 (65%); 0.6	**I: *n* = 33** **Skin-to-skin care (SSC)** Parents were shown a video demonstrating the SSC technique. Infants held in prone, semiupright position (approx. 45°) in direct skin-to-skin contact with parent's chest. Infants wore diaper and backs covered with a blanket. Parents not prohibited from offering TH **C: *n* = 27** **Traditional holding (TH)** Parents removed infants from incubator and held them in the supine position with eye-to-eye contact. Infants wore diapers and T-shirts and wrapped in a blanket. Infants not offered SSC **Both groups** All infants < 1000 g wore a hat when held. Parents sat in reclining chairs and told they could hold their infants for a total of 8 hours/day (periods of up to 4 hours, twice/day). Holding time was not prescribed	**Statistical techniques** Chi-squared or Fisher exact tests for discrete variables, Student's *t* test for continuous variables. Unadjusted Kaplan–Meier survival analyses and Cox proportional hazards models for data about time from study entry to events of interest **Breastfeeding/breastmilk-related outcomes** *Successfully breastfed before hospital discharge* SSC: 18/30 (60%) TH: 9/26(35%) OR: 2.8, 95% CI: 1.0–8.3, *p* = 0.08 **Clinical/health outcomes** Surviving infants SSC (*n* = 31) / C (*n* = 26) / *p* *Mean discharge weight (g) [SD]* 2120 [248] / 2012 [154] / 0.05 *Mean discharge length (cm) [SD]* 43 [2.2] / 42.6 [1.1] / 0.3 Mean discharge head circumference (cm) [SD] (data missing from one infant in TH) 32.1 [1.3] / 31.3 [1.0] / 0.001 Rate of head circumference growth (cm/day) [SD] 0.1 [0.03] / 0.08 [0.02] / 0.05 No significant differences found between the groups for total weight gain, total head circumference growth, total linear growth, rate of weight gain or rate of linear growth	318 infants ≤32 weeks' gestation and ≤1500 g birthweight were born at study hospital during study period 38 died before eligibility 93 did not meet criteria 115 refused participation 12 not enrolled for other cited reasons Remaining 60 infants (19%) enrolled Three infants died after randomisation (SSC 2, TH 1) from severe respiratory failure and from NEC and sepsis respectively 31 SSC infants and 26 TH infants survived to discharge	Data were not analysed using intention-to-treat model Background breastfeeding rates not reported Authors note study was underpowered for outcome of weight gain Authors note it was observed that parents in the SSC group would spontaneously begin to transition to TH as their infants matured and reached 1800–2000 g. Many parents expressed need to maintain eye-to-eye contact Funding supported in part by Ronald McDonald Children's Charities of Connecticut and Western Massachusetts

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation 45 infants per group to provide 86% power to detect a 20% difference in major outcome scale of mother–infant interaction at an alpha level of 0.05 **Outcome measures** Successfully breastfed before discharge Mean discharge weight, length and head circumference Rate of head circumference growth Adverse events Frequency and length of SSC	Major congenital abnormality Planned adoption Grade III or IV intraventricular haemorrhage Fetal growth restriction (birthweight < 10th percentile for age) Suspected sepsis *Mothers* Less than 18 years History of using illicit drugs in pregnancy	Female 15/33 (45%); 10/27 (37%); 0.5 *Mothers* Not reported No significant differences between the groups were found in infant characteristics	**Data collection** Continuous monitoring of heart rate, respiratory rate, core body temperature and oxygen saturation before, during and after all care. Parents asked to complete a self-assessment questionnaire after each intervention to determine duration and problems. Bedside nurse recorded adverse events Data on weight and nutritional source, caloric intake, length, head circumference measured using recognised procedures by the same research assistant until infants reached 2000 g or until hospital discharge, whichever came first	Infants *SSC (n = 33)* / *C (n = 27)* / *p* NEC 1 (3%) / 2 (7%) / 0.6 Sepsis 5 (15%) / 8(30%) / 0.2 Desaturations 10(30%) / 15(56%) / 0.05 Other adverse events are reported, none with statistical significance between the groups **Process outcomes** *Median days intervention occurred after randomisation (range)* 1 (0–28) / 1 (0–15) Occasions infants held (per week) 4.0 ± 2.8 / 4.8 ± 3.5 Minutes infants held (per day) 79 ± 40 / 76 ± 39 Mean days from randomisation to discharge or a weight of 2000 g 61 ± 28 / 61 ± 33 = Infant held by parent at least once per day from randomisation to discharge or a weight of 2000 g 15 ± 16 / 22 ± 15 / $p = 0.03$		

continued

TABLE 32 *Rojas 2003[121] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
			Successful breastfeeding was defined as objective evidence of consistent breastfeeding with appropriate technique as judged by a lactation specialist and confirmed by retrospective review of medical records	% total holding time fathers held infants 31% 27% $p = 0.07$ Fathers performed their assigned intervention at least once during study period 30/33 (91%) 25/27 (93%) NS Authors note that compliance was low in both groups **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported		

I, intervention group, skin-to-skin care(SSC); control group, traditional holding(TH); NEC, necrotising enterocolitis.

DOI: 10.3310/hta13400

TABLE 33 *Sloan 1994*[132]

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sloan 1994 Ecuador (Quito) The author provided additional information on breastfeeding outcomes of the study for this review **Research aim** To compare the effects of the Kangaroo mother method (KMM) and standard treatment on morbidity, growth and cost of care for infants weighing < 2000 g at birth **Study design** Randomised controlled trial **Method of group allocation** Random numbers table **Unit of allocation** Individual (infant) **Unit of analysis** Individual and group	**Selection** Infants born at the Isidiro Ayora Maternity Hospital, Quito, Ecuador, November 1991 to December 1992 **Inclusion criteria** Singleton infants weighing < 2000 g Stabilised, with: • temperature 36.5–37.0°C for 24 hours • sucking reflex or tolerance of nasogastric tube feeding • ability to ingest at least 50% of desired volume (according to weight) of breastmilk • no decrease in weight for infants < 1750 g at birth for at least 72 hours **Exclusion criteria** Infants with serious congenital abnormalities or respiratory, metabolic or infectious disease were excluded	*Mothers* Mean [SD] age at first interview (years) I (*n* = 123): 24.94 [6.18] C (*n* = 143): 24.39 [6.06] Mean [SD] years maternal education I (*n* = 132): 4.6 [1.8] C (*n* = 149): 4.4 [1.8] Married I: 64.5% C: 73.1% Living with father of child I: 74.2% C: 90.3% Mean parity [SD] I (*n* = 121): 2.02 [1.75] C (*n* = 142): 1.09 [1.95] *Infants* Mean [SD] birthweight (g) I (*n* = 130): 1704 [243] C (*n* = 152): 1704 [248]	**I: *n* = 140** Kangaroo mother method (KMM) After randomisation mothers received additional instruction on how to hold the baby upright, skin to skin (diaper allowed) against the breast to avoid vomiting and provide warmth and nurture, how to breastfeed from inside the blouse and how to sleep inclined with the infant **C: *n* = 160** Standard incubator care (control) After randomisation mothers received additional instruction about the infant's stay in the incubator or thermal crib, scheduling visits to breastfeed, positioning of baby after feeds to avoid vomiting, how to ensure maintenance of warmth and how to arrange	**Statistical techniques** Linear multiple regression analysis for infant growth and cost outcomes, Kaplan–Meier survival analysis and Cox's proportional hazards models for infant morbidity, and other analyses by unadjusted chi-squared or *t* tests **Breastfeeding/breastmilk-related outcomes** *Exclusive breastfeeding at discharge* KMC: *n* randomised (R) 140; Data available (DA) (%) 124 (88.6); Exclusive bf 124; (% DA, R) (100, 88.6) CMC: *n* randomised (R) 160; Data available (DA) (%) 144 (90); Exclusive bf 141; (% DA, R) (97.9, 88.1) *Exclusive breastfeeding at 1 month of age (KMC; control)* KMC: *n* randomised (R) 140; Data available (DA) (%) 93 (66.4); Exclusive bf 86; % DA, R 92.4, 61.4 Control: *n* randomised (R) 160; Data available (DA) (%) 111 (69.4); Exclusive bf 103; % DA, R 92.7, 64.3 *Exclusive breastfeeding at 6 months of age (KMC; control)* KMC: *n* randomised (R) 140; Data available (DA) (%) 56 (40.0); Exclusive bf (% DA, R) 6 (10.7); % DA, R 10.7, 4.2 Control: *n* randomised (R) 160; Data available (DA) (%) 74 (46.3); Exclusive bf (% DA, R) 9 (12.16); % DA, R 12.2, 5.6 No significant differences between the study groups were found for breastfeeding outcomes **Clinical/health outcomes** *Posteligibility deaths* I: 11; C: 13 *Infant growth* No significant differences were found between the groups in growth indices during the 6-month follow-up	300 infants were randomised 140 to KMM 160 to control Follow-up rate for morbidity outcomes was 94.3% (lower follow-up for other outcomes)	Available data were reported by randomised group Of 603 babies of birthweight < 2000 g, 321 were eligible Reasons for ineligibility of 282 were: • multiple birth (101) • abandoned (6) • serious maternal disability (8) • severe congenital abnormality (14) • perinatal death (28) • pre-eligibility death (102) • other (23) Mean birthweight (g) [SD] and range for these 282 babies (except for perinatal deaths) was:

continued

TABLE 33 *Sloan 1994[132] (continued)*

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation To detect 2.5% vs 7.5% of severe disorders, given α error = 0.05, 1 – ß = 0.80, two tailed-test and potential loss to follow-up 25%, 350 infants per group **Outcome measures** Infant growth Morbidity Duration of hospital stay Readmissions Costs of care		Male I: 57.7% C: 53.9% Mean [SD] weeks' gestation I (*n* = 129): 34.6 [2.5] C (*n* = 152): 34.1 [2.4] Gestation < 37weeks I: 51.2% C: 61.5% Mean [SD] age at eligibility (days) I (*n* = 127): 12.4 [10.5] C (*n* = 148): 13.7 [9.9] **Group comparability** More than 160 variables were compared to assess the study groups' similarity Only 5/160 showed significant differences, and 6 others suggested important differences to the authors, who note this rate (< 5%) of significant differences in baseline status between the groups is less than would be expected by chance	and maintain a crib at home following discharge Standard care All mothers were trained by nurses to care for their LBW infants including: basic hygiene and immediate notification of staff if infant turned blue or pale or showed rapid breathing or feeding problems **Data collection** *Clinical data* • Nurse-interviewer collected data at clinic visits at 1, 1.5, 2, 3, 4, 5 and 6 months of life on extent of skin-to-skin contact, feeding practices and the infant's condition • Infants weighed and measured (length, upper arm and head circumference) • Those who did not attend clinic were visited at home	*Cumulative frequency of morbidity indices* KMM (*n* = 131) / Controls (*n* = 152) / *p* Serious illness 7 (5%) / 27 (18%) / 0.002 Lower respiratory tract 6 (5%) / 19 (13%) / 0.020 Readmission 4 (4%) / 11 (7%) / 0.130 Signs of alarm 39 (30%) / 61 (40%) / 0.080 Moderate illness 9 (7%) / 10 (7%) / 0.910 Mild illness 84 (64%) / 102 (67%) / 0.310 Diarrhoea 14 (11%) / 25 (16%) / 0.180 The difference in the cumulative incidence of severe illness (less in the KMM group than in the control group) was highly significant from month 2 onwards After control for pre-eligibility differences in severe morbidity (not specified in the paper) the significance of this association was p < 0.007 and recruitment to the trial was halted		1612 [323] 660–1985 For the 321 eligible babies it was: 1618 [317] 660–1995 Mothers of 21 eligible babies did not consent to take part in the study KMM mothers and siblings were seen more often in clinics. Cost–benefit aspects of this are discussed in the paper **Funding:** United States Agency for International Development Contract DPE 5966 Z 00 8083 00 and John Snow Inc

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
			Cost data Equipment (incubators, heated cribs) and drugs and supplies by duration of use, professional carers' time (number of episodes of care by doctors/nurses and the product of number and duration of instruction in child care), other daily costs of postnatal clinic visits (including transport) or hospital admission (number of visits or duration of stay, retrospectively)	**Process outcomes** *Skin-to-skin contact (KMM group only)* Most infants for whom this information was available (68% at 1 months, falling to 7% at 3 months) were held against the breasts until 3 months **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** *Duration of hospital stay* KMM infants were 1.5 days younger at eligibility and 0.5 days older at discharge than control infants, so their length of hospital stay, from the point of eligibility, was 2.0 days greater than control infants ($p < 0.05$). However, more control than KMM infants were in incubators after eligibility and the cost of posteligibility, pre-discharge hospital stay was 475,000 sucres (~US$340) higher in the control group Postneonatal care for controls was 561,000 sucres (~US$401) greater for the control than KMM group at 5 months		

I, intervention group (Kangaroo mother method, KMM); C, control group (standard incubator care).

TABLE 34 *Whitelaw 1988*[147]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Whitelaw 1998, UK (London) **Research aim** Does early skin-to-skin contact (SSC) for very low birthweight infants influence mothers' confidence, infant behaviour and prolong lactation? **Study design** Randomised controlled trial **Method of group allocation** Numbered and sealed opaque envelopes previously prepared in balanced blocks of six. Eligible second twins were allocated to same group as first twin **Unit of allocation** Infant **Unit of analysis** Infant Mothers for breastfeeding outcomes	**Selection** All eligible infants in Hammersmith Hospital born between August 1985 and February 1987 **Inclusion criteria** *Infants* Very low birthweight of less than 1500 g Stable breathing with no oxygen equipment At least one parent fluent in English Stable infants with congenital abnormalities such as hydronephrosis or scoliosis, intracranial lesions such as periventricular leukomalacia or ventricular dilatation **Exclusion criteria** *Infants* None	*Infants* SSC ($n = 35$); C ($n = 36$) Mean birthweight (g) [SD] 1152 [220]; 1135 [263] Mean gestational age (weeks) [SD] 29.1 [2.3]; 29.5 [2.3] Mean age of infant at trial entry (days) (range) 16 (1–61); 16 (1–66) Mean Apgar score at 1 minute 5.6; 5.5 Singleton 26 (74%); 27 (75%) Female 14 (40%); 22 (61%) *Mothers* SSC (n=31); C (n=32) Caesarean 23; 23 White 26; 24	**I: $n = 35$** Skin-to-skin contact (SSC) A nurse explained SSC to mother, with photographs if required, as a safe and enjoyable way to hold and get to know her baby. The mother was helped to position her baby inside her clothing between her breasts. Infants had a cardiac or respiration monitor attached and wore a nappy. Smallest infants also wore a hat. After two occasions, mother encouraged to hold her infant in SSC when she visited and after discharge **C: $n = 36$** Normal handling Mother had same amount of support and encouraged to visit when she liked to take her infant(s) out of the incubator. Mother and infant remained clothed **Both groups** If an infant became unwell, the trial was discontinued until infant was stable	**Statistical techniques** Student's t test for data with a Gaussian distribution, Mann–Whitney U test and chi-squared test for data with a non-Gaussian distribution **Breastfeeding/breastmilk-related outcomes** Mothers *SSC ($n = 31$)* | *C ($n = 32$)* | *p* *Mean (median) duration of lactation (weeks)* 9.2 (7) | 5.1 (3.5) | 0.0167 *Lactated more than 6 weeks* 17 (55%) | 9 (28%) | < 0.02 **Clinical/health outcomes** Not reported **Process outcomes** Infants SSC ($n = 35$) | C ($n = 36$) Mean hours visiting/day [SD] (range) 2.1 [0.8] (0.7–3.9) | 2.2 [0.9] (0.7–11.0) Median hours left in incubator while mother visited (range) 0.1 (0–2.0) | 0.1 (0–5.9) Mean hours touched or cuddled with clothes on [SD] (range) 1.4 [0.7] (0.2–3.4) | 1.8 [1.0] (0.5–5.2) *Median hours SSC (range)*: 0.6 (0–1.5) Median days spent in study hospital (range) 30 (5–83) | 37 (5–78) **Psychosocial outcomes** No significant differences between the groups of mothers was found on any of the six-point scales at discharge or at 6 months	Data are reported for all 71 infants (SSC = 35; C = 36) and 63 mothers (SSC = 31; C = 32) recruited Five mothers in SSC group (3 Asian, 2 white) declined SSC; their data were analysed according to allocated group Six infants per group left the trial temporarily due to apnoeas, necrotising enterocolitis or sepsis Two infants per group died between study entry and reaching 6 months of age (2 septicaemia, 1 necrotising enterocolitis, 1 sudden infant death)	Data were analysed using intention-to-treat model Researchers had previously found 32–33% mothers of very low birthweight infants still lactating at 6 weeks Mothers' views not reported by group

<table>
<tr><th>Study details</th><th>Participant selection and inclusion/ exclusion criteria</th><th>Baseline characteristics of participants</th><th>Intervention details</th><th>Results</th><th>Withdrawals</th><th>Additional comments</th></tr>
<tr>
<td>Sample size calculation
36 infants per group for an 80% chance of detecting a doubling of the rate of mothers of very low birthweight infants still lactating at 6 weeks to 65% at $p < 0.05$

Outcome measures
Duration of breastfeeding
Frequency and duration of SSC
Mothers' attitudes towards infants
Infants' behaviour at discharge and 6 months</td>
<td></td>
<td>Afro-Caribbean
4; 4
Unsupported
2; 2
Intended to breastfeed
24; 26

Group comparability
No significant differences between the groups were found in infant or maternal characteristics</td>
<td>Mothers
SSC (n = 31); C (n = 32)
Caesarean
23; 23
Primiparous
21; 19
White
26; 24
Asian
5; 8

Data collection
Mothers given a questionnaire at discharge to rate themselves on a six-point scale for confidence looking after, knowing, feeling optimistic or depressed about, detached from and supported in looking after, their infant(s). A similar questionnaire was given to mothers at 6 months of corrected age. Historical data on lactation from the mother at discharge or at 6 months. At 6 months, parents asked to keep a 48-hour diary of infant's behaviour. Home visit conducted if necessary. The questionnaires and diary were piloted</td>
<td>Infant behaviour at 6 months of age
Infants
<table>
<tr><td>SSC (n = 35)</td><td>C (n = 36)</td><td>p</td></tr>
<tr><td colspan="3">Mean hours sleeping/day [SD]</td></tr>
<tr><td>13.6 [2.3]</td><td>13.4 [2.3]</td><td>NS</td></tr>
<tr><td colspan="3">Mean hours feeding/day [SD]</td></tr>
<tr><td>2.5 [1.1]</td><td>2.5 [0.9]</td><td>NS</td></tr>
<tr><td colspan="3">Mean hours being held/day [SD]</td></tr>
<tr><td>3.0 [1.3]</td><td>3.0 [1.4]</td><td>NS</td></tr>
<tr><td colspan="3">Mean hours playing/day [SD]</td></tr>
<tr><td>4.5 [1.8]</td><td>4.5 [1.8]</td><td>NS</td></tr>
<tr><td colspan="3">Median minutes crying/day (range)</td></tr>
<tr><td>25 (0–100)</td><td>38 (5–140)</td><td>0.0422</td></tr>
</table>
Cost-effectiveness outcomes
Not reported</td>
<td></td>
<td></td>
</tr>
<tr><td colspan="7">I, intervention group, skin-to-skin care(SSC); C, control group, normal handling.</td></tr>
</table>

TABLE 35 *Wilhelm 2005*[150]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Wilhelm 2005 USA **Research aim** What are the effects of early kangaroo care (EKC) on breast skin temperatures, distress and breastmilk production in mothers of premature infants? **Study design** Repeated measures, crossover study **Method of group allocation** Assigned on postpartum day 4 using a coin toss procedure for the first participant in the study. Subsequent mothers assigned to alternate groups to achieve equal numbers **Unit of allocation** Mother **Unit of analysis** Mother	**Selection** Mothers who gave birth to infants < 33 weeks' gestation and/ or < 2000 g, who were admitted to level III NICUs in three major medical centres in a US Midwest city **Inclusion criteria:** *Mothers* Expressing breastmilk Intending to breastfeed for at least 3 months Interested in participating in KC Non-smokers No breast surgery Able to speak and read English *Infants* 5-minute Apgar score of 6 or more Not expected to be ready to feed from the breast during the study period (first week of life) Early intensive care completed before postpartum day 4 Intravenous or gavage feeding 2–3 hourly Stable body temperature and vital signs for 48 hours	Reported for mothers included in the analyses *Mothers (n = 25)* Mean age in years [SD] (range) 28.76 [5.24] (19–42) *Race n (%)* • White: 22 (88) • African-American: 1 (4) • Asian: 1 (4) • Hispanic: 1(4) Mean gravida (sic) [SD] (range) 1.84 [1.32] (1–6) *Caesarean section n (%)* 17/25 (68) *Married n (%)* 19/25 (76%) *Private insurance n (%)* 18/25 (72%) *Income < $10,000/ year n (%)* 3/25 (12) *Infants (n = 25)* Mean birthweight (g) [SD] (range) 1652 [300] (820–2110)	**Intervention: Early kangaroo care (EKC)** Skin-to-skin, chest-to-chest placement of the infant between the mother's breasts beneath her clothing. The mother sat in a comfortable chair and covered herself and her infant with a blanket. Mothers spent 1 hour (9–10 am) in EKC, only on the day(s) allocated *Group ABB: n = 11* *Day 4 postpartum* Mothers participated in EKC with their infant *Days 5 and 6 postpartum* Mothers did not participate in EKC. They were allowed to visit their infant at the cotside *Group BAA: n = 14* *Day 4 postpartum* Mothers did not participate in EKC. They were allowed to visit their infant at the cotside	**Statistical techniques** Repeated measures of variance (RM-ANOVA) for a three-period, two-treatment, two-sequence crossover design. The significance of carryover effects was tested **Breastfeeding/breastmilk-related outcomes** *Mean breastmilk production days 4–6 by group (ml) [SD]* Day 4: ABB (n = 9) 428.89 [325.46]; BAA (n = 13) 382.23 [293.64] Day 5: ABB (n = 9) 557.00 [348.36]; BAA (n = 13) 465.46 [324.73] Day 6: ABB (n = 9) 674.89 [417.97]; BAA (n = 13) 474.00 [322.35] Author states that participation in EKC resulted in a decrease of 49.78 ml in milk production compared with non-participation ($p < 0.05$, two-tailed test) **Clinical/health outcomes** *Mean breast skin temperature from 0900 to 1000 by group (°C) [SD]* Day 4: ABB (n = 10) 36.37 [0.34] EKC; BAA n = (13) 4 35.34 [0.59] Day 5: ABB (n = 10) 35.94 [0.53]; BAA n = (13) 35.86 [0.50] EKC Day 6: ABB (n = 10) 35.82 [0.68]; BAA n = (13) 35.77 [0.60] EKC Author states that participation in EKC resulted in an increase of 0.46°C over non-participation ($p < 0.0001$, two-tailed test)	Four of the 29 enrolled mothers had incomplete data for all three study outcomes and were excluded from analyses. No differences were found in maternal demographics between the excluded and included mothers. The infants of the excluded mothers weighed less at birth ($p < 0.02$) and were born at earlier GA (29.5 vs 31.5 weeks, $p > 0.007$) (p value as reported in paper)	Standard care was said to differ between units One unit introduced KC as standard care and this was a factor in the decision to end recruitment to this study Author describes the numerous confounding variables in breastmilk production that may have contributed to the finding that participation in EKC resulted in a decrease of breastmilk production Author states that values of cortisol for mothers of premature infants were not known Abnormal fluctuations in cortisol may have been obtained during her study days

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation Based on Hurst (1997)[a], estimated sample size of 30 **Outcome measures** Breastmilk production Breast skin temperature Change in salivary cortisol Mothers' experiences	**Exclusion criteria** Known thyroid or other endocrine disorder Hormonal fertility treatment or steroid medications/inhalers in third trimester Could not participate on all three days of the study Mothers of infants were unable to participate in KC during that part of the study period they were allocated to KC	Mean gestational age (weeks) [SD] (range) 31.52 [0.92] (30–33) *Weight for gestational age n (%)* • small 2 (8) • appropriate 21 (84) • large 2 (8) **Group comparability** No statistically significant differences between the ABB and BAA groups were found	*Days 5 and 6 postpartum* Mothers participated in EKC with their infant Study protocol and data collection *Days 1–3* 1. Consent 2. NICU staff taught mothers double pumping and informed them about milk storage and transport 3. Mothers demonstrated pumping, collecting and measuring milk to the PI. Mothers were encouraged to pump 8 times per day 4. PI taught mothers use of the Breastmilk Production Log Book and requested entries be verified by a nurse	Mean salivary cortisol change between 0830 and 1030 by group (units not reported) Day 4: ABB ($n = 11$) −2.91 [7.11] EKC; BAA $n = (14)$ 0.28 [5.06] Day 5: ABB −3.11 [4.92]; BAA −3.83 [4.61] EKC Day 6: ABB −5.21 [4.40]; BAA −2.73 [5.36] EKC Author states that there was no statistically significant change in cortisol between the two groups **Process outcomes** Not reported **Psychosocial outcomes** *Mothers' experiences (n = 18/29)* *Did I really have a baby?* Premature delivery, very brief sight of baby in the delivery room, their own physical recovery from CS, caused some to question whether they even had a baby *EKC experience* Mothers who had not held their infants before KC were apprehensive. Once in KC mothers enjoyed KC and some felt it stimulated their milk supply *Sensory stimulation* Before KC mothers were eager to hold their infants despite their fears. Once in KC mothers could hear their infant's heartbeat and breath sounds and some mothers said they knew their baby could hear and smell them		

continued

TABLE 35 *Wilhelm 2005[148] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
			5. Mothers obtained a pump of the same type as the hospital pump (Medina Latina) for use at home *Day 4* Mothers assigned to study groups *Days 4–6* 1. Mothers were asked to use the pump before arriving in NICU for 0830 2. At 0830 each mother had a thermister probe placed on each breast approximately halfway between the chest wall and rim of the areola in a midclavicular line. Both thermister probes were connected to the MINI-LOGGER™ to record data 0830–1030 (probes removed at 1030)	*Intimacy* Before KC many mothers did not feel connected to their infants. KC provided some 'heart-to-heart' privacy and intimacy *Role recognition* Initially mothers were unsure of their role within NICU, not knowing what to say or do or even where to stand. Early KC helped many find their niche in NICU *Reality of motherhood* KC helped mothers to recognise they indeed had a baby, and that the baby was theirs and did not belong to the nurses **Cost-effectiveness outcomes** Not reported		

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
			3. At 0830 and again at 1030 each mother provided a saliva sample for assay using a salivette[b] 4. Participants were reminded to use the pump *Day 7* Mothers were asked to page the PI on arrival at NICU to provide breastmilk log data for day 6 postpartum *Day 6,7, 8 or 9* Interviews The blanket was weighed before and after EKC if necessary to ensure any breastmilk leakage was accounted for as part of the following pumping session Interviews with mothers on their experiences using a preliminary conceptual six-staged map			

EKC, early kangaroo care (defined above); Group AAB received EKC on postpartum day 4 only; Group BAA received EKC on postpartum days 5 and 6 only.
a Hurst NM, Valentine CJ, Renfro L, Burns P, Ferlic L. Skin-to-skin holding in the neonatal intensive care unit influences maternal milk volume. *J Perinatol* 1997;**17**:213–7.
b The authors state (p. 56): 'the salivette is specifically designed for saliva sampling and consists of a sterilised cotton swab, a small beaker and a plastic tube. To collect the saliva, the participant chewed on the swab and left it in her mouth for 30–60 seconds and then placed it in the small beaker. The saliva was subsequently removed from the salivette and assayed using an enzyme immunoassay (EIA) approach using microtiter plates and serial dilutions and a set of quality controls in duplicate.'

TABLE 36 *Hurst 1997*[139]

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Hurst 1997 USA (Houston, Texas) **Research aim** To evaluate the effect of early skin-to-skin (STS) holding on lactation and duration of breastfeeding **Study design** Before/after (cross-sectional) **Method of group allocation** By date **Unit of allocation** Mother **Unit of analysis** Mother Group **Sample size calculation** Not reported **Outcome measures** Milk volumes Duration of breastfeeding	**Selection** Mothers of ventilated low birthweight infants in the NICU of Texas Children's Hospital, Houston **Inclusion criteria:** A: All mothers participating in STS holding between its introduction to the study NICU on 1 July 1993 and 30 September 1993 B: Mothers in the control group were taken from the 12-month period (June 1992–June 1993) before STS holding was introduced, and partially matched with the STS mothers for age, parity, twin birth, delivery type, infant birthweight, gestational age and severity of illness **Exclusion criteria** A: Mothers who did not begin STS holding during the 4 weeks after the birth B: Mothers of infants who began breastfeeding during the 4 weeks after the birth were excluded from the analysis	Reported for mothers included in the analyses *A (n = 8); B (n = 15)* *Mothers* Mean ± SD age (years) 30 ± 5.7; 28 ± 6.3 Primiparas/multiparas 4/4; 7/8 Vaginal/Caesarean birth 3/5; 4/11 Previous breastfeeding experience 3; 2 Number of milk expressions per 24 hours 6; 6 Twin birth, socioeconomic status Not reported *Infants* Mean ± SD birthweight (g) 1129 ± 205; 1055 ± 264 Mean ± SD gestational age (weeks) 27.7 ± 1.1; 27.5 ± 1.9 Severity of illness A: STS was initiated whilst infants still receiving nasal continuous positive airway pressure B: not reported	**A: *n* = 16** STS holding began when the attending neonatologist deemed the infant physiologically stable Mothers were instructed to hold their infants once a day for at least 30 minutes Details of how mothers held their infants STS are not provided in the paper During STS contact, oxygen saturation, skin temperature and frequency/duration of apnoea/ bradycardia were measured **B: *n* = 16** No STS holding **Both groups** Lactation consultant contacted mothers 24–48 hours following birth to determine feeding plans Mothers planning to breastfeed were given instructions on pumping (to use a mechanical breast pump with double pumping attachment for approximately 15 minutes every 3 hours, starting within 48 hours of the birth), milk collection and storage	**Statistical techniques** Repeated ANOVA adjusting for baseline volumes (1 week after delivery) to evaluate the difference in milk volumes between the groups **Breastfeeding/breastmilk-related outcomes** *24-hour milk volumes (mean ± SD)* A (STS): *n* = 8; B (before STS): *n* = 15 Week 1: 499 ± 139; 218 ± 132 Week 2: 574 ± 211; 462 ± 222 Week 3: 690 ± 357; 485 ± 349 Week 4: 851 ± 259; 421 ± 315 The pattern of milk volumes from weeks 2 to 4 differed significantly between groups (group × time interaction $p = 0.0110$) At 4 weeks after the birth the adjusted mean 24-hour milk volume was: A (STS): 647 ml; B (before STS): 530 ml *Breastfeeding outcomes* A (STS): *n* = 8; B (before STS): *n* = 15 Exclusive breastfeeding 3 (37%); 1 (6%) Breast + formula feeding after discharge 2 (25%); 8 (50%) Quit pumping before discharge A: 3/8 (37%) reasons were returning to work (*n* = 2), did not intend to breastfeed (one mother of twins) 6 (37%) reason for all 6 was low milk volumes despite pumping ≥6 times per 24 hours	A: 16 STS mothers were enrolled *Eight did not begin STS holding within 4 weeks of the birth, because of extreme prematurity < 27 weeks (n = 3), sepsis (n = 4) and necrotising enterocolitis (n = 1), and were excluded* Eight were included in the analysis (50%) B: 16 non-STS mothers were initially identified One began breastfeeding during the 4 weeks after the birth and was excluded 15 were included in the analysis (94%)	Available data were analysed by group Funding not reported

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
		Group comparability Not reported	Lactation consultant contacted mothers at least once per week to document number of pumpings per 24 hours, milk volume per pumping, non-pumping interval at night, and any problems with lactation After discharge from NICU, telephone contact continued, at least once during the first week home, then approximately fortnightly until 2 months after discharge or until breastfeeding was discontinued **Data collection** Clinical records	**Clinical/health outcomes** Heart rate, respiratory rate, oxygen saturation and skin temperature measurements were within normal limits for 136/138 STS sessions In 2/138 sessions (1.4%), an infant was noted during their first STS session to have a single desaturation episode, which returned to normal limits without requiring stimulation. Both these STS sessions continued without further incident **Process outcomes** *Infants' age at STS initiation* 8–26 days (median 15 days) *Mean frequency of STS* 4 sessions per week *Mean duration of STS* Initiation week: 30 minutes Second week: 135 minutes **Psychosocial outcomes** Mothers commented favourably about STS **Cost-effectiveness outcomes** Not reported		

A, after intervention group (early STS holding); B, before intervention group (no STS holding).

TABLE 37 *Wahlberg 1992*[135]

<table>
<tr><th>Study details</th><th>Participant selection and inclusion/ exclusion criteria</th><th>Baseline characteristics of participants</th><th>Intervention details</th><th>Results</th><th>Withdrawals</th><th>Additional comments</th></tr>
<tr>
<td>Wahlberg 1992
Sweden (Helsingborg)

Research aim
What were the differences, following introduction of kangaroo care (KC), in premature infants' length of time nursed in an incubator, weight gain, length of hospital stay and rates of breastfeeding at discharge?

Study design
Before/after (cross-sectional), retrospective data analysis

Method of group allocation
By date

Unit of allocation
Infant</td>
<td>Selection
Two convenience samples of eligible infants before and after implementation of KC as routine practice in a Swedish premature care unit (equivalent to US level II nurseries providing care to infants who require monitoring with less intensive technological interventions)
B period: May 1984 to Nov 1985
A period: Nov 1985 to May 1987

Inclusion criteria:
Healthy mother with no infections or other complications
Healthy stable infant aged 1–30 days when first taken out of the incubator (no respiration problems, anomalies or other complications)</td>
<td>Reported for mothers included in the analyses

Mothers
A (n = 33); B (n = 33)
Mean age (years) [SD]
26.5 [5.0]; 27.7 [5.7]
First baby
22 (67%); 20 (61%)
Caesarean
15 (45%); 19 (58%)
Socioeconomic status not reported

Infants
A (n = 33); B (n = 33)
Mean birthweight (g) [SD]
1482 [453]; 1497 [419]
Mean gestational age (weeks) [SD]
31.09 [2.2]; 31.33 [2.5]
Interventions prior to first contact with mother outside incubator</td>
<td>A: n = 33
Kangaroo care (KC) implemented as routine practice
KC began when infants were first taken out of the incubator to be with their mothers. Infants held skin-to-skin with mothers. No other details provided, picture shows infant is unclothed and held in upright position between mother's breasts

B: n = 33
Standard prematurity care (SPC) as routine practice
SPC began when infants were first taken out of the incubator to be with their mothers. Mothers held their babies dressed and with a blanket or heating pad</td>
<td>Statistical techniques
Not reported

Breastfeeding/breastmilk-related outcomes
<table>
<tr><td>A (KC) n = 33</td><td>B (SPC) n = 33</td><td>p</td></tr>
<tr><td colspan="3">Breastfeeding at discharge n (%)</td></tr>
<tr><td>27 (82)</td><td>15 (45)</td><td>0.005</td></tr>
<tr><td colspan="3">Clinical/health outcomes</td></tr>
<tr><td colspan="3">Weight gain per week g [SD]</td></tr>
<tr><td>237.48 [96.4]</td><td>195.5 [82.9]</td><td>< 0.05</td></tr>
<tr><td colspan="3">Process outcomes</td></tr>
<tr><td colspan="3">Days in incubator n [SD]</td></tr>
<tr><td>20.9 [13.9]</td><td>30.5 [15.7]</td><td>< 0.05</td></tr>
<tr><td colspan="3">Days old when first out of incubator n [SD]</td></tr>
<tr><td>4.36 [4.7]</td><td>8.0 [5.9]</td><td>< 0.01</td></tr>
<tr><td colspan="3">Total days in hospital n [SD]</td></tr>
<tr><td>41.6 [16.9]</td><td>49.4 [18.9]</td><td>< 0.05</td></tr>
</table>
Chi-squared for all five results = 7.92 (p = 0.005)

Psychosocial outcomes
Not reported

Cost-effectiveness outcomes
Not reported</td>
<td>Retrospective data analysis for all selected participants</td>
<td>Authors explain their finding that KC-group infants were younger when first removed from the incubator as follows:
standard prematurity care involved a decision about an infant's readiness for removal from the incubator based on physical status, e.g. weight and temperature. With KC group, staff learned infants in the K position were able to maintain body temperature coming to regard the mother as a human incubator.</td>
</tr>
</table>

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of analysis Infant Mother for breastfeeding outcomes **Sample size calculation** Not reported **Outcome measures** Weight gain per week Days in incubator Days old when first out of incubator Total days in hospital Breastfeeding at discharge	**Exclusion criteria** None	Respirator 7 (18%); 7 (22%) Oxygen 26 (70%); 22 (69%) Continuous positive airway pressure 4 (11%); 3 (9%) **Group comparability** Percentages as reported in paper The two groups were matched for maternal age, parity, length of pregnancy, type of delivery, gestational age, birthweight and technological intervention prior to first contact with mother outside the incubator	**Both groups** Mothers were encouraged to hold their infants as much as they desired **Data collection** Hospital records for following variables: • date first taken out of incubator • weight gain per week • days in incubator • length of hospital stay • breastfeeding upon discharge			Infants were therefore taken out of incubators to be with their mothers at an earlier age

A, After intervention group when kangaroo care (KC) implemented as routine practice; B, Before intervention group with standard prematurity care (SPC).

TABLE 38 *Collins 2004*[119]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Collins 2004 Australia **Research aim** To determine the effect of artificial teats (bottle and dummies) and cups on breastfeeding in preterm infants < 34 weeks' gestation at birth **Study design** RCT with four groups *Method of group allocation* Random number table *Unit of allocation* Mother (twins were assigned to the same group) **Unit of analysis** Infant **Sample size calculation** Based on breastfeeding rates of 45% (unpublished hospital data) the authors calculated a sample size of 310 to detect a 16.5% increase in the proportion full	**Selection** Two large tertiary hospitals in Australia, April 1996 to November 1999 **Inclusion criteria** Women with singleton or twin infants < 34 weeks' gestation who wanted to breastfeed Infants requiring transfer to peripheral hospitals were included (54 peripheral hospitals participated) **Exclusion criteria** Infants with congenital abnormalities precluding enteral feeding	Mothers at trial entry *Randomised to cup feeding* No dummy: $n = 75$; dummy: $n = 66$ *Age (years) n (%):* < 25:8 (11); 18(27) 25–34: 47(36); 36(55) > 35: 20(27); 12(18) *Education n (%):* Incomplete high school: 21 (20); 22 (35) Complete high school: 19 (26); 24 (38) Tertiary: 32(44); 17 (27) *Parity n (%):* 1: 34 (45); 40(61) > 1: 41(55); 26(39) *Breastfed before n (%):* Yes: 32/72(44); 20/64(31) No: 40/72(56); 44/64(69) *Randomised to bottle feeding* No dummy: $n = 64$; dummy: $n = 73$ *Age (years) n (%):* < 25: 10 (16); 18 (25) 25–34: 36 (58); 41 (56) > 35: 16 (26); 14 (19)	**All participants** Cup or bottle feeds, when mothers were not available to breastfeed or additional milk was required orally after breastfeeds, commenced at the discretion of the practitioner Infants in dummy group had dummy available on trial entry. A dummy was used during tube feeds and when an infant was restless Infants in no-dummy group were encouraged to use quietening behaviours (hand to mouth actions were facilitated) Recruiting hospitals received education, written instructions, literature and one-to-one support (not specified who gave this) Peripheral hospitals received written instructions, literature and telephone contact (not specified who gave this)	**Statistical techniques** Logistic regression to estimate odds ratios and 95% confidence intervals (CI), Kaplan–Meier curves, Cox's proportional hazards models **Breastfeeding/breastmilk-related outcomes** *Any breastfeeding at discharge home* Dummy: 107/152 (70%) No dummy: 108/151 (72%) OR 0.83 (95% CI: 0.45–1.50) $p = 0.53$, NS Cup: 112/151 (74%) Bottle: 92/151 (61%) OR 1.37(95% CI: 0.78–2.38) $p = 0.27$, NS *Fully breastfeeding at discharge (%)* Dummy: 85/151 (56) No dummy: 79/152 (52) OR 0.84 (95% CI: 0.51–1.39) $p = 0.50$, NS Cup: 92/151 (61%) Bottle: 72/152 (47%) OR 1.73,(95%CI: 1.04–2.88) $p = 0.03$ Cup feeding significantly increased the odds of full breastfeeding at discharge home Number needed to be cupfed for one extra infant to go home fully breastfeeding = 7 (95% CI: 4–41)	278 mothers of 319 infants were randomised 303 infants (94.9%) of 265 mothers (95.3%) were included in the analyses Numbers of infant deaths and withdrawals are reported by group	An intention-to-treat analysis was done Funded by the Mercy Hospital for Women Nurses Research fund, and the first author received a two-year midwifery fellowship from the Women's and Children's Hospital Foundation

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
breastfeeding on discharge ($\alpha = 0.05$, 80% power) between use of dummy and not irrespective of cup or bottle and between cup and bottle irrespective of use of dummy **Outcome measures** Breastfeeding at discharge home Breastfeeding 3 and 6 months following discharge Length of hospital stay In this study, breastfeeding was defined as mother's milk given by direct breastfeeding or other feeding device Full breastfeeding meant no other types of milk or solids were given except vitamins and minerals		*Education n (%):* Incomplete high school: 21 (34); 29(43) Complete high school: 26 (42); 17 (25) Tertiary: 15 (24); 21 (31) *Parity n (%):* 1: 22/62 (35); 36/73 (49) > 1: 40/62 (65); 37/73 (51) *Breastfed before n (%):* Yes: 31/63 (49); 25/68(37) No: 32/63 (51); 43/68 (63) Infants at birth *Randomised to cup feeding* No dummy: $n = 89$; dummy: $n = 72$ *Twins n (%): 28 (31); 12 (17)* Mean [SD] g birthweight (range): 1325 [453] (552–2520); 1344 [488] (609–2560) Gestational age at birth (%): < 28 weeks: 25 (28); 17 (24) > 28 weeks: 64 (72); 55 (76)	Intervention A: Infants to be cup fed (using a small plastic medicine cup) and not given a dummy ($n = 89$) Intervention B: Infants to be cup fed (using a small plastic medicine cup) and given a dummy ($n = 72$) Intervention C: Infants to be bottle fed and not given a dummy ($n = 73$) Intervention D: Infants to be bottle fed and given a dummy ($n = 85$) **Data collection** Not described in the paper	*Any breastfeeding after discharge* *3 months* / *6 months* / *p* Dummy 53/141 (38%) / 34/140 (24%) / NS No dummy 58/142 (41%) / 43/141 (30%) / NS Cup 61/144 (42%) / 44/142 (31%) / NS Bottle 50/139 (36%) / 33/139 (24%) / NS *Median days hospital stay (interquartile range)* Dummy: 50 (33–78) No dummy: 53 (35–74) Hazard ratio 0.98, 95% CI: 0.76–1.26, $p = 0.87$ NS Infants randomised to cup feeding were found to have significantly longer hospital stays than those randomised to bottle feeding Cup: 59 (37–85) Bottle: 48 (33–65) Hazard ratio 0.71, 95% CI: 0.55–0.92, $p = 0.01$ **Clinical/health outcomes** No adverse events were found to be associated with the interventions **Process outcomes** *Non-compliance* 85/161 (52.7%) infants randomised to cup feeding had a bottle introduced 1/158 (0.6%) of infants randomised to bottle feeding had a cup introduced		

continued

TABLE 38 *Collins 2004[119] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
		Mean [SD] (range): 29.2 [2.7] (24–33); 29.5 [2.7] (23–33) *Randomised to bottle feeding* No dummy: $n = 73$; dummy: $n = 85$ Twins *n* (%): 18 (25); 24 (28) Mean [SD] g birthweight (range): 1508 [463] (720–2530); 1382 [469] (500–2580) Gestational age at birth (%): < 28 weeks: 14 (19); 20 (24) > 28 weeks: 59 (81); 65 (76) Mean [SD] (range): 30.3 [2.6] (25–33); 29.6 [2.6], (24–33) **Group comparability** Paper states most maternal and neonatal characteristics were well balanced There were ≥ 10% differences between dummy and no dummy for primiparity and previous breastfeeding, and between cup and bottle for primiparity, and these were adjusted for in the analyses		47/162 (31%) infants randomised to no dummy had a dummy introduced 5/157 (3.2%) infants randomised to dummy did not have a dummy introduced Compliance was higher in the hospital that had used cup feeding before the trial. Most peripheral hospitals had not used cup feeding. Compliance was higher among primiparous, tertiary educated women whose household income was from full-time work from either partner and who were mothers of singleton infants. Authors note non-compliance reduced the power of the study to identify real treatment effects **Psychosocial outcomes** Some staff had strong feelings against cup feeding and the withholding of dummies and some parents did not like cup feeding Reasons for introducing a bottle included infant not managing cup feeds, spilling a lot, not being satisfied, or taking too long to feed Reasons for introducing a dummy included infant unsettled and to teach the infant to suck **Cost-effectiveness outcomes** Not reported		

TABLE 39 *Gilks 2004*[120]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Gilks 2004 UK (Birmingham) **Research aim** To determine which of two methods of feeding, cup or bottle, best prepared a preterm infant for breastfeeding **Study design** RCT (pilot) **Method of group allocation** By selection of concealed cards in envelopes Stratified by gestation (< 31 and > 31 completed weeks) **Unit of allocation** Infant **Unit of analysis** Infant	**Selection** Neonatal Unit Birmingham Heartlands Hospital, Birmingham, UK **Inclusion criteria** < 35 completed weeks' gestation at birth > 30 weeks at time of study entry Infant absorbing full-strength full-volume nasogastric feeds Clinically well for at least 48 hours prior to entry Expected to be in NICU for at least 1 week prior to discharge Mother intended to breastfeed **Exclusion criteria** Infants with congenital abnormalities	*Mothers* Characteristics not reported *Infants* Cup: $n = 27$; bottle: $n = 27$ < 31 weeks: 11; 8 Median weeks' gestation (range): 31 (25–34); 32 (26–34) Median g birthweight (range): 1560 (580–2870); 1750 (944–2980) **Group comparability** No significant differences found between the groups	***I*: $n = 27$** Cup feeding (not described) Paper states cup feeding had been introduced to the unit 6 months before the trial, supported by a teaching programme and information sheet for staff. The trial started after this 'learning curve period' **C: $n = 27$** Bottle feeding (not described) Paper states that on this unit, 'historically, staff had offered bottle feeds of maternal expressed breast milk to babies when their mothers were not present, as a means of progressing from tube to breast feeds.' **Data collection** Exclusive breastfeeding: all feeds in previous 24 hours were breastfeeds	**Statistical techniques** Descriptive statistics, difference of proportions **Breastfeeding/breastmilk-related outcomes** *Breastfeeding at discharge* Cup ($n = 16$); bottle ($n = 24$) Any: 14/16; 12/24 Exclusive: 10/14; 4/12 Failed: 2/16; 4/24 Fed exclusively on breastmilk but not feeding at the breast: 0; 5/24 Exclusive breastfeeding more common in cup-feeding group Difference of proportions = 22%; 95% CI: –1 to 43% *Breastfeeding at term* Cup ($n = 16$); bottle ($n = 24$) Any: 11; 12 Exclusive: 7/11; 8/12 *Breastfeeding 6 weeks post-term* Cup ($n = 16$); bottle ($n = 24$) Any: 5; 6 Exclusive: 4/5; 3/6 **Clinical/health outcomes** Not reported **Process outcomes** *Withdrawals* Cup: 11/27 (41%) Bottle: 3/27 (11%) Difference of proportions 30%, 95% CI: 6–50%	54 infants randomised, 27 to each group 14/54 (26%) withdrew 40 infants included in the analysis (74%) 16 in the cup-feeding group 24 in the bottle-feeding group Data for the outcome breastfeeding at discharge appear to be missing for three infants in the bottle-feeding group	Available data are reported by randomised group Authors note it was difficult to differentiate between withdrawal and breastfeeding failure Authors note the number of mothers who would refuse trial entry was underestimated and suggest further research on recruitment and consent for neonatal trials **Funding:** Not reported

continued

TABLE 39 *Gilks 2004[120] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation If the rate of breastfeeding at discharge among mothers who intended to breastfeed increased from 40% to 60%, 94 babies would be needed in each arm for an 80% (ß = 20%) chance of showing a significant difference at the 5% level ($p < 0.05$) (α = 5%) **Outcome measures** Breastfeeding at discharge, term and 6 weeks post-term			Any breastfeeding: any breastfeed in previous 24 hours Withdrawal: mother said she no longer wished to breastfeed or infant was too ill to breastfeed Breastfeeding failure: cessation of breastfeeding in a mother who said she still wished to breastfeed	*Post-conceptional age at withdrawal of nasogastric tube* Cup: 250 days (35 weeks 5 days) Bottle: 251 days (35 weeks 6 days) **Psychosocial outcomes** *Reasons for withdrawal* Mother no longer wanted to breastfeed (8 cup, 3 bottle) Infant ill (2 cup, 1 bottle) Mother on medication contraindicating breastfeeding (1 cup) *Most common reasons for stopping breastfeeding* • between discharge and term: lack of milk • during 6 weeks post-term: lack of milk, poor or difficult attachment, return to work **Cost-effectiveness outcomes** Not reported		

I, intervention group (cup feeding); C, control group (bottle feeding).

DOI: 10.3310/hta13400

TABLE 40 *Kliethermes 1999*[130]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Kliethermes 1999 USA (Kansas) **Research aim** To compare NGT supplementation with bottle feeding as methods for transitioning preterm infants to breastfeeding **Study design** Randomised controlled trial **Method of group allocation** Sealed envelopes physically mixed and drawn in random sequence **Unit of allocation** Infant **Unit of analysis** Group **Sample size calculation** Not reported	**Selection** Preterm infants in the level III, 40-bed ICN of a private regional perinatal centre were enrolled over a 22-month period **Inclusion criteria** *Infants* Birthweight 1–2.5 kg < 1-week-old *Mothers* Providing own breastmilk **Exclusion criteria** Congenital and neurological abnormalities that interfered with cardiopulmonary status	**Participants** Bottle ($n = 46$) / NGT ($n = 38$) / p *Mothers: mean (range) age in years* 25 (16–42) / 30 (18–44) / 0.003 Single mothers 7 (15%) / 7 (18%) / NS Wage earners 36 (80%) / 34 (89%) / 0.02 Mean parity (range) 1.7 (1–4) / 2.3 (1–5) / 0.003 Previous breastfeeding experience 12 (27%) / 20 (56%) / 0.01 Unsuccessful breastfeeding 2 (4.4%) / 5 (14.3%) / NS *Infants: mean birthweight (range) kg* 1.64 (1.00–2.35) / 1.73 (1.05–2.43) / NS Mean weeks' gestational age (range) 32 (28–35) / 32 (26–35) / NS Small for gestational age 10 (22%) / 1 (3%) / 0.03 Twin births 16 (35%) / 8 (21%) / NS	**Bottle group: $n = 52$** Once oral feeds prescribed, if mother not available for breastfeeding or if additional supplemental feeds required, infant to receive oral feedings by bottle NGT removed at clinical discretion. If supplements necessary after removal of NGT, they were given via bottle **NGT group: $n = 47$** Once oral feeds prescribed, if mother not available for breastfeeding or if additional supplemental feeds required, infant to receive feedings via indwelling 3.5-French NGT NGT removed at rooming-in. If supplements necessary after removal of NGT, they were given via cup or syringe **Both groups** All mothers received standardised breastfeeding education provided by two registered nurse/certified lactation consultants (CLC), including method and frequency of expressing milk;	**Statistical techniques** Ordinal logistic regression models for breastfeeding status Breastfeeding/breastmilk-related outcomes Mean (range) days old at first breastfeed was 11 (1–40) in the bottle group and 16 (9–77) in the NGT group (not statistically significant) The NGT group had higher rates of breastfeeding at all time points studied (not reported numerically in the paper) Using the ordinal logistic regression model, the method of supplementation (NGT vs bottle) was predictive of continued breastfeeding at discharge ($p = 0.0001$), 3 days ($p = 0.0001$), 3 months ($p = 0.0006$) and 6 months after discharge ($p = 0.0016$) **Clinical/health outcomes** *Apnoea/bradycardia incidents* Bottle group: mean 136 NGT group: mean 127, $p = 0.0006$ *Apnoea/bradycardia incidents requiring stimulation* Bottle group: M 32.7 NGT group: M 23.3, $p = 0.0001$	99 infants were enrolled (52 to the bottle group and 47 to the NGT group) A total of 15 (15.15%) were excluded Reasons for the 6 exclusions from the bottle group were: • 2 neonatal complications that interfered with breastfeeding (necrotising enterocolitis, $n = 1$; subglottic stenosis, $n = 1$) • 1 transfer to another institution • 2 protocol violations (NGT reinserted because of poor tolerance of bottle feeding)	Available data were analysed by randomised group Paper states 'to avoid artificial deflation of the standard errors because of the presence of twins, all major results of this study were confirmed with a parallel analysis in which one twin in each pair was selected at random and excluded' **Funding** Medela, Inc., McHenry, Ill., donated electric breast pumps for all study mothers Neotube, Mullin Medical, Tustin, CA, donated the NGTs used in this study

continued

TABLE 40 *Kliethermes 1999[128] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Breastfeeding status **Complications** Length of stay Days using NGT		**Group comparability** There were significant differences between the groups. These were controlled for as appropriate in the logistic regression models	transport and storage of milk; breast care; maternal dietary and fluid intake; and instructions on how to use electric pump All mothers received an electric breast pump with double pumping capabilities Lactation consultants contacted mothers biweekly All infants were given comparable intensive care until oral feeds prescribed Mothers roomed-in with their infants 24–48 hours before discharge to establish full breastfeeding and demonstrate appropriate weight gain **Data collection** Clinical records and phone calls to mothers by lactation consultants at 3 days, 3 and 6 months after discharge	**Process outcomes** Mean length of stay was similar between the groups (34.6 vs 33 days, $p = 0.68$) NGT group infants had a NGT for an average of 7 days longer than bottle group infants (M 29.2 vs 21.7 days, $p = 0.036$) **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported	• 1 positive maternal drug screening for cocaine Reasons for the 9 exclusions from the NGT group were: • 1 infant death • 1 infant with chronic lung disease • 1 infant with delayed diagnosis of congenital heart defect • 1 transfer to another institution • 3 protocol violations (NGT removed and infant received multiple bottle feeds) • 1 positive maternal drug screening for cocaine • 1 severe maternal scleroderma	

NGT, nasogastric tube.

DOI: 10.3310/hta13400

TABLE 41 *Mosley 2001*[124]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Mosley 2001 UK **Research aim** To compare the impact of two methods of supplementary feeding of preterm infants (bottle vs cup) on subsequent breastfeeding **Study design** Pilot RCT **Method of group allocation** Group allocations taken from opaque, sealed, shuffled, sequentially numbered envelopes **Unit of allocation** Infant **Unit of analysis** Infant **Sample size calculation** Assuming a total population of preterm babies needing supplementary feeding of 4000, a confidence level of 90%, a maximum acceptable error of 17% and an estimated percentage level of an answer as 80/20, a sample size of 15 **Outcome measures** Breastfeeding at discharge	**Selection** Preterm infants being cared for in SCBU of a District General Hospital in the UK during a 3-month period **Inclusion criteria** Born at 30–37 weeks' gestation Mothers expressed desire to breastfeed **Exclusion criteria** Congenital abnormality No maternal preference for cup or bottle as the method of supplementary feeding No supplementary feed via bottle or cup prior to admission	*Mothers* Primparas Cup: 3/8 (37.5%) Bottle: 5/8 (62.5%) Spontaneous vaginal delivery Cup: 5/8 (62.5%) Bottle: 4/8 (50%) Assisted delivery Cup: 3/8 (37.5%) Bottle: 4/8 (50%) Age, socioeconomic status, breastfeeding experience, multiple births Not reported *Infants* Mean weeks gestational age Cup: 35.2 Bottle: 35.5 Gestational age < 35 weeks Cup: 3/8 (37.5%) Bottle: 2/8 (25%) Birthweight Not reported **Group comparability** Not reported	**All participants** When the infant was considered able to progress from gastric feeding, the supplementary feed was given by bottle or cup, as allocated **I: *n* = 8** Supplementary feeds given by cup **C: *n* = 8** Supplementary feeds given by bottle **Data collection** Staff were asked to continue to fill in the feed chart after each feed, as normal, to record the type and amount of milk taken at each feed and the frequency of feeds Mothers completed a visual analogue scale about their perceptions of breastfeeding support received from staff	**Statistical techniques** Fisher exact probability test **Breastfeeding/ breastmilk-related outcomes** *Exclusive breastfeeding at discharge* Cup: 4/6 Bottle: 6/8 Not statistically significant **Clinical/health outcomes, process outcomes** Not reported by randomised group **Psychosocial outcomes** The sample was redivided into two groups according to whether the support mothers perceived they had received was higher or lower than the group mean Successful breastfeeding was not found to be related to perceived level of support in this sample **Cost-effectiveness outcomes** Not reported	Mothers of 16 eligible infants consented to take part in the study, and characteristics of 16 infants are reported, 8 in each group 2 infants were excluded because they were given supplementary feeds (not clear when) Results reported for 14 infants (Cup group 6, Bottle group 8)	ITT unclear Normal hospital protocol in the study unit did not include clinical guidelines for initiation of oral feeding or implementation of supplementary feeding Authors emphasise that because of the small-scale nature of their work, the data must be treated with extreme caution Funding not reported

I, intervention group, supplementary feeds given by cup; C, control group, supplementary feeds given by bottle.

TABLE 42 *Rocha 2002*[122]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Rocha 2002 Brazil (São Paulo) **Research aim** To examine the impact of cup feeding, compared with bottle feeding, on subsequent breastfeeding in premature infants **Study design** Randomised controlled trial **Method of group allocation** Stratified by weight and randomly assigned by drawing lots **Unit of allocation** Infant **Unit of analysis** Group and individual	**Selection** Infants born at 32–36 weeks' gestation weighing < 1700 g who were admitted to the NICU of the University Hospital of the Faculty of Medicine of Ribeirão Preto at the University of São Paulo, Brazil, between August 1998 and February 2000 **Inclusion criteria** Infant whose mother wished to breastfeed, without any condition that would prevent breastfeeding Singleton infant Clinically stable Did not require intensive care Receiving a feeding quota of 150 ml/kg/day via a gastric tube **Exclusion criteria** Infant initially received parenteral nutrition Infant developed disease that prevented feeding for > 3 consecutive days Infant with major malformation or severe neurological problem	Reported for the 78 participants included in the analyses *Cup (n = 44); bottle (n = 34)* *Mothers* Mean ± SD maternal age (years): 24.8 ± 6.9; 25.8 ± 6.3 Incomplete primary schooling: 30 (68.1%); 21 (61.7%) Annual income between US$780 and US$3000: 34 (77.3%); 24 (69.7%) Primiparas: 20 (45.5%); 11 (32.4%) Breastfed other children: 16 (36.3%); 16 (47.1%) *Infants* Gestational age at birth, weeks, mean ± SD: 32.7 ± 1.8; 32.5 ± 2.0 Postconceptional age at initiation of oral feeds, in weeks, mean ± SD: 37.0 ± 1.6; 37.2 ± 2.2 Birthweight (g) mean ± SD: 1276 ± 283; 1262 ± 270	All mothers were provided with instruction and support in milk expression All infants were fed by orogastric tube until they reached 1600 g, when oral feeds commenced Breastfeeding was encouraged and prioritised; when the infant was not breastfed, the appropriate volume was offered via the assigned method Infants' supplements were mother's expressed milk, or if this was insufficient, premature infant formula At discharge, it was suggested to mothers that they use the allocated method if supplementing up to the first clinic visit	**Statistical techniques** Fisher exact test, Student's *t* test, non-parametric Wilcoxon test **Breastfeeding/breastmilk-related outcomes** Cup (*n* = 44); bottle (*n* = 34) *Any breastfeeding at discharge* 36 (81.8%); 27 (79.4%) *Any breastfeeding at 5–15 days follow-up* 19 (43.2%); 15 (44.1%) *Any breastfeeding third month after discharge* 13 (29.5%); 5 (14.7%) Cup (*n* = 19); bottle (*n* = 15) *Maintaining breastfeeding third month after discharge* 13 (68.4%); 5 (33.3%); $p = 0.04$ **Clinical/health outcomes** O_2 saturations *Oxygen saturations 1 week after commencing oral feeding* Oxygen saturation (%) before feeding, mean ± SD (range): Cup: 97.1 ± 1.7 (92–100) Bottle: 97.4 ± 1.8 (93–100) Lowest oxygen saturation (%) during feeding, mean ± SD (range): Cup: 90.8 ± 4.8 (75–99) Bottle: 87.7 ± 7.6 (68–97)	83 infants were randomised (46 to cup feeding and 37 to bottle feeding) A total of 5 (6%) were excluded Reasons for exclusion of 2 infants from the cup-feeding group were: • 1 infant with complications of bronchopulmonary dysplasia • 1 break of the protocol Reasons for exclusion of 3 infants from the bottle feeding group were: • 1 gastro-oesophageal reflux • 1 severe bronchopulmonary dysplasia • 1 mother's use of cocaine	Data were not analysed using intention-to-treat model Before the study, the entire nursing team was trained in the proper cup-feeding technique as part of a pilot project The cup used was the protective cap of the bottle. This cup was easy to sterilise and reuse, inexpensive and readily available Milk was offered by trained personnel who took care to avoid spillage; however, spillage was not measured **Funding** Not reported

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation Not reported **Outcome measures** Breastfeeding rates Oxygen saturations Infant weight gain	Mother did not wish to continue providing pumped milk Parent did not follow the randomly assigned regimen	Small for gestational age: 22 (50%); 17 (50%) Males: 22 (54.5%); 10 (35.3%) **Group comparability** No significant differences were found between the groups for maternal or infant characteristics	**I: *n* = 46** Infants were fed orally by cup Infant held slightly inclined; cup touching lower lip; infant allowed to lick or sip milk from the cup; milk not to be poured into the infant's mouth Non-nutritive sucking was provided by offering the little finger instead of a nipple or pacifier **C: *n* = 37** Infants were fed orally by bottle **Data collection** Infant data verified by researchers during daily visits to the ward and at clinic visits 5–15 days and 1, 2 and 3 months post-discharge Maternal data by interview and semistructured questionnaires	Number of infants with saturation < 90% during feeding: Cup: 18 (40.9%) vs bottle 19 (55.9%) Number of infants with saturation < 85% during feeding: Cup: 6 (13.6%) vs bottle 12 (35.3%), $p = 0.02$ Oxygen saturation (%) after feeding, mean ± SD (range): Cup: 96.2 ± 2.5 (91–100) Bottle: 96.3 ± 2.4 (89–100) No differences seen in mean values of lowest saturation levels or in proportion below 90% between the groups. When values of ≤85% were used as the cut-off point, the bottle group had significantly more desaturation episodes than the cup group ($p = 0.02$) Weight gain in first week *Weight gain (g/kg/day) mean ± SD (range), one week after commencing oral feeding* Cup: 14.1 ± 6.1 (0.9–25.3) Bottle: 14.7 ± 5.6 (3.0–28.2) Not statistically significant **Process outcomes** *Feeding time (minutes) mean ± SD (range)* Cup: 11.8 ± 4.5 (5–25) Bottle: 13.4 ± 4.8 (6–25) Not statistically significant **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported		

I, intervention group, cup-feeding; C, control group, bottle feeding.

TABLE 43 *Meier 2000*[136]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Meier 2000 USA (Chicago) **Research aim** Did introduction of nipple shields, by advanced nurse practitioners working to research-based protocols, increase volume of milk consumed by premature infants during breastfeeding? **Study design** Non-randomised crossover study with retrospective analysis of data **Method of group allocation** Before/ after **Unit of allocation** Infant/ mother pair	**Selection** Preterm infants hospitalised in two large teaching hospitals during a 12-month period 1997–8 **Inclusion criteria** Data from 34 infants and their mothers who participated and were randomised to the intervention group in either of two clinical trials of breastfeeding interventions for preterm infants The author provided extra information confirming that of all infants in the two studies that contributed data, only and all the 34 infants whose data were included in this analysis (Meier 2000) used nipple shields	*Mothers* Maternal characteristics not reported *Infants (n = 34)* Mean weeks [SD] gestational age at birth (range): 31.9 [3.0] (25–37) Birthweight g [SD] (range): 1702 [521] (770–2820) Small for gestational age: 6/34 (17.6%) Multiple gestation: 14/34 (41.2%) Ethnicity: • white, non-Hispanic: 24/34 (70.6%) • African American: 7/34 (20.6%) • Hispanic: 1/34 (2.9%) • Other: 2/34 (5.9%) Weight g [SD] at first breastfeeding (range): 1782 [403] (1080–2820)	**B: *n* = 34** The feed immediately before use of nipple shields A: (the same 34 infants acted as their own controls) The first feed using nipple shields **Intervention** Small, ultra-thin, silicone nipple shields Both trials that contributed data to this retrospective study used the same research-based study protocols Under these protocols, advanced practice nurses providing breastfeeding services introduced nipple shields, for specific indications that were recorded	**Statistical techniques** Descriptive statistics, paired *t* tests, Pearson correlations **Breastfeeding/breastmilk-related outcomes** Milk transfer during the feeds immediately before and after introduction of the nipple shield All 34 infants consumed more when the shield was used | Mean [SD] | Range | | --- | --- | | Milk transfer during first feed with shield (ml) | | | 8.4 [13.2] | 2–62 | | Milk transfer during feed immediately before first feed with shield (ml) | | | 3.9 [7.0] | 0–30 | | Increase in milk transfer with shield (ml) | | | 14.4*[9.1] | 2–41 | *$t = 9.25$, $p = 0.0001$, paired t test	None	Cut-off for prematurity unclear (range of gestational age at birth includes 37 weeks) **Funding** National Institutes of Health Grant NR03881 and a research grant from Medela, Inc. (McHenry, Ill). This company also manufactures nipple shields and the authors acknowledge this as a potential conflicting interest

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of analysis Group **Sample size calculation** Not reported **Outcome measures** Milk transfer during the feeds immediately before and after introduction of the nipple shield Findings on duration of breastfeeding are presented but not by use vs non-use of nipple shield	**Exclusion criteria** None	Median (range) number of breastfeeding attempts prior to introduction of nipple shield: 4 (1–10) Reasons for introduction of the nipple shield: • Poor latch[a]: 21/34 (61.8%) • Falling asleep[b]: 10/34 (29.4%) • Other[c]: 3/34 (8.8%) **Group comparability** Not applicable	For all infants, shields were introduced when practitioners felt use of shields would increase volume of milk consumed by preterm infants during breastfeeding **Data collection** Data were collected from standardised forms used in the two trials For each infant, volume of intake was compared for two consecutive breastfeedings: • the first feeding for which the nipple shield was used • the feeding immediately prior to that feeding Volume of intake for all breastfeedings had been measured by infant test-weights			

B, before the intervention; A, after the intervention.
a 'Poor latch' included specific indicators of infant 'slipping off the nipple' during pauses in sucking and anatomical problems such as a large or flat nipple that made it difficult for the infant to achieve/sustain an effective breastfeeding position.
b 'Falling asleep' indicated infants had been awake prior to the feeding, grasped the mother's nipple, and fell asleep almost immediately, without further sucking.
c 'Other' related to mothers' nipple pain. One mother of twins (two of the 34 babies in the sample) reported extreme nipple sensitivity that could not be attributed to any underlying pathology or improper positioning.

TABLE 44 *Fewtrell 2001*[125]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Fewtrell 2001 UK **Research aim** To test the hypothesis that the total amount of milk expressed by mothers who used a novel manual pump (MP) would be greater than that produced by mothers who used the standard electric pump (EP) **Study design** RCT **Method of group allocation** Permuted blocks of randomised length, stratified by infant's sex and gestation **Unit of allocation** Mother **Unit of analysis** Group (mothers and infants)	**Selection** NICU, Rosie Hospital, Cambridge, UK, between February 1998 and January 2000 **Inclusion criteria** Mothers of infants born at < 35 weeks' gestation who decided to provide milk for their infant Mothers of infants transferred into the study unit were also eligible **Exclusion criteria** None reported	*Mothers* *MP: (n = 74); EP: (n = 71)* Mean age (years) 29.7; 28.4 Social class 1+2 34%; 30% 'A' levels or higher professional qualification 34%; 33% Living with partner 95%; 93% Number of children breastfed: none: 75%; 75% one: 18%; 23% two: 7%; 3% Used breast pump previously 15%; 16% Singleton pregnancy 61 (82%); 64 (90%) Twin pregnancy 12 (16%); 7 (10%) Triplet pregnancy 1 (1%); 0 *Infants* Mean weeks [SD] gestational age 29.4 [3.0]; 29.1 [3.3] Mean g birthweight [SD] 1357 [540]; 1305 [565] Males 32 (53%); 35 (55%)	**MP: *n* = 74** Women expressed breastmilk using a novel manual pump with petals that simulate the infant's compressive action on the areola (Philips AVENT ISIS) **EP: *n* = 71** Women expressed breastmilk using a standard electric breast pump (Egnell Ameda Elite™); mothers were encouraged to double pump, although they decided to double or sequential pump themselves All participants were recommended to express at least six times per day, initially for 5 minutes on each breast, then increasing the length of time per breast; information and help with the pump were provided by the midwifery staff on the postnatal ward, and by the nursing staff on the neonatal unit	**Statistical techniques** Student's *t* test, Mann–Whitney *U* test for non-parametric data; chi-squared test, Fisher's exact test to compare proportions; repeated ANOVA for subgroup analyses **Breastfeeding/breastmilk-related outcomes** *Mode of feeding at discharge:* Infants receiving > 50% of their intake as breastmilk at study completion: MP 73%, EP 76% (NS) Singletons: MP 80%, EP 71% (0.3, NS) *Breastmilk expression [median (25th, 75th centiles)]* *MP (n = 60); EP (n = 58); p* Total number of expressions: 38 (15, 69); 4 (15, 74); 0.8 Mean expressions/day: 3.7 (3.0, 4.1); 3.9 (3.2, 4.4); 0.3 Total time spent expressing (minutes): 745 (289, 1321); 515 (231, 1069); 0.06 Mean time/day spent expressing: 65 (56, 85); 51(38, 63); < 0.001 Total volume expressed (ml): 1928 (322, 5408); 2062 (728, 5485); 0.6 Mean volume/day expressed: 199 (57, 323); 218 (119, 341); 0.5	145 mothers recruited (MP 74, EP 71) Data from 118 mothers (81.3%) were included in the analyses for the main outcomes 27/145 mothers (18.6%) failed to fill in the daily milk collection sheets: MP 14/74 (18.9%); EP 13/71(18.3%) MP mothers had a total of 88 infants, all of whom survived EP mothers had a total of 78 infants, 4 of whom died	Available data were analysed both by randomised group and separately by use of randomised method Supported by a grant from Canon Avent (Glemsford, Suffolk, UK), which also provided the ISIS manual pumps

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation 76 women per group to detect a 0.5 standard deviation difference in outcome measures between groups with 80% power at the 5% significance level, allowing for 12 (15%) dropouts per group **Outcome measures** Maternal milk volume (MMV) Subgroup comparisons of pattern of milk flow and creamatocrit Mothers' views of randomised pump Mode of feeding at study discharge		**Group comparability** No significant differences found between the groups in maternal characteristics No significant differences found between the groups in proportion of infants who required supplemental oxygen or ventilation or in the duration of support required	**Data collection** All mothers were recruited within 3 days of the birth and were asked to provide details of method, time and volume for each milk expression until they left the study The study had five endpoints: 1. Mother stopped using the assigned pump 2. Mother stopped completing data forms 3. Infant discharged or transferred 4. Infant fully breastfed 5. Infant died	Women in the MP group spent more time expressing milk per day than the EP group. No other significant differences were reported *Subgroup analyses* Thirty-seven mothers (23 MP and 14 EP, $p = 0.12$) who attempted to breastfeed their infant while participating in the study expressed significantly greater volumes of milk and spent more time expressing with a greater total number of sessions than women who did not attempt to breastfeed. Results for breastmilk expression were not different between MP and EP groups (see above) Forty-five mothers (MP 24, EP 21) consented to participate in an extra study and expressed milk sequentially for 20 minutes (10 minutes at each breast) *Mean [SD] volume expressed in 20 minutes (ml)* MP 112 [69]; EP 76 [44] Difference = 36 ml (95% CI: 2–71), $p = 0.04$ The authors concluded that when compared on equal terms (sequential pumping), mothers who used the MP showed greater milk volume during a fixed period		

continued

TABLE 44 *Fewtrell 2001*[123] *(continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
				Creamatocrit values Among the 45 mothers, creamatocrit values at 1-minute intervals, and mean creamatocrit during a 10-minute period were not significantly different in the breastmilk of women using the two types of pumps for either breast **Clinical/health outcomes** *Maternal health related to the use of pump:* 7% of women in both groups reported sore nipples Two mothers using the EP (2%) developed mastitis **Process outcomes** *Median days in the study* MP 16, EP 14 **Psychosocial outcomes** Mothers who used the MP reported greater ease of use, better comfort, and that the MP was pleasant to use; the overall opinion was that the MP was better than the EP **Cost-effectiveness outcomes** Costs (as reported by the author) EP = 'hundreds of pounds' MP = 'less than £25'		

MP: intervention group (novel manual pump); EP: control group (standard electric pump).

DOI: 10.3310/hta13400

TABLE 45 *Groh-Wargo 1995*[128]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Groh-Wargo 1995 USA **Research aim** To test the hypothesis that use of a bilateral breast pumping system increases the volume of milk expressed in mothers of premature infants **Study design** Randomised controlled trial **Method of group allocation** Not reported **Unit of allocation** Mother **Unit of analysis** Group **Sample size calculation** Not reported	**Selection** Mothers of infants in a 36-cot level III NICU in a large metropolitan hospital in the US Midwest **Inclusion criteria** Mothers breastfeeding infants: ≤1500 g at birth ≤7 days old To be included, a mother had to have pumped for at least 4 weeks (paper does not state whether or not any mothers were excluded on this criterion) **Exclusion criteria** Not reported	*Mothers* *Single: n = 16; bilateral: n = 16* Mean age (years) 28; 28 *Years education n (%):* 10–12: 9 (56); 8 (50) > 12: 7 (44); 8 (50) *Marital status n (%):* Married: 14 (88); 13 (82) Single: 2 (12); 2 (12) Divorced: –; 1 (6) *Multiparous n (%)* 7 (44); 7 (44) *Breastfed one other child for any length of time n (%)* 5 (31); 6 (38) *Infants* Infant characteristics not reported	**I: *n* = 16** Mothers used Medela (McHenry, IL) bilateral electric pump Protocol: pump both breasts simultaneously for a total of 20 minutes (during data collection the time to pump instruction was changed to 'as long as there is any flow of milk') **C: *n* = 16** Mothers used Medela (McHenry, IL) single electric pump Protocol: pump for 10 minutes on each breast (during data collection the time to pump instruction was changed to 'as long as there is any flow of milk') **All participants** Instructed to: • pump every 3 hours except at night • to pump at least four times in 24 hours Requested to: • pump for 6 weeks or until their baby was able to breastfeed freely, whichever came first	**Statistical techniques** Weekly means for number of pumping sessions, pumping time and milk volume Fold increase pre–post one pumping session in each subject each week, averaged for each subject and each study group (fold increase defined as doubling the original value, e.g. one fold is a 100% increase) Student's *t* test, Mann–Whitney rank sum test, Pearson's product moment correlation, multiple regression **Breastfeeding/breastmilk-related outcomes** *Milk production (ml/week)* Single: *n* = 16; bilateral: *n* = 16 2685 ± 2016; 2787 ± 1939 Not statistically significant Authors note large standard deviations show milk production varied greatly from mother to mother	None reported	It is not clear whether any randomised mothers were excluded from the analysis Data were analysed by randomised group Funding from Medela, Inc. (McHenry, IL) and from Grant RR-00080 from National Institutes of Health, General Clinical Research Center at MetroHealth Medical Center

continued

TABLE 45 *Groh-Wargo 1995[128] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Milk production per week Pumping sessions per week Time spent pumping per week Serum prolactin change		**Group comparability** No statistically significant differences found between the groups	In addition, all participants: • received a free electric pump with individual instruction • met weekly with the research nurse, who provided support and encouragement (the nurse was also available by phone) **Standard care** Not described **Data collection** Maternal questionnaire for demographics Daily milk production log kept by mothers and submitted weekly for 6 weeks Weekly State-Trait Anxiety Inventory and serum prolactin levels	**Clinical/health outcomes** *Serum prolactin change: fold increase pre-to-post-pumping* Single: $n = 16$; bilateral: $n = 16$ 11.4 ± 11.9; 7.7 ± 7.6 Not statistically significant **Process outcomes** Single: $n = 16$; bilateral: $n = 16$ *Pumping sessions per week* 28.4 ± 5.5; 28.8 ± 5.5 Not statistically significant *Minutes (hours) pumped per week* 664.94 ± 188.1 (11.1 ± 3.1); 58.380 ± 176.8 (7.6 ± 3); $p = 0.003$ **Psychosocial outcomes** State Anxiety Inventory scores obtained weekly over the 4–6 weeks of the study but results not reported in the paper **Cost-effectiveness outcomes** Not reported		

I, intervention group, bilateral pumping; C, control group, single pumping.

DOI: 10.3310/hta13400

TABLE 46 *Hill 1999*[112]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Hill 1999b (Hill 1999b[112] and Hill 2001[113] report aspects of this study) USA (Chicago, IL) **Research aim** To compare milk production in lactating mothers of non-nursing preterm infants who use either a sequential single (Seq) or simultaneous double (Sim) breast pumping regimen To examine the influence of selected variables on adequate versus inadequate milk production **Study design** Randomised controlled trial **Method of group allocation** States randomised, does not describe how	**Selection** Lactating mothers of non-nursing preterm infants from two tertiary care centres **Inclusion criteria** *Mothers* English or Spanish speakers Accessible by telephone Non-smokers No history of thyroid/ endocrine disorder Planning to mechanically express breast milk for ≥6 weeks after singleton or multiple birth Infants < 32 weeks' gestation Very low birthweight (≤1500g) Not expected to feed at the breast for ≥6 weeks	Reported for the 39 mothers who completed the study *Mothers* Seq ($n = 20$); Sim ($n = 19$) Mean age (years) ± SD 28.85 ± 3.94; 30.63 ± 5.13 Income < $50,000 17 (85.0%); 5 (26.3%) Mean years of education ± SD 14.70 ± 1.81; 14.52± 1.87 White 12 (60.0%); 17 (89.5%) Previously breastfed 7 (35.0%); 2 (10.5%) Multiple births 7 sets of twins and 2 sets of triplets, not reported by mother's randomised group	**All participants** After consent, received detailed instructions, and were tested by researchers, on how to use the Medela Lactina® (McHenry, IL) electric breast pump, milk collection, storage and transport procedures Hill 2001 adds that mothers were instructed in techniques helpful for eliciting the milk ejection reflex, such as use of warm moist breast compresses, breast massage, looking at a picture of their infant, or inhaling their infant's scent from clothing or a blanket Protocol for both groups was to pump eight times per day	**Statistical techniques** Descriptive statistics; repeated measures of ANOVA for milk weight; Spearman's rho for adequate/ inadequate milk production **Breastfeeding/ breastmilk-related outcomes** No statistically significant difference found between Seq vs Sim groups in mean weekly milk weight (weeks 2–5) $p = 0.164$ **Clinical/health outcomes** Not reported **Process outcomes** Pumping frequency per week (weeks 2–5): Seq: 40.18 ± 8.77 Sim: 42.87 ± 9.75, $p = 0.370$ **Psychosocial outcomes** Some mothers preferred the single pumping method and others the double	Forty-nine mothers consented to participate and were randomised Ten withdrew (20.4%), not reported by group Reasons: • one infant died • 8 mothers dropped the study (reasons not reported) • one data set incomplete	Available data were analysed by randomised group Hill 1999b[112] used ANOVA and found mothers with previous breastfeeding experience had significantly greater milk yield than those without Hill 2001[113] used ANOVA and found milk weight in mothers with low frequency of pumping appeared to be positively influenced by initiating pumping soon after the birth

continued

TABLE 46 *Hill 1999[112] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of allocation Individual (mother) **Unit of analysis** Group (milk weight) **Sample size calculation** Not reported **Outcome measures** Mean weekly milk weight (g) Pumping frequency Other outcomes not by randomised group	**Exclusion criteria** Not stated	*Infants* Mean gestational age (weeks) ± SD: Seq: 27.52 ± 2.10 Sim: 28.08 ± 1.81 Mean birthweight (g) ± SD: Seq: 1065.83 ± 261.14 Sim: 1050.04 ± 253.73 **Group comparability** The only statistically significant difference found between the groups was in income. More Seq group mothers reported income < $50,000 (paper reports $p = 0.000$)	**Seq: sequential (single) pumping** (reported for 20 mothers) Pump a minimum of 5 minutes then switch to the other side (when the milk stops spraying or dripping regularly); repeat, so that each breast is pumped 10 minutes minimum **Sim: simultaneous (double) pumping** (reported for 19 mothers) Pump a minimum of 10 minutes or until one breast no longer dripping **Standard care** Not described; however, similar amounts of kangaroo care were reported for mothers in both study groups	**Cost-effectiveness outcomes** Not reported Researchers conclude clinicians may encourage mothers to choose either pumping method Other results are reported but not by randomised group: • Minimum milk weights ranged from 19 to 114 g/week and maximum milk weights ranged from 3950 to 9559 g/ week among the 39 mothers		Supported by the University of Illinois at Chicago, College of Nursing, Internal Research Support Program, Chicago, IL; National Institutes of Health, National Institute of Nursing Research, 1 R55 NR04118-01A1; and Medela, Inc.

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
			Data collection Mothers kept a log recording day and time of each milk expression for 6 weeks Mothers brought expressed milk to the unit in labelled bags Researchers weighed milk bags Paper states 'the weight in grams is nearly equivalent to the volume of milk in millilitres and is a more precise method of determining the amount produced'	• Researchers defined adequate milk production as 500 g per day. A logistic regression model including frequency of kangaroo care, frequency of pumping, high vs low income, and previous breastfeeding experience was predictive of mothers providing adequate vs inadequate milk volume 79% of the time • All the mothers producing > 3500 g at week 2 produced adequate amounts at weeks 4 and 5 • No mother producing < 1700 g at week 2 reached adequate production by weeks 4 and 5 • Milk expression for a minimum of six times per day was associated with the production of ≥ 500 ml/day or ≥ 3500 ml/week		

TABLE 47 *Jones 2001*[114]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Jones 2001 UK **Research aims** 1. To compare the effect of sequential versus simultaneous breast pumping on volume of milk expressed and its fat content 2. To measure the effect of breast massage on milk volume and fat content **Study design** 1. RCT 2. Crossover trial **Method of group allocation** Randomised centrally into six groups (three for gestational age and two for parity) **Unit of allocation** Mother **Unit of analysis** Group	**Selection** Mothers of infants being cared for in the Neonatal Unit of North Staffordshire Maternity Hospital October 1997–August 1999 **Inclusion criteria** Mothers wishing to express breastmilk **Exclusion criteria** Mothers unable to express ≥ 5 times per day before the start of the study Mothers with retained products of conception Mothers living outside the study hospital's area expecting to return to their local hospital before their infant reached term	*Mothers* Age and socioeconomic status not reported *I1 (Sim): n = 16; C1 (Seq): n = 17* First pregnancy 5/16; 7/17 Breastfed previously 8/16; 6/17 Multiple births (twins) 3 sets; 3 sets *Infants* Mean weeks gestational age 29.9; 30.2 Mean kg birthweight 1.46; 1.61 **Group comparability** Not reported	**Standard care** Study unit had active breastfeeding policy All mothers provided with information leaflet on milk expression technique All mothers had opportunity to view a video made by the researchers covering milk expression and preterm breastfeeding **All participants** Egnell Ameda Electric Elite™ pump (Egnell Ameda, Taunton, Somerset, UK) with silastic shield inserts, were loaned for the length of the trial Mothers were encouraged to express × 8 per day until milk no longer entered the collection set **I1: *n* = 25 randomised to simultaneous pumping** Mothers were asked to use the study pump in simultaneous pumping mode (both breasts at once) **C1: *n* = 27 randomised to sequential pumping** Mothers were asked to use the study pump in sequential mode When milk from the first breast no longer entered the collection set, mothers were asked to switch breasts	**Statistical techniques** Repeated measures ANOVA on mean milk volume and mean fat content between days 2 and 4 (one day of massage and one day of non-massage for each woman) The means were calculated by the total daily volume/number of expressions that day. Both groups had a mean of 5.2 expressions per day. Results from 36 mothers with complete data **Breastfeeding/breastmilk-related outcomes** *Fully breastfeeding or expressing milk at term (37 weeks)* I1 (Sim): 1/17 did not establish breastfeeding C1 (Seq): 15/19 fully breastfeeding or expressing Weeks expressing/breastfeeding until term ranged from 5 to 13 weeks The authors state that differences in milk yield per expression were significant at the $p < 0.01$ level between sequential and simultaneous pumping, and between massage and non-massage. Fat concentration was similar in all groups. Total fat was significantly different between simultaneous pumping and sequential pumping ($p < 0.01$), but not for massage vs no-massage	52 randomised (27 Seq, 25 Sim) 16/52 lost (31%) Missing from Seq 27 – 19 = 8 Missing from Sim 25 – 17 = 8 Reasons given, but not by group: • 4 infant deaths • 5 critically ill infants • 2 infants transferred for surgery • 1 mother with mastitis • 4 social reasons	Available data were analysed according to randomised group for the comparison between simultaneous and sequential pumping The authors concluded that simultaneous pumping produces more milk than sequential pumping. Massage has an additive effect, improving milk production in both groups The author provided additional information about method of randomisation Funded by Baby Lifeline

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation 39 in each arm for 80% power and 5% significance based on an improvement in milk yield of 20–50%. Interim analysis of 36 complete data sets showed highly significant results and recruitment was discontinued **Outcome measures** Milk weight Milk fat Mothers' views Breastfeeding duration			**I2: Breast massage prior to pumping** (all participants on two of the four study days) Gentle tactile stimulation of mammary and nipple tissue using a hand action that rolled the knuckles downwards over the breast, beginning at the ribs and working towards the areola This technique did not involve manual expression of milk **C2: No breast massage prior to pumping** (all participants on two of the four study days) **Data collection** The study took place during two 48-hour periods (total four days), starting on day 4 or when engorgement had been relieved Mothers were randomised to massage on either days 1 and 2 or days 3 and 4 of the study On study days 1 and 3, mothers familiarised themselves with breast massage and data collection Data were collected on study days 2 and 4 only Mothers logged date, time and duration of each expression, and weight of collection bottles before expression Researchers logged weight of collection bottles after expression Capillary sample from each milk sample for creamatocrit test Two questionnaires to mothers at trial completion, and mothers were asked about feeding method at 37 weeks postconception (term)	*Mean (95% CI) breastmilk weight (g)* Seq (non-massage): 51 (46–56) Seq (massage): 79 (73–85) Sim (non-massage): 88 (79–97) Sim (massage): 125 (110–140) *Mean (95% CI) fat concentration (g/l)* Seq (non-massage): 7.1 (5.9–8.3) Seq (massage): 6.7 (5.7–7.7) Sim (non-massage): 7.0 (5.9–8.1) Sim (massage): 6.8 (5.7–7.9) *Mean (95% CI) total fat (g)* Seq (non-massage): 3.1 (2.7–3.5) Seq (massage): 4.2 (3.8–4.6) Sim (non-massage): 6.0 (5.3–6.7) Sim (massage): 8.0 (6.9–9.1) **Clinical/health outcomes** Not reported **Process outcomes** 30/36 mothers began the study on postpartum day 5 and 6/36 on day 7 Simultaneous pumping took mothers 10–15 minutes compared with 25–40 minutes for sequential pumping **Psychosocial outcomes** Women appreciated massage and simultaneous pumping to expedite milk flow, and voiced a need for larger milk collection sets **Cost-effectiveness outcomes** Not reported		

I1, intervention 1 group (simultaneous pumping on 4 days); C1, control 1 group (sequential pumping on 4 days); I2, intervention 2, all participants (breast massage prior to pumping on 2 of 4 days); C2, control 2, all participants (no breast massage prior to pumping on the other 2 days).

TABLE 48 *Paul 1996*[134]

<table>
<tr><th>Study details</th><th>Participant selection and inclusion/ exclusion criteria</th><th>Baseline characteristics of participants</th><th>Intervention details</th><th>Results</th><th>Withdrawals</th><th>Additional comments</th></tr>
<tr>
<td>Paul 1996
India (New Delhi)

Research aim
To compare hand expression of breastmilk with expression using a hand-held cylindrical pump (Medela) for output of breastmilk and mothers' views

Study design
Randomised crossover trial with two phases

Method of group allocation
Randomised (method not stated)

Unit of allocation
Mother

Unit of analysis
Milk expression session

Sample size calculation
Not reported

Outcome measures
Mean output per session
Mothers' preferences for hand or pump expression</td>
<td>Selection
Mothers of infants in NICU; infants unable to breastfeed and receiving expressed breastmilk by gavage tube

Inclusion criteria
Well and comfortable enough to come to the nursery feeding room

Exclusion criteria
Cracked/sore nipples</td>
<td>Mothers
Not reported
Infants
Phase 1 (22 mothers)
Mean gestation 34.3 weeks (range 27–40 weeks)
Phase 2 (14 mothers)
Mean gestation 33.5 weeks (range 27–37 weeks)
Number of infants not reported

Group comparability
Not applicable within each phase (crossover trials)
Not reported between phase 1 and phase 2</td>
<td>Phase 1 (22 mothers)
Expressed milk for 15 minutes at 10.00, 12.00 and 14.00 on postnatal days 4 and 5
Each mother alternated hand expression and pump methods
Eleven mothers were randomised to begin with hand expression and 11 with pumping
Mothers were advised to allocate equal time to expressing each breast at each session
Method of hand expression not described
The pump used (Medela) was cylindrical, made of plastic and hand-operated. By in-and-out motion with one hand, a piston mechanism produced suction at a breast cup placed around the areola. Vacuum-sucked breast milk flowed into a collecting bottle

Phase 2 (14 mothers, not included in phase 1)
Expressed milk for 15 minutes at 10.00, 12.00 and 14.00 on postnatal days 4 and 5 and on postnatal days 8 and 9
Each mother alternated hand expression and pump methods, following the same procedure as in phase 1</td>
<td>Statistical techniques
Descriptive statistics, Student's t test

Breastfeeding/breastmilk-related outcomes
Phase 1 (n = 22) days 4 and 5
Expression by:
<table><tr><th></th><th>Hand</th><th>Pump</th></tr><tr><td>No. sessions</td><td>66</td><td>66</td></tr><tr><td>Total ml</td><td>1430</td><td>2744</td></tr><tr><td>Mean per session</td><td>21.7</td><td>41.57</td></tr><tr><td>SD</td><td>10.54</td><td>16.09</td></tr></table>p < 0.001

Phase 2 (n = 14) days 3 and 4
Expression by:
<table><tr><th></th><th>Hand</th><th>Pump</th></tr><tr><td>No. sessions</td><td>42</td><td>42</td></tr><tr><td>Mean per session</td><td>31.2</td><td>46.8</td></tr><tr><td>SD</td><td>15.5</td><td>26.3</td></tr></table>p < 0.01</td>
<td>None reported</td>
<td>Data were analysed using intention-to-treat model
Numbers of sessions reported (66 × 2 in phase 1 and 42 × 4 in phase 2) were complete
Author notes at the time of the study the only breast pump manufactured in India was unsuitable for milk collection and states 'there is a genuine need for a relatively inexpensive, indigenous breast pump'</td>
</tr>
</table>

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
			Data collection Milk volume was measured at the end of each 15-minute session to the nearest ml using a syringe Mothers were questioned about their preferences at the end of the sixth session (tool not described)	*Phase 2 (n = 14) days 8 and 9* Expression by: No. sessions: Hand 42, Pump 42 Mean per session: Hand 38.4, Pump 50.4 SD: Hand 11.2, Pump 13.4 *p < 0.01* **Clinical/health outcomes** Not reported **Process outcomes** Not reported **Psychosocial outcomes** *Days 4 and 5:* Prefer pump: *Phase 1 (n = 22)* 19, *Phase 2 (n = 14)* 14 Prefer hand: 2, 0 Not sure: 1, 0 Pump preferred (days 4 and 5) because it provided relief from engorgement *Days 8 and 9: Phase 2 (n = 14)* Prefer pump: 1 Prefer hand: 13 Hand expression preferred (days 8 and 9) because it was more gentle and convenient **Cost-effectiveness outcomes** Not reported		

TABLE 49 *Slusher 2007*[142]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Slusher 2007 Kenya and Nigeria **Research aim** To compare mean daily maternal milk volume (MMV) using an electric breast pump, non-electric pedal breast pump, or hand (manual) expression for mothers of premature or sick infants in special care nurseries **Study design** Randomised controlled trial **Method of group allocation** Random numbers table **Unit of allocation** Mother	**Selection** Special care nurseries at Jos University Teaching Hospital in Jos, Nigeria, and Tenwek Mission Hospital, in Bomet, Kenya **Inclusion criteria** Mothers of premature or sick infants being cared for in the study units, who were unable to breastfeed Physician expected infant to be unable to breastfeed for at least 1 week **Exclusion criteria** Not reported	*Mothers* Maternal age (years) mean [range] A: 25 [17–38] B: 24 [16–38] C: 28 [17–40] First pregnancy A: 38% B: 38%, C: 44% Socioeconomic status, multiple births and breastfeeding experience not reported *Infants* Birthweight (g) mean [range] A: 1651 [907–3134] B: 1606 [850–3400] C: 1871 [1049–4600]	**Intervention A** ($n = 22$) Women expressed breastmilk by double collection Lactina electric breast pump Mothers were instructed to use the electric pump at 2–3-hour intervals **Intervention B** ($n = 24$) Women expressed breastmilk by double collection non-electric pedal pump **Control** ($n = 19$) Women expressed breastmilk by hand expression (the clinical standard in both settings)	**Statistical techniques** Descriptive statistics, one-way ANOVA, Tukey HSD test **Breastfeeding/ breastmilk-related outcomes** *Mean breastmilk volume during the study:* Intervention A group (electric pump): 578 ± 228 ml Intervention B (non-electric pedal pump): 463 ± 302 ml Control group (hand expression): 323 ± 199 ml	103 mothers were randomised at birth 38 withdrew (not reported by group) Infants of 26 mothers died Infants of 5 mothers were ready to feed directly from the breast within the first week of life 7 mothers withdrew (reasons not stated) 65 mothers were included in the analysis	Available data were analysed by randomised group Funding: not reported

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of analysis Group **Sample size calculation** Not reported, convenience sample **Outcome measures** Mean daily breastmilk volumes		Infant gestation (weeks) mean [range] A: 31.4 [27–38] B: 31.7 [26–40] C: 33.9 [28–40] **Group comparability** No significant differences found between the groups for variables reported	All participants were taught: • how to use their randomised method to express breastmilk • to completely empty both breasts at each pumping session (until milk droplets ceased flowing) **Data collection** Breastmilk volumes were measured to the nearest ml and recorded at each pumping session for 10 days. Mothers contributed data for a mean of 8.7 days. All but one mother began the study within 2 days of the birth	The Intervention A group (electric pump) result was significantly greater than the control group result ($p < 0.01$) There was no significant difference between the Intervention A group and the Intervention B group results There was also no significant difference between the Intervention B group and the control group results **Clinical/health outcomes** Not reported **Process outcomes** Not reported **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported		

TABLE 50 *da Silva 2001*[123]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
da Silva 2001 Canada **Research aim** To evaluate the effectiveness of domperidone in augmenting milk production in mothers of premature infants **Study design** RCT **Method of group allocation** Random numbers table **Unit of allocation** Mother **Unit of analysis** Group **Sample size calculation** 20 subjects to demonstrate an increase ≥25% in milk production between the groups with 80% power and $\alpha = 0.05$ **Outcome measures** Milk volume Domperidone concentrations and side effects Serum domperidone and prolactin concentrations	**Selection** Mothers of infants admitted to the NICU at St Joseph's Health Care, London, Ontario **Inclusion criteria** Milk production not meeting the infant's daily oral feeding requirements Mothers using an electric breast pump with double collection kit Mothers continuing to have problems with lactation after extensive teaching by lactation consultants **Exclusion criteria** Mothers receiving medication known to affect serum prolactin levels Mothers with any chronic or debilitating illness	*Mothers* Mean [SD] maternal age (years) I: 28.2 [5.0] C: 27.9 [6.6] SES: not reported First pregnancy I: 3/7 C: 3/9 Breastfed previously I: 1/7 C: 3/9 Multiple births I: two sets of triplets and one set of twins C: one set of multiples Mean [SD] number of days between delivery and study entry I: 31.9 [10.5] C: 33.1 [22.9] *Infants* Mean weeks [SD] gestational age I: 29.1 [2.0] C: 29.1 [3.7] Birthweight: not reported **Group comparability** No significant differences found between the groups	Domperidone tablets were crushed and mixed with lactose. The resulting white powder was placed in clear capsules. Placebo was plain lactose powder in the same type of capsule **I: *n* = 11** Domperidone 10 mg orally, three times per day for 7 days **C: *n* = 9** Placebo Standard care Extensive teaching by lactation consultants for all women failing lactation (content of teaching not described) No other components of standard care are described **Data collection** Milk volumes for 7 days Domperidone concentrations in milk on day 5 Serum domperidone and prolactin before the initial dose and on days 5 and 10 Mothers were asked to report side effects	**Statistical techniques** Chi-squared test for categorical data, Student's *t* test for continuous data, Wilcoxon rank sum test for increase in milk volumes from baseline **Breastfeeding/breastmilk-related outcomes** Mean ml [SD] milk at baseline *Domperidone (n = 7); placebo (n = 9)* 112.8 [128.7]; 48.2 [63.3] Milk volume data for the 24 hours before the trial were not available for 1/7 of the intervention group and 3/9 controls Milk volume data for the 24 hours following enrolment were used in these cases Length of time between enrolment and start of the trial not reported Mean ml [SD] milk days 2–7 *Domperidone (n = 7); placebo (n = 9)* 162.2 [127.5]; 56.1 [48.0] Mean ml [SD] increase in milk volume between baseline and days 2–7 *Domperidone (n = 7); placebo (n = 9)* 49.5[29.4]; 8.0[39.5]; $p = < 0.05$ Proportion of infants discharged home breastfeeding not stated, but reported not to differ between the groups	*Withdrawals* I: 4/11 withdrew from the Domperidone group Reasons: • infant died (1) • no milk records (3) C: no withdrawals from the control group	Available data were analysed by randomised group Compliance was monitored by capsule count Funded by a grant from the Research and Education Foundation of the Canadian Society of Hospital Pharmacists

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
				Clinical/health outcomes Mean [SD] serum prolactin at baseline (*μg*/l) I: 12.9 [7.7] vs C: 15.6 [17] *p = 0.71 (NS)* Mean [SD] serum prolactin on day 5 (*μg*/l) I: 119.3 [97.3] vs C: 18.1 [14.7] *p = 0.008* Mean [SD] serum prolactin on day 10 (*μg*/l) (3 days after last dose) I: 12.1 [5.1] vs C: 16.5 [5.2] *p = 0.11 (NS)* Domperidone in milk on day 5 Milk:serum ratio 0.4 (authors state this is relatively low and much lower than metoclopramide) No side effects detected for mothers or infants **Process outcomes** One mother assigned to domperidone stopped taking it on day 4 because she started to breastfeed successfully **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported		

I, intervention group (domperidone capsules for one week); C, control group (placebo capsules for one week).

TABLE 51 *Feher 1989*[146]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Feher 1989 USA **Research aim** To evaluate the effect of relaxation/ imagery techniques on milk volume and fat content of milk expressed by mothers of hospitalised premature infants and to improve the mothers' lactation experience **Study design** RCT **Method of group allocation** Random numbers table (open allocation) **Unit of allocation** Mother **Unit of analysis** Group **Sample size calculation** Authors decided a 20% increase in milk volume would be clinically significant and state they calculated the sample size accordingly. No details of the calculation are reported	**Selection** Breastfeeding mothers of preterm infants in two units: • a university hospital with 28 neonatal intensive care unit (NICU) cots • a private hospital with 24 NICU cots **Inclusion criteria** Mothers of infants expected to be in the unit for at least 10 days **Exclusion criteria** Not reported	*Mothers* Reported for those who completed the study I ($n = 30$); C ($n = 25$) Mean [SD] age in years 24.5 [6.2]; 26.8 [6.2] Mean [SD] years of education 13.0 [2.0]; 14.0 [1.9] Married 80%; 76% Family income < $10,000: 47%; 40% $11,000–20,000: 10%; 36% $21,000–30,000: 20%; 8% > $30,000: 23%; 16% First pregnancy 43%; 68% Breastfed previously: not reported Multiple births: not reported *Infants* Mean gestational age in weeks (SD not reported) 29.9; 27.6 Birthweight: not reported Eight infants in both groups were receiving mechanical ventilation at the time of milk collection **Group comparability** No statistically significant differences were found between the groups	Mothers were assigned 3–5 days postpartum **I: $n = 38$** Mothers received a 20-minute audio cassette tape Tape consisted of a progressive relaxation exercise (to alternately tense and relax muscle groups while taking deep, rhythmic breaths) followed by a guided imagery section (including descriptions of pleasant surroundings, milk flowing in the breasts, and the baby's warm skin against the mother) Mothers were recommended to use the tape every time they wanted to express milk If necessary, a tape player was loaned to the mother **C: $n = 33$** Routine supportive care from the nursing and medical staff, which included verbal and written instructions on how to use the electric breast pump	**Statistical techniques** Chi-squared analysis, *t* tests and analysis of variance **Breastfeeding/breastmilk-related outcomes** I ($n = 30$); C ($n = 25$) *Mean ± SD milk volume (ml)* 90.1 ± 60.0; 55.4 ± 48.2; $p < 0.05$ *Creamatocrit (%)* 7.2 ± 2.9; 6.8 ± 2.4 Not statistically significant **Clinical/health outcomes** Not reported **Process outcomes** I ($n = 30$); C ($n = 25$) *Mean expression time (days)* 7.8; 8.1 *Compliance* 15/30 intervention group mothers (50%) had listened to the tape more than five times before providing the sample Authors report a dose–response relationship between milk volume and reported tape listening:	71 mothers randomised, 38 to I group and 33 to C group Data from 55 mothers analysed: 30 in I group (79%) and 25 in C group (76%) 16 lost to follow-up, 8 from each group Reasons: • withdrew voluntarily (I = 5, C = 3) • infant died (I = 1, C = 2) • infant transferred (I = 0, C = 1) • maternal complication (I = 0, C = 1) • incomplete data (I = 30, C = 25)	Available data were analysed by randomised group The author provided additional information about method of randomisation Partial funding from University of New Mexico School of Medicine, General Clinical Research Center, NIH grant RR-00997-10, 11

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Milk volume Cream content Mothers' views of the tape			**Data collection** Volume and fat content of a single expression of breastmilk obtained at the hospital 4–13 days after enrolment	*Number of times mother reported listening to tape* 0–4 | 5–9 | ≥10 *Number of mothers* 10 | 10 | 9 *Mean volume expressed milk (ml)* 57.1 | 68.7 | 112.7 **Psychosocial outcomes** *Mothers' views of the tape* 'Many positive responses and no strong negative reactions' Examples of positive responses: • intervention 'helped her get started with the electric pump' • 'helped her be more patient with people in the hospital' • 'helped her relieve depression and negative feelings as she had lost two other babies' **Cost-effectiveness outcomes** Not reported		
I, intervention group (relaxation/imagery audiotape); C, control group (routine care, no tape).						

TABLE 52 *Fewtrell 2006*[144]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Fewtrell 2006 UK **Research aim** To test the hypothesis that oxytocin nasal spray increases early milk output in mothers expressing milk for preterm infants **Study design** RCT **Method of group allocation** Sequence drawn up by clinical trials company in permuted blocks of randomised length, stratified by parity and gestation. Identical spray containers prepared and numbered by the company with the appropriate number in the sequence **Unit of allocation** Mother **Unit of analysis** Mother and group	**Selection** Mothers who gave birth at the Elizabeth Garrett Anderson Hospital, UCLH, London, between March 2003 and April 2004 **Inclusion criteria** Infant < 35 weeks' gestation **Exclusion criteria** None stated	*Mothers* I ($n = 27$); C ($n = 24$) Mean [SD] age in years 31.5 [5.5]; 30.8 [6.7] Degree/higher professional qualification 18 (67%); 14 (58%) Married/with partner 26 (96%); 21 (87%) White/Asian 18 (67%); 16 (67%) Black 9 (33%); 8 (33%) Parity: not reported Previous breastfeeding experience 5 (19%); 5 (21%) Previous pumping experience 6 (22%); 3 (13%) Multiple birth 4 (15%); 5 (21%) *Infants* Mean weeks [SD] gestational age 29.9 [2.8]; 29.0 [3.7] Mean g birthweight [SD] 1380 [604]; 1315 [603]	All participants were advised to express milk at least every 3 hours and instructed in the use of hand massage before pumping All participants used the Egnell Ameda Elite pump, generally in single mode Advice was given by staff in postnatal and neonatal wards and by a research nurse, who saw mothers daily and was available for telephone contact at all times Mothers were advised to use their spray once (100μl) 2–5 minutes prior to expressing from each breast *I: n = 27* Syntocinon nasal spray 40IU synthetic oxytocin per ml: total 5 ml *C: n = 24* Placebo spray sterile normal saline plus benzalkonium chloride	**Statistical techniques** Chi-squared tests, repeated ANOVA. Milk weight data were skewed therefore transformed to natural logarithms **Breastfeeding/breastmilk-related outcomes** Total milk production was found not to differ between the groups Oxytocin group median 667g (25th, 75th centiles 206, 1203) vs placebo group 530g (394, 778); $p = 0.9$ Significantly different patterns of milk production were found between the groups, with more milk in the oxytocin group over the first 2 days ($p = 0.001$), then placebo matched and by day 5 exceeded them In the physiological studies of the subgroup of mothers, no significant differences were found in milk weight or fat content **Clinical/health outcomes** No adverse effects were recorded	51 mothers randomised, 27 to I group 24 to C group Individual data for the five study days are presented for 25/27 intervention group participants and 23/24 control group participants Complete 5-day milk records I: 21 C: 21 Total: 42 (82%) Incomplete 5-day milk records I: 6 C: 3 Total: 9 (18%) Reasons: Critically ill mother I: 1 (all 5 days); C: 1 (days 4 and 5) Mother did not complete any records I: 1; C: 1 Mother did not express on one or more days I: 2; C: 1 Mother ran out of spray I: 2; C: 0	Available data were analysed by randomised group The author provided additional information about method of randomisation Funded by MRC Programme grant

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation 16 in each group to detect a 5% difference with 80% power (based on previous published work) **Outcome measures** Milk volume Number of pumping sessions Milk volume and fat content over 20 minutes on day 5 (subgroup) Mothers' opinions of milk expression and spray used		**Group comparability** No significant differences between the groups were found	**Data collection** Records of start and finish time and weight of milk at each expression were completed by mothers Mothers were shown how to use the scales and complete the records	**Process outcomes** *Mean [SD] pumping sessions per day, days 1–5* Oxytocin 3.4 [0.8] Placebo 3.6 [0.9] $p = 0.4$ *Mean minutes/day expressing milk, days 1–5* Oxytocin 84 (24) vs placebo 95 (29), $p = 0.14$ **Psychosocial outcomes** *Mothers' opinions of milk expression and spray used* No significant differences in ratings found between the groups **Cost-effectiveness outcomes** Not reported		

I, intervention group (active oxytocin spray); C, control group (placebo spray).

TABLE 53 *Gunn 1996*[133]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Gunn 1996 New Zealand **Research aim** To determine the galactopoietic response to recombinant human growth hormone (hGH) in mothers of premature infants with inadequate lactation **Study design** RCT **Method of group allocation** Medication was prerandomised and issued in sequentially numbered packets **Unit of allocation** Mother **Unit of analysis** Group **Sample size calculation** Not reported	**Selection** Mothers of infants born at 26–34 weeks' gestation; infants otherwise healthy and being cared for in the Special Care Baby Unit (SCBU) **Inclusion criteria** Healthy mothers Not producing enough milk to supply their infants' nutritional needs Receiving standard management to promote and maintain lactation **Exclusion criteria** Any medication Any known contraindication to hGH therapy	*Mothers* Mean [SD] maternal age (years) I: 32.4 [3.6] vs C: 35.7 [4.6] SES: not stated First pregnancy: 15/18 Breastfed previously: not stated Multiple births: not stated Number [SD] days between delivery and study entry I: 39.7 [32] vs C: 31.3 [18.9] *Infants* Mean [SD] weeks gestational age I: 30.6 [3.2] vs C: 30.1 [3.2] Birthweight g [SD] I: 1398 [397] vs C: 1239 [552] Weight g [SD] of infants when the study began I: 2206 [455] vs C: 1576 [661] $p < 0.05$	**Standard care** Before the start of the study, all mothers had been shown how to express and were expressing from both breasts 5–6 times daily using electric pumps available in the hospital Most mothers also hired a pump to use at home **I: *n* = 10** hGH 0.21U/kg/day subcutaneously to a maximum of 161U/day, for 7 days **C: *n* = 10** Placebo **Data collection** Maternal venous blood samples on days 0 and 8 Milk volumes for days 0–1 (48 hours) and day 8 (24 hours), as the sum of milk expressed plus any suckled by the infant as determined by weighing	**Statistical techniques** Paired and unpaired Student's *t* tests (Bonferroni method) to compare groups Fisher's exact test to test incidences Linear regression for relationship between milk production and hormone levels **Breastfeeding/breastmilk-related outcomes** Mean milk volume in ml/day [SD] Days 0–1 | Day 8 | *p* I: 139 [49] | 175 [46] | < 0.01 C: 93 [50] | 102 [69] | NS Milk production increased in all hGH-treated mothers and in 4/9 placebo-treated mothers ($p < 0.04$) **Clinical/health outcomes** Plasma concentrations of both IGF-1 and IGFBP-3 rose after hGH therapy, compared with both baseline levels ($p < 0.01$) and with placebo levels ($p < 0.01$) The increases in plasma IGF-1 and IGFBP-3 were highly correlated ($r = 0.8$, $p < 0.001$)	Two withdrawals: • one hGH-treated mother developed gastroenteritis with vomiting and diarrhoea • one placebo-treated mother developed and allergic-type rash	Available data appear to have been analysed by randomised group No confidence intervals Study supported in part by the Health Research Council of New Zealand and Pharmacia AB, Stockholm, Sweden

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Milk production Plasma concentrations of insulin-like growth factor-1 (IGF-1), insulin-like growth factor binding protein-3 (IGFBP-3) and growth hormone		**Group comparability** Infants in the hGH group were heavier when their mothers began the study		Plasma concentrations of growth hormone, measured 24 hours after the last hGH injection, did not change significantly after hGH therapy or placebo No significant correlations reported from linear regression analyses of relationships between milk production and hormone levels No adverse effects with hGH treatment were seen in mothers or infants **Process outcomes** Not reported **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported		

I, intervention group (hGH injections for one week); C, control group (placebo injections for one week).

TABLE 54 *Hansen 2005*[116]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Hansen 2005 USA (Iowa) **Research aim** To investigate the effect of metoclopramide on breastmilk volume and duration of breastfeeding in women delivering preterm **Study design** RCT **Method of group allocation** Randomised using computer-generated random numbers Stratified by gestation **Unit of allocation** Mother **Unit of analysis** Group **Sample size calculation** Based on a report[240] of preterm milk volume 93 ± 19 ml before and 197 ± 32 ml after metoclopramide treatment, assuming a standard deviation	**Selection** Mothers of infants born at 23–34 weeks' gestation and being cared for at the University of Iowa Hospitals and Clinics **Inclusion criteria** Mothers planned to breastfeed **Exclusion criteria** Mothers using medication contraindicating breastfeeding or metoclopramide use HIV-positive mothers Infants with a congenital abnormality	Reported for I: 31/34 (91%) of mothers randomised C: 29/35 (83%) of mothers randomised *Mothers* Median (25–75th percentiles) age (years) I: 28 (23–33) C: 25 (23–33) *White % (n)* I: 83.87 (26) C: 89.66 (26) *Married* I: 87.10 (27) C: 65.52 (19) *Partner in white-collar occupation % (n)* I: 51.85 (14) C: 30.77 (8) *Preterm birth(s) prior to this one % (n)* I: 25.80 (8) C: 44.82 (13) *Multiple birth this time % (n)* I: 12.90 (4) C: 24.14 (7)	**I: *n* = 34** 10 mg metoclopramide tablet 3 times a day for 10 days **C: *n* = 35** 10 mg placebo tablet 3 times a day for 10 days **Both groups** Medication was started within 96 hours (4 days) of the birth A trained lactation specialist standardised all educational material (not described) given to mothers when they entered the study All study mothers were seen by a trained nurse at 3–7 days postpartum to answer questions and offer support (not described) All study mothers were provided with a Medela Classic® electric pump (Medela Inc., McHenry, IL) free of charge	**Statistical techniques** Fisher exact test and Wilcoxon rank-sum test for demographics Linear mixed-model analysis for repeated measures in comparison of milk volumes and between groups **Breastfeeding/breastmilk-related outcomes** *Milk volumes* Metoclopramide use was not associated with a significant increase in milk volume compared with placebo on any of the 17 days of the study No significant change in volume of milk produced in 24 hours between day 10 (last day of tablets) and day 17 was found between the groups Mean 24-hour milk volume (ml) | | Metoclopramide (*n* = 25–28) | Placebo (*n* = 29) | |---|---|---| | Day 10 | 519 ± 60 | 519 ± 60 | | Day 17 | 459 ± 63 | 497 ± 64 | Subgroup analysis by gestation (23–28 weeks and 28–34 weeks) also did not show any significant effect of metoclopramide use on milk volumes *Breastfeeding duration: median weeks (IQR)* I: 8.8 (3.4 to 12.0) C: 8.6 (5.6 to 16.9)	12 of the 69 mothers randomised withdrew (17%), six from each group Reasons: *I group:* Neonatal death (1) Potential drug reaction (facial rash and itching) (1) Received metoclopramide from local doctor second week postpartum (1) Stopped breastfeeding in the first week of the study (3) A further three mothers stopped breastfeeding during the second week of the study; these were excluded from some analyses, but paper states they had data analysed for baseline variables and some milk volumes	The author provided additional information about method of randomisation Both sets of tablets were white. They differed slightly in size. Therefore both sets were counted and stored in darkened plastic pill vials. Contents known only to one research nurse not involved in the study Available data were analysed using intention-to-treat model Supported by grant RR00059 from the Clinical Research Center, National Center for Research Resources,

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
[SD] of 32 ml, 30 in each group needed for the statistical test (sic), applying the Bonferroni correction, to detect a difference of at least 32 ml per day at any of the 17 days of the study period at the 0.05 significance level with 0.80 power **Outcome measures** Milk volumes Time mothers spent expressing Duration of breastfeeding Metoclopramide levels in milk		*Infants* Median weeks (25–75th percentiles) gestational age I: 28.1 (25.1–32.6) C: 28.0 (26.0–30.3) Birthweight: not reported **Group comparability** No significant differences in baseline characteristics found between the groups	**Standard care** Not described **Data collection** Mothers' journals, two verifications of milk volumes for 17 days (10 days of tablets and the 7 following days) Two milk aliquots from a subsample of mothers at days 10 ± 4 and 17 ± 5, for assessment of metoclopramide levels and fat and protein content	**Clinical/health outcomes** Mean metoclopramide level found in milk from 14 I-group mothers was 44.8 ± 20.4 ng/ml, stated to be similar to levels found in studies of term subjects. Authors calculated maximum exposure to metoclopramide would be about 3% of the recommended daily dosage for children **Process outcomes** 3/17 milk aliquots from I-group mothers had immeasurable drug levels, suggesting that some mothers did not comply with treatment **Psychosocial outcomes** The nine participants who stopped breastfeeding in the first week cited a variety of reasons including 'too little milk', 'too much stress' and 'too busy'; 4/9 (44%) were non-white, 5/9 (55%) were single, and more had had maternal complications than in the sample as a whole **Cost-effectiveness outcomes** Not reported	*C group:* Stopped breastfeeding in the first week of the study (6)	National Institutes of Health, and Children's Miracle Network grant proposal 1131

I, intervention group (metoclopramide tablets for 10 days); C, control group (placebo tablets for 10 days).

TABLE 55 *Jones 2001*[114]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Jones 2001 UK **Research aims** 1. To compare the effect of sequential versus simultaneous breast pumping on volume of milk expressed and its fat content 2. To measure the effect of breast massage on milk volume and fat content **Study design** 1. RCT 2. Crossover trial **Method of group allocation** Randomised centrally into 6 groups (3 for gestational age and 2 for parity)	**Selection** Mothers of infants being cared for in the Neonatal Unit of North Staffordshire Maternity Hospital October 1997 to August 1999 **Inclusion criteria** Mothers wishing to express breastmilk **Exclusion criteria** Mothers unable to express ≥5 times per day before the start of the study Mothers with retained products of conception Mothers living outside the study hospital's area expecting to return to their local hospital before their infant reached term	*Mothers* Age and SES not reported *I1 (Sim n = 16); C1 (Seq; n = 17)* First pregnancy 5/16; 7/17 Breastfed previously 8/16; 6/17 Multiple births (twins) 3 sets; 3 sets *Infants* Mean weeks gestational age 29.9; 30.2 Mean kg birthweight 1.46; 1.61 **Group comparability** Not reported	**Standard care** Study unit had active breastfeeding policy All mothers provided with information leaflet on milk expression technique All mothers had opportunity to view a video made by the researchers covering milk expression and preterm breastfeeding **All participants** Egnell Ameda Electric Elite pumps (Egnell Ameda, Taunton, Somerset, UK) with silastic shield inserts, were loaned for the duration of the trial Mothers were encouraged to express × 8 per day until milk no longer entered the collection set **I1: *n* = 25 randomised to simultaneous pumping** Mothers were asked to use the study pump in simultaneous pumping mode (both breasts at once) **C1: *n* = 27 randomised to sequential pumping** Mothers were asked to use the study pump in sequential mode When milk from the first breast no longer entered the collection set, mothers were asked to switch breasts	**Statistical techniques** Repeated measures ANOVA on mean milk volume and mean fat content between days 2 and 4 (1 day of massage and 1 day of non-massage for each woman) The means were calculated by the total daily volume/number of expressions that day. Both groups had a mean of 5.2 expressions per day. Results from 36 mothers with complete data **Breastfeeding/breastmilk-related outcomes** *Fully breastfeeding or expressing milk at term (37 weeks)* I1 (Sim): 1/17 did not establish breastfeeding C1 (Seq): 15/19 fully breastfeeding or expressing Weeks expressing/breastfeeding until term ranged from 5 to 13 weeks The authors state that differences in milk yield per expression were significant at the $p < 0.01$ level between sequential and simultaneous pumping, and between massage and non-massage. Fat concentration was similar in all groups. Total fat was significantly different between simultaneous pumping and sequential pumping ($p < 0.01$), but not for massage vs no massage	52 randomised (27 Seq, 25 Sim) 16/52 lost (31%) Missing from Seq 27 – 19 = 8 Missing from Sim 25 – 17 = 8 Reasons given, but not by group: • 4 infant deaths • 5 critically ill infants • 2 infants transferred for surgery • 1 mother with mastitis • 4 social reasons	Available data were analysed according to randomised group for the comparison between simultaneous and sequential pumping The authors concluded that simultaneous pumping produces more milk than sequential pumping. Massage has an additive effect, improving milk production in both groups The author provided additional information about method of randomisation Funded by Baby Lifeline

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of allocation Mother **Unit of analysis** Group **Sample size calculation** 39 in each arm for 80% power and 5% significance based on an improvement in milk yield of 20–50%. Interim analysis of 36 complete data sets showed highly significant results and recruitment was discontinued **Outcome measures** Milk weight Milk fat Mothers' views Breastfeeding duration			**I2: Breast massage prior to pumping** (all participants on two of the four study days) Gentle tactile stimulation of mammary and nipple tissue using a hand action that rolled the knuckles downwards over the breast, beginning at the ribs and working towards the areola This technique did not involve manual expression of milk **C2: No breast massage prior to pumping** (all participants on two of the four study days) **Data collection** The study took place during two 48-hour periods (total 4 days), starting on day 4 or when engorgement had been relieved Mothers were randomised to massage on either days 1 and 2 or days 3 and 4 of the study On study days 1 and 3, mothers familiarised themselves with breast massage and data collection Data were collected on study days 2 and 4 only Mothers logged date, time and duration of each expression, and weight of collection bottles before expression Researchers logged weight of collection bottles after expression Capillary sample from each milk sample for creamatocrit test Two questionnaires to mothers at trial completion, and mothers were asked about feeding method at 37 weeks postconception (term)	*Mean (95% CI) breastmilk weight (g):* Seq (non-massage): 51 (46–56) Seq (massage): 79 (73–85) Sim (non-massage): 88 (79–97) Sim (massage): 125 (110–140) *Mean (95% CI) fat concentration (g/l):* Seq (non-massage): 7.1 (5.9–8.3) Seq (massage): 6.7 (5.7–7.7) Sim (non-massage): 7.0 (5.9–8.1) Sim (massage): 6.8 (5.7–7.9) *Mean (95% CI) total fat (g):* Seq (non-massage): 3.1 (2.7–3.5) Seq (massage): 4.2 (3.8–4.6) Sim (non-massage): 6.0 (5.3–6.7) Sim (massage): 8.0 (6.9–9.1) **Clinical/health outcomes** Not reported **Process outcomes** 30/36 mothers began the study on postpartum day 5 and 6/36 on day 7 Simultaneous pumping took mothers 10–15 minutes compared with 25–40 minutes for sequential pumping **Psychosocial outcomes** Women appreciated massage and simultaneous pumping to expedite milk flow, and voiced a need for larger milk collection sets **Cost-effectiveness outcomes** Not reported		

I1, intervention 1 group (simultaneous pumping on 4 days); C1, control 1 group (sequential pumping on 4 days).
I2, intervention 2, all participants (breast massage prior to pumping on 2 of 4 days); C2, control 2, all participants (no breast massage prior to pumping on the other 2 days).

TABLE 56 *Mersmann 1993*[148]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Mersmann 1993 USA PhD dissertation, New York University **Research aim** To test the hypothesis that quantity and fat content of expressed milk in mothers of non-nursing infants will be greater following therapeutic touch (TT) than following mimic therapeutic touch (MTT) or no treatment (NT) **Study design** Randomised crossover study **Method of group allocation** Treatment sequence allocated using random numbers table **Unit of allocation** Mother	**Selection** Mothers of infants in a 58-cot NICU in a major US metropolitan medical centre **Inclusion criteria** Mothers of non-nursing preterm infants Expressing breastmilk for at least 2 weeks Literate in English **Exclusion criteria** Mothers with diabetes, hypoglycaemia or an acute illness Previously received TT	*Mothers* Age: Mean 31 ± 5.3 years 21–25: 4 (22%) 26–30: 5 (28%) 31–35: 6 (33%) 36–40: 2 (11%) 41: 1 (6%) Insurance Private: 16 (89%) Public assistance: 2 (11%) Marital status Married: 17 (94%) Not married: 1 (6%) Race Caucasian: 8 (44%) Hispanic: 6 (33%) Black: 4 (23%) Number of other children: 0: 11 (61%) 1: 3 (17%) 2: 3 (17%) 3: 1 (6%) Twin birth: 3/18 (17%) Breastfed previously: 6/18 (33%) Current milk expression: Days expressing milk 14–20: 9 (50%) 21–27: 2 (11%) 28–41: 3 (17%) > 42: 4 (22%)	**Intervention** Therapeutic touch (TT) Followed a 6-step standard procedure: 1–2. TT nurse assumes a self-aware state and forms the conscious intent to therapeutically assist the patient 3. Moves her hands, 2–4 inches above the patient's body from head to feet, without physical contact, attuning to the patient's condition by becoming aware of different sensory cues in her hands 4–5. Redirects areas of tension in the patient by hand movements, focusing her intent, via her hands, on the specific direction of these energies 6. Places her hand over the area of the patient's solar plexus (just below the waist) and directs energy to the patient TT provided by four experienced TT nurses Length of TT was determined by the nurse's assessment of the mother **Control 1:** Mimic therapeutic touch (MTT), designed as a single-blind control for TT Follows a 6-step standard procedure: 1–2. MTT nurse forms the intent to perform the movements demonstrated to her and focuses attention on subtracting from 100 by 7s 3. Moves her hands, 2–4 inches above the patient's body from head to feet, without physical contact, while continuing to subtract from 100 by 7s	**Statistical techniques** Descriptive statistics, one-way repeated measures MANOVA **Breastfeeding/breastmilk-related outcomes** *Leaking of breastmilk* during study treatments *n* (%) (*N* = 18) |	No	Yes
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TT	13 (72)	5 (28)
MTT	17 (94)	1 (6)
NT	18 (100)	0 (0)	 More mothers experienced milk leaking after TT than MTT ($p < 0.05$) *Volume (ml) milk expressed* after study treatments (not adjusted for milk leaked) (*n* = 18) Mean; SD; median; range TT: 59.9; 53.9; 47; 5–200 MTT: 49.6; 49.0; 38; 4–220 NT: 47.3; 52.6; 32; 4–220 Author notes the large SDs reflect the large interparticipant variability *Fat content* (g/100 ml) [creamatocrit %] of a hindmilk sample expressed after study treatments (*n* = 18) Mean; SD; median; range TT: 6.6 [10.2]; 2.6 [3.8]; 67 [10]; 21–103 [4–16] MTT: 7.1 [10.9]; 2.8 [4.1]; 71 [11]; 23–106 [4–16] NT: 6.8 [10.5]; 3.1 [4.4]; 67 [10]; 23–142 [4–-21]	21 mothers agreed to participate Researcher reports that three were dropped Two of these were found not to meet inclusion criterion (had expressed < 2 weeks) The third was unable to complete the study because of investigator illness Data from 18 mothers of 21 infants were analysed	Standard care on the study unit Breastfeeding pamphlets and an electric breast pump were located in a newly created breastfeeding cubicle Mothers of non-nursing preterm infants were neither encouraged to express nor discouraged from expressing milk for their infants Neither unit-based lactation consultants nor other mechanisms of support were available Lactation educators were available on request but generally assisted with infant suckling Kangaroo care was not practised

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of analysis Mother **Sample size calculation** 17 participants in a crossover design with three trials to provide a power of 0.80 to detect a medium effect size at the 0.05 level of significance Outcome measures Quantity and fat content of expressed milk		Frequency of expression (number of times/day) 2–4: 11 (61%) 5–8: 6 (33%) > 9: 1 (6%) During recruitment 16/18 reported a current problem maintaining milk supply *Infants* Gestational age in weeks (%) Mean ± SD, median: 31.5 ± 3.4, 32 < 30: 5 (24%) 30–34: 14 (67%) > 34: 2 (9%) Birthweight in g (%) Mean ± SD, median: 1660 ± 912, 1533 Birthweight (g) < 1000: 4 (19) 1001–1500: 6 (29) 1501–2000: 9 (43) 2001–2500: 0 (0) 2501–3000: 0 (0) > 3001: 2 (9) **Group comparability** Not applicable	4–5. Returns (again) to the patient's head and repeats step 3 6. Places her hand over the area of the patient's solar plexus (just below the waist) and begins counting backwards from 200 MTT provided by experienced nurses who were taught MTT movements by the investigator. They had not learned TT. Length of MTT was matched with length of previous TT treatment **Control 2:** No treatment (NT) All study mothers The 18 mothers received TT, MTT and NT in a randomly assigned order Mothers received the treatments on three of five consecutive days, immediately before expressing breast milk with an electric breast pump Time since last expression and time of day kept constant for each mother Mothers maintained their usual milk expression routine **Data collection** The investigator recorded volume and performed three creamatocrits on milk expressed at each treatment	*Study hypothesis not supported; volume of breastmilk expressed after TT was greater than after MTT or NT ($p < 0.05$) but fat content was not* **Clinical/health outcomes** Not reported **Process outcomes** Treatment time (minutes) Mean; SD; median; range TT: 11.0; 1.6; 11; 9–15 MTT: 10.7; 2.2; 10; 8–14 No significant difference between length of TT and MTT across mothers Expression time (minutes) TT: 19.1; 5.2; 20; 10–30 MTT: 19.8; 5.0; 20; 12–20 NT: 21.3; 4.8; 20; 14–30 No significant difference in time to express milk after TT, MTT and NT **Psychosocial outcomes** Mothers' perceptions of treatment (Tx) by treatment order | Perception	TT 1st	TT 2nd
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No difference	5	3
1st	2	1
2nd	2	4	 **Cost-effectiveness outcomes** Not reported		Infants did not initiate suckling until they were successful at bottle feeding Possible confounders for milk production 4/18 mothers used a manual pump as well as an electric pump 2/18 mothers used a double pump accessory kit (not for the treatments) 1/18 used a heat pad 3/18 always used massage 1/18 always used imagery **Funding** Not reported

TABLE 57 *Amali-Adekwu 2007*[140]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Amali-Adekwu 2007 Nigeria **Research aim** To evaluate the effect of selective hindmilk feeding on the growth of preterm low birthweight babies **Study design** Randomised controlled trial **Method of group allocation** Randomised (method of randomisation not stated) Stratified by birthweight and gestational age **Unit of allocation** Individual infants **Units of analysis** Infant groups Milk produced by mothers of the infant groups **Sample size calculation** None reported	**Selection** Infants admitted to SCBU of Jos University Teaching Hospital, Nigeria **Inclusion criteria** Healthy preterm infants weighing between 1000 and 1499 g with a gestational age < 37 weeks **Exclusion criteria** Infants with congenital abnormalities Infants unable to tolerate full enteral feeding by 72 hours of age Serious maternal postnatal illness Known maternal HIV infection	**Infants small for gestational age (SGA)** *I (n = 17); C (n = 17)* Mean ± SD birthweight (g) 1278.3 ± 168.2; 1267.8 ± 149.4 Mean gestational age (weeks) 33.05 ± 2.06; 33.97 ± 1.15 Age at enrolment (days) 6.05 ± 0.80; 5.82 ± 0.70 Weight on enrolment (g) 1173.45 ± 146.57; 1191.29 ± 137.06 **Infants appropriate for gestational age (AGA)** *I (n = 17); C (n = 17)* Mean birthweight (g) I: 1380.47 ± 103.52; C: 1430.88 ± 54.42	All infants were fed for the first 4 days after the establishment of enteral feeding with composite milk (whole breastmilk) to ensure uniform colostrum ingestion From day 5 feeds were 2 hourly by intermittent gavage Volume of feeds was increased daily by 15 ml/kg to a maximum 200 ml/kg/day **I: *n* = 34** (17 SGA and 17 AGA) From day 5 infants received hindmilk (defined as milk collected after the first 3 minutes of pumping; a colour difference from white to yellow was noted at the beginning of hindmilk collection) After 14 days the intervention ended and infants once more received composite milk	**Statistical techniques** Student's *t* test, ANOVA, linear regression **Breastfeeding/ breastmilk-related outcomes** *Mean ± SD daily milk production (ml)* I (mothers of infants fed on hindmilk): 356.33 ± 80.25 (foremilk 35.1%, hindmilk 64.9%) C (mothers of infants fed on composite milk): 218.64 ± 47 $p < 0.0001$ *Mean daily creamatocrit (%)* I: 9.23 ± 1.89 (hindmilk) C: 5.73 ± 1.4 (composite milk) $p < 0.0001$	77 infants were recruited Five infants developed abdominal distension and vomiting (I = 3, C = 2) Four infants developed apnoeic attacks (I = 1, C = 3) All nine of these infants died (11.7%) 68 infants completed 14 days of feeding Results reported for these 68	Available data were analysed by randomised group Funding not reported

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Milk volume and composition **Infant weight gain** Infant growth		Mean gestational age (weeks) 32.38 ± 1.68; 32.81 ± 0.81 Age at enrolment (days) 6.22 ± 0.79; 5.38 ± 0.62 Weight on enrolment (g) 1297.40 ± 144.12; 1329.76 ± 97.01 No maternal data reported **Group comparability** Comparable for all parameters	**C: *n* = 34** (17 SGA and 17 AGA) Infants received composite milk (whole breastmilk) throughout **Data collection** Breastmilk obtained via mechanical pumping Fat concentration estimated by creamatocrit Calorific values derived from creamatocrits Infants weighed naked daily on a battery-operated digital scale	*Mean calorie content (J/ml)* I: 3.73 ± 0.50 (hindmilk); 2.6 + 0.34 (foremilk, not used in the study) C: 2.8 ± 0.38 $p < 0.0001$ **Clinical/health outcomes** *Infant weight gain (SGA)* Mean daily weight gain g/kg/day (range) I: 12.92±10.95 (1.2 to 21.6) C: 5.01±17.37 (–15.2 to 24.2) p<0.0001 *Infant weight gain (AGA)* I: 12.99 ± 10.75 (–12.2 to 28.4) C: results not reported numerically *p reported as < 0.009*		

I, intervention group (hindmilk); C, control group (composite milk).

TABLE 58 *Hurst 2004*[145]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Hurst 2004 USA (Houston, Texas) **Research aim** To evaluate feeding outcomes and perceptions of mothers allocated to use test weighing, compared with those of mothers not so allocated, to manage breastfeeding of their preterm infants during the first month after hospital discharge **Study design** Randomised controlled trial **Method of group allocation** Randomised using cards previously prepared and placed in sealed envelopes Randomisation stratified by gestational age	**Selection** Mothers of infants in Texas Children's Hospital NICU between August 1996 and December 1997 **Inclusion criteria** English-speaking mothers of preterm infants 31–36 weeks' gestation Mothers who had maintained lactation throughout the NICU stay and intended to continue breastfeeding postdischarge **Exclusion criteria** Infants small for gestational age Infants with any structural or functional anomalies that might interfere with feeding	Reported for the 31 mothers who completed the study *Mothers* *I (n = 15); C (n = 16)* Mean age [SD] (range) in years 32 [5.5] (17–40); 29 [5.7] (19–40) Caucasian, non-Hispanic 11 (73%); 9 (56%) African American 2 (13%); 4 (25%) Hispanic 1 (7%); 3 (19%) Asian 1 (7%); 0 Married 14 (93%); 12 (75%) Mean years [SD] education 15 [1.7]; 16 [2.2] Income > $30,000 3 (20%); 4 (25%) Twin birth 3 (20%); 3 (19%) First birth 9 (60%); 13 (81%) Breastfed previously 3 (20%); 3 (19%)	**I: *n* = 24** Mothers were provided with an electronic scale for in-home use Mothers were instructed to weigh infants before and after each breastfeed to determine breastmilk intake (test-weighing) Mothers managed extra milk feedings based on prescribed volumes in discharge feeding plan and through consultation with their primary care provider **C: *n* = 22** Mothers had no scale Mothers were instructed to determine the need for extra feedings on the basis of clinical indices (i.e. strength and duration of infant sucking, observation of swallowing, degree of breast softening during feeding, infant behaviour) and through consultation with the primary care provider **Standard care** NICU feeding routines included skin-to-skin contact and suckling opportunities. During transition from tube feeding to breastfeeding, oral feeds when mothers not present were mainly by bottle.	**Statistical techniques** Univariant statistics and frequencies to describe data Chi-squared and Mann–Whitney *U* tests, repeated-measures ANOVA **Breastfeeding/breastmilk-related outcomes** *Breastfeeding at discharge (infants)* All infants partially breastfeeding (1–3 feeds per day) *Breastfeeding at 4 weeks (mothers)* I (*n* = 15); C (*n* = 16) Exclusive breastfeeding: I: 4; C: 4 Breastfeeding plus EBM: I: 3; C: 3 Breastfeeding plus EBM plus formula: I: 7;C: 8 No breastfeeding: I: 1; C: 1 Supplementary/complementary feeds (20–90% of daily feeds) were given by bottle *Duration of breastfeeding* I (*n* = 9): 5.9 months [SD 4 months] C (*n* = 10): 6.6 months [3 months] **Clinical/health outcomes** *Mean daily weight gain [SD] g* Week 1: 37.5 [12.4]; 35.5 [18.4] Week 2: 40.2 [15.8]; 44.7 [20.1] Week 4: 46.1 [17.1]; 48.5 [19.9] Differences not statistically significant	46 mothers consented and were randomised (I = 24, C = 22) 15 (34.6%) did not complete the 4-week study protocol (I = 9, C = 6) *Reasons:* Failure to complete daily feeding records (I = 3, C = 2) Maternal decision to exclusively bottle-feed (I = 1, C = 2) Maternal illness (I = 2, C = 1) Paediatrician recommended changing to formula (I = 1) Grandmother recommended changing to formula (C = 1) Mother returned to employment (I = 2)	Available data were analysed by randomised group Numbers for infant outcomes are unclear **Funding** Study partly funded by Medela, Inc. (McHenry, IL)

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of allocation Mother **Unit of analysis** Mothers Infants **Sample size calculation** Not reported **Outcome measures** Mothers' perceptions of using in-home weighing Mean daily infant weight gain Attainment of breastfeeding goals Mothers' breastfeeding concerns		*Infants* Gestational age (weeks) Mean [SD] (range) I: 33 [2] (31–36) C: 33 [2] (31–36) Birthweight (g) I: 1960 [526] (910–2725) C: 1998 [455] (1305–2885) First breastfeed (day of life) I: 11 [12] (1–24) C: 11 [17] (1–38) Hospital discharge (day of life) I: 23 [18] (2–51) C: 24 [16] (4–55) Weight at discharge (g) I: 2378 [304] (1820–2822) C: 2428 [373] (1742–3068) **Group comparability** The groups were found to be similar for the characteristics reported	Thin silicone nipple shields were used for infants needing help to sustain attachment to the breast. Test-weighing was used intermittently. A lactation consultant telephoned all mothers within a few days of discharge from NICU **Data collection** Demographic data from clinical records Infant weight gain recorded by research assistant at discharge and at 1, 2 and 4 weeks postdischarge Mothers maintained a record of infant feeding patterns from discharge over the first 4 weeks at home Likert-type questionnaire to rank mothers' breastfeeding concerns at 1, 2 and 4 weeks	**Process outcomes** *Breastfeeding goals at hospital discharge (breastfeeding at 4 weeks)* I ($n = 15$); C ($n = 16$) Exclusive breastfeeding: I: 3 (4); C: 2 (4) Give additional milk feeds of either EBM or formula: I: 12 (10); C: 14 (11) No breastfeeding: I: 0 (1); C: 0 (1) At 4 weeks, 19/31 mothers had met or exceeded their goals **Psychosocial outcomes** *Breastfeeding concerns* The most commonly cited concerns were the same for both groups: 'knowing that my baby is gaining enough weight'; 'knowing how much milk my baby takes at each feeding'; and 'my baby taking enough milk from the breasts' *Perceptions of using in-home test-weighing* Very/extremely helpful: 15 (100%) Did the scales make you nervous? Not at all: 10 (67%) Somewhat: 5 (33%) **Cost-effectiveness outcomes** Not reported	Paper states there were no differences in maternal or infant characteristics between those who did and did not complete the study	

EBM, expressed breastmilk.
I, intervention group, infants weighed pre- and post-breastfeeds; C, control group, standard care.

TABLE 59 *Griffin 2000*[20]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Griffin 2000 USA **Research aims** To determine the accuracy with which mothers (compared with nurses) performed creamatocrits (CRCTs) on their own mother's milk (OMM); to elicit maternal reaction to performing CRCTs; to evaluate the cost-effectiveness of this approach; to ascertain whether income, educational and ethnic background influenced accuracy, reactions, and time spent teaching the CRCT procedure **Study design** Concurrent comparison **Method of group allocation** Convenience **Unit of allocation** Mother	**Selection** Mothers expressing own mother's milk for feedings in the NICU **Inclusion criteria** CRCT measures clinically indicated for management of the infant's nutritional plan **Exclusion criteria** None stated	*Mothers* Age not reported Income ($N = 25$) *n* (%) < $30,000: 9 (36) $30,000–75,000: 8 (32) > $75,000: 8 (32) Education ($N = 26$) *n* (%) ≤ 12 years: 8 (30.8) 13–16 years: 14 (53.8) > 16 years: 4 (15.4) Occupation ($N = 26$) *n* (%) Professional: 10 (38.5) Skilled: 10 (38.5) Homemaker: 6 (23.0) Ethnicity ($N = 26$) *n* (%) African American 9 (34.6) White: 12 (46.2) Hispanic: 5 (19.2) Parity, multiple births and breastfeeding experience not reported *Infants* Characteristics not reported	**Phase 1** Mothers were taught to perform CRCTs by one of two instructional nurses (IRNs) using a standard teaching tool Mothers practised doing CRCTs over the following 72 hours **Phase 2** Each mother performed two CRCTs on the same freshly expressed OMM specimen simultaneously with one of the two validating RNs (VRNs) Mothers used the same centrifuge in both phases; VRNs used a different centrifuge in an area adjacent to NICU IRNs were blind to all CRCT measures performed in Phase 2 and VRNs were blind to teaching procedure in Phase 1. For Phase 2, mothers and VRNs were blinded to each other's CRCT measures	**Statistical techniques** Differences between mothers' and nurses' measures were compared using mean, SD, minimum and maximum differences, mean absolute difference (MAD), the percentage of differences of ≤ 0.5% and 1% CRCT, and the percentage of error. Mothers' and nurses' measures were compared using Pearson and Spearman correlation coefficients as appropriate and illustrated with Bland–Altman plots. Descriptive statistics for other outcomes **Breastfeeding/breastmilk-related outcomes** The mothers' CRCT measurements were highly accurate compared with those of the VRN (MAD 0.69; SD 0.93; min. 0; max. 2.50; 50% of errors < 0.5%; 84/6% of errors < 1.0%, $r = 0.9532$) No systemic error in the differences for high, low or individual CRCT values was revealed on the Bland–Altman plot The percentage of error in mothers' measurements (6.8%) was lower than that achieved in a pilot study by the two VRNs (10.51%) No statistically significant association was found between magnitude of maternal error and demographic variables tested Trends identified – mothers with fewer formal years of education and those who reported employment in 'skilled' vs 'professional' jobs performed CRCTs with greater accuracy **Clinical/health outcomes** Not reported **Process outcomes** Mean (range) minutes spent teaching mothers: 23.6 (10–45)	None	

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of analysis Differences in CRCTs between mothers and validating nurse **Sample size calculation** Not stated **Outcome measures** Validation CRCT for mothers and nurses Mothers' reactions to performing CRCTs Time spent teaching mothers Demographic information		**Group comparability** This group of mothers was noted to be diverse with respect to maternal age, education, occupation, income and racial/ ethnic background	CRCT measures by the VRNs served as the accurate standard to which mothers' values were compared **Data collection** Time spent teaching mothers Demographic questionnaire Phase 2 CRCT values were recorded by the mother and nurse on separate, previously prepared index cards Four-item Likert-type questionnaire on mothers' perceptions of learning CRCT procedure	**Psychosocial outcomes** *Mothers' reactions to performing CRCTs (n = 25)* 1. It was easy for me to learn the CRCT procedure Uncertain 4%, Agree 40%, Strongly agree 56% 2. I felt comfortable performing the CRCT Uncertain 4%, Agree 32%, Strongly agree 64% 3. Performing the CRCT made me feel more involved in my baby's care Uncertain 4%, Agree 20%, Strongly agree 76% 4. I would recommend that other mothers be given the opportunity to perform CRCTs Uncertain 0%, Agree 12%, Strongly agree 88% Nineteen mothers provided free text comments. Main themes of these were mothers' feelings of involvement and control with respect to infant care, and of reassurance that their lactoengineered[a] OMM had the desired calories for infant feeding **Cost-effectiveness outcomes** For the average lactoengineering intervention, approximately 186.4 minutes of nursing time would be saved per infant if a mother performed a daily CRCT measure on her OMM		

CCRT, creamatocrit; OMM, own mothers' milk.

a Lactoengineering, as described in this paper, means individualising the lipid and caloric content of OMM by separating foremilk from hindmilk, using CRCTs to individualise the OMM fractionation procedure, and matching the relative volumes of foremilk and hindmilk fed to the infant to the infant's nutritional needs.

TABLE 60 *Agrasada 2005*[117]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Agrasada 2005 The Philippines (Manila) **Research aim** To test the efficacy of home-based, postnatal peer counselling for mothers of term low-birthweight infants on breastfeeding exclusivity and duration **Study design** RCT **Method of group allocation** Random numbers table **Unit of allocation** Mother-infant pair **Unit of analysis** Mother-infant pair **Sample size calculation** 64 mothers per group for 80% power to detect a 30% absolute difference in exclusive breastfeeding	**Selection** Births at Philippine General Hospital (PGH), Manila January 2001–August 2002 PGH was assessed 'Baby-Friendly' in 1993 **Inclusion criteria** First-time mother ≥18 years old Intended to breastfeed Vaginal delivery at term (37–42 weeks) Singleton low birthweight (LBW) infant (< 2500 g) Apgar score ≥8 at 5 minutes **Exclusion criteria** Mothers taking medications that may compromise breastfeeding Mothers not staying with their infants in the study area until the infant was 6 months old	*Mothers* BC ($n = 68$); CC ($n = 67$); C ($n = 69$) Mean [SD] age (years) 22.7 [4.5]; 23.2 [4.4]; 23.2 [4.7] *Education n (%)* Primary school or none: 4 (5.9); 7 (10.4); 2 (2.9) Secondary: 41 (60.2); 36 (53.7); 33 (47.8) College: 23 (33.8); 24 (35.8); 34 (49.3) *Living with partner n (%)* 48 (70.6); 47 (70.1); 48 (69.6) *Study/work outside home n (%)* 22 (32.4); 22 (32.8); 21 (30.4) Mean [SD] income pa (US$) 1358 [126]; 1310 [100]; 1325 [126] All were first-time mothers of singleton infants *Infants* Mean [SD] age of gestation (weeks) BC ($n = 68$): 39.2 [0.5] CC ($n = 67$): 39.2 [0.6] C ($n = 69$): 39.4 [0.3] Mean [SD] birthweight (g) BC ($n = 68$): 2340.6 [165.6] CC ($n = 67$): 2368.1 [117.7] C ($n = 69$): 2365.4 [156.3]	**All study groups** Mothers who vaginally delivered term LBW infants were sent to the rooming-in ward Term LBW infants with birthweights < 2kg were observed in the NICU for 12–24 hours While separated from their mothers, these infants received (by dropper) fresh expressed breastmilk (EBM) donated by lactating mothers on the ward As soon as infants stable, they joined their mothers on the rooming-in ward No hospital staff or volunteer was tasked to educate or assist mothers with breastfeeding in the rooming-in ward Mothers recruited and randomised during hospital stay Mothers' breastfeeding knowledge tested at recruitment Mothers informed of group assignment as leaving hospital All study mothers were discharged on or before postnatal day 3, breastfeeding exclusively **Peer counsellors** 14 women health volunteers (age 22–50 years) with similar formal education to the mothers and willing to do home visits undertook 40 hours counselling training 6/14 trained by a maternal child health-care specialist became childcare counsellors (for CC)	**Statistical techniques** Descriptive statistics, chi-squared tests, general estimating equation (GEE) models, survival analyses, two-sided tests of significance **Breastfeeding/breastmilk-related outcomes** BC ($n = 68$); CC ($n = 67$); C ($n = 69$) *Exclusive breastfeeding from birth to 6 months* 22 (32%); 2 (3%); 0 *At 6 months, exclusive breastfeeding during the last 7 days* 33 (44%); 5 (7%); 0 *Any breastfeeding at 6 months* 43 (63.2); 21 (31.3); 20 (29); $p < 0.001$) About 70% of CC and C mothers stopped exclusive breastfeeding at 2 weeks Half the BC mothers stopped exclusive breastfeeding at 5 weeks Using generalised estimating equation (GEE) analysis, mothers who received breastfeeding counselling were 6.3 times more likely to breastfeed exclusively than mothers of other groups ($p < 0.001$, 95% CI: 3.53–11.3) GEE analysis also showed the proportions of mothers in CC and C groups breastfeeding exclusively were not significantly different ($p = 0.95$, 95% CI: 0.50–1.91)	204 mother-infant pairs randomised *Withdrawals* • 8/68 BC (11.8%) (relocated) • 7/67 CC (10.4%) (6 relocated, 1 infant adopted) • 10/69 C (14.5%) (9 located, 1 infant adopted) Overall dropout 25/204 (12.3%)	Data were analysed using intention-to-treat model It appears that well LBW infants with birthweight 2–-2.5 kg were not separated from their mothers for 12–24 hours observation in SCBU Results for these infants are not reported separately **Funding** Swedish International Development Cooperation Agency (SIDA), InDevelop, the Swedish Institute, Uppsala University, The Philippine Department of Science and Technology, and the University of the Philippines, Manila

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
between the two intervention groups, with $\alpha = 0.01$, a two-sided test and adjustment for 20% attrition **Outcome measures** Exclusive breastfeeding 2 weeks to 6 months Any breastfeeding at 6 months Infant growth and health outcomes, mothers' views		Median (range) birthweight (g) BC ($n = 68$): 2400 (1700–2490) CC ($n = 67$): 2400 (2000–2490) C ($n = 69$): 2440 (1750–2490) **Group comparability** Statistical significance of differences in participant characteristics between the groups not reported	8/14 with positive personal breastfeeding experience trained by a certified lactation specialist and became breastfeeding counsellors (for BC) Received local transport costs during training and home visits; did not receive a salary Eight home visits were scheduled (at infant age days 3–5, 7–10 and 21, then monthly up to 5.5 months) Counsellors used a semistructured home visitation guide **BC: $n = 68$** Counsellors informed mothers of benefits of exclusive breastfeeding to 6 months Counsellors assisted mothers in preventing and managing breastfeeding problems **CC: $n = 67$** Counsellors assisted mothers on infant care and increasing mother–infant interaction using activities such as infant massage and smile therapy **C: $n = 69$** Clinic visits only, no input from peer counsellors **Data collection** Mothers were asked to come to the hospital clinic for seven infant visits (at 2 and 4 weeks then monthly until 6 months), where study measures were taken	**Clinical/health outcomes** *Weight for age (WAZ) ± SD at 6 months* BC: -1.96 ± 0.26 to -1.10 ± 0.83 CC: -1.91 ± 0.18 to -0.92 ± 0.93 C: -1.91 ± 0.22 to -0.92 ± 0.87 No significant differences between the groups in mean WAZ scores at birth or 6 months *Death* No infant in the study died *Diarrhoea* BC: 9/60 (15%) CC: 17/60 (28.3%) C: 18/59 (30.5%) **Process outcomes** Counsellors of both groups had similar caseloads and participated until the end of the study Proportions of breastfeeding outcomes of mothers with the same breastfeeding counsellor were similar **Psychosocial outcomes** At exit interview, mothers who had counsellors stated they were satisfied with the programme BC mothers said the counsellor was the person who had influenced their feeding decisions the most CC and C mothers said the physician had influenced their feeding decisions the most **Cost-effectiveness outcomes** Not reported		

BC, Breastfeeding counselling intervention group; CC, Childcare counselling intervention group; C, no counselling control group.

TABLE 61 *Merewood 2006*[143]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Merewood 2006 US (Boston, MA) **Research aim** To examine whether peer counsellors improved the duration of breastfeeding among premature infants admitted to an urban NICU **Study design** RCT **Method of group allocation** Computer randomised (SAS) **Unit of allocation** Mother **Unit of analysis** Mother	**Selection** Mothers of infants in Level III, 15-cot NICU at Boston Medical Center (a Baby Friendly hospital) between January 2001 and September 2004 **Inclusion criteria** Healthy premature infant born at 26–37 weeks' gestation Mother intended to breastfeed Mother eligible to breastfeed[a] Mothers spoke English or Spanish **Exclusion criteria** Mothers incapacitated from participation by illness or birth complications Infants with congenital abnormalities Infants with life-threatening conditions in the immediate postpartum period	*Mothers* I ($n = 48$); C ($n = 53$) *Insurance status n (%)* Medicaid: 27 (56.3); 27 (50.9) Private/HMO: 8 (16.7); 4 (7.5) Other: 13 (27.1); 22 (41.5) *Race/ethnicity n (%)* African American non-Hispanic: 35 (72.9); 35 (66.0) White non-Hispanic: 3 (6.2); 2 (3.8) Hispanic: 5 (10.4); 14 (26.4) Other: 5 (10.4); 2 (3.8) US born: 12 (25.0); 17 (32.1) Non-US born: 36 (75.0); 36 (67.9) Age, parity, breastfeeding experience and multiple births not reported *Infants* I ($n = 48$); C ($n = 53$) Mean weeks gestational age (GA) (range): 32.6 (26.3-37); 32.7 (26.4–36.3) GA 26–32 weeks (%): 14/48 (29); 16/53 (30)	**I: $n = 48$** Initial peer counsellor contact took place within 72 hours postpartum. Peer counsellors were women with breastfeeding experience, drawn from the local community, who were trained at a 5-day breastfeeding course. After initial contact, the peer counsellor was in contact with the mother on a weekly basis for 6 weeks. After the infant was discharged from hospital, contact was by telephone unless mother went to hospital	**Statistical techniques** Chi-squared tests, hypothesis tests with a significance level of $\alpha = 0.05$ **Breastfeeding/breastmilk-related outcomes** At 12 weeks women who received peer counselling were more likely to provide '*any*'[b] breastmilk than those who did not receive the intervention (OR = 2.81; 95% CI: 1.11–7.14; $p = 0.03$)[c] At 12 weeks, women in the intervention group were also more likely to be providing '*mostly*'[d] breastmilk (OR = 2.49; 95% CI: 0.97–6.40; $p = 0.006$) but not 'all' breastmilk (OR = 1.30; 95% CI: 0.30–5.65; $p = 0.72$) than women in the control group *Subgroup analysis:* When only African American women were analysed, those receiving the intervention ($n = 30$) had odds of providing 'any' breastmilk 249% greater than those without peer counselling ($n = 29$) (OR = 3.59; 95% CI: 1.16–11.03; $p = 0.03$); however, there were no significant differences between groups for 'mostly' or 'all' breastmilk **Clinical/health outcomes** Not reported	108 randomised, 48 to the intervention group and 53 to the control group In those assigned to the intervention group, 5 did not receive intervention and 10 were lost to follow-up; 38 analysed In the control group 2 were withdrawn and 6 were lost to follow-up; 47 analysed	Available data were analysed by randomised group **Funding** Study was supported by a grant from the Bureau of Maternal Child Health, in part by a grant from the National Institute of Child Health and Human Development

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation Sample size based on an estimate that 10% of the infants would be breastfeeding at 12 weeks. Assuming that $\alpha = 5\%$ and power = 80%, the sample size needed was 78 **Outcome measures** Any breastfeeding at 12 weeks postpartum		GA > 32 weeks (%): 34/48 (71); 37/53 (70) Mean g birthweight (range): 1914.4 (724–3320); 1840.0 (682–3305) **Group comparability** No significant differences were found between the groups	**C: *n* = 53** Baby Friendly standard care, which included referrals to the lactation consultant when needed, use of a breast pump, access to three breastfeeding classes per week, and staff highly trained in lactation **Data collection** Breastfeeding status determined using infant's medical records and by maternal recall after discharge (breast and/ or formula feeds in the previous 48 hours)	**Process outcomes** Mean days hospital stay (range) I: 27.1 (2–81) C: 25.2 (1–104) Among 42/48 (90%) of the intervention group, peer counsellors discussed pumping techniques at the initial contact (100%); helped the mother pump (72.1%); accompanied the mother to NICU (72.1%); helped the mother to breastfeed, kangaroo care or both (30.2%) At 4 weeks, 37.2% of the infants remained in NICU and 81.3% of their mothers were seen in person by the peer counsellor in the NICU **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported		

I, Peer counselling intervention group; C, Baby Friendly standard care control group.

a In accordance with guidelines from the American Academy of Pediatrics.[60] These state breastfeeding is not in the best interests of the infant in the following situations: infant with galactosemia; infant whose mother has untreated active tuberculosis; infant in the US whose mother has been infected with HIV; infant whose mother is taking any of a few prescribed medications; infant whose mother uses illegal drugs. The authors of this paper (Merewood *et al.*, 2006) report they assessed 577 mother-infant pairs for eligibility and excluded 452 for not meeting the eligibility criteria, 'many' because of illicit drug use.

b *Any* breast milk feeding was defined as the combination of only breast milk, mostly breast milk, and mostly formula

c In another place in the paper, this *p* value is reported as 0.01. The author has clarified with this review team that the correct value is $p = 0.03$.

d *Mostly* breastmilk feeding was defined as receiving equal to or greater than 50% of their feeds as breastmilk (by gavage, bottle or at the breast).

TABLE 62 *Pinelli 2001*[126]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Pinelli 2001 Canada (Hamilton, Ontario) **Research aim** To examine whether supplementary structured breastfeeding counselling for parents of very low birthweight (VLBW) infants improved the duration of breastfeeding up to 1 year of age **Study design** RCT **Method of group allocation** Random number tables **Unit of allocation** Parents (couple) **Unit of analysis** Infant	**Selection** Infants in the tertiary level, 33-cot NICU at Children's Hospital of the Hamilton Health Sciences Corporation **Inclusion criteria** VLBW infants (< 1500 g) Inborn or transferred with their mother within 72 hours of birth Fed mother's milk by parental choice **Exclusion criteria** Multiple births Infants with severe congenital, surgical, or chromosomal abnormalities Non-English-speaking parents	I ($n = 64$); C ($n = 64$) *Mothers* Mean [SD] maternal age in years: 30 [6]; 29 [7] Mean [SD] paternal age in years: 32 [6]; 33 [8] Mother living with partner: 86%; 86% *Maternal education n (%)* < High school: 10 (16); 10 (16) Completed high school: 17 (28); 22 (35) Postsecondary: 10 (16); 16 (26) Completed university: 25 (40); 14 (23) *Social class n (%)* I,II: 60 (94); 54 (85) III: 1 (2); 4 (6) IV,V: 3 (4); 6 (9) Have other children (%): 26 (41); 25 (39) *Infants* Mean weeks gestational age [SD]: 29 [3]; 29 [3] Mean g birthweight [SD]: 1083 [267]; 1103 [261] **Group comparability** No significant differences between the groups were found	**I: *n* = 64** Supplemented structured breastfeeding counselling (SSBC) for both parents within 72 hours of birth. This involved viewing a video on breastfeeding for preterm infants; individual counselling by the research lactation consultant (not a member of the hospital staff); weekly contact in the hospital and frequent postdischarge contact through the infants' first year or until breastfeeding was discontinued **C: *n* = 64** Conventional hospital breastfeeding support (CHBS). This was the standard care of breastfeeding support from staff members during the period of hospitalisation At the time of the study, there was no specialised breastfeeding clinic available to the parents, and only a small number of staff had formal education in lactation or breastfeeding support	**Statistical techniques** Descriptive statistics, survival analysis, chi-squared test of proportions, Cox's regression model. Statistical significance set at $p < 0.05$ **Breastfeeding/breastmilk-related outcomes** *Mean duration of breastfeeding* I: 26.2 weeks (SE 2.7 weeks, 95% CI: 21.0–31.5) C: 24.2 weeks (SE 2.7 weeks, 95% CI: 19.0–29.4) Not statistically significant *Exclusive breastfeeding* No significant differences found between the groups at any time point (3, 6 and 12 months follow-up) **Clinical/health outcomes** Not reported **Process outcomes** *In SCBU:* SSBC mean (SD); CHBS mean (SD) Hours after birth pumping started: 29 (6); 26 (19) Frequency of pumping per 24 hours: 6 (2); 6 (2) Duration of pumping (minutes): 17 (6); 20 (8); $p = 0.01$ Milk pumped each time (ml): 72 (65); 66 (45) Day of life baby first put to breast: 25 (23); 25 (18) Breastfeeds per day: 3 (2); 4 (3) Cost of pump, Can $: 16 (8); 20 (13)	Unclear 128 were randomised, 64 to each group No dropouts are reported The numbers breastfeeding in each group are reported at term and at 1, 3, 6 and 12 months Other results are reported without denominators	Available data were reported by randomised group **Funding** Study was supported by a grant from the National Health Research Development Program, Ottawa, Ontario

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Sample size calculation Sample size was based on difference between success rate (10% of the infants breastfeeding at 3 months of age) and desired success rate (30%). Assuming $\alpha = 5\%$, $\beta = 2\%$, and a one-tailed test, the sample size needed was 116 (58 per group) Outcome measures Duration of breastfeeding			**Data collection** Duration of breastfeeding was determined using self-administered questionnaires	Before 12 months, mothers in both groups stated that they discontinued breastfeeding because they perceived they were not producing enough breastmilk; at 12 months, the mothers stated that the infants were no longer interested in breastfeeding **Psychosocial outcomes** *At home:* > 50% of mothers in both groups experienced breastfeeding problems including sore nipples, fatigue, not enough milk, infant not gaining weight and infant not interested in breastfeeding Mothers reported using a wide range of resources for solving breastfeeding problems at home The most used resource over all time periods was the lactation consultant. This included the research lactation consultant in the intervention group and community lactation consultants in both groups **Cost-effectiveness outcomes** Not reported		

I, intervention group, Structured Supplementary Breastfeeding Counselling; C, control group, Conventional Hospital Breastfeeding Support.

TABLE 63 *Gonzalez 2003*[166]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Gonzalez 2003 USA (Norfolk, VA) **Research aim** To find out whether the proportion of infants given their own mother's milk (OMM) in a children's hospital neonatal intensive care unit changed after the introduction of a lactation support service **Study design** Before/after study **Method of group allocation** Date **Unit of allocation** Infant **Unit of analysis** Group **Sample size calculation** 350, based on preliminary data (not described); the authors aimed to detect a 15% point difference between study groups using a two-sided test; $\alpha = 5\%$ and power = 80%	**Selection** Infants admitted to NICU of Children's Hospital of the King's Daughters in Norfolk, September 1996 to March 1998 **Inclusion criteria** Simple random sampling of database records of all admissions The majority of infants admitted were premature (< 37 weeks' gestation) or low birthweight (≤ 2500 g) **Exclusion criteria** Not reported	*Mothers* Maternal age (years) Before < 20: 30 (17%) ≥ 20: 141 (81%) After < 20: 28 (16%) ≥ 20: 145 (83%) Number of mothers not reported Other maternal characteristics not reported *Infants* Gestational age (weeks) *Before (n = 175)* < 37: 105 (67%) ≥ 37: 70 (40%) *After (n = 175)* < 37: 117 (67%) ≥ 37: 58 (33%) Birthweight (g) Before < 2500: 99 (57%) ≥ 2500: 76 (43%) After < 2500: 111 (63%) ≥ 2500: 64 (37%)	**B: *n* = 175** Records of infants admitted September 1996 to March 1997 Received usual support (not described) **Intervention** International Board Certified Lactation Consultant (IBCLC) service initiated July 1997 **A: *n* = 175** Data from records of infants admitted September 1997 to March 1998 Infants and mothers received IBCLC support An IBCLC contacted mothers within 24 hours of their infants' admission to NICU IBCLC counselled mothers regarding the benefits and options for providing her milk to the infant If mother chose to provide her milk, a feeding plan normally including a pumping regimen was developed IBCLC available 7 am to 6 pm to answer questions and assist with pumping	**Statistical techniques** Pearson's chi-squared, Wilcoxon rank sum test, univariate and multiple logistic regression **Breastfeeding/breastmilk-related outcomes** During hospitalisation, 47% of infants in the intervention group received their OMM compared to 31% in the control group ($p = 0.002$, OR = 2.0, 95% CI: 1.3–3.0) At discharge, 37% of infants in the intervention group received their OMM compared to 23% in the control group ($p = 0.004$, OR = 2.0, 95% CI: 1.2–3.2) Using logistic regression analysis, factors significantly associated with giving OMM to infants in the NICU were: IBCLC support ($p = 0.002$) White ethnicity ($p < 0.001$) Male gender ($p = 0.04$) 5-minute Agpar score > 7 ($p = 0.003$) NICU stay > 7 days ($p = 0.007$) **Clinical/health outcomes** Not reported	350 sets of records were abstracted Withdrawals unclear (results expressed as percentages)	Data were analysed in before/after groups Intervention provided by two IBCLCs and one in training, all of whom were registered nurses **Funding** Not reported

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Infants given OMM; factors associated with lack of OMM feedings		**Group comparability** No significant differences between groups were found	Private rooms equipped with pumps were available 24/7 for mothers to express milk A telephone message service was available after hours (IBCLC would contact mothers the following morning) **Data collection** Infant records Note: OMM was given by breastfeeding, bottle or through nasogastric tube	**Process outcomes** Length of stay in NICU (intervention; control): ≤7 days: I: 34%; C: 32% 8–14 days: I: 27%; C: 23% 15–30 days: I: 19%; C: 20% > 30 days: I: 19%; C: 25% Not statistically significant Discharged: Home: I: 47%; C: 51% Another hospital: I: 44%; C: 42% Died: I: 9%; C: 7% Not statistically significant **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Total cost of NICU stay did not differ between the groups		

B, before intervention (usual support group); A, after intervention (IBCLC support group).

TABLE 64 *Pereira 1984*[153]

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Pereira 1984 USA (Philadelphia) **Research aim** To determine the incidence and duration of breastfeeding before and after the introduction of a breastfeeding counselling programme **Study design** Before/after **Method of group allocation** Before/after initiation of the intervention **Unit of allocation** Mother **Unit of analysis** Mother **Sample size calculation** Not reported **Outcome measures** In-hospital breastfeeding rate Duration of breastfeeding Mothers' views of the programme	**Selection** Mothers of infants admitted to the Infant Intensive Care Unit (ICU) of the Children's Hospital of Philadelphia during the 6 months immediately preceding and the 6 months immediately following initiation of the intervention **Inclusion criteria** None specified **Exclusion criteria** Mothers of infants who died	*Mothers* *Before (n = 192)* BF (%); non-BF (%); *p* Age < 20: 6; 17; NS 20–30: 71; 58 > 30: 23; 24 Insurance status Private: 84; 56; < 0.01 Medicaid: 13: 42 None: 3; 2 Race White: 91; 77; < 0.01 Black: 9; 23 Other: 0; 0 *After (n = 210)* BF (%); non-BF (%); *p* Age < 20: 2; 16; NS 20–30: 75 ; 64 > 30: 23; 20 Insurance status Private: 89; 77; < 0.05 Medicaid: 9; 23 None: 2; 0	**Intervention** At infant's transfer to ICU, all mothers received verbal and written information about the programme Mothers interested in breastfeeding received full information from hospital social worker, who notified the programme coordinator of all mothers interested in breastfeeding Programme coordinator contacted mothers and assigned a counsellor living near them **Peer counsellors** Seventeen counsellors who had successfully breastfed their sick baby and were certified by the Childbirth Education Association of Greater Philadelphia were selected They received semi-annual orientation to ICU, with demonstration of the intensive care equipment and a lecture on common medical problems of the newborn Telephone counselling provided as needed	**Statistical techniques** Chi-squared and independent Student's *t* testing **Breastfeeding/breastmilk-related outcomes** Before (*n* = 192); after *n* = 210; *p* Number of mothers breastfeeding their infants: 32 (17%); 64 (30%); < 0.01 Number of mothers not breastfeeding their infants: 160 (83%); 146 (70%); < 0.01 Duration of breastfeeding (days) (mean ± SEM): 41.6 ± 9.4; 134 ± 12.9; < 0.001 Breastfeeding rates were significantly higher after counselling than before at 1 to 6 months inclusive. After 6 months relatively small proportions of mothers continued to breastfeed and the difference between the groups was not statistically significant 59/64 questionnaires sent to mothers were returned (93%) *Programme ranking* Very beneficial: 61% Somewhat beneficial: 39% Non-beneficial: 0%	None reported	Funding not reported

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
		Race White: 95; 74; < 0.01 Black: 5; 22 Other: 0; 4 Infant characteristics not reported **Group comparability** Before and after groups stated to be comparable	Counselling included empathy and emotional support as well as advice on collection, home storage and transport to hospital of expressed breastmilk; transition from tube feeding to breastfeeding; maternal diet during lactation and medications excreted in breastmilk **Data collection** Questionnaires for mothers' views, within 3 months after counselling ended	*Ranking of four aspects of the programme* Techniques of breastmilk collection (%): Very successful 90 Somewhat successful 9 Not successful 1 Nutritional information: Very successful 70 Somewhat successful 23 Not successful 7 Emotional support: Very successful 79 Somewhat successful 21 Not successful 0 Newborn care: Very successful 58 Somewhat successful 37 Not successful 5 **Clinical/health outcomes** Not reported **Process outcomes** Not reported **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported		

BF, breastfeeding; non-BF, non-breastfeeding; NS, not statistically significant.
A, after intervention group; B, before intervention group.

TABLE 65 *Senn 2004*[152]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Senn 2003 USA (Illinois) PhD thesis at Southern Illinois University at Carbondale **Research aim** To test the hypotheses that compared with historical controls, participation in the intervention will improve maternal perceptions about breastfeeding and breastfeeding rates, and that in the intervention group, attitude to breastfeeding will be associated with breastfeeding rates **Study design** Before/after study **Method of group allocation** Date	**Selection** Infants in NICU of Memorial Hospital of Carbondale Rural unit, serving southern 25 counties of Illinois, treating infants with birthweight ≥750 g not requiring surgery **Inclusion criteria** Preterm infants (≤34 weeks) who were in the study unit November 2002 to June 2003 Matched with medical records of infants in the study unit November 2001 to October 2002 Mothers of twins or triplets were invited to participate, with one infant chosen randomly for inclusion in the analyses	*Mothers* Before ($n = 25$); intervention ($n = 25$) Mean maternal age [SD] (range) in years 27.2 [6.3] (16–38); 26.3 [4.6] (18–34) ≤12 years' education *n* (%) 7/16 (44%); 6 (24%) ≥12 years' education *n* (%) 9/16 (56%); 19 (76%) Caucasian *n* (%) 18 (72%); 25 (100%) Minority *n* (%) 7 (28%); 0 (0%) Married *n* (%) 16 (76%); 19 (76%) Not married *n* (%) 5 (24%); 6 (24%) Private health insurance 12 (48%); 8 (32%) Public/no health insurance 13 (52%); 17 (68%) Primiparous 10 (40%); 13 (52%) *Infants* Mean weeks' gestation [SD] (range) Before: 33.5 [1.7] (29–36) Intervention: 33.0 [1.9] (29–36)	**Intervention: $n = 25$** *Lactation Education Breastfeeding Program* Two core sessions Participants given $25 Wal-Mart Gift Card for each session they attended 1. Mothers had an individual 20-minute meeting with lactation consultant shortly after the birth. Topics included pumping breastmilk, storing breastmilk in fridge and freezer, hand washing, cleaning the pump, attaching pump to breast, how long and how frequently to pump, transporting milk to hospital, labelling and separation of breastmilk, and time for questions. Mothers could practise using the pump during this session. Mothers who wanted to feed directly from the breast could meet the lactation consultant for an additional session when the infant was mature enough for this 2. Mothers were invited to a weekly 60-minute group educational session led by the lactation consultant. Activities covered infant and maternal benefits of breastfeeding and social support for breastfeeding	**Statistical techniques** Descriptive statistics, chi-squared test, Fisher's exact test, ANOVA **Breastfeeding/breastmilk-related outcomes** *Received breastmilk at least once* Before ($n = 25$): 15 (60%) Intervention ($n = 25$): 20 (80%) $p < 0.12$ *Received breastmilk within 2 days of feeding initiation* Before ($n = 15$): 4 (27%) Intervention ($n = 20$): 7(35%) $p = 0.6$ *Mean % days received breastmilk [SD] (range)* Before ($n = 15$): 47% [25] (7–86) Intervention ($n = 20$): 63% [23] (6–91) $p < 0.06$ *On days received breastmilk, mean % feedings breastmilk received [SD] (range)* Before ($n = 15$): 32% [22] (2–71) Intervention ($n = 20$): 35% [22] (1–78) NS *Ever fed directly from the breast ('nursed')* Before ($n = 15$): 12 (80%) Intervention ($n = 20$): 15 (75%) $p = 0.73$ *Mean % days nursed* Before ($n = 12$): 20% [18] (5–71) Intervention ($n = 15$): 53% [17] (29–83) $p < 0.01$ *On days nursed, mean % feedings nursed* Before ($n = 12$): 7% [7] (2–29)	25 mothers agreed to participate and were matched with 25 historical controls No withdrawals for primary outcome Guidelines were created to deal with missing feedings information	Data were analysed by before/after group The author notes as study limitations: • A new lactation consultant was appointed shortly before the programme was implemented. The individual meeting with the consultant was added to the programme at this point • Due to the study design, it was not possible to draw conclusions about the relative effectiveness of the two intervention components **Funding** Not reported

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of allocation Infant **Unit of analysis** Infant **Sample size calculation** Not reported **Outcome measures** Breastfeeding and breastmilk feeding up to discharge Mothers' views	**Exclusion criteria** Infant placed for adoption Mother needing intensive care postpartum Mother judged unable to provide informed consent Mother with first language other than English Mother used illicit drugs in pregnancy Mothers in the intervention group who did not attend at least one core session of the Lactation Education Breastfeeding Program	Mean g birthweight [SD] (range) Before: 2023 [432] (1206–2943) Intervention: 2125 [552] (1263–3729) **Group comparability** The only statistically significant difference found between the groups was for race; all the intervention group were white, and seven of the historical controls belonged to minority ethnic groups ($p < 0.01$)	*Before: n = 25* Historical controls selected from records of preterm infants to match the intervention group **Standard care** Mothers were not allowed in the NICU in the mornings During the implementation of the programme, the lactation consultant began to speak with all mothers of preterm babies (not as previously only those who expressed their intention to breastfeed). As a result many mothers had an individual meeting with lactation consultant as part of standard care, and filled in the pre-intervention maternal breastfeeding questionnaire (MBQ) after their meeting with the lactation consultant **Data collection** MBQ; feedback forms (post-sessions); infants' clinical and feeding records	Intervention ($n = 15$): 17% [9] (9–53) $p < 0.01$ *Breastmilk at discharge* Before ($n = 15$): 11 (73%) Intervention ($n = 20$): 16 (80%) $p = 0.64$ **Clinical/health outcomes** Not reported **Process outcomes** Infants up to 36 weeks gestational age were included Most of the group sessions were conducted with individual mothers **Process outcomes related to the educational session are reported** The lactation consultant did not know when mothers were in the Unit to breastfeed their babies for the first time, so rarely (3/25) met with mothers to assist them at the first breastfeed *Mean [SD] age at discharge (range)* Before ($n = 25$): 17.9 [11.0] (1–43) Intervention ($n = 24$): 19.6 [12.8] (5–17) NS **Psychosocial outcomes** No differences in intervention group mothers' perceptions of breastfeeding benefits, barriers or self-efficacy before and after the intervention Responses on the MBQ were related to breastmilk feeding frequency, as well as frequency of nursing from the breast **Cost-effectiveness outcomes** Not reported		

TABLE 66 *Jones 2004*[81]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Jones 2004 UK **Research aim** To evaluate the effect of a specialist preterm breastfeeding programme on staff knowledge and skills, and breastfeeding rates **Study design** Before/after **Method of group allocation** Before and after training **Unit of allocation** Individual staff member	**Selection** Staff of NICU at North Staffordshire Maternity Hospital between September 2001 and February 2002 **Inclusion criteria** Not stated **Exclusion criteria** Not stated	Professional backgrounds of staff members who completed the course ($n = 34$) Neonatal intensive care trained midwives (8) Neonatal intensive care trained paediatric nurses (8) Registered nurses (12) Paediatric nurses (3) Paediatric house officers (2) Paediatric registrar (1)	**Intervention** A training programme of five taught modules that took a total of 10 hours to complete, plus practical assessments and tutorials Additional guidance was available in CD-ROM and video formats Teaching took place away from the clinical area to ensure an environment conducive to learning Training programme delivered by neonatal breastfeeding coordinator (midwife) Content of the five modules (a) Benefits of breastfeeding • benefits of human milk • factors affecting milk consumption • requirements for growth in the preterm infant • fortification of milk for the low birthweight infant (b) Physiology of preterm lactation • effects of preterm birth on mammary development • difference between term and preterm lactation • application of an understanding of the physiology of preterm lactation on supporting breastfeeding in preterm infants	**Statistical techniques** Wilcoxon signed rank test for pre- and post-test questionnaires Chi-squared test for clinical audit data before and after staff training **Breastfeeding/breastmilk-related outcomes** (from audit of medical and nursing notes) *Mothers intending to breastfeed* Before staff training ($n = 135$); after staff training ($n = 127$) Yes: B: 90 (67%); A: 76 (60%) No: B: 29 (21%); A: 47 (37%) Unclear: B: 16 (12%); A: 4 (3%) p not reported For the two cohorts of mothers intending to breastfeed: Before staff training ($n = 90$); after staff training ($n = 76$) *Expressed breastmilk given* B: 75/86 (86%); A: 72/74 (97%); $p = 0.012$ *Documented problem-solving plan for milk expression* B: 2/84 (2%); A: 57/66 (86%); $p < 0.0001$	42 staff members enrolled in the programme Eight left during the study period and were excluded from the evaluation 34 attended all five modules and completed pre-and post-test questionnaires For each question in the clinical audit, the number of positive responses is shown followed by the total number where data were available for that question.	Number of staff working on the unit is not reported The questionnaire used for pre- and post-course tests of staff knowledge was piloted for reliability and validity with five trainee neonatal nurses Three experienced specialists advised on accuracy, relevance, construction flaws and level of readability Researchers note problems consolidating some of the practical areas of the teaching programme, primarily because of the shortage of intensive care nurses

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of analysis Group scores **Sample size calculation** Not reported **Outcome measures** Staff knowledge before and after training Breastfeeding rates before and after the intervention			(c) Breastfeeding the preterm infant • feeding reflexes • coordination and gestational age • biomechanics of suckling • attachment and positioning • overcoming feeding problems (d) Milk expression • frequency and duration • mammary storage capacity • insufficient/too much milk yield • milk ejection reflex • hand expression • breast pumps and funnels (e) Breastfeed evaluation • how to assess a breast feed • dealing with common concerns • ensuring nutritional requirements are met **Data collection** Pre- and post-course tests of staff knowledge Audit of medical and nursing records of infants admitted July to November 2000 (before the intervention, $n = 135$) and July to November 2001 (after the intervention, $n = 127$)	*Skin to skin contact* B: 15/46 (33%); A: 63/64 (98%); $p = < 0.0001$ *Cup feeds offered in mother's absence* B: 53/82 (65%); A: 56/66 (85%); $p = 0.006$ *Baby put to breast* B: 57/76 (75%); A: 65/69 (94%); $p = 0.002$ *Breastfeeding on discharge* B: 49/73 (67%); A: 54/68 (79%); $p = 0.1$ **Clinical/health outcomes** Not reported **Process outcomes** Achievable score for the pre- and post-test questionnaire was 85 Median (range) scores for the 34 staff members who completed pre- and post-test questionnaires were Pre-test: 32.5 (9–39) Post-test: 44.6 (34–60.5); $p < 0.001$ No participant scored fewer marks after training Two questions were problematic for all participants before training (one asked how to promote nutritive suckling in infants with both weak and irregular oro-motor responses, the other addressed the issue of sore nipples caused by poor milk expression technique). Answers to these questions improved significantly following training **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported	In each case this was fewer than *n*, because some answers were not clear from the notes and some infants died or were transferred to other hospitals	Researchers note that record-keeping improved greatly following the programme, and remark that some improvements seen may have been due to this rather than to change in practice After the evaluation the training programme became mandatory for all neonatal nurses on the unit **Funding** Department of Health

TABLE 67 *Pineda 2006*[149]

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Pineda 2006 USA **Research aim** To evaluate the effect on breastfeeding outcomes of a staff training intervention to deliver newly introduced individualised care plans and education and support for mothers of VLBW infants **Study design** Before/after study **Method of group allocation** Quota sampling from discharge data during study periods **Unit of allocation** Mother-infant pairs **Unit of analysis** Mother-infant pairs **Sample size calculation** Cohen's criteria to detect a standard deviation change of 0.5 with a power of 80% and alpha 0.05 = 82 participants per group	**Selection** All infants admitted into NICU during study periods: B: 15 April 2004 to 7 December 2004 I: 1 March to 14 April 2005 A: 15 April 2005 to 7 December 2005 **Inclusion criteria** VLBW (< 1500 g) Admitted to NICU within first 3 days of life Length of stay ≥ 7 days Achieved full gastric feeds during hospital stay Hospitalised < 4 months **Exclusion criteria** Transferred into the study unit after third day of life Breastfeeding medically contraindicated Hospital stay crossed over from B group into intervention period	*Mothers* *Mean age in years* B: 25.46 A: 25.62 *Marital status* B: Unmarried 56% A: Unmarried 57% *Socioeconomic status* B: Low SES 77.5% A: Low SES 70% *Ethnicity* Black B: 42% A: 48% *Infants* *Birthweight mean g* B: 1074 A: 1114 *Gestational age at birth mean weeks* B: 28.57 A: 28.70 *Singletons* B: 84.0% A: 83.3% *Mean length of stay (days)* B: 50 A: 54	**Standard care** Not described B: *n* = 81 **Intervention** A: *n* = 54 **Staff (*n* = 88)** – mostly nurses Breastfeeding support education for NICU health-care professionals Self-study or attendance at in-service training Incentives for completion of training (education credits, food, prizes) Topics included: • benefits of and barriers to breastfeeding • physiology of lactation • use of breast pumps • prefeeding interventions based on synactive theory[a] • breastfeeding interventions acknowledging readiness to infant **Mothers n = 54** Individualised care plans modified to require staff to document for each infant:	**Statistical techniques** Pearson's chi-squared test, non-parametric Mann–Whitney. Significance levels adjusted by ranked Bonferroni adjustment *Was breastmilk ever provided in hospital?* B: 60 (74%) Yes, 21 (26%) No A: 46 (85%) Yes, 8 (15%) No NS, $p = 0.124$ (OR: 2.013, CI: 0.818–4.95) *Was the infant ever breastfed while in hospital?* B: 21 (26%) Yes, 60 (75%) No A: 24 (44%) Yes, 30 (56%) No $p = 0.03$ (OR: 2.286, CI: 1.1–4.75) *Was breastmilk provided at discharge?* B: 29 (36%) Yes, 52 (64%) No A: 22 (41%) Yes, 32 (59%) No NS, $p = 0.56$ (OR: 1.233, C: 0.61–2.5) Breastmilk provided for most of hospitalisation B: 51% A: 57%	None reported Data provided for all participants by allocated group (ITT) where detailed	Participants in each group represented 80% of all admissions during study periods Authors acknowledge study limitations including lack of randomised sample, lack of participation in training programme by senior NICU staff, inadequate implementation of all intervention strategies by health professionals and the inability to control for other changes in NICU environment. Authors note health-care professional behaviour change and attitudes were not measured. The direct effect of the education and individualised care plans on health care cannot be assessed

DOI: 10.3310/hta13400

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Was breastmilk ever provided in hospital? Was the infant ever breastfed while in the hospital? Was breastmilk provided at discharge? Was breastmilk provided for most of hospitalisation?		*Transferred to another hospital* B: 43.2% A: 32.7% **Group comparability** Comparable for all parameters, race was dichotomised black/ not black	• within 6 hours of birth, teach pumping and milk storage • within 24 hours, ensure proper pumping and milk storage • days 3–5, check milk has come in and address any problems • weekly, foster continued pumping and skin-to-skin care • ensure first oral feed is a breastfeeding session • 10 days, monitor milk supply and refer as appropriate Educational booklet issued to mothers on admission Information consistent with staff education Included space to document milk production as a basis for discussing milk supply with nurses **Data collection** Retrospective chart review Inter-rater agreement on chart review procedures	*NS, p not stated* (OR: 1.219, CI: 0.61–2.4) First oral feeding at the breast occurred in 25% of mother–infant pairs in the postintervention group **Process outcomes:** 56/88 (63%) of health professionals participated in training programme All participating staff achieved a pass (80% score) in post-training test		

B: Before (control) group; A: After (intervention) group.
a Describes the process of neurobehavioural maturation related to an infant's internal and external environment.

TABLE 68 *Gunn 2000*[127]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Gunn 2000 New Zealand (Auckland) **Research aim** To determine safety and effects on breastfeeding rates of earlier hospital discharge of premature infants under the supervision of nurse specialists visiting at home **Study design** RCT **Method of group allocation** Sequential list of computer-generated numbers, stratified for birthweight and multiple births **Unit of allocation** Infant	**Selection** Preterm infants in NICU/SCBU of National Women's Hospital, Auckland, NZ **Inclusion criteria** Infants < 37 weeks' gestation In the study unit > 3 days March 1996 to August 1997 Discharged home Mother's signed consent **Exclusion criteria** If the paediatrician considered an infant not ready for early discharge the infant was not randomised Infants discharged to another hospital for ongoing care Mothers whose English was insufficient to complete questionnaires	*Mothers* Mean maternal age ± SD ED 30.5±5.7; RD29.7±5.6 Primiparous ED 63 (43%); RD 58 (36%) European ED 98 (67%); RD 105 (66%) Maori ED 20 (14%); RD 32 (20%) Pacific Islander ED 8 (5%); RD 11 (7%) Asian ED 20 (14%); RD 12 (8%) Married ED 111 (76%); RD 102 (66%) Single ED 13 (9%); RD 21 (14%) De facto ED 22 (15%); RD 32 (21%) *Prenatal employment:* Not employed ED 48 (33%); RD 62 (39%) Part-time ED 31 (21%); RD 31 (20%) Full-time ED 66 (46%; RD 64 (41%)	All participants Randomisation took place when the infant started to receive suckle feeds from breast or bottle, before full oral feeding was established *Routine discharge (RD) control group n = 160* Preterm infants discharged from hospital when: 1. Competent to suckle feed by breast or bottle without cardiorespiratory compromise 2. They had a sustained pattern of weight gain after the establishment of full suckle feeding 3. They had adequate maintenance of normal body temperature when fully clothed in an open cot A team of experienced Home Care Nurses contacted the family to enable visiting to occur in hospital and after discharge The Home Care Nurses made home visits or telephone contact during office hours on weekdays Visits/contacts were usually daily for the first 5 weekdays after discharge, then as necessary to support breastfeeding and other problems	**Statistical techniques** Chi-squared tests, *t* tests **Breastfeeding/breastmilk-related outcomes** *Any breastfeeding at discharge* ED 80%; RD 83%; NS *Exclusive breastfeeding at discharge* ED 54.8%; RD 67.4%; NS *Receiving any breastmilk 6 weeks after discharge* ED 55%; RD 60%; NS *Exclusive breastfeeding 6 weeks after discharge* ED 31.3%; RD 40.5%; NS *Receiving any breastmilk 6 months after discharge* ED 36%; RD 36%; NS *Exclusive breastfeeding 6 months after discharge* ED 0.8%; RD 3.6%; NS **Clinical/health outcomes** ED (*n* = 148); RD (*n* = 160); *p* *Mean g weight 6 weeks after discharge ± SD* 4034 ± 592; 4189 ± 731; < 0.04	308 infants randomised Dropout rate unclear (primary outcome reported as percentages)	Data were analysed by randomised group Authors note a marked 'Hawthorne effect' with this study on timing of discharge; the average duration of hospital stay decreased even in control infants **Funding** Not reported

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Unit of analysis Group **Sample size calculation** Not reported **Outcome measures** Breastfeeding at discharge, 6 weeks and 6 months after discharge; weight gain; readmission rates	Mothers who lived outside the follow-up area for the study hospital (home visiting not possible)	*Infants* ED ($n = 148$); RD ($n = 160$) Mean weeks' gestation at birth ± SD ED 33.2 ± 2.3; RD 32.9 ± 2.5; NS Mean weeks gestational age at discharge ± SD ED 36.1 ± 1.5; RD 36.4 ± 1.2; NS Mean g birthweight ± SD ED 2007 ± 503; RD 1970 ± 535; NS Mean g weight at discharge ± SD ED 2381 ± 315; RD 2460 ± 317; $p = 0.05$ Days of suckle feeding in hospital ED 2.5 ± 2.0; RD 4.4 ± 2.8; $p < 0.0001$ Twins ED 29 (20%); RD 33 (21%); NS **Group comparability** No significant differences were found between the groups prior to hospital discharge	**Early discharge (ED) intervention group $n = 148$** Infants met the same discharge criteria but without the need for weight gain For the first 7–10 days after discharge they were visited daily (including weekends) by a team of Visiting Nurse Specialists who were also available by telephone 24 hours/ day **Data collection** Questionnaires to mothers in hospital; 6 weeks after discharge, Visiting Nurse Specialists interviewed mothers, weighed infants and completed questionnaire; 6 months after discharge, telephone questionnaire	*Weight gain (g/kg/day)* 12.18 ± 2.98; 12.15 ± 3.61; NS *Readmission to hospital* Six weeks after discharge *ED 8.8%; RD 11.9%; $p = 0.37$* Six months of age *ED 20.2%; RD 20.3%; $p = 0.96$* **Process outcomes** *Days of full oral feeds in hospital before discharge* *ED 2.5 ± 2.0; RD 4.4 ± 2.8; $p < 0.001$* **Psychosocial outcomes** There was one adverse comment about early discharge, from a mother of 35-week twins: 'they were too sleepy to feed and I had to wake them round the clock. The stress and tiredness was very severe.' All other comments on early discharge were positive, e.g. 'transport, health and financial problems all disappeared when at home' **Cost-effectiveness outcomes** Not reported		

RD, routine discharge, control group; ED, early discharge, intervention group.

TABLE 69 *Ortenstrand 1999,[109] 2001[110]*

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Ortenstrand et al. 2001 and 1999 Sweden (Stockholm) **Research aim** To evaluate the effect of early discharge and domiciliary nursing care of preterm infants on parental anxiety, assessment of their infants' health and breastfeeding **Study design** Quasi-RCT **Method of group allocation** Convenience allocation to one of two rooms (1:1; 2:C) in Neonatal Special Care Unit **Unit of allocation** Infants **Unit of analysis** Families for all outcomes except clinical outcomes **Sample size calculation** None	**Selection** Infants admitted to Neonatal Special Care Unit at Sach's Children's Hospital between November 1992 and February 1994. Infants admitted from two referring hospitals or from NICU at Karolinska Hospital, Stockholm **Inclusion criteria** Gestational age < 37 weeks Clinically stable expecting special care > 1 week No apnoeic episodes Maintaining normal body temperature in open crib If required, parents able to handle oxygen equipment Staff assessment of parents' capability of caring for infants Parents are literate and conversant with Swedish language **Exclusion criteria** None stated	*Mothers* Mean ± SD maternal age (in years): I: 30.6 ± 4.5 C: 31.1 ± 5.5 Single parent: I: 3; C: 1 Education: Less than high school I: 5; C:3 High school I: 23; C:17 More than high school I: 12; C: 15 First pregnancy: I: 28; C: 21 Breastfed previously: not reported Pairs of twins: I: 5; C: 8 *Infants* Mean weeks ± SD gestational age I: 31.4 ± 2.8 C: 32.0 ± 2.3 Range: I: 24–35; C: 25–36	**I: *n* = 40 families** Individual care plan in conjunction with parent including: • infant temperature • behavioural difference between term and preterm infants • breastfeeding and bottle-feeding techniques • skin protection • signs of illness • preparation for emergency situations • home environment, smoking safety, restrictions of visitors; visits to public places Care provided by project nurse with specialist paediatric and neonatal nursing. Supported by hospital-based neonatologist, nutritionist, social worker, psychiatric team **C: *n* = 35 families** Standardised neonatal care that encouraged parents to participate in infants' care as much as possible	**Statistical techniques** *t* test, Mann–Whitney *U* test and chi-squared test **Duration of any breastfeeding after domiciliary care period** I: 2 not breastfeeding C: 3 not breastfeeding NS No data provided **Duration of any breastfeeding at 6 months** Fewer I than C mothers ($\chi^2(1) = 3.5$; $p = 0.06$) **Mean duration of breastfeeding (months)** I: 6.3 (SD: 4.1) C: 7.5 (SD: 4.0) ($t = 1.2$; $p = 0.24$) **Health outcomes during period of domiciliary care or hospital stay** (Infants: I: 45; C: 43) Respiratory infection I: 6/45; C: 16/43, $p = 0.02$ Data in favour of I group (not significant) for conjunctivitis, dermatological problems, gastrointestinal problems, jaundice requiring phototherapy,	95/225 preterm infants were eligible Reasons for non-eligibility stated and in accordance with inclusion criteria Withdrawals (infants): I: 3; C: 4 No reasons stated and not clear if postrandomisation but prior to study commencement Total study sample: 88 infants in 75 families I: 45 infants/40 families C: 43 infants/35 families Losses for 1-year follow-up: I: 4 infants/3 families C: 2 infants/2 families Reasons stated by group	Data were analysed using available case basis Nursing teams in each Special Care Unit room were switched after 8 months to minimise effects of possible differences between nursing teams Other process outcomes are reported in Ortenstrand *et al.*[109]

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Health outcomes during corresponding periods of domiciliary care and hospital stay Parental anxiety levels (personality-related 'trait' anxiety and situational 'state' anxiety) Parental experience of infant's health Duration of any or exclusive breastfeeding Total number of visits		Birthweight (g, mean ± SD) I: 1677 ± 549 C: 1737 ± 486 Range: I: 654–2905 C: 855–2830 Weight (g, mean ± SD) at onset of study: I: 2224 ± 376 C: 2122 ± 301 Range: I: 1505–2985 C: 1160–2900 Small for gestational age at birth (diagnosed at onset of study): I: 6; C: 6 Very low birthweight (< 1500 g) (diagnosed at onset of study): I: 19; C:14 Perinatal asphyxia (diagnosed at onset of study) I: 4; C: 0 **Group comparability** No statistically significant differences	**Data collection** Infant information collected from hospital records and from domiciliary nurse records Parent postal questionnaire at approximately 1 year postdischarge Home-based structured interview based on questionnaire responses 1 week later by assistant nurse Health outcomes based on clinical judgement, not laboratory tests	myoclonias, oxygen dependence, feeding problems, infection workup and antibiotic medications Data in favour of C group (not significant) Mean g/day weight gain (SD): I: 22.5 (2.4); C: 23.6 (9.2) $p = 0.54$ **Process outcomes** Number of scheduled/ unscheduled home visits: I: 235/4 **Psychosocial outcomes** Satisfaction with duration of breastfeeding I: 59.5% C: 72.7% ($\chi^2(1) = 0.8$; $p = 0.36$) Anxiety at hospital discharge, mean (SD) Mothers' trait anxiety: I: 32.8 (5.9) C: 33.3 (7.8) ($t = 0.3$; $p = 0.75$) Mothers' state anxiety: I: 30.9 (6.2) C: 36.6 (8.4) ($t = 3.3$; $p < 0.01$) Fathers' trait anxiety: I: 30.1 (5.8) C: 33.5 (7.8) ($t = 2.0$; $p < 0.05$)		

continued

TABLE 69 *Ortenstrand 1999,[109] 2001[110] (continued)*

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
				Fathers' state anxiety: I: 29.5 (5.4) C: 32.8 (9.1) ($t = 1.8$; $p = 0.08$) Anxiety at end of domiciliary care programme vs comparable period: Mothers' trait anxiety: I: 31.7 (7.1) C: 31.1 (7.8) ($t = 0.3$; $p = 0.74$) Mothers' state anxiety: I: 27.8 (5.9) C: 30.1 (7.6) ($t = 1.4$; $p = 0.16$) Fathers' trait anxiety: I: 29.0 (6.1) C: 32.3 (6.9) ($t = 2.0$; $p < 0.05$) Fathers' state anxiety: I: 27.6 (6.3) C: 29.4 (5.4) ($t = 1.3$; $p = 0.20$)		

Study details	Participant selection and inclusion/exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
				Experience of infants' health during first year (0 = maximally ill; 12 = maximally good health), mean (SD) Mothers' experience: I: 5.2 (2.7); C:4.4 (2.2) ($t = 1.3$; $p = 0.19$) Fathers' experience: I: 5.5 (2.5); C: 4.4 (1.9) ($t = 1.9$; $p = 0.06$) Experience of infants' strength compared with other infants in same postconceptional age: Mothers' experience: I: 5.0 (1.8); C:4.5 (1.8) ($t = 1.1$; $p = 0.27$) Fathers' experience: I: 5.2 (2.0); C: 4.8 (1.9) ($t = 1.0$; $p = 0.32$) **Cost-effectiveness outcomes** None reported		

I, intervention group; C, control group.

TABLE 70 *Bell 1995*[154]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Bell 1995 USA (Iowa) **Research aim** To investigate whether breastfeeding rates in the study unit increased following a structured intervention of lactation support **Study design** Before/after **Method of group allocation** Date **Unit of allocation** Mother **Unit of analysis** Mother **Sample size calculation** Not reported	Selection Mothers of infants in the Intermediate Care Nursery, University of Iowa Hospitals and Clinics (UIHC) **Inclusion criteria** Mothers intended to breastfeed their preterm or ill infants **Exclusion criteria** Not reported	15 mothers intended to breastfeed during the 3-month period in 1992 before the intervention The proportion of mothers who intended to breastfeed is not reported 102 mothers intended to breastfeed during the 1-year period after implementation of the intervention The proportion of mothers who intended to breastfeed was 58% No other participant characteristics are reported	**Before: *n* = 15** Review of charts for a 3-month period in summer 1992 **Intervention** A structured intervention of lactation support 1. Protocol for Breastfeeding for the Premature or Ill Infant developed (i) as a standard for the pediatric nursing division; (ii) as guidelines for orientation of residents and staff physicians; (iii) as an educational tool and guide for parents The Protocol included the following stages of breastfeeding: *Initial education* Nurses discuss infant feeding options with mother on her baby's admission. Mothers who choose to breastfeed to receive written information and video on breastfeeding and instruction on pumping and storing breastmilk. Nurses ensure pumping begins within 24 hours of birth. For first several weeks, 2–3-hourly pumping recommended. All mothers provided with kit for double pumping. Lactation room with two pumps next to the unit *Initiating non-nutritive time at the breast* Begin when baby's corrected gestational age is about 32 weeks; baby can swallow own secretions; baby stable outside incubator at least 10 minutes; baby tolerates kangaroo care. Aim for mother and baby to become accustomed to one another via skin-to-skin or kangaroo care. Mother housed close to the nursery if possible Nurse will help position baby at the breast. Baby not expected to suckle at this stage, will be gavage fed (via nasogastric or orogastric tube). Bottles will not be introduced *Progress towards non-nutritive sucking* When at the breast, baby may not latch on or suck. May swallow once or twice, may fall asleep at the breast. Continue pumping and gavage feeding, do not give bottles	**Statistical techniques** Percentages **Breastfeeding/ breastmilk-related outcomes** *Breastfeeding at discharge* Before: 40% (i.e. 6/15 mothers) After: 80% (i.e. 82/102 mothers) *Breastfeeding 1 week after discharge* Before: not reported After: 98% (i.e. 81/82 mothers) **Clinical/health outcomes** Not reported **Process outcomes** Not reported	Unclear	Available data are presented by before/after group The paper does not define breastfeeding **Funding** Intervention developed by Research Utilization Committee of the Division of Pediatric Nursing (in-house)

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Breastfeeding at discharge			*Progress towards nutritive sucking* At this stage baby may consistently latch onto the breast, feed for about 5 minutes and show progress on the SAIB scale. Infant-led breastfeeding. No more than 5 hours between feeds. If baby suckles for less than 10 minutes, a proportion of the volume ordered by medical staff to deliver estimated need for growth will be given by gavage. Bottles not introduced until gavage supplements not needed. Continue pumping *Transition to breastfeeding* At this stage baby wakes for feeds and feeds well on SAIB scale; baby shows adequate hydration and weight gain without supplementation; mother is confident in her ability to breastfeed at home. Nurse will complete discharge teaching and documentation, and arrange for local breastfeeding support. 2. Assessment of staff educational needs followed by program of staff training including in-service sessions, posters and videotapes. Two certified lactation consultants employed in the hospital provided staff training. Staff received resource manual and received SAIB as a pocket reference card 3. Patient/Family Teaching Record (documents breastfeeding teaching, promotes continuity of care among the different nursing shifts) revised to include the Protocol stages of breastfeeding **After: *n* = 102** Appears also to be a review of charts, for a 1-year period after implementation of the protocol **Data collection** Before and After: Numbers of mothers intending to breastfeed; successfully breastfeeding at discharge After: Proportion of mothers intending to breastfeed; number still breastfeeding; 1 week after discharge	**Psychosocial outcomes** *Main reason mothers gave for stopping breastfeeding* Before: inadequate milk production After: not reported **Cost-effectiveness outcomes** Not reported		

TABLE 71 *Bicalho-Mancini 2004*[151]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Bicalho-Mancini 2004 Brazil, Belo Horizonte **Research aim** To compare rates of exclusive breastfeeding at discharge from a neonatal intensive care unit (NICU) before and after implementation of the Baby Friendly Hospital Initiative (BFHI) **Study design** Before/after **Method of group allocation** Date **Unit of allocation** Infant **Unit of analysis** Infant **Sample size calculation** Not reported **Outcome measures** Infant feeding over the 3 days prior to discharge	**Selection** All infants who appeared in the admissions, transfers, discharges and deaths register of the high-risk ward at Odete Valadares maternity hospital (OV) May 1998 to May 2000 **Inclusion criteria** Infants born at OV **Exclusion criteria** Infants admitted between December 1998 and October 1999, when the 10 steps of BFHI were being implemented Infants who died, or were transferred to another institution or to judicial care One infant with anencephaly Mothers with contraindications for breastfeeding or transferred for treatment One mother who rejected her infant until discharge and one who had no desire to breastfeed Records incomplete	*Mothers* Mean age: 25.3 ± 6.7 years Education (years): 4 or less: 49.3% 5–12: 50.7% Married/stable relationship: 80.4% Single: 19.6% First pregnancy: 40.8% Second pregnancy: 24.1% ≥Third pregnancy: 35.1% *Infants* Gestational age < 37 weeks: 383/494 (77.5%) > 37 weeks: 111/494 (22.5%) Small for gestational age: (SGA): 65/495 (13%) Appropriate/large for gestational age (AGA/BGA): 430/495 (87%) Birthweight < 2500 g: 384/495 (77.6%) > 2500 g: 111/495 (22.4%) Multiples: 65/495 (13%) Most common reason for admission was early respiratory difficulties **Group comparability** Characteristics not reported by group	**Before: *n* = 250** Infants admitted May–November 1998, when 'old' standards and routines of care were in operation (not described) **Intervention** OV was accredited as a Baby Friendly Hospital (BFH) in May 1999 after 'training and modifications' (not described) **After: *n* = 245** Infants admitted November 1999 to May 2000, when care met BFHI standards **All participants** Parenteral nutrition was used for 20.2% By 10 days 67.7% were being fed with a cup or bottle and 57.9% had started suckling at the maternal breast Relactation was used in 8.7% Mean hospital stay was 23.4 ± 19.5 days **Data collection** From infants' dietary charts	**Statistical techniques** Chi-squared test, multiple stepwise logistic regression **Breastfeeding/breastmilk-related outcomes** *Infant feeding over the 3 days prior to discharge* | | Before | After | |---|---|---| | Exclusive breastfeeding | 36% | 54.7% | | Mixed feeding | 46.8% | 37.1% | | Artificial feeding | 17.2% | 8.2% | **Other outcomes not reported by group** Multivariate logistic regression showed independent risk factors associated with non-exclusive breastfeeding at discharge were: Use of enteral feeding (OR: 3.01, 95% CI: 1.77–5.12) < 6 antenatal consultations (OR: 2.75, 95% CI: 1.42–3.44) Relactation use (OR: 2.66, 95% CI: 1.13–6.29, $p = 0.026$) Birthweight < 2500 g (OR: 2.64, 95% CI: 1.55–4.50) Being born before BFHI was implemented (OR: 2.75, 95% CI: 1.55–4.50) **Clinical/health outcomes** Not reported **Process outcomes** Not reported **Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported	Unclear Primary outcome reported as percentages	Data were analysed by before/after group **Funding** Not reported

DOI: 10.3310/hta13400

TABLE 72 *Merewood 2003*[137]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Merewood 2003 USA, Boston **Research aim** To compare rates of breastfeeding initiation and duration in the study NICU before and after the implementation of Baby-Friendly policies **Study design** Before/after **Method of group allocation** Date **Unit of allocation** Infant **Unit of analysis** Infant **Sample size calculation** Not reported	**Selection** Medical records of all infants admitted to Boston Medical Center (BMC)'s level III, 15-bed neonatal intensive care unit (NICU) in 1995 and 1999 **Inclusion criteria** Infant directly admitted (i.e. not transferred in) Infant survived **Exclusion criteria** Infant subject of adoption or custody issue Mother ineligible to breastfeed (e.g. HIV positive, substance abuse, methadone use)	*Mothers (number not reported)* Before / After Age (%) < 20: 14 / 11 20–30: 54 / 50 > 30: 33 / 39 Payer status (%) Medicaid: 57 / 51 Uninsured: 29 / 28 Other: 13 / 20 Ethnicity (%) Black: 68 / 66 Hispanic: 19 / 15 White: 9 / 11 Other: 3 / 3 Unknown: 1 / 4	**Before: *n* = 110** In 1995, lactation support was minimal and none of the Ten Steps (Baby-Friendly policies) were in place **Intervention** From 1997, strategies to support breastfeeding were implemented, and BMC became a Baby-Friendly accredited hospital in December 1999 **After: *n* = 117** In 1999, all the Ten Steps were implemented, including Step 5 'Show mothers how to breastfeed and how to maintain lactation, even if they should be separated from their infants'	**Statistical techniques** Fisher's exact test, chi-squared test **Breastfeeding/breastmilk-related outcomes** Infants receiving any breastmilk by any means during the first week of enteral feeds were considered to have initiated breastfeeding *Breastfeeding initiation* All included infants Before: 38/110 (34.6%) After: 87/117 (74.4%), $p < 0.001$ US-born black infants Before: 10 (34.5%) After: 16 (64%), $p = 0.03$ Non-US born black infants Before: 7 (27%) After: 29 (81%), $p = 0.001$ *Breastfeeding at 2 weeks among infants still in the study unit* Exclusive breastmilk Before: 4/43 (9.3%)	Data from all eligible records included in the analysis	Data were analysed in before/after groups Boston Medical Center served a primarily impoverished population with a high number of racial minorities **Funding** Grant from the Centers for Disease Control and Prevention (PERT 01-008)

continued

TABLE 72 *Merewood 2003[135] (continued)*

<table>
<tr><th>Study details</th><th>Participant selection and inclusion/ exclusion criteria</th><th>Baseline characteristics of participants</th><th>Intervention details</th><th>Results</th><th>Withdrawals</th><th>Additional comments</th></tr>
<tr>
<td>Outcome measures
Breastfeeding initiation, breastfeeding at 2 weeks</td>
<td>Other (e.g. maternal incarceration)
Records missing
Data missing from records</td>
<td>Infants
<table>
<tr><td></td><td>Before ($n = 110$)</td><td>After ($n = 117$)</td></tr>
<tr><td colspan="3">Gestational age, weeks (%)</td></tr>
<tr><td>< 30</td><td>4.5</td><td>6.0</td></tr>
<tr><td>30–37</td><td>51.8</td><td>61.5</td></tr>
<tr><td>37+</td><td>43.6</td><td>32.5</td></tr>
<tr><td colspan="3">Birthweight, g</td></tr>
<tr><td>Mean ± SD</td><td>2619 ± 987</td><td>2506 ± 939</td></tr>
</table>
All the infants were receiving enteral feeds by 2 weeks of age

Group comparability
The only statistically significant difference found between the groups was for percentage of vaginal births (58% in 1995 and 44% in 1999, $p = 0.05$)</td>
<td>Data collection
Research assistant extracted data from medical, hospital and insurance records and from daily feed charts</td>
<td>After: 16/41 (39%)
Any breastmilk
Before: 12/43 (27.9%)

After: 27/41 (65.9%), $p < 0.001$
Exclusive formula
Before: 31/43 (72.1%)
After: 14/41 (34.1%)

Clinical/health outcomes
Not reported

Process outcomes
Not reported

Psychosocial outcomes
Not reported

Cost-effectiveness outcomes
Not reported</td>
<td></td>
<td></td>
</tr>
</table>

TABLE 73 *Oddy 2003*[138]

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Oddy 2003 Australia (Perth) **Research aim** To find out whether the rate of exclusive breastfeeding on discharge from the study unit changed, after the introduction of finger feeding as part of Baby Friendly Hospital Initiative (BFHI) accreditation **Study design** Before/after **Method of group allocation** Date **Unit of allocation** Infant **Unit of analysis** Infant **Sample size calculation** Not reported	**Selection** Infants cared for in the Special Care Nursery (SCN) of Joondalup Private Maternity Hospital, Perth, Western Australia, during 1998 and 2001 (before and after implementation of BFHI in 1999) **Inclusion criteria** Infants born at the study hospital at 34–35 weeks' gestation **Exclusion criteria** Not reported	Not reported	**Standard care** Routine progression to suck feeds was: • i.v. therapy, followed by • nasogastric tube feeds, and when able to suck • tube feeds alternating with suck feeds according to how well the baby could cope • full suck feeds Feeds were 3-hourly and took approximately 20 minutes so as not to tire the baby *Before: n = 18* When suck feeds were introduced, these were breast and bottle feeds **Intervention** In 1999 staff were trained in the BFHI, and the hospital was accredited as a 'Baby-Friendly Hospital'; the SCN was included in the assessment The following changes in hospital practice were undertaken: • consent forms for mothers to read and sign if they requested a bottle feed or pacifier for their infant • maternal education (not described) • ongoing staff education (not described) • home visiting scheme (not described) • use of finger feeding method[a]	**Statistical techniques** Percentages, *t* test for equality of means **Breastfeeding/ breastmilk-related outcomes** *Breastfeeding at discharge* Before: *n* = 18) After: *n* = 17 Not breastfeeding on discharge Before: 10 After: 5 Breastfeeding on discharge Before: 8 (44%) After: 12 (71%) *t* test for equality of means; df = 33; 2-tailed *Before: p* = 0.125 After: NS **Clinical/health outcomes** Not reported **Process outcomes** Not reported	Before: 18 infants met the inclusion criteria After: 17 infants met the inclusion criteria Outcome data for all these infants are presented	Data were analysed using intention-to-treat model Authors state the sample size was too small to demonstrate statistical power Authors note pacifier use was not documented It is not clear whether the outcome reported is exclusive or any breastfeeding **Funding** Not reported

continued

TABLE 73 *Oddy 2003[136] (continued)*

Study details	Participant selection and inclusion/ exclusion criteria	Baseline characteristics of participants	Intervention details	Results	Withdrawals	Additional comments
Outcome measures Breastfeeding at discharge			**After: *n* = 17** When suck feeds were introduced, these were breastfeeds and finger feeds Finger feeds were used if the baby refused the breast or was too tired to breastfeed; did not latch well and therefore did not get milk well; was separated from its mother; if breastfeeding was stopped temporarily; if the mother's nipples were so sore that she could not put the baby to the breast Staff taught parents how to use the finger lines and gave them a copy of Dr Newman's instructions[b] **Data collection** Paper states breastfeeding rates were measured prospectively in both groups, with available data measured and recorded by nurses in the SCN on the maternity ward	**Psychosocial outcomes** Not reported **Cost-effectiveness outcomes** Not reported		

a The paper states that as part of the BFHI Accreditation, alternative methods for feeding babies were required as staff could not promote the use of teats and dummies. The staff were introduced to the finger feeding technique by Dr Jack Newman in a seminar. The staff were also aware of information developed from Marmet 1984 (Marmet CSE. Training neonates to suck correctly. *Am J Mat Child Nursing* 1984;**9**: 401–7). The staff agreed to use finger feeding as an alternative to teats and bottles in the belief that finger feeding assists with controlling infant tongue action (Newman J. Breastfeeding problems associated with the early introduction of bottles and pacifiers. J Human Lact 1990;**6**: 59–63).

b Instructions on finger feeding (included in Oddy 2003 from Newman 1990): 1. Wash your hands. 2. Position yourself and the baby comfortably with the baby's head supported with one hand behind the shoulders. Any comfortable position is appropriate. 3. Feeding tube (5-French, 36 inches long) and a feeding bottle with expressed breastmilk (EBM), sugar water or if necessary formula depending on the situation. The end of the feeding tube is placed in the bottle into the fluid. 4. Line up the tube so it sits in the soft part of the index finger with the end of the tube no further than the end of your finger. Grip the tube where it makes a gentle curve between the thumb and middle finger. There should be no need to tape the tube to your finger but mothers may request this until they are proficient. 5. Using your finger with the tube attached, tickle the baby's mouth gently to encourage the baby to open its mouth wide, to allow the finger to carefully enter. Usually the baby will begin to suckle even if asleep and receiving food will awaken him. 6. Insert your finger with the tube so that the soft part of the finger remains upward and flat. Usually the baby will begin sucking on the finger and will not gag unless full from another feed. 7. Pull the baby's chin down if the lower lip is sucked inwards. 8. The technique is working if the baby is drinking. If slow, raise bottle above baby's head. Keep the finger straight as much as possible, flattening the baby's tongue and working the lower jaw forward.

Appendix 4.2: Health economics review

Health Economics Data Extraction template

Source
CRD summary
Type of economic evaluation
Study objective
Interventions
Location/setting
Methods
Results
Authors' conclusions

Appendix 5

Quality assessment tables – effectiveness review

Based on Centre for Reviews and Dissemination Report number 4,[102] National Institute for Health and Clinical Excellence guidance development methodology 2005[103] and *Cochrane Handbook* 2008.[104]

TABLE 74 *Quality assessment table of randomised controlled trials: increased mother and baby contact interventions*

Study	Clear inclusion and exclusion criteria	Number randomised (total *N*) and by group (*n* = I/C)	A priori sample size calculation	Adequate randomisation method[a]	Adequate concealment method[b]
Blaymore Bier 1996[115]	✓	41 (21/20)	✗	✓	Not clear
Boo 2007[141]	✓	128 (65/63)	✓	✓	✓
Cattaneo 1998[131]	✓	285 (149/136) in three sites: (50/50) (52/54) (47/32)	✗	✓	Not clear
Charpak 1997,[107] 2001[108]	✓	777 (396/381)	✓	✓	✓
Kadam 2005[118]	✓	89 (44/45)	✗	Not clear	✓
Roberts 2000[129]	✓	30 (16/14)	✗	Not clear	Not clear
Rojas 2003[121]	✓	60 (33/27)	✗ Not for bf outcomes, not met for study	✓	Not clear
Sloan 1994[132]	✓	300 (140/160)	✓	✓	✓
Whitelaw 1988[147]	✓	71 (35/36)	✓ Not met	✓	✓

a Adequate approaches to sequence generation: computer-generated random numbers, random number tables, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots. Inadequate approaches: use of alternation, case record numbers, birth dates, date of admission.
b Adequate approaches to concealment: centralised or pharmacy-controlled randomisation, serially numbered identical containers, on-site computer-based system. Inadequate approaches: use of alternation, case records, birth dates, open random number lists, serially numbered envelopes.
c Appropriate reporting of data for study's primary outcomes: point estimates and measure of variability. Appropriate reporting of data for study's non-primary outcomes: categorical variables – number randomised to each group and number with outcome in each group; continuous variables – mean, SD and number of participants contributing data for outcome.

Groups comparable at baseline	Subject and investigators blind about treatment allocation	Outcome data reported appropriately[c]	Withdrawals[d] *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	ITT/PRE analysis[e]	Overall quality rating[f]
✓	Not applicable	✗	I: 0; C: 4 < 20% ✓	✗	Moderate
✗ Infant postmenstrual age and maternal education	Not applicable	✓	None < 20%	✓	Moderate
✓Excl. bf at enrolment different in one site	Not applicable	✗	< 20% at first visit > 20% at fourth visit ✗	✗	Moderate
✓	Not applicable	✓ Study primary outcome; ✗ % data for bf at 3-12 months	< 20% ✗	✗	Moderate
✓ Age at enrolment not reported; age at birth comparable	Not applicable	✗	None < 20%	✓	Moderate
✓	Not applicable	✗	Not stated	✗	Poor
✓	Not applicable	✓	I: 1; C: 0 < 20% ✗	✗	Moderate
✓	Not applicable	✗	< 20% ✗	✗	Moderate
✓	Not applicable	✗	None	✓	Moderate

d Numbers and percentages of individuals or clusters recruited into each study minus legitimate losses to study before intervention commenced due to postrandomisation exclusions.
e Intention-to-treat analysis: all participants are analysed by the group to which they were originally allocated including those who were lost to the study. Postrandomisation exclusions: as for ITT except individuals who were lost to the study due to death, not achieving defined clinical stability or other clearly defined inclusion/exclusion criteria (e.g. discharge to original hospital) before commencement of the intervention.
f Good: all or most of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *very unlikely* to alter. Moderate: some of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *unlikely* to alter. Poor: few or no criteria fulfilled. The conclusions of the study are thought *likely* or *very likely* to alter.

TABLE 75 *Quality assessment table of concurrent comparison study: increased mother and baby contact interventions*

Study	Clear inclusion and exclusion criteria	Overall sample size (n = I/C)	A priori sample size calculation	Method of group allocation
Wilhelm 2005[150] (crossover study)	✓	25 11: 11 12: 14	✗ Interim analysis showed 100 participants needed for milk volume outcome	Coin toss on day 4 for first mother-infant pair and alternate allocation for subsequent pairs

TABLE 76 *Quality appraisal table of before/after cross-sectional studies: increased mother and baby contact interventions*

Study	Are the groups selected from a suitable sampling frame?	Are the groups selected from the same sampling frame?	Method of allocation of participants to comparison groups	Were groups comparable at baseline?	A priori sample size calculation
Hurst 1997[139]	✓	✓	All mother-infant pairs in NICU in two time frames: B: 06/92 to 06/93 A: 01/07/93 to 30/09/93	✓	✗ Very small study: B: 15 A: 8
Wahlberg 1992[135]	✓	✓	Convenience sample selected by head nurse in two time frames: B: 05/84 to 11/85 A: 11/85 to 05/87	✓	✗ B: 33 A: 33

Groups comparable at baseline	Blinded outcome assessment	Outcomes measured in standard way (info on reporting outcome)	Withdrawals n: I and C <20%/>20% ✓ ✗ Reported by group with reason	ITT/PRE analysis	Overall quality rating
Not applicable Withdrawals: significantly lower birthweight and earlier gestation age	Not applicable	✗	✗	✗	Poor

Clear inclusion and exclusion criteria	What factors (other than the intervention) may affect the outcome? (state factors)	Did the authors adjust for the effects of con-founding factors?	Withdrawals n: I & C <20% / >20% ✓ ✗ Reported by group with reason	Was the analysis appropriate	Overall quality rating
✗	Any other bf promotion activity during two study periods Retrospective, self-reported data collection on milk pumping and output for preceding week Any relevant factors that were not reported on/ selected from case records used for retrospective before group data	✗	None other than legitimate losses to study	✓ Retrospective for before group	Poor
✓	Any relevant factors that were not reported on/ selected from case records used for retrospective data analysis for both groups	✗ Authors acknowledge limitationof study design	None	✓ Retrospective for both groups	Moderate

TABLE 77 *Quality assessment table of randomised controlled trials: interim feeding methods and related interventions*

Study	Clear inclusion and exclusion criteria	Number randomised (total *N*) and by group (*n* = I/C)	A priori sample size calculation	Adequate randomisation method[a]	Adequate concealment method[b]
Collins 2004[119]	✓	278 mothers of 319 infants (161 cup, 158 bottle) Mother was unit of randomisation Infant was unit of analysis	✓	✓	✓
Gilks 2004[120]	✓	54 infants (27 cup, 27 bottle)	✓ Not met (pilot study)	✗ (Not clear)	✓
Kliethermes 1999[130]	✓	99 (52 bottle, 47 tube)	✗	✗ (Not clear)	✗ (Not clear)
Mosley 2001[124]	✓	16 infants (8 cup, 8 bottle)	✓ Not met (pilot study)	✓	✓
Rocha 2002[122]	✓	83 (46 cup, 37 bottle)	✗	✓	✗ (Not clear)

a Adequate approaches to sequence generation: computer-generated random numbers, random number tables, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots. Inadequate approaches: use of alternation, case record numbers, birth dates, date of admission.
b Adequate approaches to concealment: centralised or pharmacy-controlled randomisation, serially numbered identical containers, on-site computer-based system. Inadequate approaches: use of alternation, case records, birth dates, open random number lists, serially numbered envelopes.
c Appropriate reporting of data for study's primary outcomes: point estimates and measure of variability. Appropriate reporting of data for study's non-primary outcomes: categorical variables – number randomised to each group and number with outcome in each group; continuous variables – mean, SD and number of participants contributing data for outcome.

Groups comparable at baseline	Subject and investigators blind about treatment allocation	Outcome data reported appropriately[c]	Withdrawals[d] *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	ITT/PRE analysis[e]	Overall quality rating[f]
Cup and bottle groups appear similar	Not applicable	✓	< 20% and ✓ at discharge < 20% at 3 and 6 months Losses reported by group but without reason	✓ Notes high non-compliance rates but no pragmatic analysis presented (partial results of exploratory compliance analyses in the discussion) PRE unclear (when enrolled not stated)	Good
Paper states no significant differences but see reported birthweights	Not applicable	✗	> 20% ✓	ITT for any and exclusive breastfeeding at discharge No PRE analysis	Poor (no forest plot)
✗	Not applicable	✗	< 20% ✓	✗	Poor (no forest plot)
Can't tell from very limited information in the paper	Not applicable	✗	< 20% ✓	✓ (But babies who got a supplementary feed were legitimate PREs in this study)	Moderate
✓	Not applicable	✗	< 20% ✓	✗	Moderate

d Numbers and percentages of individuals or clusters recruited into each study minus legitimate losses to study before intervention commenced due to postrandomisation exclusions.
e Intention-to-treat analysis: all participants are analysed by the group to which they were originally allocated including those who were lost to the study. Postrandomisation exclusions: as for ITT except individuals who were lost to the study due to death, not achieving defined clinical stability or other clearly defined inclusion/exclusion criteria (e.g. discharge to original hospital) before commencement of the intervention.
f Good: all or most of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *very unlikely* to alter. Moderate: some of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *unlikely* to alter. Poor: few or no criteria fulfilled. The conclusions of the study are thought *likely* or *very likely* to alter.

TABLE 78 *Quality assessment table of before/after study: interim feeding methods and related interventions*

Study	Are the groups selected from a suitable sampling frame?	Are the groups selected from the same sampling frame?	Method of allocation of participants to comparison groups	Were groups comparable at baseline?	A priori sample size calculation
Meier 2000[136]	✓	✓	Not applicable – crossover study	Not applicable	✗

a Numbers and percentages of individuals or clusters recruited into each study minus legitimate losses to study before intervention commenced due to legitimate postallocation exclusions in accordance with clear inclusion/exclusion criteria.
b Reporting appropriate outcome data: were data presented according to correct group of allocation and were numerator and denominator data reported for both groups? Was analysis based on ITT/PRE? Intention-to-treat analysis: all participants are analysed by the group to which they were originally allocated including those who were lost to the study. Postrandomisation/allocation exclusions: as for ITT except individuals who were lost to the study due to death, not achieving defined clinical stability or other clearly defined inclusion/exclusion criteria (e.g. discharge to original hospital) before commencement of the intervention.

TABLE 79 *Quality assessment table of randomised controlled trials: methods of expressing breastmilk interventions*

Study	Clear inclusion and exclusion criteria	Number randomised (total *N*) and by group	A priori sample size calculation	Adequate randomisation method[a]	Adequate concealment method[b]
Fewtrell 2001[125]	✓	145 (74/71)	✓	✓	✓
Groh-Wargo 1995[128]	✓	At least 32 At least 16/at least 16)	✗	Not clear ✗	Not clear ✗
Hill 1999[112]	✓	49 Not clear	✗	Not clear ✗	Not clear ✗
Jones 2001[114]	✓	52 (27/25)	✓	✓	✓
Paul 1996: phase 1[134]	✓	22	✗	Not clear ✗	Not clear ✗
Paul 1996: phase 2[134]	✓	14	✗	Not clear ✗	Not clear ✗
Slusher 2007[142]	✓	103 Not clear	✗	✓	Not clear ✗

a Adequate approaches to sequence generation: computer-generated random numbers, random numbers tables, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots. Inadequate approaches: use of alternation, case record numbers, birth dates, date of admission.
b Adequate approaches to concealment: centralised or pharmacy-controlled randomisation, serially numbered identical containers, on-site computer-based system. Inadequate approaches: use of alternation, case records, birth dates, open random number lists, serially numbered envelopes.
c Appropriate reporting of data for study's primary outcomes: point estimates and measure of variability. Appropriate reporting of data for study's non-primary outcomes: categorical variables – number randomised to each group and number with outcome in each group; continuous variables – mean, SD and number of participants contributing data for outcome.

Clear inclusion and exclusion criteria	What factors (other than the intervention) may affect the outcome? (state factors)	Did the authors adjust for the effects of confounding factors?	Withdrawals[a] *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	Outcome data reported appropriately, including ITT/ PRE analysis[b]	Overall quality rating[c]
✓	Ability to transfer milk without the shield	Yes	Not applicable (retrospective analysis of data)	Unclear	Moderate

c Good: all or most of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *very unlikely* to alter. Moderate: some of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *unlikely* to alter. Poor: few or no criteria fulfilled; the conclusions of the study are thought *likely* or *very likely* to alter.

Groups comparable at baseline	Subject and investigators blind about treatment allocation	Outcome data reported appropriately[c]	Withdrawals[d] *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	ITT/PRE analysis[e]	Overall quality rating[f]
✓	Not applicable	✓	< 20% ✓	ITT but not PRE	Good
✓ Mothers, no details of babies	Not applicable	Primary ✗	Not clear ✗	✓	Moderate
Income differed	Not applicable	Primary ✗	> 20% ✗	✗	Poor
Not clear	Not applicable	Primary ✓ Secondary ✗	> 20% ✗	✗	Moderate
Not applicable	Not applicable	Primary ✗	None reported	✓	Poor
Not applicable	Not applicable	Primary ✗	None reported	✓	Poor
Not clear ✗ Term babies	Not applicable	Primary ✗	> 20% ✗	✗	Moderate

d Numbers and percentages of individuals or clusters recruited into each study minus legitimate losses to study before intervention commenced due to postrandomisation exclusions.
e Intention-to-treat analysis: all participants are analysed by the group to which they were originally allocated including those who were lost to the study. Postrandomisation exclusions: as for ITT except individuals who were lost to the study due to death, not achieving defined clinical stability or other clearly defined inclusion/exclusion criteria (e.g. discharge to original hospital) before commencement of the intervention.
f Good: all or most of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *very unlikely* to alter. Moderate: some of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *unlikely* to alter. Poor: few or no criteria fulfilled; the conclusions of the study are thought *likely* or *very likely* to alter.

TABLE 80 *Quality assessment table of randomised controlled trials: additional interventions to enhance breastmilk production*

Study	Clear inclusion and exclusion criteria	Number randomised (total *N*) and by group (*n* = I/C)	A priori sample size calculation	Adequate randomisation method[a]	Adequate concealment method[b]
da Silva 2001[123]	✓	20 11/9	✓ Not met	✓	✓
Feher 1989[146]	✓	71 38/33	Unclear	✓	✗
Fewtrell 2006[144]	✓	51 27/24	✓ Met	✓	✓
Gunn 1996[132]	✓	20 10/10	✗	✓	✓
Hansen 2005[116]	✓	69 34/35	✓ Not met	✓	✓
Jones 2001[114]	✓	52 not applicable	✓	✓	✓
Mersmann 1993[148]	✓	19 Not applicable	✓ Met	✓	Unclear

a Adequate approaches to sequence generation: computer-generated random numbers, random numbers tables, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots. Inadequate approaches: use of alternation, case record numbers, birth dates, date of admission.
b Adequate approaches to concealment: centralised or pharmacy-controlled randomisation, serially numbered identical containers, on-site computer-based system. Inadequate approaches: use of alternation, case records, birth dates, open random number lists, serially numbered envelopes.
c Appropriate reporting of data for study's primary outcomes: point estimates and measure of variability. Appropriate reporting of data for study's non-primary outcomes: categorical variables – number randomised to each group and number with outcome in each group; continuous variables – mean, SD and number of participants contributing data for outcome.

TABLE 81 *Quality assessment table of randomised controlled trials: interventions to support optimal nutritional intake from breastmilk*

Study	Clear inclusion and exclusion criteria	Number randomised (total *N*) and by group (*n* = I/C)	A priori sample size calculation	Adequate randomisation method	Adequate concealment method
Amali-Adekwu 2007[140]	✓	77 (38/39)[a]	✗	✗	✗
Hurst 2004[145]	✓	46 (24/22)[b]	✗	✗	✓

a Unit of allocation and analysis was mother's own milk and infant.

Groups comparable at baseline	Subject and investigators blind about treatment allocation	Outcome data reported appropriately[c]	Withdrawals[d] *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	ITT/PRE analysis[e]	Overall quality rating[f]
✓	✓	Primary ✗	20% ✓	✗	Moderate
✓	Not applicable	Primary ✗	> 20% ✓	✗	Moderate
✓	✓	Primary ✗	< 20% ✓	✗	Good
✓	Subject ✓ Investigators ?	Primary ✗	< 20% ✓	✓	Moderate
✓	Subject ✓ Investigators ?	Primary ✗	< 20% ✓	✗	Moderate
Crossover trial	Not applicable	Primary ✓ Secondary ✗	> 20% ✗	✗	Moderate
Crossover trial	Subject ✓ for 2 of 3 treatments	Primary ✗	< 20% ✓	✗	Moderate

d Numbers and percentages of individuals or clusters recruited into each study minus legitimate losses to study before intervention commenced due to postrandomisation exclusions.
e Intention-to-treat analysis: all participants are analysed by the group to which they were originally allocated including those who were lost to the study. Postrandomisation exclusions: as for ITT except individuals who were lost to the study due to death, not achieving defined clinical stability or other clearly defined inclusion/exclusion criteria (e.g. discharge to original hospital) before commencement of the intervention.
f Good: all or most of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *very unlikely* to alter. Moderate: some of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *unlikely* to alter. Poor: few or no criteria fulfilled; the conclusions of the study are thought *likely* or *very likely* to alter.

Groups comparable at baseline	Subject and investigators blind about treatment allocation	Outcome data reported appropriately	Withdrawals *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	ITT/PRE analysis	Overall quality rating
✓	Not clear	✗	None < 20%	✓	Poor
✓	Not applicable	✗	I: 9; C: 6 > 20% ✓	✗	Poor

b Unit of allocation and analysis was mother and infant.

TABLE 82 *Quality assessment table of controlled trials and concurrent comparison study: interventions to support optimal nutritional intake from breastmilk*

Study	Clear inclusion and exclusion criteria	Overall sample size (*n* = I/C)	A priori sample size calculation	Method of group allocation	Group comparable at baseline
Griffin 2000[20]	✓	26 milk samples[a]	✗	✓	✓

a Unit of allocation and analysis was mothers' milk.

TABLE 83 *Quality assessment table of randomised controlled trials: breastfeeding education and support interventions*

Study	Clear inclusion and exclusion criteria	Number randomised (total *N*) and by group (*n* = I/C)	A priori sample size calculation	Adequate randomisation method[a]	Adequate concealment method[b]
Agrasada 2005[117]	✓	204 68, 67, 69	✓	✓	✓
Merewood 2006[143]	✓	108 53, 55	✓	✓	✓
Pinelli 2001[128]	✓	128 64, 64	✓	✓	✓

a Adequate approaches to sequence generation: computer-generated random numbers, random numbers tables, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots. Inadequate approaches: use of alternation, case record numbers, birth dates, date of admission.
b Adequate approaches to concealment: centralised or pharmacy-controlled randomisation, serially numbered identical containers, on-site computer-based system. Inadequate approaches: use of alternation, case records, birth dates, open random number lists, serially numbered envelopes.
c Appropriate reporting of data for study's primary outcomes: point estimates and measure of variability. Appropriate reporting of data for study's non-primary outcomes: categorical variables – number randomised to each group and number with outcome in each group; continuous variables – mean, SD and number of participants contributing data for outcome.

Blinded outcome assessment	Outcomes measured in standard way (info on reporting outcome)	Withdrawals *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	ITT/PRE analysis	Overall quality rating
✓	✓	None < 20%	✓	Good

Groups comparable at baseline	Subject and investigators blind about treatment allocation	Outcome data reported appropriately[c]	Withdrawals[d] *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	ITT/PRE analysis[e]	Overall quality rating[f]
✓	Subjects NA Investigators ✓	✓	< 20% ✓	✓	Good
✓	Subjects NA Investigators ✓	✓	> 20% ✓	✗	Moderate
✓	Subjects NA Investigators unclear	✓	10% dropout to 1 year except at 1 month when dropout was 24% Reported by group but no reasons	✓	Good

d Numbers and percentages of individuals or clusters recruited into each study minus legitimate losses to study before intervention commenced due to postrandomisation exclusions.
e Intention-to-treat analysis: all participants are analysed by the group to which they were originally allocated including those who were lost to the study. Postrandomisation exclusions: as for ITT except individuals who were lost to the study due to death, not achieving defined clinical stability or other clearly defined inclusion/exclusion criteria (e.g. discharge to original hospital) before commencement of the intervention.
f Good: all or most of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *very unlikely* to alter. Moderate: some of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *unlikely* to alter. Poor: few or no criteria fulfilled; the conclusions of the study are thought *likely* or *very likely* to alter.

TABLE 84 *Quality assessment table of before/after and cross-sectional studies: breastfeeding education and support interventions*

Study	Are the groups selected from a suitable sampling frame?	Are the groups selected from the same sampling frame?	Method of allocation of participants to comparison groups[a]	Were groups comparable at baseline?	A priori sample size calculation
Gonzalez 2003[166]	✓	✓	By date	✓	✓
Pereira 1984[153]	✓	✓	By date	✓	✗
Senn 2004[152]	✓	✓	By date	✗	✗

a Unit of allocation and analysis was mother, not infant.
b Numbers and percentages of individuals or clusters recruited into each study minus legitimate losses to study before intervention commenced due to legitimate postallocation exclusions in accordance with clear inclusion/exclusion criteria.
c Reporting appropriate outcome data: were data presented according to correct group of allocation and were numerator and denominator data reported for both groups? Was analysis based on ITT/PRE? Intention-to-treat analysis: all participants are analysed by the group to which they were originally allocated including those who were lost to the study. Postrandomisation/allocation exclusions: as for ITT except individuals who were lost to the study due to death, not achieving defined clinical stability or other clearly defined inclusion/exclusion criteria (e.g. discharge to original hospital) before commencement of the intervention.

Clear inclusion and exclusion criteria	What factors (other than the intervention) may affect the outcome? (state factors)	Did the authors adjust for the effects of confounding factors?	Withdrawals[b] *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	Outcome data reported appropriately, including ITT/ PRE analysis[c]	Overall quality rating[d]
✓	Any concurrent changes in standard care	✓	No withdrawals	Outcomes reported as % data	Moderate
✓	Any concurrent changes in standard care	✗	No withdrawals	Outcomes reported as % data	Moderate
✓	Concurrent changes in standard care (some are described)	?	No withdrawals	✓	Poor

d Good: all or most of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *very unlikely* to alter. Moderate: some of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *unlikely* to alter. Poor: few or no criteria fulfilled; the conclusions of the study are thought *likely* or *very likely* to alter.

TABLE 85 *Quality assessment table of before/after and cross-sectional studies: staff training interventions*

Study	Are the groups selected from a suitable sampling frame?	Are the groups selected from the same sampling frame?	Method of allocation of participants to comparison groups	Were groups comparable at baseline?	A priori sample size calculation
Jones 2004[81]	✓	✓	✓	✓	✗
Pineda 2006[149]	✓	✓	✓	✓	✓ Not achieved

a Numbers and percentages of individuals or clusters recruited into each study minus legitimate losses to study before intervention commenced due to legitimate postallocation exclusions in accordance with clear inclusion/exclusion criteria.
b Reporting appropriate outcome data: were data presented according to correct group of allocation and were numerator and denominator data reported for both groups? Was analysis based on ITT/PRE? Intention-to-treat analysis: all participants are analysed by the group to which they were originally allocated including those who were lost to the study. Postrandomisation/allocation exclusions: as for ITT except individuals who were lost to the study due to death, not achieving defined clinical stability or other clearly defined inclusion/exclusion criteria (e.g. discharge to original hospital) before commencement of the intervention.

Clear inclusion and exclusion criteria	What factors (other than the intervention) may affect the outcome? (state factors)	Did the authors adjust for the effects of confounding factors?	Withdrawals[a] *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	Outcome data reported appropriately, including ITT/ PRE analysis[b]	Overall quality rating[c]
✓	Missing data from medical record review Improved documentation of data and information	✗	✗	✗	Moderate
✓	Not all mothers were given the intervention booklet on admission Some mothers were not given the booklet Old versions of the individualised care plan used in the postintervention period Breastfeeding intervention may not have resulted in behavioural change in the health-care professionals	✗	✓	✓	Moderate

c Good: all or most of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *very unlikely* to alter. Moderate: some of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *unlikely* to alter. Poor: few or no criteria fulfilled; the conclusions of the study are thought *likely* or *very likely* to alter.

TABLE 86 *Quality assessment table of randomised controlled trials: early hospital discharge with home support interventions*

Study	Clear inclusion and exclusion criteria	Number randomised (total *N*) and by group (*n* = I/C)	A priori sample size calculation	Adequate randomisation method[a]	Adequate concealment method[b]
Gunn 2000[127]	✓	308 (148/160)	✗	✓	Not stated
Ortenstrand 1999,[109] 2001[110]	✓	88 (45/43)	✗	✗	✗

a Adequate approaches to sequence generation: computer-generated random numbers, random numbers tables, coin tossing, shuffling cards or envelopes, throwing dice, drawing of lots. Inadequate approaches: use of alternation, case record numbers, birth dates, date of admission.
b Adequate approaches to concealment: centralised or pharmacy-controlled randomisation, serially numbered identical containers, on-site computer-based system. Inadequate approaches: use of alternation, case records, birth dates, open random number lists, serially numbered envelopes.
c Appropriate reporting of data for study's primary outcomes: point estimates and measure of variability. Appropriate reporting of data for study's non-primary outcomes: categorical variables – number randomised to each group and number with outcome in each group; continuous variables – mean, SD and number of participants contributing data for outcome.
d Numbers and percentages of individuals or clusters recruited into each study minus legitimate losses to study before intervention commenced due to postrandomisation exclusions.

Groups comparable at baseline	Subject and investigators blind about treatment allocation	Outcome data reported appropriately[c]	Withdrawals[d] *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	ITT / PRE analysis[e]	Overall quality rating[f]
✓ ✗ Days on full oral feeds in hospital; weight at discharge	Not applicable	✓ No supporting numerator or denominator data reported	✗ Not for losses after randomisation prior to intervention ✓ Losses prior to randomisation	Not clear: no data on losses to study and reported results as percentage data	Moderate
✓	Not applicable	✗	< 20% ✓	Not clear for breastfeeding outcomes: percentage data reported	Poor

e Intention-to-treat analysis: all participants are analysed by the group to which they were originally allocated including those who were lost to the study. Postrandomisation exclusions: as for ITT except individuals who were lost to the study due to death, not achieving defined clinical stability or other clearly defined inclusion/exclusion criteria (e.g. discharge to original hospital) before commencement of the intervention.

f Good: all or most of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *very unlikely* to alter. Moderate: some of the criteria have been fulfilled; where they have not been fulfilled the conclusions of the study are thought *unlikely* to alter. Poor: few or no criteria fulfilled; the conclusions of the study are thought *likely* or *very likely* to alter.

TABLE 87 *Quality assessment table of before/after studies: organisation of care interventions*

Study	Are the groups selected from a suitable sampling frame?	Are the groups selected from the same sampling frame?	Method of allocation of participants to comparison groups	Were groups comparable at baseline?	A priori sample size calculation
Bell 1995[154]	✗ Not stated how mothers identified	✗ Before: 3-month period After 12-month period	Mothers of infants in Intermediate Care Nursery	✗ No characteristics reported	✗
Bicalho-Mancini 2004[151]	✓	✓	All newborn babies on high-risk ward at two time points	✗ No data by group	✗
Merewood 2003[137]	✓	✓	All surviving infants for one year at two time points	✓ ✗ Significantly fewer vaginal births in After group	✗
Oddy 2003[138]	✗	✗	All babies meeting retrospectively applied inclusion criteria	✗ No characteristics reported	✗

Clear inclusion and exclusion criteria	What factors (other than the intervention) may affect the outcome? (state factors)	Did the authors adjust for the effects of confounding factors?	Withdrawals *n*: I and C < 20%/> 20% ✓ ✗ Reported by group with reason	Outcome data reported appropriately, including ITT/ PRE analysis	Overall quality rating
✗	Any other bf promotion or changes in care during unknown period between data collection	✗	None	✓	Poor
✓	Any other bf promotion or changes in care during 11-month period between data collection	✗	None	✓	Moderate
✓	Any other bf promotion or changes in care during 3-year period between data collection	✗	None	✓	Good
✓	Any other bf promotion or changes in care during 2-year period between data collection	✗	None (assumes only babies with complete records were selected)	✓ Excluding bf at discharge ✗ Mean % bf at discharge	Poor

Appendix 6
Excluded studies

Appendix 6.1: Effectiveness review

Full paper copies for 138 citations were obtained. Eighty-seven of these papers reported studies that did not meet the inclusion criteria for this review. Fourteen of the 87 papers were duplicates, and one reported an ongoing study. Reasons for exclusion of the remaining 72 papers are listed below.

	Reason for exclusion			
Study	**Not an evaluation of an intervention**	**Not special care infants**	**Intervention does not specifically address breastfeeding/ breastmilk feeding in SCBU/NICU**	**Breastfeeding/ breastmilk outcomes not reported**
Secretariat of Health of the City of Rio de Janeiro 1999[222]	✗			
Contemporary Pediatrics (commentary) 2006[223]	✗			
Alexandre 2007[224]	✗			
Anderson 1999[225]	✗			
Blaymore Bier 1997[24]			✗	
Bingham 2007[226]			✗	
Blumenfeld 2006[227]				✗
Cabral 2006[228]	✗			
Callen 2005[229]	✗			
Carfoot 2003[230]		✗		
Castrucci 2007[231]	✗			
Charpak 2007[232]	✗			
Charpak 1994[233]	✗			
Cobb 2002[234]	✗			
Cockerill 2006[235]	✗			
Conseil d'Evaluation des Technologies de la Santé du Québec (CÉTS)1997[236]		✗		
Dall'Oglio 2007[237]	✗			
Damanik 2006[238]		✗		
Ehrenkranz 1986[239]	✗			
Elliott 1998[240]				✗
Forsythe 1998[241]				✗
Gilks 2007[242]	✗			
Glazebrook 2007[243]				✗
Gotsch 1991[244]	✗			

continued

Study	Reason for exclusion			
	Not an evaluation of an intervention	Not special care infants	Intervention does not specifically address breastfeeding/ breastmilk feeding in SCBU/NICU	Breastfeeding/ breastmilk outcomes not reported
Gray 2001[245]			✗	
Gupta 1999[246]	✗			
Harding 2006[247]	✗			
Hill 2005[248]	✗			
Hurst 2007[249]	✗			
Jones 1994[96]	✗			
Jones 1995[250]	✗			
Jones 2000[251]	✗			
Jones 2001[252]	✗			
Lawrence 2001[253]	✗			
Liu 2007[42]				✗
Marinelli 2001[192]				✗
Meier 2004[21]	✗			
Meier 2002[90]	✗			
Meier 2007[254]	✗			
Milsom 1998[255]		✗		
Moore 2007[84]		✗		
Narayanan 1988[256]	✗			
Narayanan 1991[257]	✗			
Nyqvist 1997[258]		✗		
Page-Wilson 2007[259]		✗		
Patel 2007[260]				✗
Peterson 2002[261]		✗		
Phillips 2005[44]	✗			
Pinelli 2005[213]				✗
Premji 2002[262]			✗	
Preyde 2007[263]	✗			
Schanler 1999[264]			✗	
Senarath 2007[265]		✗		
Sheppard 2007[266]	✗			
Sisk 2006[106]	✗			
Slusher 2003[195]	✗			
Spatz 2005[267]				✗
Symington 2006[85]			✗	
Thomas 1986[268]	✗			
Toppare 1994[269]				✗

Study	Reason for exclusion			
	Not an evaluation of an intervention	Not special care infants	Intervention does not specifically address breastfeeding/ breastmilk feeding in SCBU/NICU	Breastfeeding/ breastmilk outcomes not reported
Tosh 2006[270]			✗	
Tyson 2007[271]				✗
VandenBerg 1999[272]			✗	
Vohr 2007[12]	✗			
Wallis 2007[273]	✗			
Ward 2006[274]	✗			
Warren 2000[275]	✗			
Weimers 2007[276]	✗			
Wheeler 1999[277]	✗			
Woldt 1991[278]	✗			
Young 1994[279]	✗			
Zukowsky 2007[280]	✗			

Ongoing studies

One of the 138 full paper copies reported an ongoing study. Authors we contacted informed us of another four ongoing studies. These five studies are listed below.

Campbell-Yeo 2006[281]	Ongoing
Smith[282]	Ongoing
Stola 2007[283]	Ongoing
Ward[274]	Ongoing
Welt[284]	Ongoing

Paper published since our update search

The following paper published after our update search meets the inclusion criteria for this review. It is summarised in Appendix 10: Hake-Brooks SJ, Cranston Anderson G. Kangaroo care and breastfeeding of mother-preterm infant dyads 0–18 months, a randomised controlled trial. *Neonatal Network* 2008;**27**:1–9.

Appendix 6.2: Health economics review

Quality assessment

The quality assessment planned to use two methods; firstly, a modified version of the 35-point checklist developed for the authors of economic evaluations submitted to the *British Medical Journal*. The modification took the form of an additional item (no. 36) intended to ascertain whether the authors had assessed the generalisability of the results. Each checklist item could be given one of four outcomes: (a) yes, (b) no, (c) not clear or (d) not applicable. The checklists were to be completed by two health economists and any discrepancies discussed until final consensus was reached.

Secondly, for each study that met the inclusion criteria, a critical textual summary was planned. This included an appraisal of the choice of comparator(s), the validity of the clinical effectiveness results, the validity of the measure of benefit, the validity of the cost estimates, an assessment of the methodology used, and a variety of other important issues. The data extraction form developed is shown in Appendix 4.2.

Excluded studies

Author	Title	Reason for rejection
Barton 2001[285]	Clinical and economic outcomes of infants receiving breastmilk in the NICU	The aim of the study was to evaluate breastmilk compared with formula. No interventions related to the promotion or encouragement of breastfeeding were considered
Drane 1997[286]	Breastfeeding and formula feeding: a preliminary economic analysis	The aim of the study was to evaluate breastmilk compared with formula in terms of cases of illness episodes. This was a preliminary analysis and did not meet the criteria of a full economic analysis
Cattaneo 1998[130]	Kangaroo mother care for low birth weight infants: a randomised controlled trial in different settings	The study compared kangaroo mother care to conventional treatment. Only limited aggregate cost difference data were provided; therefore the analysis did not meet the criteria of a full economic analysis
Daga 1985[287]	Impact of breast milk on the cost-effectiveness of the special care unit for the newborn	The study evaluated the impact of introducing sleeping facilities adjacent to the SCBU for mothers whose infants were in the unit. However, due to the setting and age of the study it did not meet the inclusion criteria specified

Appendix 7

Data extraction tables of five systematic reviews used to identify studies for the effectiveness review

<table>
<tr><th>First author, year, design</th><th>Review/Research question</th><th>Included studies</th><th>Main results</th><th>Confounders/ comments</th><th>Quality (mark ✓ or ✗)</th></tr>
<tr>
<td>Collins 2003[160]
Cochrane SR</td>
<td>Review question
What are the effects of a policy of early discharge of stable preterm infants with home support of gavage (tube) feeding compared with a policy of discharge of such infants when they have reached full sucking feeds?

Data sources
The authors state that they used the standard search strategy of Cochrane Neonatal Group with additional searches including the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (1966–April 2003), CINAHL (1982 to April 2003), and EMBASE (1980 to 2003 week 15)
Free text and MeSH terms specified
No language restrictions

Inclusion criteria
Study types
Randomised or quasi-randomised trials</td>
<td>One quasi-randomised trial was included in the review:

Örtenstrand 1999
Sample: 88 physiologically stable infants < 37 weeks at birth with need for special care for at least 1 week
Singletons and twins included
Intervention: early discharge with home visits, gavage feeding at home by parents
Control: infants discharged home when clinically well, on full breast and/or bottle feeds
Study quality:
Allocation concealment – no; the nursery in the trial had two separately staffed rooms. The rooms were randomly designated as experimental or control. The infants were allocated according to bed availability

Blinding of treatment – not possible</td>
<td>Breastfeeding/breastmilk-related outcomes
There were no significant differences between the groups for duration of any or exclusive breastfeeding at any time point:
<table>
<tr><th></th><th>Home gavage</th><th>Control</th><th>RR (fixed) [95% CI]</th></tr>
<tr><td colspan="4">Women who had stopped fully breastfeeding</td></tr>
<tr><td>Discharge</td><td>13/41</td><td>10/41</td><td>1.30 [0.64–2.62]</td></tr>
<tr><td>3 months</td><td>8/41</td><td>6/41</td><td>1.33 [0.51–3.50]</td></tr>
<tr><td>6 months</td><td>24/41</td><td>24/41</td><td>1.00 [0.69–1.44]</td></tr>
<tr><td colspan="4">Women who had stopped any breastfeeding</td></tr>
<tr><td>Discharge</td><td>2/41</td><td>4/41</td><td>0.50 0.10–2.58]</td></tr>
<tr><td>3 months</td><td>8/41</td><td>5/41</td><td>1.60 [0.57–4.48]</td></tr>
<tr><td>6 months</td><td>20/41</td><td>12/41</td><td>1.67 [0.94–2.95]</td></tr>
</table>
Clinical/health outcomes
Weight:
No significant difference between weight gain from trial entry to discharge from home gavage programme (experimental group) and weight gain from trial entry to hospital discharge (control group) was detected [Weighted mean difference (WMD) –1.10 g/day (–3.94 to 1.74)]
Infection:
Infants in the home gavage programme had a lower risk of infection during the home gavage period than the control group during the corresponding period in hospital (RR 0.35 [0.17, 0.69]), $p = 0.003$
Mortality:
No significant difference seen between the groups in death within the first 12 months postdischarge</td>
<td>The study included in this review was conducted in Sweden
The mean age of the infants has not been reported; a potential confounding factor
No economic data were presented to compare the costs of the 19.6 days on the home programme with the costs saved on the 9.3 days</td>
<td>The review was well conducted; however, the one study included in the review has methodological limitations
Inclusion/exclusion criteria reported: ✓
Description of SR methodology: ✓
Rigorous literature search: ✓
Quality of studies assessed and taken into account: ✓
Sufficient details about individual studies: ✓
Studies appropriately combined: only one study</td>
</tr>
</table>

DOI: 10.3310/hta13400

First author, year, design	Review/Research question	Included studies	Main results	Confounders/ comments	Quality (mark ✓ or ✗)
	Participants Infants born at less than 37 weeks' gestation and not requiring intravenous supplementation at discharge (infants receiving supplemental oxygen were not excluded) *Interventions* Early discharge home with gavage feeds and health-care support, vs later discharge home when full sucking feeds attained (studies without home support for gavage feeding were excluded) *Outcomes* Primary: feeding and growth, hospital readmission, adverse events Secondary: satisfaction and anxiety, cost, health service use **Quality assessment** The reviewers state that they used standard methods of the Neonatal Review Group	*Blinding of outcome assessment – yes* *Follow-up – 7% attrition for primary outcomes* All data were analysed according to the treatment group allocated	**Process outcomes** Length of hospital stay: Mean stay 9.3 days shorter for gavage group [WMD –9.30 (–18.49 to –0.11)] Infants in the gavage group spent a mean of 19.6 [SD 9.2] days on the home gavage programme **Psychosocial outcomes** Parental confidence in handling their infant, parental feelings of preparedness to take responsibility for the care of their infant and parental anxiety were measured at time of discharge from home gavage programme (intervention group) or discharge from hospital (control group). No significant differences were found either for mothers or for fathers **Cost-effectiveness outcomes** Not reported **Were outcomes reported for different gestational ages of the baby and/or ability to co-ordinate sucking and swallowing?** No Planned subgroup analyses were not undertaken due to lack of data		

First author, year, design quality	Review/research question	Included studies	Main results	Confounders/ comments	Quality (mark ✓ or ✗)
Conde-Agudelo 2003[164] Cochrane SR	**Review question** Is there evidence to support the use of kangaroo mother care (KMC) in low birthweight (LBW) infants as an alternative to conventional care, after the initial common period of stabilisation with conventional care? **Data sources** The authors followed Cochrane Neonatal Group methods, which included searches of MEDLINE, EMBASE, LILACS, POPLINE and CINAHL databases and the Cochrane Controlled Trials Register (January 1982 to December 2002) using key word terms 'kangaroo mother care' or 'kangaroo care' or 'kangaroo mother method' or 'skin-to-skin contact' and 'infants' or 'low birth weight infants'; relevant trials were sought from the Neonatal Review Group's Specialised Register; cross-referencing, conference proceedings and journal hand searching (journals unspecified) No language restrictions were imposed	Three trials were included in the review: Sloan 1994 (RCT) Intervention: KMC (kept in upright position, in skin-to-skin contact, diapers allowed) against the mother's breasts and had frequent breastfeeding ($n = 140$) Control: Incubator or thermal crib and were breastfed at scheduled times ($n = 160$) Charpak 1997 (RCT) Intervention: KMC (24 hours/day in a strict upright position, in skin-to-skin contact firmly attached to the mother's chest) ($n = 396$) Control: Infants kept in an incubator until they were able to regulate temp. or were thriving ($n = 381$) Cattaneo 1998 (RCT)	Reviewer states intention-to-treat analysis was impossible because of incomplete outcome data, but does not specify whether available data were or were not analysed according to treatment group All results except those for breastfeeding at 1 month are based on data from one trial **Breastfeeding/breastmilk-related outcomes** Not exclusively breastfeeding at discharge: Significantly fewer KMC infants 'not exclusively' breastfeeding (i.e. more exclusively breastfeeding) at discharge (RR 0.41 [95% CI 0.25, 0.68], $p = 0.0005$) (Cattaneo 1998) No differences seen in exclusive breastfeeding at 41 weeks corrected gestational age, 1 or 6 months or 12 months corrected age **Clinical/health outcomes** Infant mortality: No differences seen in infant mortality assessed from eligibility to any of the review time points Infection/illness Nosocomial infection at 41 weeks corrected gestational age: KMC associated with lower risk (RR 0.49 [95% CI 0.25, 0.93], $p = 0.03$) Severe illness at 6-month follow-up: KMC associated with lower risk (RR 0.30 [95% CI 0.14, 0.67], $p = 0.003$) Lower respiratory tract disease at 6-month follow-up: KMC associated with lower risk (RR 0.37 [95% CI 0.15, 0.89], $p = 0.03$) No differences seen in severe infection at 41 weeks corrected gestational age or at 12 months corrected age, diarrhoea, or mild or moderate illness at 6 months follow-up	Sloan 1994: Ecuador Charpak 1997: Colombia Cattaneo 1998: Ethiopia, Indonesia and Mexico; conventional care was not defined and Conde-Agudelo 2003 states insufficient detail about breastfeeding promotion and maternal involvement in care of the newborn was provided for control groups This review focused on low birthweight infants and may not be applicable to all premature infants Conde-Agudelo 2003 states that respiratory, thermal and feeding stabilisation are crucial for the success of this intervention, but 'stabilisation' was not defined. Gestational age and weight were stated to be the main variables associated with respiratory, thermal and feeding functions	Inclusion/exclusion criteria reported: ✓ Description of SR methodology: ✓ Rigorous literature search: ✓ Quality of studies assessed and taken into account: ✓ Sufficient details about individual studies: ✓ Studies appropriately combined: not enough data to combine

First author, year, design quality	Review/research question	Included studies	Main results	Confounders/ comments	Quality (mark ✓ or ✗)
	Inclusion criteria *Study types* Randomised controlled trials *Participants* LBW infants (birthweight less than 2500 irrespective of gestational age) *Interventions* KMC versus standard neonatal care in LBW infants *Outcomes reported* Primary: mortality Secondary: infection/ illness, failure to establish breastfeeding, readmission to hospital, growth, psychomotor development, parental dissatisfaction, mother's attachment behaviour Quality assessment The authors assessed each paper on the following criteria: allocation concealment, completeness of follow-up and blinding of assessment outcome (they also described methods of randomisation)	Intervention: KMC (close and continuous skin-to-skin between mother's breasts, diaper only) Control: skin-to-skin contact between mothers and infants not allowed. Infants kept in incubators (two hospitals) and in a warm room with open cribs with the possibility of rewarming in a bulb-heated cot at the third (unknown number of infants initially randomised to each group) Conde-Agudelo 2003 state the included trials were of moderate to poor quality: No trial described procedures of allocation concealment or reported blinding No trial provided complete outcome data	Growth Daily weight gain at discharge (g/day): *KMC infants gained more (WMD 3.6 g/day [95% CI 0.8 to 6.4], p = 0.01)* No differences seen in weight, length or head circumference at 41 weeks corrected gestational age, at discharge or at 12 months corrected age **Process outcomes** Readmission to hospital: No differences seen at 41 weeks corrected gestational age or at 6 months follow-up **Psychosocial outcomes** Maternal dissatisfaction with method of care: *KMC associated with lower risk (RR 0.41 [95% CI 0.22 to 0.75], p = 0.004)* **Cost-effectiveness outcomes** Costs stated to be less for KMC in two studies, but incompletely reported **Were outcomes reported for different gestational ages of the baby and/or ability to co-ordinate sucking and swallowing?** No – planned subgroup analyses were not undertaken due to lack of data		

First author, year, design	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
Edmond 2006[155] SR (World Health Organization Technical Review)	**Review question** What is the evidence on feeding low birthweight (LBW) infants? How should LBW infants in developing countries be fed in the first 6 months of life? **Data sources** *Search terms:* LBW, preterm, premature, SGA, intrauterine growth restriction/ retardation (IUGR), mortality, breastfeeding, human milk *Electronic databases:* Cochrane database of SRs of RCTs, Cochrane controlled trials register, DARE, Cochrane Neonatal collaborative review group specialised register, MEDLINE (1966–2005), EMBASE (1966–2005) Reference lists of articles, personal communications, technical reports, conference proceedings, review articles, books, dissertations and experts in the field were also accessed Key journals (unspecified) were hand searched Non-English language articles and abstracts actively sought	80 studies listed in summary tables Other studies referred to in the text Number of studies included in the review not stated Exposures/interventions stratified and reported under six headings: *1. Nutrition* This section did not report bf/ breastmilk-related outcomes *2. Feeding methods* **Two studies evaluated the effects of cup feeding compared with bottle-feeding on bf patterns:** **Collins 2004 (RCT)** (LII)[a] After bf or when mother unable to be present, infants (GA < 34 weeks) to be fed by cup ($n = 151$) or bottle ($n = 152$) **Rocha 2002 (RCT)** (LII) Infants (GA 32–36 weeks) to be fed by cup ($n = 44$) or bottle ($n = 34$) *3. Feeding schedules (oral and intragastric feeding)* This section did not report bf/breastmilk-related outcomes **4. Support** **Four studies evaluated the effects of kangaroo mother care (KMC) compared with conventional care on bf patterns:** **Cattaneo 1998 (RCT)** (LII) KMC ($n = 146$) compared with conventional care ($n = 133$); stable infants BW 1000–2000 g **Charpak 1997 (RCT)** (LII) KMC ($n = 343$) compared with conventional care ($n = 320$); stable infants BW < 2000 g	For the interventions that report bf/ breastmilk-related outcomes, the authors report their findings as follows: **Cup feeding compared with bottle feeding** Cup feeding led to higher rates of exclusive/predominant bf at hospital discharge than bottle feeding Cup feeding was associated with lower risk of bradycardia or desaturation than bottle feeding No evidence of increased risk of aspiration when cup feeding correctly done (infant upright and milk not poured into the mouth; 'lapping milk') Most of the evidence came from studies conducted in developed countries No data for term LBW infants **KMC compared with conventional care** In clinically stable preterm infants with BW < 2000 g, there is evidence that KMC is at least as effective as conventional care in reducing mortality KMC may improve exclusive BF rates and weight gain and may reduce infections Insufficient data on effects of KMC in infants with BW < 1500 g. Many of these infants were excluded from the available studies because they were not clinically stable Preliminary evidence from resource-poor settings that KMC may be effective even in clinically unstable LBW infants including those with BW < 1500 g Most of the evidence came from studies conducted in developing countries No data for term LBW infants	**Applicability to the UK** The aim of this technical review was to develop guidelines for feeding LBW infants in developing countries. Due to the paucity of data from developing countries, most of the evidence came from studies conducted in developed countries. The authors state that care was taken in extrapolating information from developed countries to developing country settings. Similarly, care should be taken when applying conclusions intended to guide practice in developing countries to the UK and other developed country settings **Additional information** The Background to the Results section presents: • Physiological principles of feeding LBW infants • Nutritional requirements • Nutritional sources for LBW infants (human milk, human milk supplements, breastmilk substitutes) • Development of feeding ability **Gaps in evidence on interventions relevant to the current review** *Breastfeeding supplementer* The authors note they found two small case series that described the impact of the	Inclusion/ exclusion criteria reported: inclusion ✓ exclusion û Description of SR methodology: ✓ This technical review considered consensus statements, expert committee reports and advice from experts in the field as well as evidence from the studies Rigorous literature search: ✓ Some papers found after the searches had been done were included in the review Quality of studies assessed and taken into account: ✓ Authors state they assessed limitations, internal and external validity, and wider implications of each study but do not say how

DOI: 10.3310/hta13400

First author, year, design	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
	Inclusion criteria *Study types:* systematic and non-systematic reviews, randomised and quasi-randomised trials, cohort and case–control studies related to feeding of LBW infants *Participants* Infants with birthweight (BW) < 2500 g or gestational age (GA) at birth < 37 weeks *Interventions* All nutritional exposures or interventions to improve feeding of LBW infants in the first 6 months of life **Outcomes reported** Mortality Severe morbidity Neurodevelopment Growth Other outcomes (including rates of any and exclusive breastfeeding (bf)) Quality assessment Authors comment on quality of evidence (Annex 3), but quality assessment criteria are not described	**Charpak 2001 (RCT)** (LII) KMC ($n = 320$) compared with conventional care ($n = 305$); stable infants BW < 2000 g **Sloan 1994 (RCT)** (LII) KMC ($n = 93$) compared with conventional care ($n = 111$); stable infants BW < 2000 g **Three studies evaluated the effects of breastfeeding counselling on bf patterns:** **Pinelli 2001 (RCT)** (LII) Bf counselling package ($n = 64$) compared with standard package ($n = 64$); parents of infants BW < 1500 g who intended to bf **Bhandari 2003 (cluster RCT)** (LII) Subgroup of intervention group (community promotion of exclusive bf for 6 months, $n = 159$) compared with control group ($n = 124$); mothers of infants BW < 2500 g **Agrasada 2005 (RCT)** (LII) Home-based bf counselling ($n = 60$) compared with home-based counselling in general child care ($n = 59$) and no counselling at home ($n = 71$); mothers of term infants BW < 2500 g who were admitted to hospital **Three studies evaluated the effects of metoclopramide or domperidone therapy on daily breastmilk volume in women who gave birth at < 34 weeks' gestation:** **Ehrenkranz 1986 (cohort study)** (LIII-3 or above) Metoclopramide 10 mg three times per day for 7 days	**Breastfeeding counselling** Among preterm infants 32–36 weeks' gestation and term LBW infants, bf counselling improves the rates of exclusive bf at 3 months No disadvantage in growth rates or malnutrition prevalence apparent The evidence came from developing and developed countries Few data on infants < 32 weeks' gestation **Metoclopramide or domperidone therapy** The available evidence suggests that metoclopramide or domperidone increases breastmilk volume in mothers of infants of < 32 weeks' gestation, particularly those who were having difficulty in maintaining milk production No efficacy data for mothers of infants 32–36 weeks' gestation or of term LBW infants **Cost-effectiveness outcomes** Not reported **Were outcomes reported for different gestational ages of the baby and/or ability to co-ordinate sucking and swallowing?** Infants classified by GA and (where GA not available) on BW as follows: i) GA < 32 weeks or BW < 1500 g ii) GA 32–36 weeks or BW 1500–1900 g iii) Term infants with BW 2000–2499 g	breastfeeding supplementer on exclusive breastfeeding rates. However, they judged these studies were likely to suffer from selection and observer bias so did not draw conclusions from them *Non-nutritive sucking* Executive summary states that encouraging the infant to suck on the 'emptied' breast, after expression of breastmilk, may result in improved breastfeeding rates at discharge and follow-up. Text on p. 85 states this evidence came from a small study in 32 babies with an average gestation of 33 weeks, but this study is unreferenced *Demand feeding* Executive summary states demand feeding may be feasible for some infants of 32–36 weeks' gestation and may reduce length of hospitalisation. Text on p. 78 lists limitations of this evidence. What and how the babies were fed is not mentioned. The authors note that starting demand feeding as early as possible may be advantageous because of risks and costs of hospitalisation. They also note demand feeding initially requires more monitoring and training	Some details of individual studies not clearly or consistently reported: ✓ e.g. country not specified, date appears only in the reference list, not all studies appear in summary tables and details of these may be missing (as with the studies on metoclopramide or domperidone therapy) Studies appropriately combined: ✓ (narrative synthesis)

First author, year, design	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
		de Silva 2001 (randomised study) (LIII-3 or above) Women having difficulty maintaining milk production by expression randomised to domperidone or placebo for 7 days **Hansen 2005 (randomised study)** (LIII-3 or above) Metoclopramide 10 mg or placebo three times per day for 7 days *5. Monitoring* This section did not report bf/breastmilk-related outcomes *6. Feeding in exceptionally difficult circumstances (HIV)* This section did not report bf/breastmilk-related outcomes	Authors note it was not possible to present the findings of most studies separately for preterm infants whose size was appropriate for gestational age (AGA) from those who were small for gestational age (SGA). Some studies only reported BW, not GA		

a Levels of evidence (L) were rated according to study design, using the US Preventative Services Task Force (1989) scale, for both safety and efficacy, as follows:
I Evidence obtained from a systematic review of all relevant RCTs.
II Evidence obtained from at least one properly designed RCT.
III-1 Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2 Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case–control studies, or interrupted time series with a control group.
III-3 Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
IV Evidence obtained from case series, either post-test or pre-test and post-test.

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First author, year, design quality	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
Flint 2007[163] Cochrane SR	**Review question** What are the effects of cup feeding vs other forms of supplemental enteral feeding on weight gain and achievement of successful breastfeeding in newborn infants who are unable to fully breastfeed?[a] **Data sources** The authors state that they used the Cochrane Neonatal Group methods including the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 2, 2006), CINAHL (1987–April 2006), MEDLINE (1966–April 2006). Electronic searches were based on MeSH terms 'Infant, Newborn' OR 'Nurseries, Hospital' OR 'Intensive Care Units, Neonatal' AND the textword 'cup' Previous reviews, abstracts, and conference proceedings were searched as well as expert informants English-language journals were hand searched (journals unspecified) No other language restrictions applied **Inclusion criteria** *Study types* Randomised and quasi-randomised trials (crossover studies were excluded)	Four trials were included in the review: **Rocha 2002 (RCT)** Intervention: Supplemental feeds via cup ($n = 46$) Control: bottle feeds ($n = 37$) Mean gestational age = 32.5–32.7 weeks **Collins 2004 (RCT)** Intervention: Supplemental feeds via cup ($n = 161$; mean gestational age = 29.3 weeks) Control: bottle feeds ($n = 158$; 30.0 weeks) **Gilks 2004 (RCT)** Intervention: Supplemental feeds via cup in addition to tube feeds and breastfeeding ($n = 27$; mean gestational age = 31.0 weeks) Control: Bottle feeds ($n = 27$; 32.0 weeks) **Mosley 2001 (pilot RCT)** Intervention: Supplemental feeds via cup ($n = 8$)	**Breastfeeding/breastmilk-related outcomes** Not breastfeeding at hospital discharge: No significant difference between the groups (meta-analysis of three trials, I^2 0%) RR 0.82 [95% CI 0.62 to 1.09] Not breastfeeding at 3 months: No significant difference between the groups (meta-analysis of two trials, I^2 0%) RR 0.88 [95% CI 0.76 to 1.03] Not breastfeeding at 6 months: No significant difference between the groups (one study reported this outcome) RR 0.90 [95% CI 0.78 to 1.05] Not fully breastfeeding at hospital discharge: Significantly more of the infants allocated to cup feeding were fully breastfed at hospital discharge (meta-analysis of three trials, I^2 0% – Rocha 2002 did not report this outcome); RR 0.75 [95% CI 0.61 to 0.92], $p = 0.007$, number needed to treat 7.3 Not fully breastfeeding at 3 months: No significant difference between the groups (one study reported this outcome); RR 1.18 [95% CI 0.88 to 1.58] Not fully breastfeeding at 6 months: No significant difference between the groups (one study reported this outcome); RR 1.31 [95% CI 0.89 to 1.92] **Clinical/health outcomes** Weight gain: No significant difference between the groups (one study reported this outcome) Mean difference – 0.60 g/kg/day [95% CI – 3.21 to 2.01] **Process outcomes** Average time per feed: No significant difference between the groups (one study reported this outcome) Mean difference – 1.60 minutes [95% CI – 3.69 to 0.49] Length of hospital stay: Significantly increased length of stay among infants allocated to cup feeding (only one study, Collins 2004, reported this outcome – see comments). Mean difference 10.1 days [95% CI 3.9 to 16.3]	Applicability to the UK: Rocha 2002: conducted in Brazil – single centre trial Collins 2004: conducted in Australia – involved two tertiary hospitals and 54 peripheral hospitals that received babies from the tertiary hospitals Gilks 2004: conducted in the UK – single-centre trial Mosley 2001: conducted in the UK – single-centre trial Flint 2007 states Collins 2004 reports high levels of non-compliance to the experimental intervention, with 85/151 of infants allocated to cup feeding (65%) having a bottle introduced. Collins 2004 contributes 76.3% of the weight to the finding of significantly more infants allocated to cup feeding being fully breastfed at discharge Flint 2007 states that in Collins 2004 (the only study that reported length of stay), infants were not permitted to go home cup feeding (thus confounding the results). Also, this may not be the case in UK hospitals that are not referring babies to peripheral hospitals over a large geographical area	Inclusion/exclusion criteria reported: ✓ Description of SR methodology: ✓ Rigorous literature search: ✓ Quality of studies assessed and taken into account: partially; no info provided on randomisation methods. Sufficient details about individual studies: ✓ Studies appropriately combined: a meta-analysis was conducted

First author, year, design quality	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
	Participants Newborn infants, up to 44 weeks postmenstrual age or 28 days postnatal age, unable to fully breastfeed *Interventions* Oral feeding of either expressed breastmilk or a combination of expressed breastmilk and artificial formula via a cup (or a container of similar design that allows the infant to 'lap' the milk) versus other forms of supplemental enteral feeding such as tube or bottle feeds *Outcomes reported* Primary: weight gain, proportion not breastfeeding/ not fully breastfeeding at hospital discharge and at ages 3 and 6 months Secondary: average time per feed, length of hospital stay **Quality assessment** The reviewers state that they used standard methods of the Neonatal Review Group	Control: Bottle feeds ($n = 158$) Mean gestational age = 35.2–35.5 weeks For all studies, Flint 2007 states that allocation concealment was adequate (with the exception of Rocha 2002, where allocation concealment was unclear), blinding could not be achieved because of the nature of the intervention, and follow-up appeared to be complete at hospital discharge but decreased over time. Data were analysed according to the treatment group allocated	**Psychosocial outcomes** Not reported by group In Collins 2004, some of the mothers of infants allocated to cup feeding introduced a bottle. Some of the mothers who made this decision reported they did not like/had problems with cup feeding, including: infant not managing cup feeds, spilling a lot, not being satisfied or taking too long to feed. Mothers also reported that staff refused to cup feed their infant **Cost-effectiveness outcomes** Not reported **Were outcomes reported for different gestational ages of the baby and/or ability to co-ordinate sucking and swallowing?** No	The authors conclude that cup feeding may not be recommended over bottle feeding. However, it appears that there is a lack of good-quality evidence to make these conclusions. Also, there are many confounding factors (i.e. training of hospital staff, time provided to staff) that would likely affect the results in a direction towards bottle feeding. Although the authors suggest that more research would be futile, firm recommendations can't be made until this is done	

a In Flint 2007, full breastfeeding is defined as 'only having breast feeds and no other supplemental feeds'.

First author, year, design quality	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
McInnes 2006[161] NHS Health Scotland SR	**Review question** What interventions support breastfeeding in neonatal units? **Data sources** The authors searched CDSR, DARE, AMED, British Nursing Index, CINAHL, EMBASE, MEDLINE, PsycINFO for studies published in English from 1990 to June 2005. In addition, MIDIRS was searched. Bibliographies of included studies were also checked for additional relevant studies. A list of specific search terms was not provided **Inclusion criteria** *Study types* Experimental studies were included in the review (the actual studies included were RCTs and CTs, with one cohort study and one case–control study *Participants* Preterm, low birthweight infants or their parents or neonatal unit staff *Interventions* The authors did not specify interventions of interest in their inclusion criteria *Outcomes reported* To be included in the review, studies had to examine breastfeeding or the provision of breastmilk as an outcome	36 studies were included in the review: **Four studies evaluated expression of breast milk:** **Fewtrell 2001 (RCT)** (UK, quality score 82%) Standard electric pump vs hand pump in mothers with preterm infants (< 35 weeks) ($n = 145$) **Jones 2001 (RCT)** (UK, quality score 66%) Sequential vs simultaneous breastmilk expression in mothers with preterm infants (mean gestation = 30 weeks) ($n = 36$) **Paul 1996 (quasi-experimental)** (India, quality score 63%) Manual expression (hand) vs pump in mothers of infants in NICU (size/age of infants not specified) ($n = 22$) **Groh-Wargo 1995 (RCT)** (USA, quality score 53%) Sequential vs simultaneous breastmilk expression in mothers with infants ≤ 1500 g and ≤ 7 days old ($n = 32$) **Two studies evaluated support for parents:** **Gonzalez 2003 (case–control)** (USA, quality score 83%) Lactation counselling service for women of preterm (< 37 weeks) or LBW (< 2.5 kg) infants ($n = 175$) **Pinelli 2001 (RCT)** (Canada, quality score 61%) Breastfeeding counselling for both parents of VLBW healthy babies (< 1.5 g) ($n = 128$)	The authors of the SR summarised their main findings as follows: **Expression of breastmilk** Simultaneous pumping with an electric pump was quicker than sequential pumping with an electric pump; however, an appropriate hand pump may be more effective; breast massage assisted breastmilk expression; mothers preferred simultaneous electric pumping compared to sequential electric pumping, although a hand pump was preferred over an electric pump; none of the mothers in the UK studies expressed milk as many times a day as recommended **Support for parents (counselling)** Counselling and support services for both parents did not affect breastfeeding duration or exclusivity in an advantaged and motivated population; provision of clinical support and individualised care planning may increase the number of mothers willing to express their own milk for their infants **The use of bottles, teats, cups and dummies** The impact of cup feeding on breastfeeding is inconclusive; however, there is no evidence that cup feeding has a negative impact There is a lack of studies on the use of dummies, but their use in preterm infants is not currently associated with any adverse effects in terms of breastfeeding duration The impact of nipple shields on breastfeeding has not been adequately assessed **Early discharge from the neonatal unit** Breastfeeding rates were not significantly affected by early discharge with home support; early discharge with support was acceptable to both parents	Applicability to the UK: The authors of the SR noted that only five of the studies were UK based, thus the findings from other studies may be less applicable to the UK The authors also noted that due to the heterogeneity of the studies, it was difficult to draw any firm conclusions about effective practice Many of the studies had small sample size	Inclusion/exclusion criteria reported: partially Description of SR methodology: ✓ Rigorous literature search: ✓ (search terms not provided) Quality of studies assessed and taken into account: partially; no info provided on randomisation methods Sufficient details about individual studies: ✓ Studies appropriately combined: ✓ (narrative synthesis)

First author, year, design quality	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
	Quality assessment The reviewers included a lengthy list of criteria to assess quality (not referenced)	**Nine studies evaluated cup feeding, bottles, teats or dummies (seven that evaluated breastfeeding duration as an outcome are listed here):** **Collins 2004 (RCT)** (Australia, quality score 86%) Cup feeding vs bottle feeding in preterm infants (< 34 weeks) ($n = 303$) **Mosley 2001(RCT)** (UK, quality score 75%) Cup feeding vs bottle feeding in preterm infants (30–37 weeks) ($n = 16$) **Rocha 2002 (RCT)** (Brazil, quality score 71%) Cup feeding vs bottle feeding in preterm (32–36 weeks) or LBW (< 1700 g) infants ($n = 78$) **Kliethermes 1999 (RCT)** (USA, quality score 53%) NG vs bottle supplementation in infants weighing 1–2.5 kg ($n = 84$) **Gilks 2004 (RCT)** (UK, quality score 25%) Cup feeding vs bottle feeding in preterm infants (< 35 weeks at birth and > 30 weeks at start of trial) ($n = 54$) **Meier 2000 (quasi-experimental)** (USA, quality score 46%) Use of nipple shields in preterm infants (25–37 weeks) ($n = 34$) **Oddy 2003 (quasi-experimental)** (Australia, quality score 7%) Finger feeding in preterm infants (< 37 weeks)	**Neonatal staff education** There is a lack of studies that evaluate the impact of educational interventions on knowledge or attitudes of neonatal staff or on breastfeeding/expression rates in the neonatal unit **Kangaroo mother care and skin-to-skin contact** KMC or SSC may increase breastfeeding amongst LBW infants, particularly in countries where breastfeeding is less prevalent Large trials that the examine the short- and long-term effectiveness of KMC and SSC on breastfeeding duration have not been conducted in westernised countries **Galactagogues** Short-term use of domperidone was associated with increased milk volumes; growth hormone achieved modest increases in milk volumes; metoclopramide did not demonstrate an effect There is no evidence that the use of galactagogues increases breastfeeding duration in mothers of premature infants; however, they do not decrease breastfeeding duration **The Baby Friendly Initiative** There is limited evidence of an impact of BFI in neonatal units where breastfeeding rates have traditionally been low; further research is needed **Cost-effectiveness outcomes** Not reported **Were outcomes reported for different gestational ages of the baby and/ or ability to co-ordinate sucking and swallowing?** No		

First author, year, design quality	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
		Two studies evaluated early discharge: **Gunn 2000 (RCT)** (New Zealand, quality score 78%) Early discharge with home support ($n = 308$) **Örtenstrand 2001 (quasi-experimental)** (Sweden, quality score 71%) Early discharge with home support ($n = 75$) **One study evaluated neonatal staff education:** **Siddell 2003 (cohort)** (USA, quality score 57%) BF education ($n = 51$) **Eleven studies evaluated kangaroo mother care (KMC) and skin-to-skin contact (SSC):** **Rojas 2003 (RCT)** (USA, quality score 94%) SSC vs traditional holding in preterm infants (≤32 weeks) or LBW (≤1500 g) ($n = 60$) **Charpak 1997 (RCT)** (Colombia, quality score 86%) KMC in LBW infants (≤2000 g) ($n = 746$) **Charpak 2001 (RCT)** (Colombia, quality score 78%) KMC in LBW infants (≤2000 g) ($n = 693$) **Cattaneo 1998 (RCT)** (Ethiopia, Mexico and Indonesia, quality score 76%) KMC in LBW infants (1000–1999 g) ($n = 285$)			

First author, year, design quality	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
		Kadam 2005 (RCT) (India, quality score 73%) KMC in LBW infants (≤1800 g) ($n = 89$) **Blaymore Bier 1996 (RCT)** (USA, quality score 72%) SSC vs standard care ($n = 41$ mothers, 50 infants) **Charpak 1994 (RCT)** (Colombia, quality score 71%) KMC in LBW infants (≤2000 g) ($n = 332$) **Wahlberg 1992 (CT)** (Sweden, quality score 57%) KMC ($n = 66$) **Hurst 1997 (quasi-experimental)** (USA, quality score 47%) SSC ($n = 23$) **Sloan 1994 (RCT)** (Ecuador, quality score 44%) KMC in LBW infants (≤2000 g) ($n = 275$) **Roberts 2001 ('randomised trial')** (Australia, quality score 21%) KMC vs cuddling care ($n = 30$) One study evaluated breastmilk fortification (but will not be addressed here) **Three studies evaluated galactagogues:** **DaSilva 2001 (RCT)** (Canada, quality score 100%) Domperidone on milk production ($n = 20$)			

First author, year, design quality	Review/research question	Included studies	Main results	Confounders/comments	Quality (mark ✓ or ✗)
		Hansen 2005 (RCT) (USA, quality score 87%) Metoclopramide on milk production ($n = 57$) **Gunn 1996 (RCT)** (New Zealand, quality score 65%) Growth hormone on milk production ($n = 20$) **One study evaluated The Baby Friendly Initiative:** **Merewood 2003 (quasi-experimental)** (USA, quality score 72%) ($n = 227$) Two studies evaluated test weighing (but they did not evaluate breastfeeding)			

Appendix 8

Probabilistic sensitivity analysis distributions – health economics review

Description	Parameters/info
Odds ratio of NEC given own mother's milk vs some mothers' milk plus donor milk	Log-normal, *u* (mean of logs) = −0.1223, sigma (SD of logs) = 0.692; expected value: 1.124267823
Odds ratio of NEC given some mothers' milk plus donor milk vs some mothers' milk plus formula	Log-normal, *u* (mean of logs) = −0.7663, sigma (SD of logs) = 0.656; expected value: 0.576297073
Odds ratio of NEC given formula vs some mothers' milk plus formula	Log-normal, *u* (mean of logs) = 1.1007, sigma (SD of logs) = 0.396; expected value: 3.251472595
Odds ratio of sepsis given own mother's milk vs some mothers' milk plus donor	Log-normal, *u* (mean of logs) = −0.3446, sigma (SD of logs) = 0.378; expected value: 0.760972544
Odds ratio of sepsis given some mothers' milk plus donor milk vs some mothers' milk plus formula	Log-normal, *u* (mean of logs) = −0.0028, sigma (SD of logs) = 0.341; expected value: 1.056900428
Odds ratio of sepsis given formula vs some mothers' milk plus formula	Log-normal, *u* (mean of logs) = −0.2189, sigma (SD of logs) = 0.149; expected value: 0.812369901
Odds ratio of mortality given Gram-positive infection	Log-normal, *u* (mean of logs) = 0.476, sigma (SD of logs) = 0.119; expected value: 1.621060395
Odds ratio of mortality given Gram-negative infection	Log-normal, *u* (mean of logs) = 1.983, sigma (SD of logs) = 0.141; expected value: 7.337076747
Odds ratio of mortality given fungal infection	Log-normal, *u* (mean of logs) = 1.787, sigma (SD of logs) = 0.183; expected value: 6.072342834
Odds ratio of mortality given medical NEC	Log-normal, *u* (mean of logs) = 0.720, sigma (SD of logs) = 0.141; expected value: 2.074957144
Odds ratio of mortality given surgical NEC	Log-normal, *u* (mean of logs) = 1.139, sigma (SD of logs) = 0.123; expected value: 3.147361554
Odds ratio of NDI given sepsis	Log-normal, *u* (mean of logs) = 0.825, sigma (SD of logs) = 0.069; expected value: 2.287319253
Odds ratio of NDI given medical NEC	Log-normal, *u* (mean of logs) = 0.172, sigma (SD of logs) = 0.194; expected value: 1.210239169
Odds ratio of NDI given surgical NEC	Log-normal, *u* (mean of logs) = 0.686, sigma (SD of logs) = 0.188; expected value: 2.0211608
Odds ratio of normal vs enhanced staff contact	Log-normal, *u* (mean of logs) = -0.6931, sigma (SD of logs) = 0.2018; expected value: 0.510309242
Level one cost	Gamma, alpha = 9.16, lambda = 0.009758; expected value: 938.716950195
Level two cost	Gamma, alpha = 14.15, lambda = 0.021088; expected value: 670.997723824
SCBU cost	Gamma, alpha = 16.47, lambda = 0.040662; expected value: 405.046480744
Disutility for no disability	Gamma, alpha = 0.25, lambda = 4.167; expected value: 0.0599952
Disutility for mild disability	Gamma, alpha = 2.11, lambda = 14.048; expected value: 0.150199317
Disutility for moderate disability	Gamma, alpha = 9.53, lambda = 26.843; expected value: 0.355027381
Disutility for severe disability	Gamma, alpha = 4.49, lambda = 8.480; expected value: 0.529481132

continued

Description	Parameters/info
Probability of intention to breastfeed	Beta, integer parameters only, $n = 8210$, $r = 5911$; expected value: 0.719975639
Major cost	Gamma, alpha = 3.26, lambda = 0.002155; expected value: 1512.761020882
Probability of mothers' milk given ITB	Dirichlet, Alphas list = List(78;32;5); expected value: 0.67826087; 0.27826087; 0.043478261
Probability of some mothers' milk given ITB	Dirichlet, Alphas list = List(32;78;5); expected value: 0.27826087; 0.67826087; 0.043478261
Probability of mothers' milk given NITB	Dirichlet, Alphas list = List(13;41;27); expected value: 0.160493827; 0.50617284; 0.333333333
Probability of some mothers' milk given NITB	Dirichlet, Alphas list = List(41;13;27); expected value: 0.50617284; 0.160493827; 0.333333333
Probability of formula only given ITB	Dirichlet, Alphas list = List(5;78;32); expected value: 0.043478261; 0.67826087; 0.27826087
Distribution information for the 500–999 g population	
Baseline death no disease	Beta, integer parameters only, $n = 4401$, $r = 905$; expected value: 0.205635083
Baseline probability of NDI given no disease	Beta, integer parameters only, $n = 402$, $r = 195$; expected value: 0.485074627
Probability of sepsis given some mothers' milk plus supplement	Dirichlet, Alphas list = List(185;24;22;449); expected value: 0.272058824; 0.03529411 8; 0.032352941; 0.660294118
Probability of medical NEC given some mothers' milk plus supplement	Dirichlet, Alphas list = List(24;185;22;449); expected value: 0.035294118; 0.272058824; 0.032352941; 0.660294118
Probability of surgical NEC given some mothers' milk plus supplement	Dirichlet, Alphas list = List(22;185;24;449); expected value: 0.032352941; 0.272058824; 0.035294118; 0.660294118
Probability of no disease given some mothers' milk plus supplement	Dirichlet, Alphas list = List(449;185;24;22); expected value: 0.660294118; 0.272058824; 0.035294118; 0.032352941
Probability of mild disability	Dirichlet, Alphas list = List(105;58;32); expected value: 0.538461538; 0.297435897; 0.164102564
Probability of moderate disability	Dirichlet, Alphas list = List(58;105;32); expected value: 0.297435897; 0.538461538; 0.164102564
Distribution information for the 1000–1749 g population	
Baseline death no disease	Beta, integer parameters only, $n = 4401$, $r = 352$; expected value: 0.079981822
Baseline probability of NDI given no disease	Beta, integer parameters only, $n = 431$, $r = 178$; expected value: 0.412993039
Probability of sepsis given some mothers' milk plus supplement	Dirichlet, Alphas list = List(17;60;17;2776); expected value: 0.005923345; 0.020905923; 0.005923345; 0.967247387
Probability of medical NEC given some mothers' milk plus supplement	Dirichlet, Alphas list = List(60;17;17;2776); expected value: 0.020905923; 0.005923345; 0.005923345; 0.967247387
Probability of surgical NEC given some mothers' milk plus supplement	Dirichlet, Alphas list = List(17;17;60;2776); expected value: 0.005923345; 0.005923345; 0.020905923; 0.967247387
Probability of no disease given some mothers' milk plus supplement	Dirichlet, Alphas list = List(2776;17;60;17); expected value: 0.967247387; 0.005923345; 0.020905923; 0.005923345
Probability of mild disability	Dirichlet, Alphas list = List(122;42;14); expected value: 0.685393258; 0.235955056; 0.078651685
Probability of moderate disability	Dirichlet, Alphas list = List(42;122;14); expected value: 0.235955056; 0.685393258; 0.078651685

Description	Parameters/info
Distribution information for the 1750–2500 g population	
Baseline death no disease	Beta, integer parameters only, $n = 4401$, $r = 220$; expected value: 0.049988639
Baseline probability of NDI given no disease	Beta, integer parameters only, $n = 767$, $r = 263$; expected value: 0.342894394
Probability of sepsis given some mothers' milk plus supplement	Dirichlet, Alphas list = List(19;96;19;19155); expected value: 0.000985017; 0.00497693; 0.000985017; 0.993053035
Probability of medical NEC given some mothers' milk plus supplement	Dirichlet, Alphas list = List(24;185;22;449); expected value: 0.035294118; 0.272058824; 0.032352941; 0.660294118
Probability of surgical NEC given some mothers' milk plus supplement	Dirichlet, Alphas list = List(22;185;24;449); expected value: 0.032352941; 0.272058824; 0.035294118; 0.660294118
Probability of no disease given some mothers' milk plus supplement	Dirichlet, Alphas list = List(449;185;24;22); expected value: 0.660294118; 0.272058824; 0.035294118; 0.032352941
Probability of mild disability	Dirichlet, Alphas list = List(171;55;37); expected value: 0.650190114; 0.209125475; 0.140684411
Probability of moderate disability	Dirichlet, Alphas list = List(55;171;37); expected value: 0.209125475; 0.650190114; 0.140684411

Appendix 9

Sensitivity analyses – health economics review

Sensitivity analyses incremental values for enhanced staff support compared to normal support

		500 to 999 g			1000 to 1749 g			1750 to 2500 g		
		Δ Cost (£)	Δ Effect (QALY)	Δ C/E (ICER) (£/QALY)	Δ Cost (£)	Δ Effect (QALY)	Δ C/E (ICER) (£/QALY)	Δ Cost (£)	Δ Effect (QALY)	Δ C/E (ICER) (£/QALY)
1	Base case	−586.02	0.251		−293.04	0.056		−66.08	0.009	
2	Gonzalez effect only	−571.18	0.246		−284.25	0.054		−62.12	0.009	
3	0.6 ITB + 0.4 NITB	−516.57	0.217		−246.80	0.049		−45.21	0.008	
4	0.4 ITB + 0.6 NITB	−705.38	0.304		−369.28	0.066		−100.50	0.010	
5	Midwife	−514.42	0.251		−221.43	0.056		5.77	0.009	663.22
6	Half length of stay	−286.71	0.251		−131.74	0.056		14.26	0.009	1,639.08
7	Donor, no formula	−78.18	0.290		225.25	0.064	3530.56	328.11	0.009	34,905.32
8	Formula	−709.39	0.284		−375.30	0.060		−101.53	0.009	
9	Expression kits	−332.59	0.251		−100.27	0.056		48.64	0.009	5,590.80
10	Formula + Express	−388.72	0.251		−182.54	0.060		13.19	0.009	1,516.09
11	Donor + Formula	−149.69	0.290		161.58	0.064	2532.60	283.06	0.009	30,112.77
12	Donor + Formula + Express	103.00	0.290	354.68	354.11	0.064	5550.31	397.63	0.009	42,301.06
13	Reduced donor costs	−458.71	0.290		−115.36	0.064		89.30	0.009	9,500.00
14	Red donor + F	−530.22	0.290		−179.03	0.064		44.09	0.009	4,690.43
15	N Ireland ITB 56%	−569.27	0.231		−277.72	0.053		−61.77	0.008	
16	ITB 50%	−563.00	0.223		−271.97	0.052		−60.15	0.008	
17	ITB 90%	−604.87	0.274		−310.27	0.059		−70.93	0.009	
18	Lower disability 1750 to 2500 g							−56.06	0.008	
19	Vohr formula effect	81.82	0.080	Intervention dominated	152.38	−0.005	Intervention dominated	134.96	−0.001	Intervention dominated

DOI: 10.3310/hta13400

Sensitivity analyses for enhanced staff support compared to normal support

1	**Base case**	Base-case assumptions
2	**Gonzalez effect only**	The effectiveness estimate of enhanced staff support was based on Gonzalez *et al.* alone
3	**0.6 ITB + 0.4 NITB**	The effectiveness of enhanced support was higher for mothers who intended to breastfeed
4	**0.4 ITB + 0.6 NITB**	The effectiveness of enhanced support was higher for mothers who did not intend to breastfeed
5	**Midwife**	A midwife rather than a registered nurse was assumed to provide the support at higher cost
6	**Half length of stay**	All length of stay assumptions were halved
7	**Donor, no formula**	The cost of donor milk was added for mothers who expressed milk but could not supply all the infant's milk intake
8	**Formula**	The cost of formula milk was added for all milk intake other than mother's milk
9	**Expression kits**	The costs of expression kits were added
10	**Formula + Express**	The costs of formula milk and expression kits were added
11	**Donor + Formula**	The costs of donor milk and formula milk were added
12	**Donor + Formula + Express**	The costs of donor milk, formula milk and expression kits were all added
13	**Reduced donor costs**	The cost of producing a litre of donor milk was reduced from £289.12 to £119.89
14	**Red donor + F**	The lower costs of donor milk and formula milk were added to the base case
15	**N Ireland ITB 56%**	The intention to breastfeed rate was lowered from 72% to the N Ireland rate of 56%
16	**ITB 50%**	The intention to breastfeed rate was reduced to 50%
17	**ITB 90%**	The intention to breastfeed rate was increased to 90%
18	**Lower disability 1750 to 2500 g**	The rate of severe disability was reduced from 14.1% to 5% for the 1750 to 2500-g subgroup
19	**Vohr formula effect**	The odds ratio of getting confirmed NEC was reduced from 3.01 to 1.48

Appendix 10

Mother and baby contact interventions – additional study

A recent RCT evaluating the kangaroo method of skin-to-skin contact was identified,[288] which was published outside the search dates for this review. As this study met the remaining inclusion criteria for this review, a brief analysis is provided to be considered in conjunction with the existing evidence base.

The intervention comprised a 'medium'-level kangaroo method of skin-to-skin contact (mean of 4.47 hours per day) among healthy, English-speaking mothers of singleton infants with a birthweight of 1300–3000 g and gestational age of 32–36 weeks. This trial excluded infants with a condition that could prevent KMC or a severe congenital abnormality, or who required CPAP or mechanical ventilation by 48 hours postbirth. All mothers included in the analysis for this paper intended to breastfeed. The authors also report that the nurse researchers assisted mothers with initial breastfeeding experiences and recognition of subtle infant feeding cues and encouraged self-regulatory feedings in response to these cues. Infants were brought to mothers remaining on the labour and delivery unit due to a medical complication. Standard care includes access to lactation consultants although the authors note that coverage is likely to be incomplete.

This study reported that KC dyads breastfed significantly longer than control dyads (5.08 ± 5.48 months vs 2.05 ± 2.15 months; $p = 0.003$; $t = -2.86$) and more KC dyads than control dyads breastfed exclusively at discharge (I: 72%; C: 60%) and at 1.5 (I: 33%; C: 17%), 3 (I: 19%; C: 3%) and 6 (I: 8%; C: 0%) months. Exclusive breastfeeding is defined as Index of Breastfeeding Status levels 1 and 2, namely 'exclusive' (only human milk) and almost exclusive (allows vitamins, small amounts of water or juice or ritual feedings).

A rapid appraisal of study quality suggests this RCT is of moderate quality overall having employed an adequate randomisation method and incurring small losses, reported by group with reason. An ITT analysis was not conducted, breastfeeding rates are self-reported, and it is not clear if adequate concealment of allocation was achieved. Acceptability of the intervention was not reported although losses to study following commencement of the intervention were small.

Findings from this trial suggest that the combination of 'medium'-level kangaroo skin-to-skin contact and personal education and support from a skilled nurse is feasible among women in the USA and will increase duration of any and exclusive breastfeeding up to 6 months among mothers who intend to breastfeed.

Appendix 11

UNICEF UK Baby Friendly Initiative Best Practice Standards

Appendix 11.1: UNICEF UK Baby Friendly Initiative Best Practice Standards for establishing and maintaining lactation and breastfeeding in neonatal units

1. Have a written (neonatal unit) breastfeeding policy which is routinely communicated to all staff

The neonatal unit should have a written breastfeeding policy that addresses all these standards and protects breastfeeding. The policy should be formulated in conjunction with the maternity and community services (where relevant) in order to ensure a seamless delivery of care. It should identify clearly the professional groups which will act as the point of first referral to support mothers to breastfeed.

A summary of the policy should be prominently displayed in the unit. The full policy and any supporting guidance should be available on request. The policy and summary should be translated into other languages where appropriate. All neonatal unit managers should be able to locate easily a copy of the policy and be able to describe the process of staff orientation to the policy.

Compliance with the policy should be audited annually and the results of this audit used to ensure continuing full implementation of all standards.

Breastmilk feeding and breastfeeding rates on discharge from the unit should be recorded and progress reported to all staff.

All policies and procedures should support breastmilk feeding and the establishment of breastfeeding in line with these standards.

2. Educate all health-care staff in the skills necessary to implement the policy

All health-care staff should receive orientation to both the breastfeeding policy and any supporting guidance as soon as their employment on the neonatal unit begins.

Education programmes that cover all of the standards will be provided for each professional group and area of responsibility.* Clear curricula or course outlines for each group should be developed. A training schedule for new employees should exist.

All staff caring for mothers and their babies should have received breastfeeding training appropriate to their role or, if new, have received orientation on arrival and be scheduled to receive training within 6 months.

**It is recommended that the training for staff who have primary responsibility for supporting mothers to initiate and maintain lactation have at least 18 hours breastfeeding education including a minimum of 3 hours supervised clinical practice relating to teaching a mother how to breastfeed and how to hand express breastmilk.*

3. Inform all parents of the benefits of breastmilk and breastfeeding for babies in the neonatal unit

All parents whose baby is admitted, or is likely to be admitted, to the neonatal unit should have a one-to-one discussion with a suitably qualified* health professional about the crucial importance of breastmilk to the preterm and ill infant.** This discussion along with the parents' decision should be documented in the baby's records.

Written materials provided to parents on the benefits of breastmilk and breastfeeding should be accurate and effective.

**Suitably qualified health professionals would include paediatricians, infant feeding specialists, midwives and nurses who have been appropriately educated in breastfeeding and lactation management.*

***The discussion on the importance of breastfeeding should emphasise the particular importance of breastmilk to the preterm and ill infant and will need to include information about the importance of breastmilk in*

relation to the prevention of necrotising enterocolitis and improvement of neurological development. The longer term benefits of breastfeeding to babies and mothers should also be explained.

4. Facilitate skin-to-skin contact (kangaroo care) between mother and baby

The benefits of skin-to-skin contact should be discussed with all parents at an appropriate time to allow informed decision-making. Skin-to-skin contact between mother and baby should be initiated in an unhurried environment as soon as the baby's condition allows.

Skin-to-skin contact should continue to be offered as often as possible (at least on a daily basis) or whenever the mother is available and the baby's condition allows.

5. Support mothers to initiate and maintain lactation through expression of breastmilk

All mothers with a baby on the neonatal unit should be encouraged to initiate lactation as soon after delivery as the mother's condition allows. All mothers whose babies cannot breastfeed or take full feeds from the breast should be taught how to express their milk by hand and by pump. Expression of breastmilk should be encouraged at least 6–8 times in 24 hours, including at night. Emphasis should be on frequent expressing and the avoidance of long intervals between expressions.

Well-maintained equipment for the safe expression of breastmilk should be available at all times.

Facilities should be available to allow mothers to express breastmilk in comfort either near their baby or in private if preferred.

Local policies on the safe handling, storage and transportation of breastmilk should be developed in line with nationally agreed guidelines.

A system for the provision of breast pumps for home use should also be in place.

6. Support mothers to establish and maintain breastfeeding

All breastfeeding mothers should be offered help with a first breastfeed as soon their baby's condition permits. Breastfeeding mothers should receive information, help and support to achieve correct positioning and attachment.*

When the baby is not yet able to take a full feed from the breast, mothers should be encouraged to practise positioning techniques.

Parents should be given information on the importance of baby-led feeding (as soon as appropriate) for the continuation of breastfeeding. They should be taught to recognise feeding cues and be encouraged to use all available opportunities to initiate breastfeeds.

The unit should have a policy of open visiting for parents. Facilities for rooming-in should be available and where possible mothers and babies should be enabled to room-in together.**

All written materials on infant feeding provided for parents should be accurate and effective.

**It is recognised that some mothers may not wish to breastfeed, but may decide to continue expressing breastmilk. In this circumstance the mothers should be supported to continue providing breastmilk and given an informed choice regarding the short- and long-term benefits to baby of feeding directly from the breast.*

***It is recognised that rooming-in facilities may not be available within the neonatal unit. However, new mothers should at least be cared for in the same hospital as their baby. Where facilities are available, breastfeeding mothers should be encouraged to room-in with their baby in the neonatal unit.*

7. Encourage exclusive breastmilk feeding

No food or drink other than breastmilk should be given to a baby who is being breastfed or receiving breastmilk unless this is clinically indicated or the result of a fully informed parental decision.

A mother's own breastmilk is the first choice for infant feeding. Where mother's own milk is not available the use of donor milk should be considered and where possible obtained.

When mothers are separated from their babies, mechanisms should exist to enable the regular transportation of the mother's milk to the facility caring for the baby.

All written guidelines and protocols should support exclusive breastfeeding.*

No promotion for breastmilk substitutes, feeding bottles, teats or dummies should be displayed or distributed to parents or staff in the facility.

**Protocols for conditions such as hypoglycaemia, jaundice requiring phototherapy or slow weight gain should protect exclusive breastfeeding. If breastmilk fortifiers are used, protocols should be developed to ensure use is limited to clear clinical indication, for example for very low birthweight (< 1500-g) babies when a biochemical assessment indicates a need.*

8. Avoid the use of teats or dummies for breastfed babies unless clinically indicated

Babies who are unable to feed directly from the breast should be fed breastmilk by a method appropriate to the baby's developmental ability. Parents wishing to breastfeed who request that their baby be fed by teat must have the potential risks discussed and alternatives offered.

Dummy use should be limited to when there is a clear clinical indication or fully informed parental choice.

Skin-to-skin contact and breastfeeding should be promoted for comforting babies and relieving pain during minor procedures such as heel pricks. Feeding and comforting methods appropriate to the baby's condition, and with reference to the presence or absence of the parents at any given time, should be discussed with the parents. The discussion should be evidence based and include all potential benefits, risks and alternatives to allow informed decision-making. The discussion and the parents' choice should be recorded in the baby's notes or care plan.

9. Promote breastfeeding support through local and national networks

All mothers should be provided with the contact details of midwives, health visitors, community neonatal nurses (where these exist), breastfeeding support networks and organisations that support parents of ill and premature babies for help with breastfeeding on admission to a neonatal unit and on discharge of the baby from hospital.

A formal mechanism should exist to ensure that information on breastfeeding progress is passed on during handover of care from the neonatal unit to the community health-care team.

Appendix 11.2: UNICEF UK Baby Friendly Best Practice Standards in neonatal units – interventions examined in this review

Baby Friendly accreditation of maternity services has been demonstrated to be a highly effective framework, and guidance for promotion of initiation of breastfeeding in maternity services generally[80,204–206] (UNICEF UK BFI 2000, Bartington *et al.*[204] in Dyson *et al.* 2006[59]). This is reflected in national guidance recommending increased implementation in the UK.[3,59] Neonatal units are included to a limited extent within the Baby Friendly best practice standards for maternity units. Maternity units seeking Baby Friendly accreditation are expected to ensure that all staff working on the neonatal unit are trained to support breastfeeding adequately. The information and support given to mothers who are separated from their baby to express their breastmilk is also assessed.

The UNICEF UK Baby Friendly Initiative standards for neonatal units were created in recognition of the need for clear guidance on what constitutes best practice for breastfeeding when babies are preterm or ill and separated from their mothers. They provide guidance on the specific standards required in order to allow neonatal unit staff to fully promote, protect and support breastfeeding within their clinical area (see Appendix 11a for the BFI standards for neonatal units). At present, UNICEF UK does not provide an accreditation programme for neonatal units.

To assist in the analysis of the review findings, and in the implementation of best practice, we have mapped the findings of the effectiveness of interventions from this review onto the Best Practice standards for neonatal units (*Table 88*). The findings from this mapping process can assist policy makers and practitioners in two key areas:

1. To identify effective interventions to inform the successful implementation of specific Baby Friendly standards within each unit.
2. To highlight the integrated nature of the Baby Friendly standards and the likelihood of one intervention having a positive effect on several standards simultaneously.

There is currently no accreditation programme for these standards, therefore no evaluations of the effectiveness of Baby Friendly accreditation for neonatal units have yet been undertaken. Studies evaluating the effectiveness of Baby Friendly accreditation for maternity hospitals in improving breastfeeding outcomes in neonatal units have been conducted. These, and studies evaluating any interventions that are consistent with one or more of the Baby Friendly neonatal care standards, are included in the matrix. Results from poor-quality studies are excluded from this matrix due to potential for misinterpretation. Use of ITT analysis to generate findings of effectiveness for good and moderate quality studies is also reported for each study. This is based on ITT analysis conducted by the authors of this review, including adjustment for postrandomisation exclusions as appropriate. Details of all studies are provided in Chapter 4.

DOI: 10.3310/hta13400

TABLE 88 *Mapping of evidence of effectiveness against Baby Friendly (BFI) Best Practice standards for neonatal care*

Baby Friendly Best Practice standard for neonatal units	Study	Intervention	Study design	Targeted population group/country	Quality rating of study	Breastfeeding outcome(s)	Effect of intervention
1. Written neonatal unit breastfeeding policy	See Related evidence below: 'BFI accreditation of maternity hospital comprising neonatal units'						
2. Education of health-care staff on skills to implement policy	Jones 2004[81]	Evidence-based staff education programme taught over 10 hours in five modules by neonatal breastfeeding coordinator	Before/after	Range of health professionals Mothers who planned to breastfeed UK	Moderate Not ITT analysis	Infants receiving expressed breastmilk, cup feeds offered, put to the breast	Positive for all three transitional outcomes
						Any breastfeeding at discharge	Positive
	Pineda 2006[149]	Comprehensive educational programme, use of individualised pathway of care plan and education and support to mothers	Before/after	VLBW infants USA	Moderate ITT analysis	Mothers ever providing breastmilk	No effect
						Mothers who ever breastfed	Positive
						Provision of breastmilk in hospital and at discharge	No effect
3. Inform parents of benefits of breastmilk and breastfeeding	See related standard on 'Education of health-care staff on skills to implement policy' above						
4. Facilitate skin-to-skin contact (kangaroo care) between mother and baby	Charpak 1997,[107] 2001[108]	Kangaroo skin-to-skin, early discharge and regular bf	RCT	LBW/VLBW Colombia	Moderate ITT	Any breastfeeding at 40–41 weeks corrected age	No effect
						Exclusive breastfeeding at 40–41 weeks corrected age	No effect
	Cattaneo 1998[131]	Kangaroo skin-to-skin	RCT	LBW/VLBW Ethiopia/Mexico/ Indonesia	Moderate ITT	Exclusive breastfeeding at discharge	No effect
	Sloan 1994[132]	Kangaroo skin-to-skin	RCT	LBW/VLBW Ecuador	Moderate ITT	Exclusive breastfeeding at discharge	No effect

continued

TABLE 88 *Mapping of evidence of effectiveness against Baby Friendly (BFI) Best Practice standards for neonatal care (continued)*

Baby Friendly Best Practice standard for neonatal units	Study	Intervention	Study design	Targeted population group/country	Quality rating of study	Breastfeeding outcome(s)	Effect of intervention
	Kadam 2005[118]	Kangaroo skin-to-skin	RCT	LBW/VLBW India	Moderate ITT	Timing of initiation	No effect
	Rojas 2003[121]	Kangaroo skin-to-skin	RCT	VLBW USA	Moderate ITT	Any breastfeeding before discharge	No effect
	Boo 2007[141]	Short kangaroo skin-to-skin	RCT	VLBW Malaysia	Moderate ITT	Any breastfeeding before discharge	Positive
						Any breastfeeding at discharge	Positive
	Blaymore Bier 1996[115]	Kangaroo skin-to-skin	RCT	VLBW USA	Moderate ITT	Any breastfeeding at discharge	No effect
						Any breastfeeding one month after discharge	Positive
	Whitelaw 1988[147]	Kangaroo skin-to-skin	RCT	VLBW UK	Moderate ITT	Any breastfeeding for more than 6 weeks	Positive
	Wahlberg 1992[135]	Kangaroo skin-to-skin	Before/after	LBW Sweden	Moderate ITT	Any breastfeeding at discharge	Positive
5. Support mothers to express breastmilk	Fewtrell 2001[125]	Hand-powered sequential pumping vs electric sequential or simultaneous pumping	RCT	Mothers expressing for infants of < 35 weeks' gestation UK	Good Not ITT	Breastmilk output by volume	No effect
						Any breastmilk feedings at discharge or transfer	No effect
						> 50% intake as breastmilk at discharge or transfer	No effect
	Groh-Wargo 1995[128]	Electric simultaneous pumping vs electric sequential pumping	RCT	Mothers expressing for infants of VLBW USA	Moderate ITT	Breastmilk output by volume	No effect
	Jones 2001[114]	Electric simultaneous pumping vs electrical sequential pumping	RCT	Mothers expressing for infants of VLBW UK	Moderate Not ITT	Breastmilk output by weight	Positive

Baby Friendly Best Practice standard for neonatal units	Study	Intervention	Study design	Targeted population group/country	Quality rating of study	Breastfeeding outcome(s)	Effect of intervention
	Slusher 2007[142]	Electrical simultaneous pumping vs hand expression	RCT	Mothers expressing for infants of all birthweights and gestational age Kenya and Nigeria	Moderate Not ITT	Breastmilk output by volume	Positive
	Griffin 2000[20]	Teaching mothers CRCT technique to measure fat content of expressed breastmilk	Concurrent comparison	Mothers expressing (no infant characteristics) USA	Good ITT	Accuracy of mothers' measurements vs registered nurses	Positive
	Fewtrell 2006[144]	Five-day course of oxytocin nasal spray plus daily support from research nurse	RCT	Mothers who had recently given birth to premature infants UK	Good ITT	Total milk weight over days 1–5 Fat content of expressed milk	No effect No effect
	Hansen 2005[116]	Ten-day course of oral metoclopramide 10 mg three times a day	Randomised crossover	Mothers who had recently given birth to premature infants USA	Moderate Not ITT	Milk volume on day 10 and 1 week after Median weeks duration of breastfeeding	No effect No effect
	da Silva 2001[123]	Seven-day course of oral domperidone 10 mg three times a day	RCT	Mothers who had been expressing for at least a month and whose milk production was not meeting their infants' needs Canada	Moderate Not ITT Very small sample: I: 7; C: 9	Mean milk volume at baseline and over study days 2–7	Positive
	Gunn 1996[133]	Seven-day course of recombinant human growth hormone 0.2 IU/kg/day subcutaneously to a maximum of 16 IU/day	RCT	Mothers who had been expressing for at least a month and whose milk production was not meeting their infants' needs New Zealand	Moderate Not ITT	Mean daily milk volume over study days 0–1 compared to mean milk volume on day 8 for each group	Positive (significant for I group but not C)

continued

TABLE 88 *Mapping of evidence of effectiveness against Baby Friendly (BFI) Best Practice standards for neonatal care (continued)*

Baby Friendly Best Practice standard for neonatal units	Study	Intervention	Study design	Targeted population group/country	Quality rating of study	Breastfeeding outcome(s)	Effect of intervention
	Feher 1989[146]	20-minute audio-cassette of relaxation imagery/ techniques recommended for use when mothers wanted to express	RCT	USA	Moderate Not ITT	Mean milk volume at a single expression during second postnatal week	Positive
						Fat content of a single sample using a creamatocrit test	No effect
	Jones 2001[114]	Breast massage by mother vs no breast massage prior to pumping (in addition to simultaneous pumping vs sequential pumping detailed above	Randomised crossover	UK	Moderate Not ITT	Milk yield per expression	Positive Breast massage improved milk production for both groups conducting simultaneous or sequential pumping
	Mersmann 1993[148]	Therapeutic touch (TT) vs mimic therapeutic touch vs no treatment	Randomised crossover	Mothers who had been expressing for 2 weeks USA	Moderate Not ITT	Milk volume	Positive after TT vs mimic TT and no treatment
6. Support mothers to establish and maintain breastfeeding	Pinelli 2001[126]	Individual counselling by lactation consultant with video and regular (weekly) contact in hospital and at home while breastfeeding	RCT	No details Canada	Good ITT	Intake from breastmilk/ breastfeeding at term	No effect
						Any breastfeeding at 12 and 24 weeks	No effect
	Gonzalez 2003[166]	Individual support service to mothers within the NICU by an International Board Certified Lactation Consultant	Before/after	USA	Moderate Not ITT	Ever receiving mother's own milk	Positive
						Receiving mother's own milk at hospital discharge	Positive
	Gunn 2000[127]	Early discharge with home support for suckle feeding infants without demonstrated sustained weight gain	RCT	Mothers of European and Maori descent who mainly intended to breastfeed their preterm, LBW or VLBW infant(s) New Zealand	Moderate Not clear if ITT	Any breastfeeding at discharge or at 6 weeks and 6 months after discharge	No effect

Baby Friendly Best Practice standard for neonatal units	Study	Intervention	Study design	Targeted population group/country	Quality rating of study	Breastfeeding outcome(s)	Effect of intervention
7. Encourage exclusive breastmilk feeding	See related standard 'Support mothers to establish and maintain breastfeeding' above						
8. Avoid use of teats or dummies for breastfed babies unless clinically indicated	Collins 2004[119]	Cup vs bottle feeding	RCT	< 34 weeks' gestation Australia	Good but low compliance ITT	Any breastfeeding at discharge	No effect
						Exclusive breastfeeding at discharge	Positive effect
						Any breastfeeding at 3 or 6 months	No effect
	Collins 2004[119]	Pacifier vs no pacifier	RCT	< 34 weeks' gestation Australia	Good but low compliance ITT	Any breastfeeding at discharge and 3 or 6 months after discharge	No effect
						Exclusive breastfeeding at discharge	No effect
	Mosley 2001[124]	Cup vs bottle feeding	RCT	30–37 weeks' gestation UK	Moderate ITT	Exclusive breastfeeding at discharge	No effect
	Rocha 2002[122]	Cup and finger feeding vs bottle feeding and pacifier	RCT	32–36 weeks' gestation LBW/VLBW Brazil	Moderate ITT	Any breastfeeding at discharge	No effect
						Any breastfeeding at 5–15 days or 3 months	No effect
	Meier 2000[136]	Ultra-thin silicone nipple shields vs no shield for mothers with breastfeeding problems	Retrospective crossover	Preterm LBW USA	Moderate Unclear if ITT	Milk transfer to infant	Positive

continued

TABLE 88 *Mapping of evidence of effectiveness against Baby Friendly (BFI) Best Practice standards for neonatal care (continued)*

Baby Friendly Best Practice standard for neonatal units	Study	Intervention	Study design	Targeted population group/country	Quality rating of study	Breastfeeding outcome(s)	Effect of intervention
9. Promote breastfeeding support through local and national networks (see standard 6 for related evidence base)	Agrasada 2005[117]	Community-based breastfeeding peer counselling vs community-based child care peer counselling vs no peer counselling	RCT	Mothers exclusively breastfeeding their term LBW infants Philippines	Good ITT	Any breastfeeding at 12 and 24 weeks	Positive for breastfeeding peer counselling group only
						Exclusive breastfeeding from birth to 6 months	Positive for breastfeeding peer counselling group only
	Merewood 2006[143]	(Trained) Peer counsellor support within 73 hours of birth and for six weeks (BFI accredited care for both groups)	RCT	Mothers of preterm, healthy infants USA	Moderate Not ITT	Any breastfeeding at 12 weeks	Positive
	Pereira 1984[153]	(Trained) peer counsellor support by community-based volunteer counsellors	Before/after	Mothers of infants in NICU who intended to breastfeed USA	Moderate Not ITT	Duration of any breastfeeding prior to hospital discharge	Positive
						Mean duration of breastfeeding	Positive
Related evidence from this review							
BFI accreditation of maternity hospital comprising neonatal unit	Merewood 2003[137]	BFI accreditation	Before/after	Preterm infants of mainly black American or Hispanic mothers USA	Good ITT	Receiving any breastmilk during first week of enteral feeds	Positive
						Exclusive breastfeeding at 2 weeks (in hospital)	Positive
						Any breastfeeding at 2 weeks (in hospital)	Positive
	Bicalho-Mancini 2004[151]	BFI accreditation	Before/after	Mothers who wished to breastfeed their preterm infants of LBW/VLBW Brazil	Moderate ITT	Any breastfeeding at discharge	Positive

Baby Friendly Best Practice Standards in neonatal units: summary

Evidence from this review has identified three types of intervention to directly inform the successful implementation of four Baby Friendly standards in UK neonatal units:

- training and education of health-care staff – Standards 2 and 6
- kangaroo method of skin-to-skin contact – Standards 4 and 6
- community-led peer support interventions – Standards 9 and 6.

The evidence base to inform implementation of Standards 2 and 4 comprises studies conducted in the UK, USA and Malaysia (Kuala Lumpar) among clinically stable, very low and low birthweight infants. The effective promotion of breastfeeding support through local and national networks (Standard 9) has been most clearly demonstrated by community-led peer counselling programmes delivered in both the hospital and home settings. These studies include one RCT and one before/after study conducted in the USA and one RCT in the Philippines. Community-led peer counselling programmes,[115,141,151] education of health-care staff (Pineda 2006,[149] Jones 2004[81]) and the kangaroo method of skin-to-skin contact[24,133,139,145] have also been demonstrated to support mothers to establish and/or maintain breastfeeding (Standard 6). Details of the characteristics of these interventions and mother-infant dyads for whom these interventions have been found to be effective are provided in Chapter 4.

Several of these interventions also included an educational component to inform parents of the benefits of breastmilk and breastfeeding (Standard 3). Such information may promote breastfeeding among this vulnerable population although it is more likely that the combination of information with practical and emotional support, delivered through peer counselling programmes or as a result of appropriate staff training, will improve breastfeeding outcomes.

Findings from this evidence review are promising, although not conclusive, in relation to some interventions to support mothers to express breastmilk (Standand 5). Relaxation techniques,[144] breast massage[113] and therapeutic touch[146] have been found to increase milk volume among mothers of preterm or low birthweight infants. Evidence from one moderate-quality RCT conducted in the UK shows that electrical simultaneous pumping compared to electrical sequential pumping had a significant effect on breastmilk output by weight.[113] However, in a study conducted in the USA[126] a similar intervention did not report a positive effect on breastmilk output by volume. The positive finding reported in the UK study may be due to the lack of time restrictions placed on pumping and/or a lack of intention-to-treat analysis. One moderate-quality trial conducted in Kenya and Nigeria found that electrical pumps significantly increased breastmilk output by volume compared to hand pumps.[140] These findings suggest that strategies to support relaxation and other therapeutic approaches may warrant consideration at the local level and/or strategies to facilitate and support electrical pumping, particularly unrestricted double pumping, in neonatal units to increase volumes of expressed breastmilk. Limited evidence suggests that use of domperidone[121] and recombinant human growth hormone[131] may have a positive effect on milk volumes among women who had been expressing for at least a month and whose milk production was not meeting their infant's needs.

The findings of effectiveness for Baby Friendly accreditation for the maternity service on breastfeeding outcomes in neonatal settings lend support to the potential extension of principles, and findings, from Baby Friendly accreditation in term, healthy infants to preterm and/or low birthweight infants in neonatal units. Two large before/after studies of good and moderate quality demonstrated significant increases in the number of infants being fed breastmilk during their first week of enteral feeds, any breastfeeding at discharge and any and exclusive breastfeeding at 2 weeks during the hospital stay. These studies were conducted among preterm infants, mostly of low birthweight, suggesting that replication of the benefits of Baby Friendly accreditation can be extended from the clinically stable, term population to clinically stable infants of low birthweight with a gestational age of 30 weeks or more.

One study included mothers who wished to breastfeed and the other was conducted among a population with typically low breastfeeding rates. These findings suggest that Baby Friendly accreditation can be effective among relatively lower risk infants of mothers with different feeding intentions. Generalisability of these findings to

the UK may be problematic, however, as one study was conducted in Brazil and the other among mainly black American or Hispanic mothers. White Americans represented approximately 20% of the total sample. A pattern of effectiveness for Baby Friendly accreditation across a diverse range of populations and country settings does appear to be emerging, however.

Findings from this evidence review are inconclusive in relation to breastfeeding outcomes for Standard 8 (Avoid use of teats or dummies), although there are also important safety considerations in relation to this standard. One retrospective study in the USA demonstrated a significant increase in milk transfer to preterm, low birthweight infants as a result of ultra-thin silicone nipple shields for mothers with breastfeeding problems.

A lack of evidence was available to inform the effectiveness of interventions to encourage exclusive breastmilk feeding among infants in neonatal care (Standard 7). No studies were identified that evaluated the effect of a written neonatal unit breastfeeding policy (Standard 1).

Baby Friendly standards for neonatal units: conclusion

Implementation of the kangaroo method of skin-to-skin contact and training of health professionals in the neonatal unit have been shown to be effective at increasing breastfeeding outcomes among mainly preterm infants of very low birthweight. Community-led peer support interventions in the hospital and home settings have been shown to be effective among mainly lower risk, preterm infants of low birthweight. Increased implementation of these interventions would progress neonatal units towards complying with Best Practice Standards 2, 4, 6, 9 and standard 8 (in relation to safety outcome). Neonatal units should also encourage and support the achievement of Baby Friendly accreditation status for the maternity hospital to achieve significant increases in breastfeeding rates.

Feedback

The HTA programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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ISSN 1366-5278