National Institute for Health and Care Excellence

Final

Postnatal care

[P] Breastfeeding interventions (Appendix D: clinical evidence tables)

NICE guideline NG194

Evidence reviews

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Final

These evidence reviews were developed by National Guideline Alliance, part of Royal College of Obstetricians and Gynaecologists

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Appendix D – Clinical evidence tables

Clinical evidence tables for review questions:
What interventions are effective in starting and maintaining breastfeeding (single births)?
What interventions are effective in starting and maintaining breastfeeding (twins or triplets)?

Table 1: Clinical evidence table

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Abbass-Dick, J., Dennis, C. L., Maternal and paternal experiences and satisfaction with a co-parenting breastfeeding support intervention in Canada, Midwifery, 56, 135-141, 2018 **Ref Id** 966776 **Country/ies where the study was carried out** Canada **Study type** RCT **Aim of the study**	**Sample size** N randomised=214 couples Intervention: n=107 couples Control: n=107 couples Loss to follow-up: * Intervention: outcome data at 6 weeks (mother: n=98 complete data; n=104 primary outcome data); father: n=93); outcome data at 12 weeks (mother: n=100 complete data; n=104 primary outcome data). Control: outcome data at 6 weeks (mother: n=91 complete data; n=102 primary outcome data); father: n=95); outcome data at 12 weeks (mother: n=96 complete data; n=105 primary outcome data). *Data taken from Abbass-Dick (2015). **Characteristics**	**Interventions** Intervention: usual care plus in-hospital face-to-face discussion (~15 mins), co-parenting booklet, breastfeeding booklet, video on co-parenting and breastfeeding, access to a secure website with information, follow-up emails to parents at 1 and 3 weeks postpartum, telephone call at 2 weeks postpartum. Control: Usual care, which included standard in-hospital breastfeeding support and any breastfeeding assistance that was proactively sought in the community. Setting: teaching hospital in Toronto, Canada.	**Details** **Data collection** Follow-up data were collected at 6 weeks for both mothers and fathers, and at 12 weeks for mothers only via questionnaires completed online or by telephone interview. **Analysis** To achieve 80% power, accounting for 25% loss to follow-up, 214 couples were required. Data were analysed on an intention-to-treat basis. For dichotomous data, frequencies and percentages were calculated and differences between groups examined using Pearson chi-square tests, supplemented where necessary by Fisher exact	**Results** Any breastfeeding at 12 weeks*: intervention (n=104): 100 vs control (n=105): 92 Exclusive breastfeeding at 12 weeks*: intervention (n=104): 70 vs control (n=105): 63 * Denominators calculated based on numerators and percentages provided in the paper, and correspond to numbers in figure 1 Maternal perception of helpfulness of intervention component (n=100): agreed component was helpful: in-hospital discussion: 82, co-parenting workbook: 76, Breastfeeding Matters book: 79, Co-parenting DVD: 46, website: 54, emails and calls: 67; most helpful component: in-hospital discussion: 49, co-parenting workbook: 31, Breastfeeding Matters book: 66, Co-parenting	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (unclear how random numbers were generated) Allocation concealment: Low risk (opaque sealed envelopes) Baseline differences: High risk (significantly more couples in the intervention group than in the control group attended a prenatal class (n = 74, 69.2% compared with n = 57, 53.3%))

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To assess the effects of a co-parenting intervention on breastfeeding rates and parental satisfaction with the intervention. **Study dates** March to July 2012. **Source of funding** No funding received.	Maternal age (years) - mean (±SD) Intervention: 30.4 (3.7); control: 30.7 (3.8) Plan to exclusively breastfeed - n (%) Intervention: 95 (88.8); control: 95 (88.8) Plan to exclusively breastfeed at >6 months - n (%) Intervention: 75 (70.1); control: 65 (60.7) Annual household income >$60,000 - n (%) Intervention: 87 (81.3); control: 77 (72.0) Data taken from Abbass-Dick (2015). **Inclusion criteria** • Primiparous women; • Able to speak and read English; • Living with a partner; • Older than 18 years • Given birth to full term singleton infant. **Exclusion criteria**		test. For continuous data, means and standard deviations (SDs) were calculated, and differences between groups were analysed using independent 2-sample *t*-tests and Mann-Whitney *U*-tests.	DVD: 16, website: 23, emails and calls: 5 Paternal perception of helpfulness of intervention component (n=93): agreed component was helpful: in-hospital discussion: 77, co-parenting workbook: 67, Breastfeeding Matters book: 69, Co-parenting DVD: 52, website: 53, emails and calls: 42; most helpful component: in-hospital discussion: 51, co-parenting workbook: 31, Breastfeeding Matters book: 44, Co-parenting DVD: 26, website: 20, emails and calls: 9 Satisfaction data not comparative therefore not presented in the evidence review	**Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (97.2% of mothers and fathers both received the intervention) Analysis of participants in the group to which they were randomised: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Infant of maternal health issues which could impact breastfeeding; • Infant not discharged home with mother; • Planning to breastfeed for less than 12 weeks; • Not having internet or telephone access.				(analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (Complete follow-up data were collected from 87.9% (n = 188) of fathers at 6 weeks and 88.3% (n = 189) of mothers at 6 weeks and 91.6% (n = 196) at 12 weeks) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (self-reported web-based questionnaire or telephone interview) Blinding of outcome assessors: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					(interviewer was blinded to group allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (trial registered with NCT and all outcomes reported) **Judgement on risk of bias arising from selection of the reporting result: Low risk** **Overall risk-of-bias judgement: Some risk** **Other information** Exclusive breastfeeding defined as no food or liquid other than breast milk given to infant in the last 24 hours and included feeding expressed breast milk and undiluted drops or syrups consisting of vitamins, minerals, supplements, or medicines.
Full citation	**Sample size** See Abbass-Dick 2018	**Interventions** See Abbass-Dick 2018	**Details** See Abbass-Dick 2018	**Results** See Abbass-Dick 2018	**Limitations** See Abbass-Dick 2018

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Abbass-Dick J, Stern SB, Nelson LE, Watson W, Dennis CL., Coparenting breastfeeding support and exclusive breastfeeding: a randomized controlled trial., Pediatrics, 13, 102-10, 2015 **Ref Id** 1000567 **Country/ies where the study was carried out** **Study type** See Abbass-Dick 2018 **Aim of the study** See Abbass-Dick 2018 **Study dates** See Abbass-Dick 2018 **Source of funding** See Abbass-Dick 2018	**Characteristics** See Abbass-Dick 2018 **Inclusion criteria** See Abbass-Dick 2018 **Exclusion criteria** See Abbass-Dick 2018				
Full citation	**Sample size**	**Interventions**	**Details**	**Results**	**Limitations**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ahmed AH, Roumani AM, Szucs K, Zhang L, King D., The effect of interactive web-based monitoring on breastfeeding exclusivity, intensity, and duration in healthy, term infants after hospital discharge., Journal of Obstetric, Gynecologic, & Neonatal Nursing, 45(2):143–154., 2016 **Ref Id** 997252 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effect of an interactive web-based intervention on breastfeeding outcomes in healthy term infants after discharge from hospital.	N=141 Intervention: n=84 Control: n=57 Lost to follow-up: Intervention: n=35 dropouts (n=49 received intervention); at 1 month n=49 included in analysis; n=1 lost to follow-up; at 2 months n=48 included in analysis; n=4 lost to follow-up; included in analysis at 3 months n=44. Control: n=57 received intervention; n=2 lost to follow-up; at 1 month n=55 included in analysis; n=1 lost to follow-up; at 2 months n=54 included in analysis; n=2 lost to follow-up; at 3 months n=52 included in analysis. **Characteristics** <u>Age (years) - mean (±SD)</u> Intervention: 29.9 (6.5); control: 29.2 (6.3) <u>Age (years) - number (%)</u> <20: Intervention: 4 (8.2); control: 4 (7.0) 20-29: Intervention: 17 (34.7); control: 25 (43.9) ≥30: Intervention: 28 (57.1); control: 28 (49.1) <u>Race/ethnicity - number (%)</u> Hispanic: Intervention: 1 (2.0); control: 3 (5.3)	Intervention: in addition to usual care, women had access to an interactive breastfeeding monitoring system. They were asked to input breastfeeding data, wet and dirty diapers data, and any problems for at least 30 days. The system automatically sent feedback via notifications with tailored interventions if the mother entered data that indicated breastfeeding problems. The system also provided positive notifications when the mother breastfed 8 to 10 times per day. Professional educational resources were also available through the system. Control: usual care. Setting: 3 Midwest hospitals, US.	**Data collection** Breastfeeding patterns were assessed on discharge, and at 1, 2 and 3 months post discharge. Mothers in the intervention group entered data on 24-hour breastfeeding daily in the system for 30 days. A researcher and trained research assistant monitored the mothers' data online twice daily, once in the morning and once in late afternoon. At follow-up, all women completed a follow-up form and postpartum depression scale online. **Analysis** To achieve 80% power, and accounting for attrition an rate of 35%, 80 mothers per intervention group were required. Data were analysed on an intention-to-treat basis. Between group differences were analysed using chi-square or Fisher's Exact tests, Student *t*-tests (if data normally distributed) or Mann-Whitney *U* tests (if not) were used for other continuous outcomes.	Any breastfeeding at 3 months: intervention (n=49): 39 vs control (n=57): 38 Exclusive breastfeeding at 3 months: intervention (n=49): 27 vs control (n=57): 11	Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (computer-generated random numbers using mode of delivery and parity as stratifying factors to control for) Allocation concealment: Some risk (not described) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Not stated. **Source of funding** Indiana CTSI Collaboration in Biomedical/Translational Research Pilot Programme Grants.	Asian: Intervention: 2 (4.0); control: 1 (1.9) Black or African American: Intervention: 9 (18.4); control: 15 (28.3) White: Intervention: 36 (73.5); control: 36 (67.9) More than 1 race: Intervention: 2 (4.1); control: 1 (1.9) Parity - number (%) First infant: Intervention: 21 (42.9); control: 33 (57.9) Second infant: Intervention: 16 (32.7); control: 16 (28.1) Third infant: Intervention: 8 (16.3); control: 6 (10.5) Fourth infant or more: Intervention: 4 (8.2); control: 2 (3.5) **Inclusion criteria** • Women aged ≥18 years; • Able to read and speak English; • intention to continue breastfeeding after discharge; • No serious medical condition that prevents breastfeeding (e.g. HIV positive);				Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (41.6% of mothers 35/84 dropped out of the intervention arm) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Basic knowledge of how to use the Internet; • Access to email and the Internet through with a standard computer or a smartphone. • Singleton full-term pregnancy; • ≥37 weeks gestational age. **Exclusion criteria** • Infants born with cleft lip/palate; • Congenital heart defects; • Down Syndrome; • Neural tube defects; • Other conditions that either required the newborn's admission to a neonatal intensive care unit or interfere with breastfeeding.				Missing outcome data: Low risk (data was available over the first, second and third month from the control group: 96%, 91% and 80% compared to 100%, 92% and 88% in the intervention group) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (online survey) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from selection of the reporting result: Some risk **Overall risk-of-bias judgement: Some risk** **Other information** Exclusive breastfeeding was defined as no other food or drink, not even water, except breast milk (including expressed milk), but allows the infant to receive vitamins, minerals and medicines. Predominant breastfeeding was defined as breast milk was the predominant source of nourishment (including milk expressed as the predominant source of nourishment); infant may also receive liquids (water and water-based drinks, fruit juice) ritual fluids and vitamins, minerals and medicines. Partial breastfeeding referred to mixed feeding of breast milk and other food or food-based fluids, such as formula milk or weaning foods. A thank-you letter with a $30 gift card was sent to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					each mother after completing the survey for month 1, and a $10 gift card was sent after each of the second and third month surveys were completed.
Full citation Anderson A K, Damio G, Young S, Chapman DJ, Perez-Escamilla R., A randomised trial assessing the efficacy of peer counseling on exclusive breastfeeding in a predominantly Latina low-income community., Archives of Pediatric and Adolescent Medicine, 159, 836–41, 2005 **Ref Id** 997006 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study**	**Sample size** N randomised=182 Intervention: n=90 Control: n=92 Lost to follow-up: Intervention: n=13 ineligible (n=9 missed at delivery or moved away; n=4 low birthweight); n=14 lost to follow-up; n=63 completed the study at 3 months postpartum. Control: n=7 ineligible (n=7 missed at delivery or moved away; n=2 low birthweight); n=13 lost to follow-up; n=72 completed study at 3 months postpartum. **Characteristics** <u>Maternal age (years) - number (%)</u> <20: Intervention: 6 (9.5); control: 12 (16.7) 20-30: Intervention: 43 (68.3); control: 48 (66.7) ≥30: Intervention: 14 (22.2); control: 12 (16.7) <u>Race/ethnicity - number (%)</u>	**Interventions** Intervention: standard care plus 3 prenatal home visits, daily in-hospital visits after birth and 9 postpartum home visits from a peer counsellor until 6 weeks after birth. Peer counsellors had a 40-hr training and were observed for 2 months by a lactation consultant. Control: Standard care, certified Baby-Friendly Hospital, hands-on breastfeeding support on maternity ward, 24hr support telephone line. Setting: Low-income inner-city hospital (Ambulatory Health Services Clinic) in Hartford, Conneticut, US.	**Details** **Data collection** A bilingual and bicultural research staff member conducted interviews for data collection, including baseline screening at recruitment (demographics, previous breastfeeding experience, intended breastfeeding), during postpartum hospitalisation (information on intervention received, use of breastmilk substitutes and support; medical records were also assessed), and follow-up (weekly interviews during the first month and biweekly during the second and third months via telephone) to collect data on infant feeding practices. **Analysis** Data were analysed on an intention-to-treat basis. Chi-square tests were used to analyse relevant outcome data.	**Results** Initiated breastfeeding by hospital discharge*: intervention (n=63): 57 vs control (n=72): 55 Any breastfeeding by hospital discharge*: intervention (n=63): 26 vs control (n=72): 40 Any breastfeeding at 3 months*: intervention (n=63): 50 vs control (n=72): 71 Exclusive breastfeeding at 3 months*: intervention (n=63): 13 vs control (n=72): 1 *Numerators calculated based on number of women not initiated breastfeeding or not exclusively breastfeeding reported in the paper.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (SPSS software was used to assign subjects) Allocation concealment: Low risk (Once recruited subjects were entered into a database to receive their allocation) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To evaluate the effect of peer counselling on breastfeeding rates among low-income inner-city Latina women. **Study dates** January 2003 to July 2004. **Source of funding** Centres for Disease Control and Prevention.	Hispanic: Intervention: 51 (81.0); control: 46 (63.9) Black: Intervention: 9 (14.3); control: 15 (20.8) Caucasian: Intervention: 1 (1.6); control: 9 (12.5) Other: Intervention: 2 (3.1); control: 2 (2.8) Parity - number (%) Primiparous: Intervention: 35 (55.6); control: 35 (48.6) Multiparous: Intervention: 28 (44.4); control: 37 (51.4) Planned breastfeeding duration (months) - number (%) <6: Intervention: 10 (20.4); control: 24 (46.2 6-12: Intervention: 37 (75.5); control: 26 (50.0) >12: Intervention: 2 (4.1); control: 2 (3.8) Birthweight (kg) - mean (±SD) Intervention: 3.39 (0.43); control: 3.46 (0.46) **Inclusion criteria** • Women aged 18 years or older; • Healthy baby with gestational age 32 weeks or younger; • Absence of any medical condition		Analyses to examine the role of ethnicity on outcomes was also conducted and reported in Anderson 2007.		DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (Intervention was received by 88.9% of women for the prenatal home visit and 63.5% of women for the 6 week postpartum visit) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	likely to impair breastfeeding (e.g. diabetes, hypertension, HIV/AIDS, or using illegal drugs); • Woman should be considering breastfeeding; • Planning to deliver at Hartford Hospital; • Willing to stay in the study area for at least 3 months postpartum; • Living in a household earning <185% of the federal poverty level; • Available to be contacted via telephone; • Willing to participate. Newborn inclusion criteria: • Born at term (≥36 weeks) gestation); • Normal birthweight (≥2.5 kg); • No neonatal medical complications requiring treatment in the neonatal intensive care unit;				**from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Low risk (83.3% of women completed the 3-month follow-up interview) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (interviewer did not know the participants allocation until final questions based on peer contact details) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Apgar scores at 1 and 5 minutes greater than or equal to 6. **Exclusion criteria** Not stated.				risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Exclusive feeding defined using '24 hours recall' (for the past 24 hours, did your baby receive any other food besides breastmilk?), 'previous week recall' (over the past week, how did you feed your baby?), and the 'ever given recall' (did the infant receive any foods other than breastmilk since birth?).
Full citation Anderson AK, Damio G, Chapman DJ, Perez-Escamilla R., Differential response to an exclusive breastfeeding peer counseling intervention: the role of ethnicity., Journal of	**Sample size** See Anderson 2005 **Characteristics** See Anderson 2005 **Inclusion criteria** See Anderson 2005	**Interventions** See Anderson 2005	**Details** See Anderson 2005	**Results** See Anderson 2005	**Limitations** See Anderson 2005

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Human Lactation, 23, 16–23, 2007 **Ref Id** 997162 **Country/ies where the study was carried out** US **Study type** See Anderson 2005 **Aim of the study** See Anderson 2005 **Study dates** See Anderson 2005 **Source of funding** See Anderson 2005	**Exclusion criteria** See Anderson 2005				
Full citation Bonuck K, Stuebe A, Barnett J, Labbok MH, Fletcher J, Bernstein PS., Effect of primary care intervention on breastfeeding duration	**Sample size** BINGO RCT N randomised=666 N analysed= 628 • Intervention (1), electronic prompts only: n=236 • Intervention (2), lactation consultant only: n=77	**Interventions** Intervention (1; EP): Electronic prompts that appeared in the medical records during 5 prenatal visits. Included 2-3 brief open-ended questions for providers to ask that	**Details** **Data collection** Infant feeding assessed at 1, 3, and 6 months postpartum by study staff via phone interviews, using modified questions from the	**Results** BINGO: Initiation of breastfeeding*: EP (n=223): 207 vs LC (n=73): 70 vs LC+EP (n=226): 218 vs usual care (n=73): 65 Any breastfeeding at 3 months*: EP (n=229): 102 vs	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
and intensity., American Journal of Public Health, 104, S119-S127, 2014 **Ref Id** 997127 **Country/ies where the study was carried out** US **Study type** This study reported on 2 RCTs, called BINGO and PAIRINGS. **Aim of the study** To compare the effects of primary care-based interventions on breastfeeding at 1, 3 and 6 months postnatally. **Study dates** February 2008 to June 2010. **Source of funding** National Institute of Child Health and	• Intervention (3), electronic prompts and lactation consultant: n=238 • Control: n=77 PAIRINGS RCT: N randomised=275 N analysed=262 • Intervention (3): n=129 • Control: n=133 THE BINGO analytic sample included 94% of those randomised, the PAIRINGS analytic sample included 95% of those randomised. Comparing women analysed to women lost to follow-up, in BINGO women analysed were less likely to participate in the WIC programme, whereas in PAIRINGS women analysed were more likely to plan to return to work in the first 3 months. **Characteristics** BINGO: primarily low-income women. PAIRINGS: economically diverse population **Maternal age (years) - mean (±SD)** BINGO	portrayed breastfeeding as the norm. Intervention (2; LC) *: Lactation consultant that held 2 prenatal sessions with the woman, a hospital visit, telephone calls for up to 3 months postpartum. Intervention (3; LC+EP) *: Lactation consultant and electronic prompts. Control: Usual care – no explicit breastfeeding promotion or support. Setting: 2 urban medical centres in New York. *Nursing bras and breast pumps were provided to lactation groups as required. Postpartum home visits were optional, based upon women and lactation consultant preference and comfort.	Infant Feeding Practices Survey II. Exclusive breastfeeding was defined as feeding only breast milk or vitamin supplements, with no water, juice, formula, or solid foods during the last week. Breastfeeding intensity was defined as the percentage of all feeds that were breast milk in the last 7 days. Breastfeeding initiation was defined as ever having been breastfed or fed breast milk. Total duration was defined as the time (days) until the mother stopped breastfeeding or feeding breast milk completely. **Analysis** BINGO: To achieve 80% power, based on breastfeeding intensity (<20%: low; 20% to 80%; medium; >80%; high): EP (n=192); LC (n=63); LC+EP (n=192); control (n=63). PAIRINGS: To achieve 80% power, based on assumed exclusive breastfeeding rates at 3 months of 20% in the intervention group and 6% in the control group, 104	LC (n=73): 37 vs LC+EP (n=226): 127 vs usual care (n=74): 28 Any breastfeeding at 6 months*: EP (n=227): 75 vs LC (n=74): 30 vs LC+EP (n=231): 80 vs usual care (n=74): 20 Exclusive breastfeeding at 3 months*: EP (n=227): 10 vs LC (n=73): 8 vs LC+EP (n=226): 24 vs usual care (n=74): 2 PAIRINGS: Initiation of breastfeeding*: LC+EP (n=124): 122 vs usual care (n=130): 123 Any breastfeeding at 3 months*: LC+EP (n=125): 76 vs usual care (n=128): 57 Any breastfeeding at 6 months*: LC+EP (n=122): 46 vs usual care (n=122): 31 Exclusive breastfeeding at 3 months*: LC+EP (n=125): 20 vs usual care (n=129): 8 *The number analysed in each group were not provided in the paper and were calculated by the NGA technical team based on the number of women breastfeeding and the corresponding percentage provided in the paper.	DOMAIN 1 - Randomisation Random sequence generation: Low risk (women were randomised using sequentially numbered envelopes, generated by the study's statistician; randomisation used an undisclosed blocking factor and nativity status (US-born versus foreign-born); in PAIRINGS, a 1:1 ratio was used, in BINGO, women were randomised in a 1:3:3:1 ratio to usual care, electronic prompts only, lactation consultant plus electronic prompts, and lactation consultant only) Allocation concealment: Low risk (sequentially numbered opaque sealed envelopes) Baseline differences: Low risk (the study authors report that there were no statistically significant differences in baseline characteristics between the groups)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Human Development and the National Institute on Minority Health and Health Disparities.	EP: 28.1 (5.8); LC: 26.8 (5.5); LC+EP: 27.6 (6.0); Control: 28.1 (6.5) PAIRINGS LC+EP: 28.2 (5.9); Control: 28.1 (5.6) **Gestation (weeks) - mean (±SD)** BINGO EP: 38.9 (2.1); LC: 38.7 (2.1); LC+EP: 38.8 (2.4); Control: 38.8 (2.1) PAIRINGS LC+EP: 39.1 (1.6); Control: 39.3 (1.7) **BMI (kg/m^2) - number (%)** BINGO Normal/low (<25): EP: 75 (33.8); LC: 24 (32.0); LC+EP: 72 (31.0); Control: 28 (37.3) Overweight (25 - 29.9): EP: 59 (26.6); LC: 23 (30.7); LC+EP: 66 (28.4); Control: 16 (21.3) Obese (≥30): EP: 88 (39.6); LC: 28 (37.3); LC+EP: 94 (40.5); Control: 31 (41.3) PAIRINGS Normal/low (<25): LC+EP: 45 (34.9); Control: 59 (44.4) Overweight (25 - 29.9): LC+EP: 41 (31.8); Control: 36 (27.1) Obese (≥30): LC+EP: 43 (33.3); Control: 38 (28.6) **Parity (nulliparous) - number (%)**		women per group were required. Outcome data for the 2 trials were analysed separately, using the same procedures. Categorical data were analysed using chi-squared or Fisher exact test, continuous data were analysed using analysis of variance. See limitations section for more details on methods.		**Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded, the study authors mention that blinding was infeasible) Blinding of personnel: High risk (not blinded, the study authors mention that blinding was infeasible) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (crossovers not reported; recall of prenatal care providers discussing 5 out of 5 electronic prompt items was greater in the intervention groups

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	BINGO EP: 85 (36.0); LC: 31 (40.3); LC+EP: 99 (41.6); control: 31 (40.3) PAIRINGS LC+EP: 50 (38.8); control: 64 (48.1) **Race/ethnicity - number (%)** BINGO Non-Hispanic White: EP: 7 (3.0); LC: 2 (2.6); LC+EP: 12 (5.0); Control: 7 (9.1) Hispanic: EP: 133 (56.4); LC: 47 (61.0); LC+EP: 134 (56.3); Control: 43 (55.8) Non-Hispanic Black: EP: 74 (31.4); LC: 23 (29.9); LC+EP: 63 (26.5); Control: 19 (24.7) Non-Hispanic Asian: EP: 2 (0.8); LC: 1 (1.3); LC+EP: 8 (3.4); Control: 1 (1.3) Biracial/multiracial/other: EP: 20 (8.5); LC: 4 (5.2); LC+EP: 21 (8.8); Control: 7 (9.1) PAIRINGS Non-Hispanic White: LC+EP: 6.0 (4.7); Control: 7 (5.3) Hispanic: LC+EP: 69 (53.5); Control: 77 (57.9) Non-Hispanic Black: LC+EP: 42 (32.6); Control: 33 (24.8) Non-Hispanic Asian: LC+EP: 2 (1.6); Control: 5 (3.8) Biracial/multiracial/other: LC+EP: 10 (7.8); Control: 11 (8.3)				compared to the control group in both BINGO and PAIRINGS) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (94% analysed of those randomised to BINGO, and 95% analysed of those randomised to PAIRINGS, but comparing women analysed to women lost to follow-up, in BINGO women analysed were less likely to participate in the WIC programme, whereas in PAIRINGS women analysed were more likely to plan to return to work in the first 3 months.) **Judgement on risk of bias arising from missing**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Feeding intention (parous) - number (%) BINGO Exclusive breastfeeding: EP: 89 (37.7); LC: 25 (32.5); LC+EP: 92 (38.7); Control: 29 (37.7) Exclusive formula feeding: EP: 16 (6.8); LC: 6 (7.8); LC+EP: 21 (8.8); Control: 11 (14.3) Both breast and formula: EP: 125 (53.0); LC: 41 (53.2); LC+EP: 116 (48.7); Control: 33 (42.9) PAIRINGS Exclusive breastfeeding: LC+EP: 83 (64.3); Control: 79 (59.4) Exclusive formula feeding: LC+EP: 3 (2.3); Control: 12 (9.0) Both breast and formula: LC+EP: 43 (33.3); Control: 42 (31.6) **Inclusion criteria** • English or Spanish-speaking women aged 18 years or older; • First of second trimester of singleton pregnancy.				**outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (group assignment stripped from databases accessed by research staff, group identifiers omitted from participant interview forms) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 - reporting Selective reporting: Low risk (the McFadden Cochrane review reports having checked the Clinicaltrials.gov record and reports that the key breastfeeding outcome data seemed to be reported in the paper) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria • Risk for premature birth, or maternal or infant conditions that would prevent or complicate breastfeeding (e.g. maternal HIV positive, infant congenital anomaly).				**selective reporting: Low risk** **Overall risk-of-bias judgement: Some concerns** **Other information** Only the BINGO RCT focused on an antenatal intervention (as well as on 2 additional interventions performed across the antenatal and postnatal period, which were analysed in relation to intervention 2). The PAIRINGS RCT was only included in relation to intervention 2.
Full citation Bonuck KA, Freeman K, Trombley M., Randomized controlled trial of a prenatal and postnatal lactation consultant intervention on infant health care use., Archives of Pediatrics & Adolescent Medicine, 160, 953–60, 2006 **Ref Id**	**Sample size** N randomised=382 Intervention: n=188 Control: n=194 Lost to follow-up: Intervention: n=175 eligible for postnatal follow-up (n=15 with no infants (n=4 twins; n=3 changed mind; n=8 infants died); n=163 analytic sample (n=12 had neither outside medical centre data for infant, or computerised medical centre data). Control; n=189 eligible for postnatal follow-up (n=6 with	**Interventions** Intervention: Lactation consultant - 2 individual meetings with each woman prenatally and 1 postpartum hospital and/or 1 home visit and was available for telephone consultation up to 12 months. Free nursing bra and pump. * Control: Standard care – no established protocol for breastfeeding education or support.	**Details** **Data collection** Prenatal baseline interview data included demographics and breastfeeding experience and intentions. Postpartum telephone interviews were conducted at 1, 2, 3, 4, 6, 8, 10 and 12 months to assess infant feeding and health care use. **Analysis**	**Results** Any breastfeeding at 2 weeks*: intervention (n=143): 124 vs control (n=157): 102 Exclusive breastfeeding at 2 weeks*: intervention (n=143): 29 vs control (n=157): 30 Any breastfeeding at 6 weeks*: intervention (n=137): 99 vs control (n=155): 85 Exclusive breastfeeding at 6 weeks*: intervention (n=137): 21 vs control (n=155): 25	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (undisclosed blocking factor, stratified by center) Allocation concealment: Some risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
996999 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effects of a prenatal and postpartum lactation support intervention on infant health care use. **Study dates** August 2000 to November 2002. **Source of funding** US Department of Agriculture, the Maternal and Child Health Bureau, and the Agency for Healthcare Quality and Research.	no infants (n=2 with twins; n=2 changed mind; n=2 infants died); n=175 analytic sample (n=14 had neither outside medical centre data for infant or computerised medical centre data). **Characteristics** Age (years) - mean (±SD) Intervention: 25.7 (6.4); control: 24.8 (5.9) Race/ethnicity - number (%) African American: Intervention: 67 (35.6); control: 75 (38.7) Hispanic: Intervention: 103 (54.8); control: 107 (55.2) Other: Intervention: 18 (9.6); control: 12 (6.2) Medicaid recipient - number (%) Intervention: 101 (53.7); control: 113 (58.2) Intention - number (%) Only breast milk: Intervention: 62 (33.0); control: 55 (33.7) Only formula: Intervention: 16 (8.5); control: 15 (9.2) Both: Intervention: 89 (47.3); control: 73 (50.3) Do not know: Intervention: 21 (11.2); control: 14 99.7) **Inclusion criteria**	*Information on free nursing bra and pump extracted from Bonuck 2005. Setting: 2 urban community health centres, New York.	138 women per intervention group were required (Bonuck 2006). Between group differences in the proportion of women reporting any breastfeeding, 50% or more of breastfeeding, and exclusive breastfeeding for postpartum weeks 1 to 52 were analysed using the Mantel-Haenszel chi-square or chi-square test.	Any breastfeeding at 26 weeks*: intervention (n=115): 51 vs control (n=136): 45 *Denominators in each group calculated by the NGA technical team based on numerators and percentages provided in table 3 of Bonuck 2006.	(sealed envelope, not described if it was opaque or not) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded, but research assistants were trained in standard data collection procedures) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• English and Spanish speaking women; • Twin or singleton pregnancy; • Gestation <24 weeks. **Exclusion criteria** • Medical or obstetric complications for which breastfeeding is contraindicated; • Long-term use of medications incompatible with breastfeeding.				DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (76% of the intervention group received any intervention) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (at 6 months, data available from 69.9% of intervention and 71.4% of control group) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (Unclear if all outcome assessors were blinded, for extraction of data from medical centers, researchers were blinded) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Participants were compensated (no further details provided).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Exclusive breastfeeding defined as no artificial milk (i.e. formula) or solids. Intake of water, liquids other than artificial milk, and vitamin drops was not assessed.
Full citation Bonuck KA, Trombley M, Freeman K, McKee D., Randomized, controlled trial of a prenatal and postnatal lactation consultant intervention on duration and intensity of breastfeeding up to 12 months., Pediatrics, 116, 1413–26, 2005 **Ref Id** 996987 **Country/ies where the study was carried out** US **Study type** See Bonuck 2006 **Aim of the study** See Bonuck 2006	**Sample size** See Bonuck 2006 **Characteristics** See Bonuck 2006 **Inclusion criteria** See Bonuck 2006 **Exclusion criteria** See Bonuck 2006	**Interventions** See Bonuck 2006	**Details** See Bonuck 2006	**Results** See Bonuck 2006	**Limitations** See Bonuck 2006

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates See Bonuck 2006 **Source of funding** See Bonuck 2006					
Full citation Brent NB, Redd B, Dworetz A, D'Amico F, Greenberg JJ., Breast-feeding in a low income population: program to increase incidence and duration., Archives of Pediatrics & Adolescent Medicine, 149, 798-803, 1995 **Ref Id** 1000574 **Country/ies where the study was carried out** US **Study type** RCT	**Sample size** N randomised: 115 Intervention: 58 Control: 57 7 were excluded from the intervention group because they only had one prenatal consultation. For the present review, in agreement with ITT principles, these women were included in the analysis on initiation of breastfeeding as data were available to do so. However, for breastfeeding outcomes relating to 2 weeks, 2 months and 6 months, no data were provided in the paper for these women. Moreover, 8 women in the control group were excluded from the 2 weeks, 2 months and 6 months follow-ups for receiving lactation consultation and no data were provided in the paper on these women.	**Interventions** Intervention: 2-4 prenatal sessions with LC (10 min-15 min each); daily inpatient rounds by LC after birth; telephone call 48 h after discharge; visit to lactation clinic at 1 week postpartum (staffed by paediatrician or LC); contact with LC at each health supervision visit until weaning or 1 year; professional education of nursing and medical staff. Control: women were offered optional prenatal breastfeeding classes, postpartum breastfeeding instruction by nurses and physicians and outpatient follow-up by nurses and physicians in the paediatric ambulatory department. Setting: ambulatory care centre for prenatal and paediatric care and inpatient	**Details** **Data collection** Data were collected using questionnaires and administered in person. **Analysis** Categorical data were analysed using the chi-square test. When expected frequencies were small, Fisher's Exact Probability Test was used. Student's *t*-test was used to compare groups for continuous outcomes. For ordinal data, Wilcoxon's rank sum test was used.	**Results** Breastfeeding initiation*: intervention (n=58): 33 vs control (n=57): 18 Any breastfeeding at 2 weeks: intervention (n=51): 24 vs control (n=49): 9 Any breastfeeding at 2 months: intervention (n=51): 19 vs control (n=49): 4 Any breastfeeding at 6 months: intervention (n=51): 7 vs control (n=49): 4 *Numerator and denominator for intervention group for breastfeeding initiation was calculated by the NGA technical team by adding 7 to 51 (7 women were excluded by study authors because they received less than two prenatal visits, but added by the NGA technical team as per ITT principles as data was available for these women). Denominators for 2 weeks, 2	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 – randomisation Random sequence generation: Some risk (block sizes of 8, no further details) Allocation concealment: Some risk (not described) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess the effects of a comprehensive breastfeeding intervention on breastfeeding rates in a low-income, inner-city population. **Study dates** Not stated. **Source of funding** The Mercy Foundation and Care of the Poor Fund.	**Characteristics** Age (years - number (%) <20 years: Intervention: 21 (41); control: 24 (42) Race (white) - number (%) Intervention: 39 (78); control: 38 969) Socioeconomic status - number (%) Eligible for supplemental nutrition programme for women, infants, and children: Intervention: 46 (92); control: 51 (89) Eligible for Department of Public Assistance: Intervention: 24 (47); control: 33 (58) Probable choice of breastfeeding at first prenatal visit - number (%) Intervention: 19 (37); control: 17 (30) **Inclusion criteria** • English speaking women; • Nulliparous pregnant women;	maternity unit of a primary care centre that serves a low-income, inner-city population in Pittsburgh, US.		months and 6 months were calculated by the NGA technical team based on data provided in the paper but these were not ITT, as 7 women were excluded from the intervention group for receiving less than 2 prenatal visit and 8 women were excluded from the control group for receiving lactation consultation.	**randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (7 of 58 recruited in intervention did not receive 2 lactation consultant visits, therefore were excluded from analysis, 8/65 controls received lactation consultant visits, therefore were excluded from analysis)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Minimum of 2 prenatal lactation consultations. **Exclusion criteria** • Women separated from their infants at birth; • Infants born at <37 weeks of gestation; • Infants who stayed in the neonatal intensive care unit for >72 hours; • Taking medications that contraindicated breastfeeding; • Infants would not receive paediatric care at the Mercy Hospital.				Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Low risk (none reported) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (delivered and collected in person questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from measurement of the outcome: Some risk DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: High risk** **Other information** Breastfeeding defined as any human milk feedings, including infants who received some breast milk, even if supplementation with breast milk substitutes, other liquids, and solids occurred. Exclusive breastfeeding included human milk only.
Full citation Bunik M, Shobe P, O'Connor M E , Beaty B,, Are 2 weeks of daily breastfeeding support	**Sample size** N randomised=341 Intervention: n randomised=161 Control: n randomised=180 Lost to follow-up:	**Interventions** Intervention: Standard care plus daily telephone calls by a nurse starting on the day of discharge and continuing	**Details** **Data collection** Data on breastfeeding were collected via telephone at 1, 3, and 6 months postpartum.	**Results** Any breastfeeding at 3 months*: intervention (n=124): 61 vs control (n=142): 77	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
insufficient to overcome the influences of formula?, Academic Pediatrics , 10, 21-8, 2010 **Ref Id** 1000579 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effects of proactive telephone breastfeeding support on breastfeeding rates and duration and health care utilisation. **Study dates** February 2005 to May 2006. **Source of funding** Centre for Disease Control and Prevention,	Intervention: n=155 received intervention; n=6 unable to reach. At 1 month, n=12 lost to follow-up. At 3 months, n=19 lost to follow-up. At 6 months, n=5 lost to follow-up. n=119 analysed. Control: n=180 allocated; n=2 discontinued (did not want to participate). At 1 month, n=15 lost to follow-up. At 3 months, n=21 lost to follow-up. At 6 months, n=12 lost to follow-up. n=130 analysed. **Characteristics** <u>Maternal age (years) - median</u> Intervention: 21.9; control: 22.0 <u>Race/ethnicity - number (%)</u> Hispanic: Intervention: 138 (86); control: 162 (90) White/non-Hispanic: Intervention: 7 (4); control: 8 (4) Black/African American: Intervention: 14 (9); control: 7 (4) Other: Intervention: 2 (1); control: 3 (2) <u>Planned feeding method - number (%)</u> Breastfeeding only: Intervention: 80 (50); control: 99 (55)	daily for the first 2 weeks postpartum. Control: Standard care – including health care visit at 3 to 5 days and 2 weeks at the clinic, as well as formula company discharge bags. Both groups received handouts, a hand breast pump, lanolin cream, and a water bottle. Setting: Community health centre providing care for the medically underserved in Denver county.	**Analysis** To achieve 80% power, and accounting for attrition rate of 20%, 350 women were recruited. Data were analysed on an intention-to-treat basis and excluded lost to follow-up and dropouts similarly. The chi-squared and Fisher's exact tests were used to compare categorical data, and 2-sample *t*-tests were used to analyse continuous data. Regarding the number of calls received, data were skewed toward more days of the intervention, and data were therefore analysed as a categorical variable and not as a dose-response variable.	Any breastfeeding at 6 months*: intervention (n=119): 33 vs control (n=130): 48 *Denominators calculated by the NGA technical team based on losses to follow-up reported in figure 1, numerators calculated based on this and on percentages provided in figure 2.	DOMAIN 1 - randomisation Random sequence generation: Low risk (block random allocation) Allocation concealment: Low risk (using sequentially numbered opaque sealed envelopes) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
the Children's Outcomes Research Programme, and the Colorado Department of Public Health and Environment.	Breastfeeding and formula: Intervention: 80 (50); control: 80 (45) **Inclusion criteria** • Women aged 18 years or older who gave birth to a healthy, term, singleton infant; • Primiparous; • Willing to consider breastfeeding. **Exclusion criteria** • Women were excluded if their primary language was not English or Spanish; • Women with a medical complication that interfered with breastfeeding; • Hospital stay longer than 72 hours for vaginal deliveries or longer than 96 hours				**intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (119/161 (73.9%) analysed in intervention group and 130 /180 (72.2%) in the control group)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	for caesarean section; • Infants with medical problems that required admission to the intensive care nursery or hospitalisation for more than 72 hours.				**Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (trial registration available and all outcomes reported) **Judgement on risk of bias arising from selection of the reporting result: Low risk** **Overall risk-of-bias judgement: Some risk** **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Data were not extracted for predominant breastfeeding as this was defined as feeding 4 oz or less of formula per day.
Full citation Carlsen, E. M., Kyhnaeb, A., Renault, K. M., Cortes, D., Michaelsen, K. F., Pryds, O., Telephone-based support prolongs breastfeeding duration in obese women: a randomized trial, American Journal of Clinical Nutrition, 98, 1226-32, 2013 **Ref Id** 431739 **Country/ies where the study was carried out** Denmark **Study type** RCT **Aim of the study** To assess the effects of telephone-based	**Sample size** N randomised=226 Intervention: n=108 Control: n=118 Women included in the analysis to calculate odds ratios: intervention: n=105, control: n=102 (n=3 in the intervention arm and n=16 in the control arm lost to follow-up). **Characteristics** <u>Maternal age (years) - mean (±SD)</u> Intervention: 31.2 (4.5); control: 31.8 (4.1) <u>Pre-pregnancy BMI (kg/m2) - median (range)</u> Intervention: 32.5 (30.0 to 50.3); control: 32.8 (30.0 to 45.6) <u>Parity - number (range)</u> Intervention: 1 (1 to 4); control: 1 (1 to 2) <u>Primiparous - %</u> Intervention: 67; control: 54 <u>Infant birthweight (g) - mean (±SD)</u>	**Interventions** Intervention: Standard care plus telephone -based advisory support service performed by certified lactation consultant. Starting within the first week (~20min call) followed by a minimum of 8 follow-up calls (~5-10mins) during the first 6 months Control: Standard care (no details). All women had contact with a health visitor (paediatric nurse) who makes home visits during the first 18 months of the child's life. Setting: Hvidovre Hospital - not a Baby Friendly Hospital, but encourages and supports breastfeeding.	**Details** **Data collection** Baseline characteristics were collected from self-reported questionnaires filled in during the first trimester. Data were collected by blinded assessors at 1, 3 and 6 months. Unclear about the 1st and 3rd months but the 6th month data was collected in person. **Analysis** Taking into account a dropout rate of 20%, 200 dyads were required Post hoc, the authors stated that a total of 1570 dyads should have been included. Descriptive statistics, means and standard deviations (SDs) were calculated for all outcomes. For normally distributed data, independent Student's *t*-tests were used and the Mann-Whitney U test was used to compare medians for non-normally	**Results** Exclusive breastfeeding at 2 weeks*: Crude OR (95% CI), 2.40 (1.30 to 4.41) p=0.005 Exclusive breastfeeding at 3 months*: Crude OR (95% CI), 2.14 (1.23 to 3.74) p=0.007 Any breastfeeding at 6 months*: Crude OR (95% CI), 1.85 (1.06 to 3.21) p=0.03 - outcome reported in paper given as 'partial breastfeeding'. *numerators and denominators calculated by the NGA technical team.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Mothers assigned using a web based independent program) Allocation concealment: Some risk (not described) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
support on breastfeeding duration in obese women. **Study dates** December 2010 to June 2012. **Source of funding** Hvidovre Hospital, Copenhagen University, Johannes Fogs Fond, and Dagmar Marshals Fond.	Intervention: 3607 (633); control: 3716 (472) Gestational age (days) - mean (±SD) Intervention: 280 (10); control: 281 (9) Sex (male) - % Intervention: 50; control: 59 **Inclusion criteria** • Healthy infants born at term (>258 days of gestation) with a postnatal age of <48 hours; • Singleton pregnancies; • Women who intended to breastfeed and had no history of breast surgery; • Women who had participated in the 'Treatment of Obese Pregnant Study'. **Exclusion criteria** • Ill infants who required admission to		distributed data. Fisher's exact and chi-square tests were used to analyse differences between proportions. Binary logistic regression was used to calculate crude and adjusted odds ratios and 95% confidence intervals for breastfeeding in relation to random assignment at 3 and 7 days, and at 4 weeks and 3 months postnatally for exclusive breastfeeding, and also at 6 months for partial breastfeeding.		Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	a neonatal intensive care unit; • Infants suffering from congenital disease or malformations.				DOMAIN 3 – missing data Missing outcome data: Low risk (Data on breastfeeding were collected in 97% (105 of 108) of the intervention group and in 86% (102 of 118) in the control group) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (The intervention was blinded to the study staff, which collected data on breastfeeding status) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some concerns (Not all outcomes reported as per trial registration, however none

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					of the missing outcomes were relevant to this review question) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Exclusive breastfeeding defined according to WHO criteria of breastfeeding only supplemented with vitamins, mineral supplements, and water. Partial breastfeeding defined as breastfeeding supplemented with formula milk or solid food.
Full citation Caulfield L E , Gross SM, Bentley ME, Bronner Y, Kessler L, Jensen J, et al. , WIC-based interventions to promote breastfeeding among African-American women in Baltimore: effects on breastfeeding initiation and continuation. ,	**Sample size** N=548 enrolled N=425 at 34 weeks gestation N=123 at 7 to 10 days postpartum (n=114 lost to follow-up) N=242 analysed (intervention 1: n=64; intervention 2: n=55; intervention 3: n=66; control: n=57)	**Interventions** Intervention (1): Video played continuously in waiting area; posters, pamphlets and counselling from service provider. Largely a prenatal intervention. Intervention (2): Peer-counselling activities (one-to-one counselling, and group support sessions on infant feeding; peer counsellors	**Details** **Data collection** Women were interviewed at enrolment and at 34 weeks gestation about their infant feeding intentions. At 7 to 10 days postpartum, and infant feeding checklist and 24-hour recall were used to determine whether women had initiated breastfeeding and whether this was being continued. Women were	**Results** Breastfeeding initiation*: antenatal video and service provider counselling (n=64): 32 vs peer counselling (n=55): 34 vs video and peer counselling (n=66): 34 vs control (n=57): 15 Any breastfeeding at 7 to 10 days: antenatal video and service provider counselling (n=64)*: 20 vs peer counselling (n=55): 21 vs video and peer	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described; A cluster RCT with four treatment arms

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Journal of Human Lactation , 14, 15-22, 1998 **Ref Id** 996968 **Country/ies where the study was carried out** US **Study type** Cluster-RCT **Aim of the study** To compare the effects of different Women, Infants and Children (WIC) based interventions on breastfeeding initiation and continuation among African-American women in Baltimore. **Study dates** April 1992 to January 1994 **Source of funding**	**Characteristics** <u>Age (years) - number (%)</u> <18: video: 17 (27); peer counselling: 18 (33); video and peer counselling: 15 (23); control: 21 (37) 18-25: video: 34 (53); peer counselling: 22 (40); video and peer counselling: 35 (53); control: 23 (40) >25: video: 13 (20); peer counselling: 15 (27); video and peer counselling: 16 (24); control: 13 (23) <u>Parity - number (%)</u> 0: video: 31 (48); peer counselling: 11 (20); video and peer counselling: 21 (32); control: 13 (23) 1: video: 12 (19); peer counselling: 14 (25); video and peer counselling: 18 (27); control: 15 (26) >1: video: 21 (33); peer counselling: 30 (55); video and peer counselling: 27 (41); control: 29 (51) The authors stated that although characteristics of the women were comparable across the 4 clinics, there were differences in the evaluation by clinic (i.e. differences in parity, education and employment status before and during pregnancy).	followed up women interested in breastfeeding 3 or more times during pregnancy and then weekly to 16 weeks postpartum at the Women, Infants and Children (WIC) clinic, at home, or by telephone. All counsellors completed a 5-week training programme. Intervention (3): Video and peer counselling activities as per intervention 1+2. Control: Standard Women, Infant and Children infant-feeding education, including individualised encouragement and support, and written materials. Setting: 4 WIC clinics in Baltimore, US.	also interviewed at 4 and 16 weeks postpartum. All interviews were conducted by personnel trained in both in-person and telephone interview techniques, using unstructured, open-ended interviews. **Analysis** Contingency tables, including chi-squared tests, were used to analyse outcomes by treatment group. Differences in characteristics of the women were adjusted for in the analysis. Odds ratios (OR) and 95% confidence intervals (CI) were used to compare the likelihood of breastfeeding initiation and continuation at 7 to 10 days by women in treatment group compared to women in the control group. Women with missing data were not included in the analyses. Analysis of the characteristics of women who could and could not be followed up was undertaken.	counselling (n=66): 25 vs control (n=57): 8 *Numerators were not provided in the paper and were calculated by the NGA technical team based on the denominators and the percentages provided in the paper.	that were randomly assigned to four clinics) Allocation concealment: Low risk (Cluster RCT where each clinic was allocated a particular treatment at the same time) Baseline differences: High risk (some statistically significant differences across baseline characteristics) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Maternal and Child Health Bureau, Health Resources and Services Administration, Department of Health and Human Services.	**Inclusion criteria** • African-American women entering prenatal care before 24 weeks gestation; • Eligible to attend a WIC clinic; • Singleton pregnancy; • Planning to keep the baby and remain in the clinic's catchment area. **Exclusion criteria** • Women in whom breastfeeding contraindicated (e.g. HIV positive, taking specific medication).				DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (Use of cluster RCT was to 'minimise crossover and contamination between groups') Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: High risk (n=548 enrolled, data was available for n=242) **Judgement on risk of bias arising from missing outcome data: High risk** DOMAIN 4 – outcome measurement

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (no information provided) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Low risk** **Overall risk-of-bias judgement: Some concerns** **Other information** Women received a modest payment. The authors did not adjust for cluster design effect. ICC for breastfeeding

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					cessation from Lavender 2005 was used: ICC=0.01.
Full citation Chan, M. Y., Ip, W. Y., Choi, K. C., The effect of a self-efficacy-based educational programme on maternal breast feeding self-efficacy, breast feeding duration and exclusive breast feeding rates: A longitudinal study, Midwifery, 36, 92-98, 2016 **Ref Id** 805478 **Country/ies where the study was carried out** Hong Kong **Study type** RCT **Aim of the study** To assess the effectiveness of a self-efficacy-based breastfeeding educational programme	**Sample size** N randomised=71 Intervention: n randomised=35 Control: n randomised=36 Lost to follow-up: Intervention: n=2 discontinued; n=1 lost to follow-up. Control: n=4 discontinued; n=2 lost to follow-up. **Characteristics** Maternal age (years) - mean (±SD) Intervention: 32.6 (3.5); control: 31.4 (4.2) Monthly family income (HK$) - number (%) <$15,000: Intervention 8 (22.9); control: 13 (36.1) $15,001 to $25,000: Intervention: 16 (45.7); control: 15 (41.7) $25,001 or above: Intervention: 11 (31.4); control: 8 (22.2) Antenatal plan to breastfeed - number (%) ≤12 weeks: Intervention: 11 (31.4); control: 6 (16.6) 13 to 24 weeks: Intervention: 14 (40); control: 19 (52.8)	**Interventions** Intervention: standard care plus a 2.5-hour group breastfeeding workshop at 28–38 weeks of gestation involving a PowerPoint presentation, watching a DVD, discussions, using dolls and a breast model, and 30–60 minutes of telephone counselling at 2 weeks postpartum. Control: standard care (included breast feeding support provided by midwives in the hospital, access to a lactation consultant, and post-partum follow-up by midwives or doctors). Setting: Obstetric unit of university-affiliated public hospital in Hong Kong.	**Details** **Data collection** Data were collected at 5 time points (20 to 38 weeks of gestation/baseline at pregnancy, at 2, 4 and 8 weeks and at 6 months postpartum) using questionnaires, including the Breast Feeding Self-Efficacy Scale - Short Form (Chinese Hong Kong version) and a postpartum questionnaire relating to data on infant's condition after birth and breastfeeding. **Analysis** To achieve 80% power, accounting for an attrition rate of 25%, 35 women per treatment group were required. Data were analysed on an intention-to-treat basis. Missing data were imputed using the last observation carried forward method. Pearson's chi-squared test was used to compare proportions of exclusive breastfeeding at 2, 4, and 8	**Results** Initiation of breastfeeding: intervention (n=35): 29 vs control (n=36): 30 Any breastfeeding at 2 weeks*: intervention (n=35): 32 vs control (n=36): 28 Exclusive breastfeeding at 2 weeks: intervention (n=35): 14 vs control (n=36): 8 Any breastfeeding at 8 weeks*: intervention (n=35): 26 vs control (n=36): 22 Exclusive breastfeeding at 8 weeks: intervention (n=35): 11 vs control (n=36): 2 Any breastfeeding at 6 months*: intervention (n=35): 11 vs control (n=36): 6 *Calculated by the NGA technical team by summing exclusive breastfeeding and partial breastfeeding data.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (computer-generated random codes) Allocation concealment: Low risk (sequentially numbered opaque sealed envelopes) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
(SEBEP) on breastfeeding among mothers in Hong Kong. **Study dates** Not stated. **Source of funding** Association of Hong Kong Nursing Staff (AHKNS).	>24 weeks: Intervention: 10 (28.6); control: 11 (30.6) Infant's sex (male) - number (%) Intervention: 21 (60); control: 20 (55.6) Infants body weight at birth (g) - number (%) <2500: Intervention: 0; control: 0 2500 to 4000: Intervention: 34 (97.1); control: 36 (100) >4000: Intervention: 1 (2.9); control: 0 **Inclusion criteria** • Married women aged 18 years or older; • Primigravidas; • Normal breast and nipple examination results as recorded at the antenatal assessment; • No anticipated medical or pregnancy complications that contraindicate breastfeeding; • Able to understand and communicate in Chinese;		weeks ant 6 months postpartum.		Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Willing to participate. **Exclusion criteria** • Women who developed health complications postnatally (e.g. acute uterine inversion, post-partum haemorrhage or post-partum depression); • Infants were admitted to the neonatal intensive care unit; • Infants diagnosed with cleft palate; • Infants with low birth weight (<2500g); • Infants born prematurely (<37 weeks of gestation); • Non-Hong Kong Chinese residents; • No access to a telephone for follow-up.				DOMAIN 3 – missing data Missing outcome data: Low risk (3/35 (8.6%) in intervention group and 6 of 36 (16.7%) from control group did not provide outcome data) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Research assistant blinded to group allocation to assess duration of breastfeeding) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some riskOther information** Exclusive breastfeeding defined as infants receiving only breast milk, with no other liquid or solid food given to the infant. Expressed breast milk was included. Partial breast feeding defined as an infant receiving at least one bottle of artificial milk each day.
Full citation Chapman DJ, Damio G, Perez-Escamilla R., Differential response to breastfeeding peer counseling within a low-Income, predominantly Latina population., 2004 **Ref Id**	**Sample size** See other Chapman 2004 **Characteristics** See other Chapman 2004 **Inclusion criteria** See other Chapman 2004	**Interventions** See other Chapman 2004	**Details** See other Chapman 2004	**Results** See other Chapman 2004	**Limitations** See other Chapman 2004

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
1000581 **Country/ies where the study was carried out** See other Chapman 2004 **Study type** See other Chapman 2004 **Aim of the study** See other Chapman 2004 **Study dates** See other Chapman 2004 **Source of funding** See other Chapman 2004	**Exclusion criteria** See other Chapman 2004				
Full citation Chapman DJ, Damio G, Young S, Perez-Escamilla R., Effectiveness of breastfeeding peer	**Sample size** N randomised=219 Intervention: n randomised=113 Control: n randomised=106 Lost to follow-up:	**Interventions** Intervention: Standard care plus breastfeeding peer counselling services including at least 1 prenatal home visit, daily in-hospital perinatal visits, at least 3	**Details** **Data collection** Women were interviewed in English or Spanish and infant feeding data were collected at recruitment. During hospitalisation,	**Results** Initiation of breastfeeding*: intervention (n=90): 82 vs control (n=75): 58 Any breastfeeding at 3 months*: intervention (n=81): 36 vs control (n=72): 21	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
counseling in a low-income, predominantly Latina population., Archives of Pediatrics & Adolescent Medicine , 158, 897-902, 2004 **Ref Id** 1000582 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effectiveness of a breastfeeding peer counselling programme on breastfeeding among inner-city, low-income Latinas in the United States. **Study dates** July 2000 to August 2002.	Intervention: n=90 received intervention and included in breastfeeding initiation analysis; n=23 ineligible (NICU admission, relocation, HIV+, dropped out, miscellaneous). 1 month postpartum analysis: n=6 lost to follow-up; n=84 included in analysis. 3 months postpartum: n=9 lost to follow-up; n=81 included in analyses. 6 months postpartum: n=13 lost to follow-up; n=77 included in analyses. Control: n=75 served as controls and included in breastfeeding initiation analyses; n=31 ineligible (NICU admission, relocation, HIV+, miscellaneous). 1 month postpartum: n=2 lost to follow-up; n=73 included in analyses. 3 months postpartum: n=3 lost to follow-up; n=72 included in analyses. 6 months postpartum: n=8 lost to follow-up; n=67 included in analyses. **Characteristics** <u>Maternal age (years) - mean (±SD)</u> Intervention: 25.0 (5.6); control: 24.6 (6.2) <u>Parity - mean (±SD)</u> Intervention: 2.0 (1.2); control: 1.9 (1.1)	post-partum home visits, and participants could contact the peer counsellor by pager. Peer counsellors had 30 hours of classroom training. Free mini-electric breast pumps provided during postpartum home visits to those who need them. Control: routine breastfeeding education offered by the hospital including hands-on assistance, individualised education from maternity ward nurses, written breastfeeding materials, access to lactation consultant for serious problems and access to a nurse on the phone for breastfeeding questions. Setting: urban hospital serving a large population of low-income Latinas in Hartford, Conneticut.	women were interviewed regarding infant feeding methods, demographics, and sources of prenatal and perinatal breastfeeding education. Medical records were also reviewed, and women were interviewed via telephone on a monthly basis until breastfeeding was stopped and for a maximum of 6 months postpartum. **Analysis** Analyses were performed on an intention-to-treat basis. Between group differences were analysed using *t*-test (unpaired, 2-tailed) and chi-squared test. Results were reported as relative risk of not breastfeeding and 95% confidence intervals.	Any breastfeeding at 6 months: intervention vs control: RR 0.94 (95% CI 0.79 to 1.11) *Numerators calculated based on number of women not breastfeeding provided in the paper	Random sequence generation: Low risk (Randomised using computer software (SPSS)) Allocation concealment: Low risk (Allocation happened as a cohort, all in one go) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Funding for the peer counselling programme is provided by the University of Connecticut Family Nutrition Programme, through a grant from the US Department of Agriculture Food Stamp Family Nutrition Programme, and by Hartford Hospital. Funding for the study was received by Dr Perez-Escamilla from the Centres for Disease Control and Prevention, through a subcontract with the Association of Teachers of Preventive Medicine; Connecticut Family Nutrition Program for Infants, Toddlers, and Children; and the Hartford Hospital Research Foundation.	<u>Primiparous - %</u> Intervention: 42.2; control: 42.7 <u>Ethnicity - %</u> Hispanic: Intervention: 80.0; control: 80.0 African American: Intervention: 8.9; control: 8.0 White: Intervention: 3.3; control: 4.0 Other: Intervention: 7.8; control: 8.0 <u>Intended breastfeeding duration (months) - mean (±SD)</u> Intervention: 6.3 (3.8); control: 7.0 (4.8) <u>Infant birthweight (kg) - mean (±SD)</u> Intervention: 3.4 (0.4); control: 3.4 (0.4) **Inclusion criteria** • Women aged at least 18 years of age; • Women considering breastfeeding; • Resident of the greater Hartford area; • Available for telephone follow-up; • Low income (i.e. WIC participant, food				**intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (53% received a prenatal visit, 94% received a perinatal contact, 50% received postpartum home visit and 53% postpartum telephone calls. Mothers in the intervention group were asked if they discussed the study with other new mothers. It did not appear that any contamination between study groups occurred) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	stamp recipient, or household income <180% of federal poverty level; • No more than 26 weeks' gestation; • Not yet enrolled in the peer counselling programme; • Healthy, full-term singleton; • Absence of congenital anomalies; • No maternal history of HIV. **Exclusion criteria** • Infants admitted to the neonatal intensive care unit.				Missing outcome data: Some risk (77/113 (68.1%) of intervention and 67/106 (63%) of controls available for assessment at 6 month follow-up from initial randomised) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not explicit that assessors were blinded, but data related to peer counsellor contact were collected at the end of each interview) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** #Due to staff turnover, the programme was understaffed for approximately half of the study period; thus women received less than the specified number of visits. There was some limited, inadvertent exposure to peer counselling among women in the control group.
Full citation Chapman DJ, Morel K, Bermudez-Millan A, Young S, Damio G, Perez-Escamilla R. , Breastfeeding education and support trial for overweight and obese women: a randomized	**Sample size** N randomised=206 Intervention: n randomised=103 Control: n randomised=103 Lost to follow-up: Intervention: n=27 did not receive intervention (NICU/low birthweight, declined, breastfeeding contraindicated, relocated, miscellaneous).	**Interventions** Intervention: standard care plus specialised breastfeeding peer counselling (SBFPC) intervention promoting exclusive breastfeeding. Intervention included access to 3 prenatal visits, daily in-hospital visits after birth, and up to 11 postpartum home	**Details** **Data collection** Women were interviewed in Spanish or English. Prenatal demographics were collected at recruitment and a 36-week gestation telephone interview was conducted to assess previous breastfeeding experience,	**Results** Any breastfeeding at 2 weeks*: intervention (n=76): 71 vs control (n=78): 66. Adjusted odds ratio was presented for any breastfeeding at 2 weeks but this was not extracted for the present review. Exclusive breastfeeding at 2 weeks*: intervention (n=76): 16 vs control (n=78): 12	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
trial. , Pediatrics , 131, e162-e170, 2013 **Ref Id** 997186 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effects of a specialised breastfeeding peer counselling intervention on promoting exclusive breastfeeding among overweight or obese, low-income women. **Study dates** May 2006 to July 2009. **Source of funding** Partially supported by the Patrick and Catherine Weldon Donaghue Medical	N=76 received intervention; n=9 lost to follow-up. At 1 month: n=67 analysed; n=10 lost to follow-up. At 3 months: n=57 analysed; n=2 lost to follow-up. At 6 months: n=55 analysed. Control: n=25 did not receive intervention (NICU/low birthweight, declined, breastfeeding contraindicated, relocated, miscellaneous). N=78 received intervention; n=12 lost to follow-up. At 1 month: n=66 analysed; n=4 lost to follow-up. At 3 months: n=62 analysed; n=9 lost to follow-up. At 6 months: n=53 analysed. **Characteristics** Maternal age (years) - median (IQR) Intervention: 23 (21 to 28); control: 25 (22 to 31) Ethnicity - % Hispanic: Intervention: 80.3; control: 83.3 African American: Intervention: 13.2; control: 7.7 White: Intervention: 5.3; control: 5.1 Other: Intervention: 1.3; control: 3.8 Pre-pregnancy BMI - median (IQR)	visits from an SBFPC during the first 6 months post-partum. The SBFPCs received 50 hours of training and also shadowed experienced Peer Counsellors. Control: routine breastfeeding support from hospital personnel, including lactation consultants, able to call hospital's 'warm line', optional breastfeeding support from Breastfeeding : Heritage and Pride Peer Counsellors. Setting: Baby-Friendly Hospital in Hartford, Conneticut.	and intended breastfeeding duration. Within 24 hours postnatally, women were interviewed to collect data on infant feeding methods and peer counsellor contact. Medical records were reviewed. The Breastfeeding Self Efficacy scale was used to collected data on the day of birth and 2 weeks postpartum. Women were followed-up at 2 weeks and then monthly through 6 months postpartum to assess infant feeding methods, infant health outcomes, and peer counsellor contact. **Analysis** To achieve 80% power and allowing for an attrition rate of 35%, 103 women per intervention group were required. Data were analysed on an intention-to-treat basis. Baseline between group differences were analysed using chi-square tests, Student's *t*-tests (if normally distributed data) and Mann-Whitney *U* tests (if not normally distributed data). Logistic regression models were used to analyse	Exclusive breastfeeding at 3 months*: intervention (n=57): 3 vs control (n=62): 6 *Numerators calculated from percentages and denominators provided in the paper. For exclusive breastfeeding data, 'exclusive since birth' was extracted. Denominators at 2 weeks were not given so denominators of women with available data at the beginning of the study, as presented in figure 1, were used.	(Allocation using SPSS software) Allocation concealment: Low risk (Each week participants were allocated to their group) Baseline differences: High risk (The intervention group was significantly younger and differed in delivery mode, compared with controls) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Research Foundation and the National Centre on Minority Health and Health Disparities, National Institutes of Health EXPORT grant.	Intervention: 32.0 (29.3 to 37.0); control: 31.6 (28.5 to 34.9) Parity - median (IQR) Intervention: 2.0 (1 to 2); control: 2.0 (1 to 3) Receiving supplemental nutrition assistance programme - % Intervention: 40.8; control: 48.7 Infant birthweight (kg) - mean (±SD) Intervention: 3.5 (0.4); control: 3.4 (0.4) Infant gestation age (weeks) - mean (±SD) Intervention: 38.7 (3.8); control: 39.0 (1.2) Infant gender (male) - % Intervention: 40.8; control: 51.9 **Inclusion criteria** • Women considering breastfeeding; • Pre-pregnancy BMI ≥27.0 based on documented breastfeeding difficulties above this cut-of. • Women aged 18 years or older;		differences in breastfeeding outcomes, breastfeeding intensity, infant health outcomes, and amenorrhoea.		**(effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (Control participants had access to (and seeked) optional breastfeeding support) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (At 6 months 55/103 (53%) in the intervention and 53/103 (51%) in the control group were available for analysis) **Judgement on risk of bias arising from missing outcome data: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• ≤36 weeks of gestation; • Singleton pregnancy; • Absence of medical conditions interfering with breastfeeding; • Planning to remain in the area for 6 months postpartum; • Income <185% of the federal poverty level; • Access to a telephone. Postnatal inclusion criteria: • ≥36 weeks' gestation; • birthweight ≥2.5 kg and ≤3.9 kg; • 1 and 5 Apgar scores of ≥6; • No NICU admission. **Exclusion criteria** Not stated.				DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (interviewer collected peer contact data, but at the end of the interview) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (trial registry NCT available and all outcomes reported as intended) **Judgement on risk of bias arising from selection of the reporting result: Low risk** **Overall risk-of-bias judgement: Some risk** **Other information** Exclusive breastfeeding defined as infants not receiving water, formula,

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					juice, tea or any other solids/liquids.
Full citation Curro, V., Lanni, R., Scipione, F., Grimaldi, V., Mastroiacovo, P., Randomised controlled trial assessing the effectiveness of a booklet on the duration of breast feeding, Archives of Disease in Childhood, 76, 500-3; Discussion 503-4, 1997 **Ref Id** 985555 **Country/ies where the study was carried out** Italy **Study type** RCT **Aim of the study** To assess the effects of an information booklet on the duration of breastfeeding up to 6 months of age.	**Sample size** N randomised=200 Intervention: n randomised=103 Control: n randomised=97 No women were lost to follow-up. **Characteristics** <u>Maternal age (years) - %</u> <20: Intervention: 1.0; control: 0 20 to 24: Intervention: 14.5; control: 11.4 25 to 29: Intervention: 40.8; control: 43.3 30 to 34: Intervention: 36.9; control: 31.9 35 to 39: Intervention: 4.9; control: 12.4 ≥40: Intervention: 1.9; control: 1.0 <u>Infant's sex (male) - %</u> Intervention: 41.7; control: 50.6 <u>Birthweight (g) - median (IQR)</u> Intervention: 3300 (3100 to 3510); control: 3270 (3080 to 3540) <u>Birthweight (g) - %</u> 2500 to 2999: Intervention: 12.6; control: 15.5	**Interventions** Intervention: Booklet with instructions for practical breast feeding management and with information on advantages of exclusive breast feeding, particularly if prolonged for the first 6 months of life. This was additional to a 10-minutes verbal counselling session. Control: 10-minutes verbal counselling session only. Setting: Well baby outpatient clinic of the Paediatric Institute of the Catholic University of Rome, Italy.	**Details** **Data collection** Structured telephone interviews were conducted to assess infant feeding methods up to 6 months at approximately 7 months' postpartum. **Analysis** To achieve 80% power, 95 women per treatment group were required. Log rank test was used to compare outcome data. The probability of being still exclusive or complementary breastfed at each week of life was estimated using the Kaplan-Meyer method.	**Results** Any breastfeeding at 26 weeks (6 months)*: intervention (n=103): 59.2% vs control (n=97): 51.5% outcome defined as complimentary breastfeeding in paper. 82% of women in the intervention group found the booklet useful, 57% of control women reported that they would have been pleased to have available a specific booklet. *numerators calculated by the NGA technical team.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Some risk (not described) Baseline differences: Some risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates September 1993 to June 1994. **Source of funding** Supported by the Fondazione ASM per la Salute dell'Infanzia.	3000 to 3499: Intervention: 60.2; control: 55.7 ≥3500: Intervention: 27.2; control: 28.8 Gestational age (weeks) - median (IQR) Intervention: 40 (39 to 42); control: 40 (39 to 42) Gestational age (weeks) - % <37: Intervention: 3.9; control: 4.1 ≥37: Intervention: 96.1; control: 95.9 **Inclusion criteria** • Primiparous women; • Infant with a birthweight of 2500 g and without any major problem; • Currently exclusively breastfeeding; • Fluent in Italian. Eligible mothers were those who gave birth in 11 hospitals and clinics (private and public) in Rome. **Exclusion criteria** Not stated.				interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (no mothers received commercial discharge packs) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (no women were lost to follow up)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from missing outcome data: Low risk DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (interviewer was unaware of the treatment status of the study mothers up to the final question about the booklet) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Overall risk-of-bias judgement: Some risk **Other information** Exclusive breastfeeding defined as infant receiving only breast milk; water or water based drinks and medicines were allowed. Complementary breastfeeding defined as having given any breast milk and any food or liquid including non-human milk.
Full citation Dennis CL., Breastfeeding peer support: maternal and volunteer perceptions from a randomised controlled trial. , Birth, 29, 169-76, 2002 **Ref Id** 997181 **Country/ies where the study was carried out** Canada **Study type** See Dennis 2002	**Sample size** See Dennis 2002 **Characteristics** See Dennis 2002 **Inclusion criteria** See Dennis 2002 **Exclusion criteria** See Dennis 2002	**Interventions** See Dennis 2002	**Details** See Dennis 2002	**Results** See Dennis 2002	**Limitations** See Dennis 2002

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study See Dennis 2002 **Study dates** See Dennis 2002 **Source of funding** See Dennis 2002					
Full citation Dennis CL, Hodnett E , Gallop R, Chalmers B. , The effect of peer support on breastfeeding duration among primiparous women: a randomized controlled trial. , Canadian Medical Association Journal , 166, 21-8, 2002 **Ref Id** 997131 **Country/ies where the study was carried out** Canada **Study type**	**Sample size** N=258 Intervention: n=132 Control: n=126 Lost to follow-up: Intervention: n=0 lost to follow-up. Control: n=2 lost to follow-up; n=124 completed trial. **Characteristics** <u>Maternal age - number (%)</u> 16 to 24: Intervention: 19 (14.4); control: 16 (12.9) 25 to 34: Intervention: 99 (75.0); control: 92 (74.2) ≥35: Intervention: 14 (10.6); control: 16 (12.9) Annual household income ($) - number (%) ≤39999: 23 (18.5); control: 18 (15.5)	**Interventions** Intervention: Standard care, plus women were paired to a peer volunteer. Peer volunteers contacted the mother 48hrs after hospital discharge and as frequently thereafter as the mother deemed necessary. Control: Standard care – access to conventional in-hospital and community postpartum support services such as those provided by hospital-based nursing and medical staff, a hospital-based breast-feeding clinic managed by lactation consultants, a telephone breast-feeding support line managed by hospital nursing staff, and support services provided by public health nurses at the local regional	**Details** **Data collection** Questionnaires were completed before randomisation (questions on demographics and hospital variables), and at 4, 8 and 12 weeks postpartum (questions on infant feeding methods, breastfeeding problems, health services utilisation, and perceptions of peer support). **Analysis** To achieve 90% power, 252 women were required. Data were analysed on an intention-to-treat basis. The Pearson chi-squared test (supplemented, where necessary, by the Fisher Exact test) was used to	**Results** Any breastfeeding at 12 week: intervention (n=132): 107 vs control (n=124): 83 Exclusive breastfeeding at 12 week: intervention (n=132): 75 vs control (n=124): 50 Mean maternal satisfaction questionnaire score: intervention (n=132): 53.81 vs control (n=124): 52.98 p=0.73	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (randomly generated numbers from a statistician not involved in recruitment) Allocation concealment: Low risk (consecutively numbered, sealed, opaque envelopes) Baseline differences: High risk (significantly more mothers in the intervention group had decided to breast-feed before

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
RCT **Aim of the study** To assess the effect of peer (mother-to-mother) support on breastfeeding duration among first-time breastfeeding mothers. **Study dates** September 1997 to June 1998. **Source of funding** Supported by the University of Toronto Faculty of Nursing and Maternal, Infant, and Reproductive Health Research Unit.	40000 to 79999: Intervention: 52 (41.9); control: 49 (42.2) ≥80000: Intervention: 49 (39.5); control: 49 (42.2) **Inclusion criteria** • In-hospital, primiparous, breastfeeding women; • Aged at least 16 years of age; • Able to speak English; • Singleton birth at 37 weeks' gestation or later; • Resided in the surrounding region accessible by a local telephone call. **Exclusion criteria** • Women with conditions that could significantly interfere with breastfeeding (e.g. serious maternal illness, infant congenital	community health department and by community-based physicians and paediatricians. Setting: 2 semi-urban community hospitals near Toronto, Canada.	analyse between group differences for categorical data; independent 2-sample *t*-tests were used to analyse data at the interval level of measurement. Pearson's correlations were used to examine the relation between the frequency of peer volunteer contacts and the infant feeding category. To assess the relation between the frequency of peer volunteer contracts and the perception of peer support with the experimental group, Spearman's rank order correlation coefficients were calculated. Relative risks (RRs) and corresponding 95% confidence intervals were estimated.		pregnancy (73.5%) compared to those in the control group (58.9%)) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (Women in the intervention group received the intervention, but not described whether women

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	abnormality or an infant in the special care nursery who would not be discharged home with the mother); • Women had enrolled prenatally with the participating volunteer breastfeeding organisation.				in the control received the intervention) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (2/126 from the control group were lost to follow-up, none in the intervention arm) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Blinding of outcome assessors: Low risk (assessor blinded to allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement:** **Other information** Exclusive breastfeeding defined as breast milk only; almost exclusive (breast milk and other fluids (e.g. vitamins) but not formula); high (breast milk and less than 1 bottle of formula per day); partial (breast milk and at least 1 bottle of formula per day); token (breast given to comfort baby, not for nutrition);

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					bottle-feeding (no breast milk).
Full citation Duffy EP, Percival P, Kershaw E. , Positive effects of an antenatal group teaching session on postnatal nipple pain, nipple trauma and breast feeding rates., Midwifery , 13, 189–96, 1997 **Ref Id** 997025 **Country/ies where the study was carried out** Western Australia **Study type** RCT **Aim of the study** To 'assess whether an antenatal teaching session on position and attachment of the baby on the breast had an effect on postnatal nipple pain, nipple	**Sample size** N=75 Intervention: n=37 Control: n=38 Losses to follow-up were due to exclusions: Intervention group: 2 women informed the observer-blind researcher of their group allocation Control group: 1 woman had a stillbirth, 1 a baby with congenital abnormalities, 1 was advised to discontinue due to a positive Hepatitis C result. **Characteristics** <u>Age (years) - mean (±SD)</u> Intervention: 24.5 (error in reported SD – reported as 44) vs control: 26.0 (4.7) 70% of women had a low family income. Range of educational levels from 3 years of high school to undergraduate degree. No statistically significant differences in baseline characteristics between groups.	**Interventions** Intervention: standard care plus 1-hr antenatal group session on position and attachment of the baby on the breast by lactation consultant. Control: Standard educational programme of the study hospital. Setting: one public hospital in Perth, Western Australia.	**Details** **Data collection** The LATCH instrument (Latch on, Audible swallow, Type of nipple, Comfort and Help) was used to measure position and attachment of the baby on the breast (scored from 0 to 2 with range of 0 to 10 at the end of each day). Nipple pain was measured using the Visual Analogue Scale (VAS) (scored from 0 to 10, with 0 representing 'no pain' and 10 representing ' pain as bad as it could possibly be'. The Nipple Trauma Index (NTI) was used to measure nipple trauma (nipple status, discharge and mother's assessment of her nipples) (scored from 0 to 34 with higher scores indicating less nipple trauma). Observations were made during the first 4 postnatal days, mainly in the hospital setting. Women discharged before the fourth postnatal day were visited at home by the researchers. In addition,	**Results** Any breastfeeding at 6 weeks: intervention (n=35): 32 vs control (n=35): 10; p<0.001	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 Random sequence generation: Some risk (not described; only details provided: randomisation was achieved using blocks of 12, 6 per group, as the intervention required 6 participants) Allocation concealment: Some risk (sealed envelope, not described if it was opaque or not) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
trauma and breast feeding duration'. **Study dates** Women who attended the antenatal clinic during August 1995. **Source of funding** Not stated.	**Inclusion criteria** • Primiparous women >36 weeks pregnant; • Intention to breastfeed. **Exclusion criteria** • Babies born before 37 weeks gestation; • Babies with medical complications.		demographic and obstetric data were collected using a questionnaire at 24 hours, 4 days and 6 weeks postnatally. **Analysis** Data were analysed using analysis of variance (ANOVA) with repeated measures and the chi-squared test.		Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions(effect of assignment to intervention): High risk** Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low Risk** DOMAIN 3

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Missing outcome data: Low risk (losses to follow-up due to post-randomisation exclusions were 6.6% (5/75)) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (blinded) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 Selective reporting: Some risk (no information on trial registration) **Judgement on risk of bias arising from selective reporting: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Overall risk-of-bias judgement: Some concerns **Other information** Random assignment was undertaken by the lactation consultant giving the education sessions. The study was planned as a pilot study to allow an adequate sample size to be calculated for a larger study. However this is not taken into account for the risk of bias assessment to avoid double-counting
Full citation Edwards C, Thullen J, Korfmacher J, Lantos D, Henson G, Hans L., Breastfeeding and complementary food: randomized trial of community doula home visiting. , Pediatrics , 132, S160-6, 2013 **Ref Id** 997192 **Country/ies where the study was carried out**	**Sample size** N randomised=248 Intervention: n randomised=124 Control: n randomised=124 Lost to follow-up: Intervention: n=123 received intervention; n=1 refused to participate. At follow-up, n=1 lost to follow-up; n=1 infant died; n=122 analysed. At 4 months, n=14 lost to follow-up; n=13 unable to locate; n=1 infant died. n=108 analysed. Control: n=124 received control. At follow-up, n=1 lost to follow-up, n=1 infant died, n=123 analysed. At 4 months,	**Interventions** Intervention: standard care plus support from a doula. Doulas visited women at home weekly in the antenatal period, were present during birth and encouraged first latching after birth. Doulas visited during the first 3 months postpartum (average 10-12 home visits) and were available by phone 24hrs. Doulas provided breast pumps for women who were returning to work or school. Control: Standard care (no details).	**Details** **Data collection** Data on breastfeeding attempts were collected by research staff through interviews with mothers and chart review. At 4 months postpartum, mothers participated in an interview on topics such as health, feeding practices, and parenting. **Analysis** Data were analysed on an intention-to-treat basis. Data were analysed on an intention-to-treat basis.	**Results** Attempted breastfeeding: intervention (n=122): 78 vs control (n=123): 61 Breastfed for more than 6 weeks: intervention (n=108): 31 vs control (n=113): 19 Breastfed for more than 4 months: intervention (n=108): 9 vs control (n=113): 5	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Randomisation took place in blocks of 4, 6, or 8, with equal numbers assigned to the intervention and control groups within each block, prepared by a biostatistician)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
US **Study type** RCT **Aim of the study** To assess the effects of a Community doula home visiting intervention on infant feeding practices among low-income, African American mothers. **Study dates** January 2001 to April 2004. **Source of funding** Maternal and Child Health Bureau Research Programme, Irving B Harris Foundation, the Blowitz-Ridgeway Foundation, the Prince Charitable Trusts, the Visiting Nurses Association Foundation, and the	n=10 lost to follow-up, n=10 unable to locate, n=113 analysed. **Characteristics** Maternal age (years) - mean (±SD) Intervention: 18.2 (1.7); control: 17.9 (1.7) Gestational age at enrolment (weeks) - mean (±SD) Intervention: 23.3 (4.6); control: 23.8 (5.3) Expecting first child - number (%) Intervention: 110 (88.7); control: 109 (87.9) Considering breastfeeding at enrolment - number (%) Intervention: 82 (66.1); control: 72 (58.1) **Inclusion criteria** • Women <34 weeks pregnant; • Aged under 21 years of age; • Planning to give birth at the affiliated hospital.	Setting: community health centre and prenatal clinic affiliated with an urban university hospital.	Chi-square test were used to assess between group differences in attempted breastfeeding at the hospital, breastfeeding duration, and timing of cereal/solid food introduction.		Allocation concealment: Low risk (opaque envelopes opened with the mother) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Michael Reese Health Trust.	**Exclusion criteria** • Women who were aware at the time or recruitment that they would require a surgical birth; • Women planning to move from the area; • Women who planned to give up custody of the infant.				DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (108/123 of the intervention and 113/124 of control reported 4 month outcome data) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (Data not reported for all outcomes, but these outcomes are not relevant to our review question) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Efrat M W, Esparza S, Mendelson SG, Lane CJ. , The effect of lactation educators implementing a	**Sample size** N=289 Intervention: n=146 Control: n=143 Lost to follow-up: Intervention: lost to follow-up (n=18); disenrolled (n=10). At	**Interventions** Intervention: standard care plus 4 prenatal and 17 postpartum phone calls with a lactation educator until 6 months after birth. Lactation	**Details** **Data collection** Questionnaires via telephone were conducted to collect data at baseline, including data on sociodemographics and	**Results** Any breastfeeding at 3 days: intervention (n=76): 76 vs control (n=76): 75	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
telephone-based intervention among low-income Hispanics: a randomised trial. , Health Education Journal , 74, 424–41, 2015 **Ref Id** 997133 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effect of a telephone-based intervention provided by lactation educators on exclusive breastfeeding among low-income Hispanic women in the US. **Study dates** July 2011 to July 2012.	72 hours: n=118; lost to follow-up (n=0); disenrolled (n=15). At 1 month: n=103; lost to follow-up (n=11); disenrolled (n=16). At 3 months: n=76; lost to follow-up (n=2); disentrolled (n=3). At 6 months: n=71. Control: lost to follow-up (n=14); disenrolled (n=10). At 72 hours: n=119; lost to follow-up (n=0); disenrolled (n=20). At 1 month: n=99; lost to follow-up (n=8); disenrolled (n=9). At 3 months: n=82; lost to follow-up (n=10); disenrolled (n=3). At 6 months: n=69. **Characteristics** <u>Maternal age (years) - mean (±SD)</u> Intervention (n=111): 27.8 (5.8); control (n=109): 27.1 (6.3) <u>Intention to breastfeed at baseline (average) - mean (±SD)</u> Intervention (n=111): 4.3 (1.2); control (n=109): 3.8 (1.5) <u>Parity - number (%)</u> 0: Intervention: 1 (1.3); control: 2 (2.7) 1: Intervention: 40 (50.6); control: 34 (45.3) 2: Intervention: 26 (32.9); control: 25 (33.3)	educators' phone number available to the mothers. Control: Standard care – including routine breastfeeding education and support offered by the local health corporation. Setting: 5 community health clinics in Los Angeles County (US) serving low-income, Hispanic women.	breastfeeding intentions. Data on breastfeeding intervention were collected at 72 hours, 1, 3 and 6 months. **Analysis** Data were analysed on an intention-to-treat basis. For continuous outcomes, between group comparisons (means for normally distributed data and medians for non-normally distributed data) were analysed using the independent *t*-test or Mann-Whitney *U* tests. Categorical outcomes were compared using chi-square tests, Fisher's exact if there were 2 categories and Pearson's chi-square if there were more than 3 categories. Fisher's exact chi-square test was used to test the difference in breastfeeding initiation rates at 72 hours. Breastfeeding status was examined using longitudinal generalised linear models to compare rates across 6 months. Odds ratios were estimated for each time and across 6 months.	Exclusive breastfeeding at 3 days: intervention (n=76): 28 vs control (n=76): 29 Any breastfeeding at 3 months: intervention (n=55): 54 vs control (n=56): 53 Exclusive breastfeeding at 3 months: intervention (n=55): 17 vs control (n=56): 13 Any breastfeeding at 6 months: intervention (n=54): 51 vs control (n=49): 42	Random sequence generation: Low risk (Computer randomised software, blocked by weeks of recruitment) Allocation concealment: Some risk (not described) Baseline differences: High risk (significantly higher proportion of women in the intervention group intended to breastfeed than in the control group) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Centres for Medicare and Medicaid Services, USDA/NIFA Hispanic-Serving Institutions (HIS) Education Grants Programme, NIH Research Infrastructure in Minority Institutions (RIMI) from the National Institute of Minority Health and Health Disparities, P20 MD003938, NIH Minority Biomedical Research Support Research Initiative for Scientific Enhancement and California State University Sponsored Projects.	3: Intervention: 7 (8.9); control: 9 (12.0) 4: Intervention: 4 (5.1); control: 4 (5.3) 5: Intervention: 0; control: 1 (1.3) 6: Intervention: 1 (1.3); control: 0 Full term baby - number (%) Intervention: 79 (91.9); control: 85 (94.4) NICU - number (%) Intervention: 7 (8.1); control: 11 (12.4) Breastfed at hospital - number (%) Intervention: 76 (98.7); control: 79 (98.8) *1 baby in the control group reported to have birth defects. **Inclusion criteria** • Women 26 to 34 weeks pregnant; • Medicaid recipient; • Self-identified Hispanic; • Available via telephone; • Not assigned to a WIC peer counsellor. Postpartum inclusion criteria:				**intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (From those who reported 72hr data and were not disenrolled based on exclusion criteria, 69/119 (58%) in the intervention and 71/118 (60%) in the control were

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Birth of healthy, singleton pregnancy; • Absence of congenital abnormality; • Infant not admitted to a neonatal intensive care unity. **Exclusion criteria** Not stated.				still active in the study at 6 months) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: High risk (not blinded) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Other information Exclusive breastfeeding defined as baby only fed breast milk (no water, formula, folk remedies or other foods received by babies). Not exclusive breastfeeding defined as baby breastfeed at least once since birth, but baby also received water, formula, folk remedies or another food.
Full citation Ekstrom, A., Kylberg, E., Nissen, E., A Process-Oriented Breastfeeding Training Program for Healthcare Professionals to Promote Breastfeeding: An Intervention Study, Breastfeeding Medicine, 7, 85-92, 2012 **Ref Id** 694540 **Country/ies where the study was carried out** Sweden **Study type**	**Sample size** See Ekstrom 2006. **Characteristics** See Ekstrom 2006. **Inclusion criteria** See Ekstrom 2006. **Exclusion criteria** See Ekstrom 2006.	**Interventions** See Ekstrom 2006.	**Details** See Ekstrom 2006.	**Results** See Ekstrom 2006.	**Limitations** See Ekstrom 2006.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Cluster-RCT **Aim of the study** See Ekstrom 2006. **Study dates** See Ekstrom 2006. **Source of funding** See Ekstrom 2006.					
Full citation Ekstrom A, Widstrom AM, Nissen E ., Does continuity of care by well-trained breastfeeding counselors improve a mother's perception of support?, Birth, 33, 123-30, 2006 **Ref Id** 1000586 **Country/ies where the study was carried out** Sweden	**Sample size** N=540 Intervention: n=206 Control A: n=162 Control B: n=172 Lost to follow-up (Ekstrom 2012): Intervention: 1 and 3 days postpartum: n=206; response rate (n=172). 2 and 3 months: response rate (n=145). 3 and 9 months: response rate (n=131). Control A: 1 and 3 days postpartum: n=162; response rate (n=148). 2 and 3 months: response rate (n=126). 3 and 9 months: response rate (n=116).	**Interventions** Intervention: Additional training at the centre - a process-oriented training in breastfeeding counselling and continuity of care at the antenatal and child health centre. Control A: Standard care – included attending family classes. Control B: Second control group with differing data collection time points. Setting: 10 municipalities, each with an antenatal centre and child health centre, in southwest Sweden.	**Details** **Data collection** Data collected using 3 questionnaires (relating to family classes and encounters with midwives and postnatal nurse) at 3 days, and 3 and 9 months postpartum. Data were also collected from birth records. **Analysis** Questionnaires (Likert scales: 1=disagree completely to 7=agree completely) were recoded to obtain all positive assessments at the higher endpoint. One-way analyses of variances were used to test between group	**Results** Breastfeeding initiation*: intervention (n=172): 172 or 100% vs control A (n=148): 144 or 97% vs control B (n=160): 155 or 97% *Numerators calculated by the NGA technical team based on denominators and percentages provided in the paper. For use in analysis, data were adjusted for clustering effect of study design by the NGA technical team. **At 3 days postpartum** Satisfied with knowing 'where to ask if any problems with	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Low risk (not described, but as cluster RCT likely to be low) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Cluster-RCT **Aim of the study** To assess the effects of continued care by well-trained breastfeeding counsellors on mother's perceptions of care and breastfeeding support. **Study dates** April 2000 to June 2002. **Source of funding** Supported by Skaraborg Institute for Research and Development, School of Life Sciences of the University of Skovde, the Primary Care Unit in Skaraborg and the Science Committee, Central Hospital, Skovde, and the Board of Research for Health and Caring Sciences, Swedish Research Council.	Control B: 1 and 3 days postpartum: n=172; response rate (n=160). 2 and 3 months: response rate (n=132). 3 and 9 months: response rate (n=125). **Characteristics** <u>Maternal age (years)* - mean (±SD)</u> Intervention: 26.6 (4.5); control A: 27.2 (4.6); control B: 27.0 (5.0) <u>Gestational age (weeks)* - mean (±SD)</u> Intervention: 40.4 (1.4); control A: 40.5 (1.4); control B: 40.4 (1.4) *Data from Ekstrom 2006. **Inclusion criteria** • Swedish speaking mothers; • Singleton births; • Healthy, full-term babies delivered spontaneously, by vacuum extraction, or by caesarean section.		differences. Tukey's HSD test was used for post hoc comparisons. Categorical data were analysed using chi-square tests. Continuous data were presented as means and standard deviations (SD).	baby or breastfeeding' mean (±SD): intervention (n=143): 5.45 (1.69) vs control A (n=135): 5.04 (1.93) vs control B (n=149): 5.33 (1.65) Satisfied with 'breastfeeding information' mean (±SD): intervention (n=143): 5.08 (1.63) vs control A (n=133): 4.51 (1.83) vs control B (n=148): 4.53 (1.80) **At 3 months postpartum** Satisfied with knowing 'where to ask if any problems with baby or breastfeeding' mean (±SD): intervention (n=116): 5.51 (1.61) vs control A (n=55): 5.35 (1.58) vs control B (n=76): 4.94 (1.87) Satisfied with 'breastfeeding information' mean (±SD): intervention (n=116): 4.86 (1.73) vs control A (n=55): 4.64 (1.80) vs control B (n=76): 4.09 (1.89)	**Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: Low risk (Women did not know if their healthcare professional had taken part in the training) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): Some risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (no details given, however based on study design of cluster RCT and the intervention given to the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria • Babies with life-threatening diseases or malformations.				Healthcare professionals, unlikely to have occurred) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (145/172 (84%) in the intervention group and 126/148 (85%) in Control A and 132/160 (83%) of Control B provided 3 month data) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Low risk** **Other information** The authors did not adjust for cluster design effect. ICC for breastfeeding cessation from Lavender 2005 was used: ICC = 0.01. Ekstrom (2012): Exclusive breastfeeding defined as

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					breastfeeding with occasional use of water, breastmilk substitutes (not more than a few times, and/or solids (not more than 1 tablespoon per day). Partial breastfeeding was defined as infants receiving breastmilk and breastmilk substitutes (every day) and/or solids (more than 1 tablespoon per day).
Full citation Elliott-Rudder M, Pilotto L, McIntyre E, Ramanathan S. , Motivational interviewing improves exclusive breastfeeding in an Australian randomised controlled trial. , Acta Paediatrica , 103, e11–6, 2014 **Ref Id** 997040 **Country/ies where the study was carried out** Australia **Study type** Cluster-RCT	**Sample size** N randomised=330 (15 clusters) Intervention: n=154 (8 clusters) Control: n=176 (7 clusters) For the 6-month outcome assessment, data were available for n=150 in the intervention group and n=172 in the control group. **Characteristics** <u>Maternal age - number (%)</u> <20: Intervention: 2 (1); control: 4 (2) 20-29: 67 (44); control: 55 (32) 30-39: Intervention: 79 (52); control: 107 (62) >39: Intervention: 5 (3); control: 6 (4)	**Interventions** Intervention: a structured conversation to support continuation of breastfeeding following a Conversation Tool flowchart that used a motivational interviewing approach. Control: standard care from nurses who had not received WHO breastfeeding support training and who commonly asked whether the woman had any problems. Setting: rural family doctor's practices.	**Details** **Data collection** Birth data were collected from medical records. Outcome data were collected through telephone interview at 4 and 6 months. **Analysis** To achieve 80% power, allowing for 10% clustering, 278 women were required. Data were analysed on an intention-to-treat basis to enable adjustment for clustering. Pearson chi-square tests were used to analyse whether potentially confounding variables were distributed equally across treatment groups. Logistic regression analysis was	**Results** Any breastfeeding at 6 months: intervention (n=150): 118 vs control (n=172): 135 Data were adjusted for clustering effect by NGA technical team.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Computer randomised) Allocation concealment: Low risk (Cluster RCT design) Baseline differences: High risk (Planning for maternal employment or study was higher 70% in the intervention group compared to the control group 56%)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess the effects of a motivational interviewing approach on breastfeeding rates in a rural family practice setting. **Study dates** August 2008 to October 2009. **Source of funding** University of New South Wales PhD scholarship for one author. No other funding.	Low family income - number (%) Intervention: 16 (10); control: 19 (14) First baby - number (%) Intervention: 58 (33); control: 60 (39) Birthweight (g) (<2500g) - number (%) Intervention: 2 (1); control: 6 (3) Gestation <40 weeks - number (%) Intervention: 71 (46); control: 85 (44) Feeding plans noted during pregnancy - number (%) Duration of breastfeeding >6 months: Intervention: 83 (54); control: 105 (60) **Inclusion criteria** • Pregnant women registered to give birth at one of the three local hospitals; • Planned to have postnatal care at a participating general practice; • 24 to 36 weeks of pregnancy;		adjusted for confounding variables where there was significantly unequal distribution.		**Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details on adherence but based on cluster RCT design, cross over unlikely) Analysis of participants in the group to which they were randomised: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Continued breastfeeding to at least 8 weeks. **Exclusion criteria** Not stated.				(analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (150/154 in the intervention and 172/176 provided 6 month outcome data) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (assessors blinded to group assignment) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					measurement of the outcome: Low risk DOMAIN 5 – reporting Selective reporting: Some risk (Data not reported for all outcomes, but these outcomes are not relevant to our review question) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** The authors did not adjust for cluster design effect. ICC for breastfeeding cessation from Lavender 2005 was used: ICC = 0.01. Exclusive breastfeeding permits medicines but no breast-milk substitutes. Full (or predominant) breastfeeding permits partial substitution with water-based fluids. Any breastfeeding permits partial substitution with

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					infant formula, other fluids, or solid foods.
Full citation Finch C, Daniel EL., Breastfeeding education program with incentives increases exclusive breastfeeding among urban WIC participants., Journal of the American Dietetic Association, 102, 981-4, 2002 **Ref Id** 1000588 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effects of intensive breastfeeding education and incentives on initiation and continuation of breastfeeding among urban Women, Infant	**Sample size** N=60 (intervention: n=30; control: n=30) At 2 months follow-up: intervention: n=19 (11 women lost to follow-up: 3 miscarriage or infant death; 1 due to participant relocation; 7 missing appointments and not attending intervention); control: 29 (1 woman lost to follow-up due to miscarriage). **Characteristics** <u>Age (years) - number (%)</u> <16: Intervention: 2 (11); control: 2 (7) 16-18: Intervention: 6 (32); control: 5 (17) 19-24: Intervention: 7 (37); control: 19 (66) ≥25: Intervention: 4 (21); control: 3 (10) <u>Race - number (%)</u> African-American: Intervention: 15 (79); control: 17 (59) Hispanic: Intervention: 3 (16); control: 11 (38) White: Intervention: 1 (5); control: 1 (3) <u>Breastfeeding - number (%)</u>	**Interventions** Intervention: breastfeeding education by a trained counsellor plus small group 'truth or myth' activity, followed by discussion and hand-outs. Control: usual prenatal education regarding general benefits and barriers to breastfeeding. Women in both groups were offered educational materials and support. Setting: urban WIC programme in western New York serving a mostly minority population with the highest poverty level in the city.	**Details** **Data collection** Data collected through questionnaires, interviews, and patient records. Data on knowledge, perceptions, attitudes, and breastfeeding intentions before and after breastfeeding education were obtained using questionnaires, which included an open-ended question. **Analysis** Between group differences were analysed using the chi-squared test.	**Results** Breastfeeding initiation: intervention (n=19): 15 vs control (n=29): 20* *Numerators calculated by the NGA technical team based on denominators and percentages provided in the paper.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Some risk (not described) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: Some risk (not described)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
and Children (WIC) participants. **Study dates** Not stated. **Source of funding** Not stated.	Exclusive*: Intervention: 9 (47); control: 5 (17) Partial*: Intervention: 6 (32); control: 15 (52) None: Intervention: 4 (21); control: 9 (31) *Exclusively breastfeeding participants did not receive formula from the WIC programme during the study. Partially breastfeeding participants received formula in addition to breastfeeding. **Inclusion criteria** • Pregnant, English speaking women; • HIV negative **Exclusion criteria** Not stated.				Blinding of carers and people delivering the interventions: Some risk (not described)) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): Some risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (6/30 (20%) in treatment arm did not attend intervention session) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Missing outcome data: High risk (11/30 (37%) in the treatment arm and 1/30 (3%) in the control arm were lost to follow up / not included in the follow-up data collection) **Judgement on risk of bias arising from missing outcome data: High risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					selection of the reporting result: Some risk **Overall risk-of-bias judgement: High concerns** **Other information** *Eligibility for enhanced food package (valued at $50 per month) and extended programme was offered to women who breastfed exclusively, or did not receive formula. Mothers who breastfed exclusively for at least 2 months were also eligible to receive a $25 gift certificate.
Full citation Forster D, McLachlan H, L umley J, Beanland C, Waldenstrom U, Amir L. , Two mid-pregnancy interventions to increase the initiation and duration of breastfeeding: a randomized controlled trial. , Birth, 31, 176-82, 2004	**Sample size** N randomised=984 • Intervention 1 (practical skills): n randomised=327 • Intervention 2 (attitudes): n randomised=329 • Standard care: n randomised=328 Information on attrition and crossovers: Practical skills intervention: 327 randomised, 324 births, 308 at 1st interview, 297 at 6-month interview. 213 received	**Interventions** Intervention (1): Single 1.5hr session focused on practical breastfeeding skills, using teaching aids (partners not included). Access to standard care options. Intervention (2): Two 1-hr sessions that focused on changing attitudes to breastfeeding (partners or significant others were encouraged to attend).	**Details** **Data collection** Data were collected at recruitment using questionnaires. Primary and secondary outcome data were collected through interviews in hospital postnatally (or by telephone if the woman had been discharged) and by telephone at 6 months, using structured questionnaires. Research	**Results** Any breastfeeding at 2-4 days*: practical skills (n=306): 296 vs attitudes (n=308): 291 vs standard care (n=310): 297 Any breastfeeding at 6 months*: practical skills (n=297): 162 vs attitudes (n=293): 146 vs standard care (n=299): 162 Women's satisfaction with intervention - variables below, only based on who attended, median score based on Likert-	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (a computerised system of biased urn randomisation was used)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 996972 **Country/ies where the study was carried out** Australia **Study type** RCT **Aim of the study** To 'determine the influence of mid-pregnancy breastfeeding education, with a focus on attitudes to breastfeeding or on technical aspects of breastfeeding, on the proportions of women breastfeeding at hospital discharge, and on the duration of breastfeeding (primary outcomes)'. **Study dates** Women booking to have a baby at the hospital	the intervention. Reasons for losses to follow-up: 20 could not be contacted, 1 miscarriage, 2 terminations, 2 withdrawals, 3 stillbirths, 1 infant with severe morbidity, 1 seriously ill mother. Attitudes intervention: 329 randomised; 2 randomisation errors, 324 births, 312 at 1st interview, 293 at 6-month interview. 190 women received the first class, 132 received the second class. Reasons for losses to follow-up: 23 could not be contacted, 5 neonatal deaths, 1 withdrawal, 3 stillbirths, 2 terminations. Standard care: 328 randomised; 1 randomisation error, 322 births, 313 at 1st interview, 299 at 6-month interview. Reasons for losses to follow-up: 21 could not be contacted, 1 miscarriage, 1 withdrawal, 3 stillbirths, 1 infant with severe morbidity, 1 seriously ill mother. **Characteristics** <u>Age at recruitment (years) - mean (±SD)</u> Practical skills: 28.0 (5.9) vs attitudes: 28.2 (5.6) vs standard care: 28.7 (5.5)	Access to standard care options. Control: Standard care which included formal breastfeeding education; peer support by means of community breastfeeding groups; lactation consultant support as necessary; breastfeeding information evenings; videos or education on breastfeeding presented in the postnatal ward during their stay; 24-hr telephone counselling support; postnatal home visit by a midwife. Setting: Royal Women's Hospital in Melbourne, Australia.	midwives conducted the interviews. Medical and obstetric hospital data were obtained from the hospital electronic data system. **Analysis** To achieve 80% power, and allowing for 20% loss to follow-up, 324 women per treatment group were required. Analysis was based on intention-to-treat. Proportions of women breastfeeding at hospital discharge and at 6 months were compared between intervention groups versus control using odds ratios (ORs). Comparisons of means were made using *t*-tests. Ranked or Likert-type scales were analysed using Mann-Whitney *U* tests or cumulative ORs.	type scale from 1=disagree strongly to 5=agree strongly. For the attitudes group, partners or support people also completed evaluations and some groups filled the forms at both classes. Class was enjoyable: practical skills (n=197): 4 vs attitudes (n=225): 4 Information was useful in deciding how to feed the baby: practical skills (n=197): 5 vs attitudes (n=225): 4 Did not learn anything new in classes: practical skills (n=197): 1 vs attitudes (n=225): 1 Sufficient opportunities to ask questions: practical skills (n=197): 5 vs attitudes (n=225): 5 Class leader was able to answer questions: practical skills (n=197): 5 vs attitudes (n=225): 5 I felt uncomfortable participating in the classes: practical skills (n=197): 1 vs attitudes (n=225): 1 Time and place of class was convenient: practical skills (n=197): 4 vs attitudes (n=225): 4 I would recommend to other women: practical skills	Allocation concealment: Low risk (A computerised system of biased urn randomisation was accessed by telephone by the research midwife to ascertain women's group allocation) Baseline differences: Some risk (Some baseline differences between participant groups inc. income and smoking before pregnancy) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
between May 1999 and August 2001. **Source of funding** A grant from the National Health and Medical Research Council, Canberra, funded the trial, with additional doctoral scholarship funding from the Royal Women's Hospital and the Victorian Health Promotion Foundation, Melbourne.	<u>Pension/benefit primary family income - (%)</u> Practical skills: 16.0% vs attitudes: 14.6% vs standard care: 7.2% **Inclusion criteria** • Primiparous women, between 16 and 24 weeks pregnant at the time of recruitment; • Booking as public patients and able to speak, read, write in English. **Exclusion criteria** • Physical problems that prevented breastfeeding; • Choosing birth centre or private obstetric care.			(n=197): 5 vs attitudes (n=225): 5	**(effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (To the Practical skills intervention attendance was 213/324 (66%) and for the Attitudes intervention attendance was 190/323 (59%) to the first class and 132/323 (41%) to the second class) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Low risk (Each arm lost 9% of participants between randomisation and 6-month interview)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from missing outcome data: Low risk DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (Data were collected by research midwives and blinding was not described. It is not clear if the same midwife was responsible for allocation and data collection) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (The Balogun Cochrane review reports 'all primary outcomes reported in study protocol were reported in this study') **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					selection of the reporting result: Low risk **Overall risk-of-bias judgement: Some risk** **Other information** Included in Cochrane reviews by Balogun and Lumbiganon. Excluded from Cochrane review by McFadden *Any breastmilk, defined as breastmilk and formula, and at 6 months may include solids, water, or juice.
Full citation Fu IC, Fong DY, Heys M, Lee IL, Sham A, Tarrant M., Professional breastfeeding support for first-time mothers: a multicentre cluster randomised controlled trial. , BJOG: an International Journal of Obstetrics and Gynaecology, 121, 1673–84, 2014 **Ref Id** 997018 **Country/ies where the study was carried out**	**Sample size** N randomised=724 In-hospital support (intervention 1)*: n=191 randomised, n analysed at 3 months=189, n analysed at 6 months= 188 Telephone support (intervention 2)*: n randomised=269, n analysed at 3 months=256, n analysed at 6 months= 255 Standard care (control)*: n randomised=264, n analysed at 3 months=257, n analysed at 6 months= 257 *N analysed calculated by the NGA technical team based on figure 1	**Interventions** Intervention (1): Standard care plus three in-hospital professional breastfeeding support sessions (30-45 mins) from a midwife or lactation consultant within the first 48 hours Intervention (2): Standard care plus weekly post-discharge breastfeeding telephone support (20-30mins) for 4 weeks from a midwife or lactation consultant. Control: Standard care – consisting of care according to mode of birth, group postnatal lactation education from a midwife or lactation	**Details** **Data collection** Women completed questionnaires relating to demographics; a research nurse collected data on obstetric and neonatal care from women. Follow-up infant feeding data were collected by telephone at 1, 2, 3, and 6 months or until breastfeeding stopped. **Analysis** To achieve 80% power, a total of 33 clusters (sample size of 198 women per treatment group) were required.	**Results** Any breastfeeding at 3 months, OR adjusted for cluster and hospital*: in-hospital versus standard care: 1.16 (0.79 to 1.70); telephone versus standard care: 1.37 (0.96 to 1.95), telephone versus in-hospital: 1.18 (0.81 to 1.72). Exclusive breastfeeding at 3 months, OR adjusted for cluster and hospital*: in-hospital versus standard care: 1.26 (0.76 to 2.11); telephone versus standard care: 1.20 (0.74 to 1.94), telephone versus in-hospital: 0.95 (0.58 to 1.56) Any breastfeeding at 6 months, OR adjusted for cluster and	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (online randomisation programme used to assign hospitals) Allocation concealment: Some risk (Cluster randomised) Baseline differences: Some risk (statistical significant differences in baseline characteristics not reported,

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Hong Kong **Study type** Cluster RCT **Aim of the study** To assess the effect of two postnatal professional support interventions for first-time mothers on duration of breastfeeding. **Study dates** Not stated. **Source of funding** Health and Medical Research Fund of the Food and Health Bureau, Government of Hong Kong Special Administration Region.	**Characteristics** Maternal age (years) - mean (±SD) Intervention (1): 31.0 (4.6); intervention (2): 30.3 (4.3); control: 30.2 (4.5) Monthly family income (HK$) - number (%) <14999: intervention (1): 21 (11.1); intervention (2): 43 (16.2); control: 39 (14.9) 15000-29999: intervention (1): 73 (38.6); intervention (2): 116 (43.6); control: 121 (46.2) >30000: intervention (1): 95 (50.3); intervention (2): 107 (40.2); control: 102 (38.9) Mother planning to exclusively breastfeed - number (%) Intervention (1): 101 (53.2); intervention (2): 161 (60.5); control: 153 (58.2) **Inclusion criteria** Infants: • Gestational age at least 37 weeks; • Birthweight at least 2500 g;	consultant, one-on-one assistance with breastfeeding if problems arose and time permitted, post discharge follow-up, information on available peer-support groups. Setting: postnatal units of 3 public hospitals providing obstetrical services in Hong Kong.	Mixed-effects logistic regression models were used to compare intervention efficacy on breastfeeding rates between treatment groups at follow-up, accounting for any intracluster correlation between participants. Multiplicity was adjusted for using the Holm procedure. Participants lost to follow-up were considered to have stopped breastfeeding at the point of last follow-up.	hospital*: in-hospital versus standard care: 1.13 (0.73 to 1.74); telephone versus standard care: 1.33 (0.90 to 1.98), telephone versus in-hospital: 1.18 (0.78 to 1.79) *See sample size section for n analysed	from looking at the data, some differences do seem likely) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (2 of the original 274 randomised did not enter the study, everyone

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• 5-minute Apgar score at least 8. Women: • At least 18 years of age; • Hong Kong Chinese; • Intending to breastfeed; • Primiparous. **Exclusion criteria** Women: • Major obstetric complications or serious medical problems. Infants: • Physical anomalies that would complicate breastfeeding. Women who were planning to live in mainland China.				entered completed received the intervention/usual care) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (Follow-up data for analysis was available from 98% of the usual care, 99% of the in hospital support and 97% of the telephone support) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Blinding of outcome assessors: Low risk (A study research assistant, who was blinded to the participants' treatment allocation, conducted the telephone follow-ups) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** The authors did not adjust for cluster design effect. ICC for breastfeeding cessation from Lavender

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					2005 was used: ICC = 0.01. Exclusive breastfeeding defined as giving only breast milk without food or other liquids, with the exception of vitamins or medications.
Full citation Gagnon AJ, Dougherty G, Jimenez V, Leduc N., Randomized trial of postpartum care after hospital discharge., Pediatrics, 109, 1074-80, 2002 **Ref Id** 1000595 **Country/ies where the study was carried out** Canada **Study type** RCT **Aim of the study** To compare the effects of community nurse follow-up versus hospital nurse follow-up	**Sample size** N randomised=586 Intervention: n randomised=292 Control: n randomised=294 Lost to follow-up: Intervention: received intervention at follow-up (n=283); number analysed for primary outcome (n=252); withdrawn (n=12), lost to follow-up (n=10), other (n=18); completed trial and analysed for primary outcome (n=252). Control: n=282 received standard intervention; number analysed for primary outcome (n=247); withdrawn (n=15), lost to follow-up (n=13), other (n=19); completed trial and analysed for primary outcome (n=247). **Characteristics** Maternal age (years) - mean (±SD)	**Interventions** Intervention: Nurse telephone contact at 48hrs post birth and a nurse visit at 3 to 4 days' postpartum in the woman's home. Control: Nurse telephone contact at 48hrs post birth and a nurse visit at 3 to 4 days' postpartum in the hospital clinic. Setting: urban university hospital.	**Details** **Data collection** Data on breastfeeding frequency, infant weight gain, and maternal anxiety were collected using various questionnaires at 2 weeks postpartum. Satisfaction was measured at 2 months' postpartum using a diary and medical records. **Analysis** To achieve 95% power, and taking into account loss to follow-up, 151 women per treatment group were required. Analyses were based on intention-to-treat. Between group differences were analysed using means and relative risks and corresponding 95% confidence intervals.	**Results** Any breastfeeding≠ at 2 weeks*: community follow-up (n=259): 247 vs hospital follow-up (n=254): 243 Exclusive breastfeeding≠≠ at 2 weeks: community follow-up (n=259): 183 vs hospital follow-up (n=254): 171 Service satisfaction, CSQ-8, mean (SD): community follow-up (n=259): 27.1 (4.8) vs hospital follow-up (n=253): 27.2 (4.2) *Numerators calculated by the NGA technical team by adding up exclusive breastfeeding and mixed feeding.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (stratified by parity in blocks of 8 using a computer-generated table of random numbers) Allocation concealment: Some risk (not described) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
on maternal and infant outcomes and satisfaction with interventions. **Study dates** January 1997 to September 1998. **Source of funding** Fonds de la recherche en sante du Quebec.	Intervention (n=291): 30.1 (4.8); control (n=293): 29.9 (4.7) Primiparous - % Intervention (n=292): 32.5; control (n=294): 32.7 Planning to breastfeed exclusively - % Intervention (n=292): 87.7; control (n=294): 90.5 Planning to breastfeed for ≥3 months - % Intervention (n=291): 63.6; control (n=290): 67.9 Gestational age (weeks) - mean (±SD) Intervention (n=292): 39.7 (1.1); control (n=294): 39.7 (1.0) Birthweight (g) - mean (±SD) Intervention (n=292): 3476 (382); control (n=294): 3451 (420) Sex (male) - % Intervention (n=292): 54.1; control (n=294): 46.9 **Inclusion criteria** • Participation in hospital's short stay programme; • Infant breastfed at least once in the hospital;				DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (9/283 in the control and 12/282 in the intervention did not receive intervention as allocated) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Living in a defined catchment area proximal to the hospital. **Exclusion criteria** Non-participation in short stay programme, i.e.: • Caesarean birth; • Parity ≥5; • Blood loss at birth ≥500 mL; • >second-degree perineal tear; • Maternal inability to void adequately; • Non-receipt of indicated RhoGAM; • Mother unable to care for self or infant; • Multiple birth; • Birth weight <2500 g; • Gestational age <37 weeks; • Abnormal neonatal examination; • Infant unable to maintain body temperature; • Breastfeeding not tolerated in hospital;				**Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (252/283 (89%) in the control and 247/282 (88%) were analysed for primary endpoint) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (assessors were blind to both treatment group allocation and the aim of the study) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Language barrier; • Need for social services referral.				**measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** ≠Mixed (breast milk plus breast milk and formula or water). ≠≠Breast milk only.
Full citation Graffy, J, Taylor, J., What information, advice, and support do women want with breastfeeding?, Birth (Berkeley, Calif.), 32, 179-186, 2005 **Ref Id** 1000597	**Sample size** See Graffy 2004 **Characteristics** See Graffy 2004 **Inclusion criteria** See Graffy 2004	**Interventions** See Graffy 2004	**Details** See Graffy 2004	**Results** See Graffy 2004	**Limitations** See Graffy 2004

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out See Graffy 2004 **Study type** See Graffy 2004 **Aim of the study** See Graffy 2004 **Study dates** See Graffy 2004 **Source of funding** See Graffy 2004	**Exclusion criteria** See Graffy 2004				
Full citation Graffy J, Taylor J, Williams A, Eldridge S . , Randomised controlled trial of support from volunteer counsellors for mothers considering breast feeding. , BMJ , 328, 26-31, 2004 **Ref Id** 997009	**Sample size** N randomised=720 Intervention: n randomised=363 Control: n randomised=357 Lost to follow-up: Intervention: neonatal deaths (n=2), premature birth (n=6), withdrew (n=5); participants after birth (n=350); lost to follow-up (n=14); follow-up at 6 weeks (n=336); lost to follow-up (n=26); follow-up at 4 months (n=310).	**Interventions** Intervention: Women received 1 antenatal visit from a National Childbirth Trust trained breastfeeding counsellor, who offered postnatal support by telephone or further home visits if the mother requested this after the birth. Control: Standard care (no details). Setting: 32 general practices in London and south Essex.	**Details** **Data collection** Data on any breast feeding at 6 weeks and the proportion of women giving any breast feeds or bottle feeds at 4 months were collected. Women were also asked about satisfaction with breastfeeding, problems encountered and whether advice received was	**Results** Breastfeeding initiation*: Intervention (n=336): 320 vs control (n=336): 324. Any breastfeeding at 6 weeks*: Intervention (n=336): 218 vs control (n=336): 213 Exclusive breastfeeding at 6 weeks*: Intervention (n=336): 103 vs control (n=336): 86	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Permuted block design stratified by GP practice and parity, randomisation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out UK **Study type** RCT **Aim of the study** To assess the effects of support from volunteer counsellors for mothers on breastfeeding. **Study dates** Recruitment April 1995 to August 1998. **Source of funding** The Royal College of General Practitioners Scientific Foundation Board and NHS North Thames responsive funding programme supported the study. Statham Grove Surgery received NHS research and development support funding through the East London and	Control: neonatal death (n=1), premature birth (n=6); participants after birth (n=350); lost to follow-up (n=14); follow-up at 6 weeks (n=336); lost to follow-up (n=26); follow-up at 4 months (n=310). **Characteristics** <u>Primiparous - number (%)</u> Intervention: 269 (74); control: 270 (76) <u>Maternal age - number (%)</u> <20: Intervention: 20 (5); control: 24 (7) 20-24: Intervention: 63 (18); control: 54 (15) 25-29: Intervention: 119 (33); control: 111 (31) 30-34: Intervention: 106 (29); control: 119 (34) ≥35: Intervention: 53 (15); control: 45 (13) <u>Ethnic group - number (%)</u> White (UK): Intervention: 212 (59); control: 205 (59)		helpful, using postnatal questionnaires (open and closed questions). **Analysis** Sample size calculation was performed and indicated that 790 women had to be recruited to detect a 10% increase at 6 weeks. Chi-square tests were used to compare the incidence and prevalence of breastfeeding, Kaplan-Meier survival analysis to compare duration of feeding, and Mann-Whitney U tests to compare non-parametric data on satisfaction and feeding problems. Cox regression analysis was performed to assess whether an imbalance in the number of undecided women at baseline could have influenced the significance of the observed duration of breastfeeding.	Any breastfeeding at 4 months*: Intervention (n=310): 143 vs control (n=310): 131 The paper also reports any bottle feeding at 7 days*, but this outcome was not extracted because it was not clear if this meant formula feeding or if it included breast milk feeding. Data on women's satisfaction with the intervention were reported as below but not used for the present review because non-comparative: Women's opinion on whether the counsellor was helpful (169 respondents who had tried to contact a counsellor postnatally): 123 very helpful, 28 fairly helpful, 12 a little helpful, 6 not helpful. Women's opinion on most helpful advice they received (counsellor vs midwife) (250 women in the intervention group): 141 from a counsellor, 75 cited advice from a midwife.	schedule prepared by statistician) Allocation concealment: Low risk (Numbered sealed envelopes) Baseline differences: Some risk (Groups were similar at baseline although more women in the intervention group (16) than the control group (6) were undecided about breastfeeding intention at the antenatal assessment.) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Essex Network of Researchers. The Royal College of General Practitioners provided a research training fellowship to enable one author to study for a higher degree. A second author was funded by an NHS Primary Care Researcher Development Award.	White (other): Intervention: 37 (10); control: 37 (11) African or Caribbean: Intervention: 61 (17); control: 48 (14) Indian subcontinent: Intervention: 24 (7); control: 31 (9) Other: Intervention: 23 (6); control: 26 (7) <u>Feeding plan - number (%)</u> Breast: Intervention: (240 (67); control: 244 (70) Both breast and bottle: Intervention: 104 (29); control: 101 (29) Undecided: Intervention: 16 (4); control: 6 (2) <u>Intended duration of breastfeeding - number (%)</u> <6 weeks: Intervention: 22 (7); control: 28 (8) 6 weeks-3 months: Intervention: 75 (23); control: 77 (23)				**intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (720 women recruited and randomised. 97% available for follow-up at birth, 93% at 6 weeks and 86% at 4 months)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	>3-6 months: Intervention: 150 (45); control: 152 (45) >6-9 months: Intervention: 51 (15); control: 36 (11) >9-12 months: Intervention: 25 (8); control: 30 (9) >1 year: Intervention: 8 (2); control: 15 (4) **Inclusion criteria** • Mothers considering breastfeeding who had not breastfed a previous child for 6 weeks after birth. • Speaking sufficient English; • Not planning to move from the area until at least 4 months after the birth. **Exclusion criteria** • Planning to contact a breastfeeding counsellor; • When it was considered unsafe for home visits;				**Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Reported that responses to follow-up questionnaires were coded by blinded assessors) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (Cochrane authors state that they did not have access to the trial registration or protocol, so could not evaluate this) **Judgement on risk of bias arising from selection of the reporting result: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Baby born before 36 weeks' gestation.				**Overall risk-of-bias judgement: Some risk**
Full citation Gross, R. S., Mendelsohn, A. L., Gross, M. B., Scheinmann, R., Messito, M. J., Randomized Controlled Trial of a Primary Care-Based Child Obesity Prevention Intervention on Infant Feeding Practices, Journal of Pediatrics, 174, 171-177.e2, 2016 **Ref Id** 806046 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effects of a child obesity	**Sample size** N randomised=533 Intervention: n randomised=266 Control: n randomised=267 Lost to follow-up: Intervention: n=2 still birth; n=1 missing birth data; n=263 babies born; n=42 missing 3 month data; n=221 completed 3-month assessment. Control: n=1 still birth; n=266 babies born; n=31 missing data at 3 months; n=235 completed 3-month assessment. **Characteristics** <u>Maternal age (years) - mean (±SD)</u> Intervention: 28.5 (6.0); control: 27.9 (5.8) <u>Primiparous - number (%)</u> Intervention: 92 (34.6); control: 107 (40.1) <u>Pre-pregnancy obese status - number (%)</u> Intervention: 76 (28.5); control: 79 (29.6)	**Interventions** Intervention: standard care plus a family-centred primary care-based early child obesity prevention intervention beginning in the third trimester of pregnancy and continuing after birth until the child is aged 3 years. The intervention was delivered by registered dieticians who had been trained as certified lactation counsellors. The intervention components included: individual 45-60 minute counselling sessions in the prenatal and newborn periods; nutrition and parenting support groups that met at 1, 2, 4, 6, 9 and 12 months old and then every 3 months for the following 2 years; handouts, DVDs. Control: standard care. Prenatal visits with attending or resident obstetrician or nurse midwife, initial individual consultation with a nutritionist. Women were offered antenatal group	**Details** **Data collection** Data were collected through telephone-administered surveys and medical records. Infant feeding methods were assessed using the adapted Infant Feeding Practices study II; breastfeeding was assessed using survey questions and a 24-hour diet recall. **Analysis** To achieve 80% power, assuming 30% loss to follow-up, 500 women were required. The study achieved 90% power (n=456 women) to show an increase in exclusive breastfeeding from 30% to 45%. Data were analysed on an intention-to-treat basis. Bivariate analyses were conducted to assess relationships between group status and maternal infant feeding knowledge	**Results** Breastfeeding initiation*: intervention (n=221): 212 vs control (n=235): 224 Any breastfeeding at 3 months*: intervention (n=221): 184 vs control (n=235): 189 Exclusive breastfeeding at 3 months*: intervention (n=221): 73 vs control (n=235): 55 *Numerators calculated by the NGA technical team based on denominators and percentages provided in the paper.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (random number generator, stratified by site) Allocation concealment: Some risk (not described) Baseline differences: Some risk (lower education status higher in intervention group (37.6%) compared to control group (28.8%), all other baseline variables not significantly different) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
prevention intervention on infant feeding methods in low-income Hispanic families. **Study dates** August 2012 to December 2014. **Source of funding** National Institute of Food and Agriculture, US Department of Agriculture and the National Institute of Health/Eunice Kennedy Shriver National Institute of Child Health and Human Development.	Household food insecurity - number (%) Intervention: 74 (28.2); control: 87 (33.5) Sex (male) - number %) Intervention (n=263): 132 (50.2); control (n=266): 127 (47.7) Premature <37 weeks gestational age - number (%) Intervention (n=262): 10 (3.8); control (n=265): 5 (1.9) Birthweight (kg) - mean (±SD) Intervention (n=257): 3.35 (0.45); control (n=262): 3.39 (0.49) Large for gestational age - number (%) Intervention (n=257): 21 (8.3); control (n=262): 32 (12.4) **Inclusion criteria** • Pregnant women aged at least 18 years; • Self-identified as Hispanic/Latina; • Fluent in English/Spanish; • Singleton, uncomplicated pregnancy;	childbirth and breastfeeding classes; nurses on the postpartum unit were trained in lactation support; a lactation counsellor was available on the postpartum unit and in the paediatric clinic for women with breastfeeding difficulties. Individual paediatric visits at 5 days of age, and at 1, 2 and 4 months. Setting: Primary care prenatal and paediatric clinics and postpartum ward of a large urban public hospital and an affiliated satellite neighbourhood health centre in New York City.	and infant feeding practices using independent samples *t*-tests and chi-square tests for continuous and categorical data, respectively. For continuous data, effect sizes were calculated using mean differences with 95% confidence intervals and Cohen's d was calculated.		Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (All intervention subjects attended the prenatal session following randomization (221/221). 41.0% received all four intervention sessions. 71.4% received three or more.) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Able to provide phone numbers; • Intending to receive care at the study sites. Women with obesity, diabetes, hypertension, thyroid disease or depression were not excluded. **Exclusion criteria** • Women with significant medical or psychiatric illness (e.g. cardiovascular disease, lupus, neuromuscular disorders, psychosis, drug addiction); • Homeless; • Severe foetal anomalies on ultrasound (e.g. neural tube defects, chromosomal abnormalities).				**from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Low risk (86.2% completed the 3-month assessment) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (concealed from research assistants, who conducted the follow-up assessments) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Selective reporting: Some risk (Data not reported for all primary outcomes, but these outcomes are not relevant to our review question) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Exclusive breastfeeding defined as breast milk only versus formula only, both formula and breast milk, or ever giving complementary foods or liquids.
Full citation Gross SM, Caulfield LE, Bentley ME , Bronner Y, Kessler L, Jensen J, et al. , Counseling and motivational videotapes increase duration of breast-feeding in African-American WIC participants who initiate breast-feeding., Journal of the American Dietetic	**Sample size** See Caulfield 1998 **Characteristics** See Caulfield 1998 **Inclusion criteria** See Caulfield 1998	**Interventions** See Caulfield 1998	**Details** See Caulfield 1998	**Results** See Caulfield 1998	**Limitations** See Caulfield 1998

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Association, 98, 143–8, 1998 **Ref Id** 997165 **Country/ies where the study was carried out** US **Study type** Cluster-RCT **Aim of the study** See Caulfield 1998 **Study dates** See Caulfield 1998 **Source of funding** See Caulfield 1998	**Exclusion criteria** See Caulfield 1998				
Full citation Harari, N., Rosenthal, M. S., Bozzi, V., Goeschel, L., Jayewickreme, T., Onyebeke, C., Griswold, M., Perez-Escamilla, R.,	**Sample size** N=58 Intervention: n=32 randomised Control: n=26 randomised Lost to follow-up: Intervention: n=31 received intervention; moved out of area prior to birth (n=1);	**Interventions** Intervention: Breastfeeding peer counselling support programme with texting. Automated text messages that provided breastfeeding education, in addition, texts could be sent to peer	**Details** **Data collection** Breastfeeding status was assessed using a telephone survey at 2 weeks postpartum and/or via text. If a mother could not be reached, then the 2-week	**Results** Exclusive breastfeeding at 2 weeks: intervention (n=30): 15 vs control (n=22): 7	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Feasibility and acceptability of a text message intervention used as an adjunct tool by WIC breastfeeding peer counsellors: The LATCH pilot, Maternal and Child Nutrition, 14 (1) (no pagination), 2018 **Ref Id** 806118 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the feasibility and acceptability of a text message breastfeeding support intervention, in addition to WIC breastfeeding peer counselling. **Study dates** Not stated.	discontinued intervention (n=1); n=30 analysed at 2-weeks postpartum. Control: n=26 received control; n=3 moved out of area; n=1 disqualified; n=22 analysed at 2-weeks postpartum. **Characteristics** Maternal age (years) - mean (range) Intervention: 26.4 (18 to 42); control: 26.9 (18 to 41) Race - number (%) Black: Intervention: 5 (17); control: 4 (18) Hispanic: Intervention: 23 (77); control: 16 (73) White: Intervention: 2 (6); control: 1 (5) Other: Intervention: 0 (0); control: 1 (5) Parity - number (%) 0: Intervention: 13 (43); control: 9 (41) 1: Intervention: 13 (43); control: 6 (27) 2: Intervention: 2 (7); control: 4 (18) ≥3: Intervention: 2 (7); control: 3 (14) Gestational age at delivery (weeks) - mean Intervention: 41; control: 37.3	counsellor and would be replied to between 8am and 5pm Monday to Friday. Control: Breastfeeding peer counselling support programme without texting. Setting: Hospital-based primary care centre and a federally qualified community health centre.	breastfeeding outcomes from the administrative records of the peer counsellor were used. Data on participant satisfaction were also collected. **Analysis** Data were analysed on an intention-to-treat basis. Breastfeeding related data were analysed using t-test for continuous outcomes and chi-square test for categorical outcomes to demonstrate between-group differences. Breastfeeding status (exclusive or not) were classed as dichotomous outcomes and assessed using chi-square test at 2 weeks postpartum.		Random sequence generation: Low risk (The allocation sequence for randomisation, stratified by PC and language, was generated by an independent biostatistician via a computer-generated random-number sequence) Allocation concealment: Low risk (the PC contacted the principal investigator who assigned the randomisation arm based on allocation sequence.) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Yale School of Medicine Dean's Office.	**Inclusion criteria** • Women who intended to breastfeed; • Unlimited text message mobile phone plan; • Fifth grade or above literacy level and fluency in English or Spanish. **Exclusion criteria** • Infants born prematurely (<37 weeks); • Infants admitted to neonatal intensive care unit for >3 days; • Major medical problem affecting breastfeeding; • Birthweight <5 lbs.				interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (92.4%

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					completed two week phone survey) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews and / or text message reporting - women's self-report on breastfeeding) Blinding of outcome assessors: High risk (not blinded) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 – reporting Selective reporting: Some risk (feasibility trial for a NCT registered trial - no information on this specific trials analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Overall risk-of-bias judgement: Some Risk **Other information** Mothers received a $25 gift card after completion of the 2-week postpartum follow-up survey. Exclusive breastfeeding defined as the intake of only breast milk in prior 48 hours, i.e. no solids, water or other liquids.
Full citation Henderson A, Stamp G, Pincombe J. , Postpartum positioning and attachment education for increasing breastfeeding: a randomized trial. , Birth, 28(4): 236–42. , 2001 **Ref Id** 997268 **Country/ies where the study was carried out** Australia **Study type** RCT	**Sample size** N randomised=160 Intervention: n randomised=80 Control: n randomised=80 Lost to follow-up: Intervention: at 6 weeks n=1 lost to follow-up; at 3 months n=1 lost to follow-up; at 6 months n=3 lost to follow-up. Control: at 6 weeks n=1 lost to follow-up; at 3 months n=3 lost to follow-up; at 6 months n=1 lost to follow-up. **Characteristics** Maternal age (years) - mean (±SD) Intervention: 27.6 (5.6); control: 27.2 (5.7) Intention to breastfeed - number (%)	**Interventions** Intervention: usual care plus postpartum positioning and attachment education (~30mins) on a one-to-one basis within the first 24 hours; on each subsequent day in the hospital, the woman's positioning and attachment technique was assessed and immediate feedback given. Control: Usual postpartum breastfeeding care from hospital midwives (variation in support provided by midwives, most often midwives attached the infant for the woman, formal education and assessment of positioning and attachment were not a usual focus).	**Details** **Data collection** Data on breastfeeding or artificial feeding methods were collected through a purpose-designed, self-report questionnaire. All participants were contacted at 6 weeks, 3 months, and 6 months postpartum by telephone. **Analysis** A sample size of 150 women was required. Data were analysed on an intention-to-treat basis. Data were analysed using a Student *t*-test for continuous data. Categorical data were analysed using chi-square 2 x 2 contingency tables	**Results** Any breastfeeding at 3 months: intervention (n=78): 56 vs control (n=76): 57 Any breastfeeding at 6 months: intervention (n=75): 42 vs control (n=75): 48	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: low risk (Computer-generated balanced blocks of 20) Allocation concealment: Low risk (Sealed opaque envelopes) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess the effects of postpartum positioning and attachment education on breastfeeding outcomes in first time mothers. **Study dates** June to September 1999. **Source of funding** Not stated.	Before pregnancy: Intervention: 53 (66); control: 55 (69) During pregnancy: Intervention: 27 (34); control: 25 (31) <u>Planned duration of breastfeeding - number (%)</u> 6-11 weeks: Intervention: 2 (2); control: 2 (2) 3-6 months: Intervention: 24 (30); control: 18 (23) 7-12 months: Intervention: 19 (24); control: 19 (24) >12 months: Intervention: 7 (9); control :8 (10) As long as possible: Intervention: 24 (30); control: 26 (32) Unsure: Intervention: 4 (5); control: 7 (9) <u>Health insurance - number (%)</u> Public: Intervention: 72 (90); control: 74 (93) Private: Intervention: 8 (10); control :6 (7) **Inclusion criteria** • First time, English speaking mothers; • Women who planned to breastfeed; • Singleton, term infants;	Setting: public hospital in Adelaide, South Australia.	and relative risks with 95% confidence intervals. For a cell value of less than 5, Fisher's exact tests were used.		**Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Infants with Apgar score of 7 or more at 5 minutes. **Exclusion criteria** Not stated.				(analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (5 women in each arm were lot to follow up by 6 months (94%)) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Researcher blinded to treatment allocation) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					measurement of the outcome: Low risk DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Hoddinott, P, Britten, J, Pill, R., Why do interventions work in some places and not others: A breastfeeding support group trial, Social Science and Medicine, 70, 769-778, 2010 **Ref Id** 1000601 **Country/ies where the study was carried out** See Hoddinott 2009	**Sample size** See Hoddinott 2009 **Characteristics** See Hoddinott 2009 **Inclusion criteria** See Hoddinott 2009 **Exclusion criteria** See Hoddinott 2009	**Interventions** See Hoddinott 2009	**Details** See Hoddinott 2009	**Results** See Hoddinott 2009	**Limitations** See Hoddinott 2009

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type See Hoddinott 2009 **Aim of the study** See Hoddinott 2009 **Study dates** See Hoddinott 2009 **Source of funding** See Hoddinott 2009					
Full citation Hoddinott, P, Britten, J, Prescott, G. J, Tappin, D, Ludbrook, A, Godden, D. J., Effectiveness of policy to provide breastfeeding groups (BIG) for pregnant and breastfeeding mothers in primary care: cluster randomised controlled trial, BMJ (Clinical research ed.), 338, a3026, 2009 **Ref Id**	**Sample size** N=14 areas, corresponding to 18858 women Intervention: 7 areas, corresponding to n=9747 Control: 7 areas, corresponding to n=9111 Lost to follow-up: Intervention: clusters analysed intention-to-treat (n=7); valid feeding data (n=9635); eligible 7 day valid feeding data (n=9872); eligible 6 to 8 week valid feeding data (n=8991). Control: clusters analysed intention-to-treat (n=7); valid feeding data (n=8968); eligible 7 day valid feeding data	**Interventions** Intervention: a policy aimed at locality areas rather than at individual women. The policy aimed to double the number of local breastfeeding support groups and to make weekly support groups open to all pregnant women and breastfeeding mothers. These local breastfeeding support groups were facilitated by health professionals. Control: standard care; breastfeeding support groups existed in some control areas.	**Details** **Data collection** Data on breastfeeding rates were collected at birth, 5 to 7 days, 6 to 8 weeks and 8 to 9 months (using postal return questionnaire), along with maternal satisfaction (using Duke-UNC functional social support scale). **Analysis** To achieve 80% power, 14 areas were required. Data were analysed at cluster level on an intention-to-treat basis. Between group differences in breastfeeding rates were	**Results** <u>Initiation of breastfeeding - mean (±SD)</u> Pre-intervention: Intervention: 0.50 (0.05); control: 0.51 (0.10) Post-intervention: Intervention: 0.51 (0.06); control: 0.53 (0.09) <u>Any breastfeeding at 5 to 7 days - mean (±SD)</u> Pre-intervention: Intervention: 0.43 (0.04); control: 0.46 (0.09) Post-intervention: Intervention: 0.42 (0.04); control: 0.45 (0.09) <u>Any breastfeeding at 6 to 8 weeks - mean (±SD)</u> Pre-intervention: Intervention: 0.27 (0.03); control: 0.29 (0.08)	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Statistician used random number tables to randomise locality pairs to intervention or control) Allocation concealment: Low risk (Cluster RCT design, so unlikely to be an issue)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
1000602 **Country/ies where the study was carried out** Scotland, UK **Study type** Cluster-RCT **Aim of the study** To assess the clinical and cost-effectiveness of a policy to provide breastfeeding groups for pregnant and breastfeeding mothers in primary care in Scotland. **Study dates** February 2005 to January 2007. **Source of funding** Chief Scientists' Office of the Scottish Government Health Directorate. One author funded through a primary care research career award and the	(n=9234); eligible 6 to 8 week valid feeding data (n=8491). **Characteristics** **Pre-intervention** General practices classified as urban, rural, remote - number Any practice classified as 4 cities: Intervention: 2; control: 2 ≥7 practices classified as 'other urban areas: Intervention: 3; control: 2 <7 practices classified as 'other urban areas': Intervention: 2; control: 2 % in least deprived fifth Intervention: 17.1; control: 9.9 % in most deprived fifth Intervention: 25.2; control: 32.1 Maternal age at time of first Child Health Surveillance Programme assessment - median (IQR) Intervention: 29 (24 to 33); control: 29 (23 to 33) **Post-intervention** % in least deprived fifth Intervention: 15.7; control: 8.7 % in most deprived fifth Intervention: 26.4; control: 32.9 Maternal age at time of first Child Health Surveillance	Setting: Primary care in Scotland.	analysed using analysis of covariance, with pre-intervention breastfeeding rates as the covariate. Individual secondary outcomes were analysed using linear or Poisson regression with adjustment for clustering. Binary data required logistic regression, and counts of group attendances needed zero inflated Poisson regression, both adjusted for clustering.	Post-intervention: Intervention: 0.26 (0.03); control: 0.30 (0.07) Satisfaction with intervention - functional social support scale - median (IQR)* Intervention (valid responses: n=822): 4.25 (3.63 to 4.75); control (valid responses: n=517): 4.25 (3.63 to 4.75) *Interclass correlation coefficient: 0.003.	Baseline differences: Some risk (Intervention localities had fewer general practices classified as rural, fewer maternity unites and slightly less deprived than control) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not described but assumed to be not blinded) Blinding of carers and people delivering the interventions: High risk (not described but assumed to be not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Health Economics Research Unit, University of Aberdeen received core funding.	<u>Programme assessment - median (IQR)</u> Intervention: 29 (24 to 33); control: 28 (23 to 33) **Inclusion criteria** • 66 clusters of general practices (localities) that routinely collected breastfeeding data through the Child Health Surveillance Programme of the National Health Service Scotland. **Exclusion criteria** Not stated.				Non-adherence: Low risk (Cluster RCT design, so unlikely to be an issue) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (22% of mothers in the intervention and 15% in the control completed the questionnaire on intervention satisfaction) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire -

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Researchers were blinded to allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (ISRCTN registered - all outcomes reported) **Judgement on risk of bias arising from selection of the reporting result: Low risk** **Overall risk-of-bias judgement: Some risk** **Other information** Breastfeeding initiation defined as having given baby breast milk at least once.
Full citation Hoddinott P, Craig L, MacLennan G, Boyers	**Sample size** N= 69. Assigned to intervention: n=35. Assigned to control: n=34	**Interventions** Intervention: proactive telephone calls (intervention) daily for 1 week following	**Details** **Data collection** Data on breastfeeding were collected via telephone by a	**Results** Any breastfeeding at 6 to 8 weeks*: proactive calls (n=32): 22 vs reactive calls (n=26): 12	**Limitations** Limitations were assessed using the revised Cochrane

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
D, Vale L. , The Feeding Support Team (FEST) randomised controlled feasibility trial of proactive and reactive telephone support for breastfeeding women living in disadvantaged areas., 2012 **Ref Id** 997085 **Country/ies where the study was carried out** UK **Study type** RCT **Aim of the study** To compare the effectiveness and feasibility of implementing proactive and reactive versus reactive only telephone support on women living in more disadvantaged areas who were feeding infants some breast milk at the time of hospital discharge.	Lost to follow-up: Intervention: withdrew (n=0); calls discontinued by day 7 (n=3) and days 8 to 13 (n=17. Feeding outcome at 6 to 8 weeks (n=32); lost to follow-up (=3); response rate (91%). Control: withdrew (n=0); feeding outcome at 6 to 8 weeks (n=26); lost to follow-up (n=8); response rate (76%). **Characteristics** <u>Maternal age (years) - mean (±SD)</u> Proactive calls (n=35): 28.7 (5.0) vs reactive calls (n=34): 27.5 (4.2) <u>Deprivation, SIMD 2009* - number (%)</u>: Proactive calls (n=35): 10 (29) in SIMD 1, 13 (37) in SIMD 2, 12 (34) in SIMD 3 Reactive calls (n=34): 3 (8) in SIMD 1, 14 (41) in SIMD 2, 17 (50) in SIMD 3. (*Note from NGA technical team: the Scottish Index of Multiple Deprivation (SIMD) ranks small areas (called data	hospital discharge. Calls were terminated at the woman's request or if breastfeeding ceased. At 1 week following discharge, women could choose to continue receiving daily calls for a further week, change the frequency of calls, or have no further calls. Women could telephone the feeding team at any point over the 2 weeks following discharge. Text and answer phone messaging was available. All proactive calls stopped 14 days after hospital discharge. Control: reactive telephone calls; women could telephone the feeding team at any point over the 2 weeks following discharge. Text and answer-phone messaging was available. Setting: Maternity unit serving a mixed urban and rural population in Scotland.	researcher. Women were also asked to score their satisfaction with the help they received with breastfeeding in hospital and at home (rating scale of 1 to 10, with 0 being most dissatisfied and 10 being the most satisfied). **Analysis** Data were analysed on an intention-to-treat basis. A generalised linear model with Poisson link function and robust SE was used to estimate the effect of the intervention (presented as risk ratios and 95% confidence intervals) on any breastfeeding at 6 to 8 weeks. Satisfaction with care outcomes were analysed using linear regression to estimate the difference between groups (with 95% confidence intervals).	Exclusive breastfeeding at 6 to 8 weeks*: proactive calls (n=32): 17 vs reactive calls (n=26): 8 Satisfaction with help at home, mean (±SD): proactive calls (n=32): 8.7 (1.7) vs reactive calls (n=26): 8.1 (1.8) Satisfaction with help in hospital provided in the paper, but unrelated (or indirectly related) to intervention under study, so not extracted.	risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (website randomisation sequence service set up by an independent statistician) Allocation concealment: Low risk (Performed by an independent statistician) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Women admitted to the ward between July and October 2010. **Source of funding** NHS Grampian through the Scottish Government: nutrition of women of childbearing age, pregnant women and children under 5 years in disadvantaged areas, NHS Health Scotland.	zones) from most deprived (ranked 1) to least deprived (ranked 6,976)). <u>Multiple births - number (%)</u> Proactive calls (n=35): 0 (0) vs reactive calls (n=34): 0 (0) <u>Admitted to neonatal unit - number (%)</u> Proactive calls (n=35): 6 (17) vs reactive calls (n=34): 7 (21) <u>Feeding method at hospital discharge - number (%)</u> Proactive calls (n=35): 35 (100) any breastfeeding and 26 (74) exclusive breastfeeding vs reactive calls (n=34): 34 (100) any breastfeeding and 25 (74) exclusive breastfeeding. <u>Primiparous - number (%)</u> Proactive calls (n=35): 21 (60); reactive calls (n=34): 22 (65) <u>Gestational age (weeks + days) - mean (±SD)</u> Proactive calls (n=35): 38+6 (2+1); reactive (n=34): 39+0 (2+1)				interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (3/35 (9%) in intervention group and

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria • Women admitted to the ward who lived in the 3 most disadvantaged postcode area quintiles for the Scottish Index of Multiple Deprivation (SIMD 1-3) in 2009; • Women who were breastfeeding. **Exclusion criteria** • Women aged < 16 years; • Women with serious medical or psychiatric problems; • Women with insufficient spoken English to communicate by telephone.				8/34 (23%) in control group were lost to follow-up) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Outcomes were collected by telephone by a researcher who was blind to randomisation and who had no other contact with study women) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					selection of the reporting result: Some risk **Overall risk-of-bias judgement: Some risk** **Other information** *Any breastfeeding defined as any breast milk given to the baby, and exclusive breastfeeding defined as no other liquids (except medicines) within the previous 24 hours.
Full citation Jenik AG, Vain NE, Gorestein AN, Jacobi NE, for the Pacifier and Breastfeeding Trial Group., Does the recommendation to use a pacifier influence the prevalence of breastfeeding? , 2009 **Ref Id** 997156 **Country/ies where the study was carried out** Argentina	**Sample size** N=1021 Intervention: n=493 Control: n=528 Loss to follow-up: Intervention: n=22 lost to follow-up (n=20 unreachable; n=2 refused to keep participating). N=471 included in primary outcome. Control: n=26 lost to follow-up (n=25 unreachable; n=1 refused to keep participating). N=499 included in primary outcome. **Characteristics**	**Interventions** Intervention: not offered pacifiers – parents were given a guide with other ways for comforting a crying baby. Control: given 6 pacifiers and a guide on pacifiers for the parents. Setting: 5 tertiary centres in Argentina.	**Details** **Data collection** Mothers were interviewed at 1, 2, 3, 4, 5, 6, 8, 10 and 12 months postnatally or until breastfeeding ended. Interviews were conducted via the telephone using a structured questionnaire. **Analysis** To achieve 75% power, assuming a dropout rate of 5%, 1010 participants were required. Primary analysis was intention-to-treat. Group comparisons were analysed using chi-squared	**Results** Exclusive breastfeeding at 3 months: not offered pacifiers (n=471): 406 vs offered pacifiers (n=499): 428 Any breastfeeding at 3 months: not offered pacifiers (n=471): 468 vs offered pacifiers (n=499): 494 Any breastfeeding at 4 months*: not offered pacifiers (n=462): 452 vs offered pacifiers (n=487): 482 *Denominators calculated by the NGA technical team based on numerators and percentages provided in the paper	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Assigned randomly generated numbers constructed by an independent statistician) Allocation concealment: Low risk (Consecutively numbered, sealed, opaque

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type RCT **Aim of the study** To assess the impact of recommendations to offer pacifiers on breastfeeding rates and duration. **Study dates** November 2005 to May 2006. **Source of funding** International Children Medical Research Association, Switzerland.	<u>Maternal age (years) - mean (±SD)</u> Intervention: 29.33 (5.8); control: 29.30 (5.6) <u>Infant birthweight (g) - mean (±SD)</u> Intervention: 3659 (418); control: 3690 (477) **Inclusion criteria** • Infants born at least 37 weeks of gestation; • Infant birthweight 2500 g; • Exclusively breastfeeding; • Women who reported an intention to breastfeed for at least 3 months; • Well established lactation at the age of 2 weeks; • Not using pacifiers. **Exclusion criteria** • Breast problems that could interfere with breastfeeding		or Fisher exact tests for categorical data.		envelopes) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (In the offer pacifier group

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(persistently sore nipples, mastitis, earlier breast surgery, and severely flat or inverted nipples). • Mothers who indicated a preference in the introduction or not of a pacifier.				67% used a pacifier, 33% did not use a pacifier; in the do not offer a pacifier group 40% used a pacifier and 60% did not use a pacifier - a statistically significant difference P<0.001) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): High risk** DOMAIN 3 – missing data Missing outcome data: Low risk (26/528 (5%) in the offer pacifier and 22/493 (4%) in the do not offer pacifier were lost to follow-up) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Research assistant was blinded to group assignment) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (trial registration reported and all outcomes included) Judgement on risk of bias arising from selection of the reporting result: Low risk **Overall risk-of-bias judgement: Some concerns** **Other information** Infants exclusively breastfed received breast milk only. No other liquids (other than vitamins or medications) or solid foods were given. Partially

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					breastfed infants received formula or semisolids in addition to breast milk. Any breastfeeding included both the above.
Full citation Jolly, K, Ingram, L, Freemantle, N, Khan, K, Chambers, J, Hamburger, R, Brown, J, Dennis, C. L, Macarthur, C., Effect of a peer support service on breast-feeding continuation in the UK: a randomised controlled trial, Midwifery, 28, 740-5, 2012 **Ref Id** 1000610 **Country/ies where the study was carried out** UK **Study type** Cluster-RCT **Aim of the study** To evaluate the effects of a peer support worker	**Sample size** Macarthur 2009 paper, which provides initiation data: N=2511 randomised Jolly 2012 paper: N=2724 randomised Intervention group, Jolly paper: n=1267 randomised. Macarthur paper: n=1140 randomised. Control: Jolly paper: n=1457 randomised. Macarthur paper: n=1371 randomised and had birth in local hospitals. Data on initiation of breastfeeding was obtained from 1083/1140 women in intervention group and from 1315/1371 in control group (data from MacArthur paper). Data on breastfeeding at 10-14 days was available for 1193 women out of 1267 randomised to intervention group, and for 1370 women out of 1457 randomised to	**Interventions** Intervention: Standard care plus antenatal peer support, and postnatal peer support for women who initiated breastfeeding. Community peer support workers were trained in line with WHO/ UNICEF Baby Friendly breastfeeding management course. Antenatal support was aimed to be 2 support sessions (at least 1 at home, although almost all actually took place in the clinic/Children's Centre setting). The support workers were informed when the women were discharged from hospital so that they could contact and visit them within 24 h-48 h. Further contact would be needs-based, but with a minimum of 1 more contact in the first week. Additional needs-based contacts could be by telephone or home visits Control: Standard care (antenatal and postnatal midwife care (some home-	**Details** **Data collection** Data on breast feeding at 10-14 days was collected by health visitors (routinely collected data). Breastfeeding at 6 weeks and 6 months was obtained from follow-up questionnaires. **Analysis** To achieve 90% power, just under 3000 women were required to estimate a 6% absolute difference in initiation of breast feeding. Data were analysed on an intention-to-treat basis. Breastfeeding initiation was analysed using a non-linear mixed model with a logit link and binomial error, including a random effect with a Gaussian error structure. Missing data were not imputed.	**Results** Initiation of breastfeeding: intervention (n=1083): 747 vs control (n=1315): 896. Cluster adjusted odds ratio: 1.11 (95% CI 0.87 to 1.43). (Data from MacArthur 2009 paper). This excludes women with missing data on breastfeeding. Imputation techniques provided a similar result to the analysis using complete data: cluster adjusted odds ratio: 1.10 (0.86 to 1.42).* Any breastfeeding at 10-14 days: intervention (n=1193): 818 vs control (n=1370): 928. Cluster adjusted OR (ICC=0.05):1.07 (95% CI 0.87 to 1.13) Exclusive breastfeeding at 10-14 days:* intervention (n=1193): 446 vs control (n=1370): 470. Cluster adjusted OR (ICC=0.04): 1.21 (95% CI 0.96 to 1.52)	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described other than randomised by statistician) Allocation concealment: Some risk (not described) Baseline differences: Some risk (no differences between group other than for British/Pakistani split where the intervention had lower British and higher Pakistani proportion of women) **Judgement on risk of bias arising from the randomisation process: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
service on continuation of breastfeeding in the UK. **Study dates** Women with an estimated delivery date between February 2007 and July 2007. Follow-up questionnaires were completed by women between August 2007 and April 2008. **Source of funding** The study was funded by the Heart of Birmingham Teaching Primary Care Trust. Some study authors were part-funded by the National Institute for Health Research through the Collaborations for Leadership in Applied Health Research and Care for Birmingham and Black Country programme.	control group. 416 consented to follow-up at 6 months in intervention group, and 271 of these responded at 6 months. 432 consented to follow-up at 6 months in control group, and 301 responded at 6 months. **Characteristics** Baseline characteristics from MacArthur 2009. Maternal age (years) - number (%) <20: Intervention: 105 (9.7); control: 135 (10.3) 21-25: Intervention: 331 (30.6); control: 398 (30.3) 26-30: Intervention: 359 (33.1); control: 399 (30.3) 31-35: Intervention: 194 (17.9); control: 249 (18.9) ≥36: Intervention: 94 (8.7); control: 134 (10.2) Parity - number (%) Primiparous: Intervention: 376 (35.1); control: 440 (33.9) Multiparous: Intervention: 695 (64.9); control: 858 (66.1) Not Known: Intervention: 12; control: 17 Ethnic group - number (%) White British: Intervention: 87 (8.4); control: 129 (10.3) African-Caribbean: Intervention: 130 (12.6); control: 217 (17.3)	based), which included breastfeeding advice. Health visitors also saw women postnatally from 10 to 14 days, sometimes at home, and gave breastfeeding advice as appropriate. Breastfeeding advice was available from midwives and peer supporters in the hospital. Setting: Primary Care Trust in Birmingham, serving a multi-ethnic, socio-economically disadvantaged population.	Adjustments were not made for multiple testing. Multiple imputation techniques were used to examine the potential effects of missing data.	Any breastfeeding at 6 weeks:* intervention (n=271): 170 vs control (n=301): 194. Cluster-adjusted OR (ICC=0.23): 0.93 (0.64 to 1.35) Exclusive breastfeeding at 6 weeks:* intervention (n=271): 204 vs control (n=301): 123. Cluster-adjusted OR (ICC=0.22): 0.91 (0.62 to 1.34) Any breastfeeding at 6 months:* intervention (n=271): 93 vs control (n=301): 117. Cluster-adjusted OR (ICC=0.17): 1.06 (0.71 to 1.58) Women who reported less breastfeeding advice and help from the health service postnatally than they wanted: intervention (n=271): 26.9% vs control (n=301): 30.2%	DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (Uptake of peer support in intervention arm: 912 women (80%) had a record of a peer support worker contact antenatally. 64 women (7%) refused a peer support session because they had already decided to bottle feed (n=21) or breast feed (n=43) (info from MacArthur paper). Of those who accepted a first support session, 48.4% had

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Pakistani: Intervention: 435 (42.0); control: 490 (39.0) Indian: Intervention: 115 (11.1); control: 91 (7.2) Bangladeshi: Intervention: 110 (10.6); control: 133 (10.6) Other Asian: Intervention: 40 (3.9); control: 42 (3.3) Mixed: Intervention: 40 (3.9); control: 38 (3.0) Other: 78 (7.5); control: 117 (9.3) Not Known: Intervention: 48; control: 58 **Inclusion criteria** • All pregnant women registered with a GP within the PCT; • Estimated delivery date between 1 February 2007 and 31 July 2007. Follow-up 10-14 days. All these women were eligible for 6-month follow-up, but only a part of them was recruited for longer follow-up, often due to them not being informed because of midwives' workload. **Exclusion criteria**				a second antenatal session. Postnatally, out of 747 women who initiated breastfeeding, 460 had a visit or were telephoned by a peer support worker. Only 58.8% of first contacts took place within a week of birth. Of women in the consented sample who initiated breastfeeding, 75% reported peer support worker contact within 48 hours of hospital discharge and 86% within 72 hours) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Some risk (Follow up at 6 months was 69.7% in the intervention group and 65.1% in control group. When based on the number

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	None stated.				actually in the clusters this number is 21.4% in intervention group and 20.5% in the control group) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (choice of postal questionnaire or phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (assessor blinded to intervention) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: :Low risk (Outcomes match those pre-specified in ISRCTN registry) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					selection of the reporting result: Low risk **Overall risk-of-bias judgement: Some risk** **Other information** Any breast feeding defined as baby offered breast milk at least once in 24 hours); exclusive breastfeeding defined in relation to milk, in the absence of any artificial milk feeding.
Full citation Kellams, A. L., Gurka, K. K., Hornsby, P. P., Drake, E., Conaway, M. R., A randomized trial of prenatal video education to improve breastfeeding among low-income women, Breastfeeding Medicine, 13, 666-673, 2018 **Ref Id** 985669 **Country/ies where the study was carried out** See Kellams 2016	**Sample size** See Kellams 2016 **Characteristics** See Kellams 2016 **Inclusion criteria** See Kellams 2016 **Exclusion criteria** See Kellams 2016	**Interventions** See Kellams 2016	**Details** See Kellams 2016	**Results** See Kellams 2016	**Limitations** See Kellams 2016

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type See Kellams 2016 **Aim of the study** See Kellams 2016 **Study dates** See Kellams 2016 **Source of funding** See Kellams 2016					
Full citation Kellams, A. L., Gurka, K. K., Hornsby, P. P., Drake, E., Riffon, M., Gellerson, D., Gulati, G., Coleman, V., The Impact of a Prenatal Education Video on Rates of Breastfeeding Initiation and Exclusivity during the Newborn Hospital Stay in a Low-income Population, Journal of human lactation: official journal of International Lactation Consultant	**Sample size** N=522 Intervention: n randomised=263* Control: n randomised=259* Number of women without missing data on breastfeeding initiation, included in the analysis*: intervention: n=211 vs control: n=220 Number of women used for calculating participant characteristics: 497 (intervention: n=249, control: n=248). Data were missing for the other women. *extracted from Kellams 2018	**Interventions** Intervention: 25-minute educational breastfeeding video viewed during the prenatal period. Control: 20-minute educational video about nutrition during pregnancy. Videos were shown in waiting room/examination room while the participant waited to be seen by the physician or nurse practitioner. Setting: 4 participating prenatal clinics between the University of Virginia Health System and the Virginia	**Details** **Data collection** Interviews were conducted by research assistants to collect demographic data, employment information, social support, parity, previous infant feeding experience, and intended infant feeding method(s). Postnatally, data were collected from medical records regarding labour, delivery, hospital stay, feeding methods and complications. **Analysis**	**Results** Initiation of breastfeeding: intervention (n=211): 159 vs control (n=220): 152* *numerators and denominators taken from Kellams 2018	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (a computer-generated block randomisation sequence using random block sizes of two or four, stratified by prenatal clinic, was used) Allocation concealment: Low risk (one member of the study team with no

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Association, 32, 152-159, 2016 **Ref Id** 698824 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** 'To determine whether a low-cost prenatal education video improves hospital rates of breastfeeding initiation and exclusivity in a low-income population'. **Study dates** 2009 to 2012 **Source of funding** Virginia Department of Health.	**Characteristics** Age (years) - mean (±SD) Intervention (n=249): 25.0 (5.7) vs control (n=248): 24.9 (5.5) Gestational age (≥37 weeks) - % Intervention (n=249): 89% vs control (n=248): 89% Gestational age (34 to <37 weeks) - % Intervention (n=249): 9% vs control (n=248): 9% Gestational age (<34 weeks) - % Intervention (n=249): 2% vs control (n=248): 2% Admitted to intermediate care nursery (ICN) or neonatal intensive care unit (NICU) - % Intervention (n=249): 17% vs control (n=248): 12% Race/ethnicity - % Non-Hispanic, white: intervention (n=249): 40% vs control (n=248): 43% Non-Hispanic, black: intervention (n=249): 47% vs control (n=248): 44% Non-Hispanic, other: intervention (n=249): 6% vs control (n=248): 5% Hispanic: intervention (n=249): 7% vs control (n=248): 8% BMI - mean (±SD)	Commonwealth University Health System, Virginia.	Analysis was conducted on an intention-to-treat basis.		direct contact with participants prepared all of the consecutively-numbered, sealed, opaque envelopes, which the research assistant opened just prior to loading the video for the participant to view) Baseline differences: High risk (Statistical differences between baseline characteristics for: Other adults living at home: partner, parents, other) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Intervention (n=249): 32.0 (8.3) vs control (n=248): 32.0 (9.2) <u>Infant birthweight (g) - mean (±SD)</u> Intervention: 3293.5 (603.1); control: 3302.6 (625.1) **Inclusion criteria** • Women of 24 to 41 weeks gestation eligible for the US Special Supplemental Nutrition Program for Women, Infants and Children (WIC); • Low income corresponding to 185% or less of the federal poverty income guidelines). **Exclusion criteria** • Multiple gestation; • Any known contraindication to breastfeeding (e.g. HIV infection, drug use, or receipt of chemotherapy);				**intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (data provided for n=497 of n=522 enrolled (10% missing)) **Judgement on risk of bias arising from missing outcome data: Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Primary language was not English.				DOMAIN 4 – outcome measurement Method of measuring the outcome: Some risk (data abstracted from medical records) Blinding of outcome assessors: Low risk (Research assistants abstracting data were blinded to the group the participant was assigned to) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					This study was included in the Cochrane reviews Balogun 2016 and Lumbiganon 2016.
Full citation Kools EJ, Thijs C, Kester AD, Vanden Brandt PA, De Vries H. , A breast-feeding promotion and support program a randomized trial in The Netherlands. , Preventive Medicine, 40, 60-70, 2005 **Ref Id** 997180 **Country/ies where the study was carried out** The Netherlands **Study type** Cluster-RCT **Aim of the study** To assess the effects of a breastfeeding promotion programme on breastfeeding continuation.	**Sample size** N randomised=781 Intervention: n randomised=408 Control: n randomised=373 Lost to follow-up: Intervention: at 1 month postpartum (n=371); at 3 months postpartum (n=368); at 6 months postpartum (n=364). Control: at 1 month postpartum (n=330); at 3 months postpartum (n=330); at 6 months postpartum (n=319). **Characteristics** <u>Maternal age (years)- number (%)</u> <25: Intervention: 27 (10); control: 26 (8) 25-30: Intervention: 163 (44); control: 148 (45) ≥31: Intervention: 168 (46); control: 156 (47) <u>Intention to breastfeed - number (%)</u> Intervention: 243 (66); control: 233 (71) <u>Parity - number (%)</u>	**Interventions** Intervention: structured health counselling; booklet to transfer information between caregivers and between mother and caregivers and used at each consultation; phone number to contact the caregiver if breastfeeding problems arose; lactation consultancy available via caregiver faxing consultant with details of problem (LC would then contact the caregiver or mother within 24 h of receiving the fax). Caregivers were nurses and physicians who received brief training in counselling and breastfeeding. Control: not specified. Setting: Three home health care organisations (including 10 geographically separated centres of maternity and child health care) in Limburg, The Netherlands	**Details** **Data collection** Women completed baseline questionnaires and follow-up questionnaires at 1, 3 and 6 months. **Analysis** To achieve 80% power, 253 participants were needed for each treatment group with complete follow-up. Chi-square tests were used to analyse categorical data and *t*-tests were used for continuous data. The main effect of the intervention on the proportion of mothers who breastfed at 3 months was analysed at the level of participating mothers (questionnaires) and level of the caregivers (registry forms) by comparing the proportion between intervention and control groups, using chi-square test. Univariate logistic regression was used to compute odds ratios and their 95% confidence intervals.	**Results** Initiation of breastfeeding: intervention (n=371): 254 vs control (n=330): 238 Any breastfeeding at 3 months: intervention (n=368): 119 vs control (n=330): 124 Odds ratio from multilevel analysis random intercepts model (used to account for variability in breastfeeding rates between the 10 centres, including regional differences) for any breastfeeding at 3 months, intervention versus control: 0.82 (0.58 to 1.14), based on 368 women in intervention group and 330 women in control group. Odds ratio from multivariate logistic regression (used to account for potential baseline differences of maternal age, maternal education, previous breastfeeding experience) for any breastfeeding at 3 months, intervention versus control: 0.82 (0.62 to 1.07), based on 368 women in intervention group and 330 women in control group.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (coin flip to decide between 2 centres which would be intervention and which control) Allocation concealment: Low risk (cluster RCT design) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates December 2000 to December 2002. **Source of funding** National Prevention Programme of ZONMw ("Netherlands Organisation for Health Research Development) and CZ-group.	Primiparous: Intervention: 207 (56); control: 183 (55) Multiparous: Intervention: 161 (44); control: 147 (45) **Inclusion criteria** • Pregnant women who applied for maternity care in the 3 home health care organisations. **Exclusion criteria** • Infants with birthweight <2000 g were excluded from the analysis.			Exclusive breastfeeding at 3 months: intervention (n=368): 99 vs control (n=330): 104 Opinions of women about feeding advice measured a scale from 1=not at all to 5=very much - see below: Are you satisfied with feeding advice by hospital nurse, mean score (±SD): intervention (n=187): 2.53 (1.09) vs control(n=155): 2.35 (1.07) Are you satisfied with feeding advice by general practitioner, mean score (±SD): intervention (n=139): 2.31 (0.84) vs control (n=105): 2.31 (0.89) Are you satisfied with feeding advice by paediatrician, mean score (±SD): intervention (n=127): 2.35 (0.95) vs control (n=99): 2.30 (0.89) Are you satisfied with feeding advice by child health care nurse, mean score (±SD): intervention (n=300): 1.98 (0.75) vs control (n=268): 2.05 (0.76) Are you satisfied with feeding advice by child health care physician, mean score (±SD): intervention (n=297): 2.01 (0.79) vs control (n=269): 2.10 (0.78) Are you satisfied with feeding advice by lactation consultant, mean score (SD): intervention	Blinding of participants: High risk (not described but assumed to be not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				(n=73): 2.07 (0.84) vs control (n=28): 2.18 (1.02) Satisfaction with the reach of caregivers, mean score (±SD): intervention (n=327): 2.05 (0.87) vs control (n=283): 2.03 (0.84) Did you receive contradictory feeding advice, mean score (±SD): intervention (n=329): 1.71 (0.45) vs control (n=287): 1.79 (0.41)	**(effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (n=3 in intervention and n=0 in control were lost to follow up) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from selection of the reporting result: Some risk **Overall risk-of-bias judgement: Some risk** **Other information** The authors did not adjust for cluster design effect. ICC for breastfeeding cessation from Lavender 2005 was used: ICC = 0.01. Exclusive breastfeeding defined as breastfeeding without supplemental liquids or solid foods other than medicines or vitamins; complementary breastfeeding defined as breast milk complemented by formula food or solid food.
Full citation Kramer MS, Barr RG, Dagenais S, Yang H, Jones P, Ciofani L, et al. , Pacifier use, early weaning, and cry/fuss behavior: a randomized controlled trial. , JAMA , 286, 322-6, 2001	**Sample size** N=281 Intervention: n=140 Control: n=141 Loss to follow-up: Intervention: n=13 lost to follow-up; n=127 completed trial. Control: n=10 lost to follow-up; n=131 completed trial.	**Interventions** Intervention: asked to avoid pacifiers when the infant cried or 'fussed' and suggested alternative ways to provide comfort. Control: all options were discussed for calming an infant including pacifier use. Both groups received a 45-minute session on	**Details** **Data collection** Mothers completed a validated behaviour diary (infant behaviours) on 3 consecutive days, including 2 weekdays and 1 weekend day, when infants were 4, 6 and 9 weeks of age. Mothers were interviewed at 3 months to determine	**Results** Exclusive breastfeeding at 3 months*: intervention (n=127): 46 vs control (n=131): 44 *Numerators calculated based on percentages of women stopping exclusive breastfeeding provided in the paper.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Women were stratified by

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 997029 **Country/ies where the study was carried out** Canada **Study type** RCT **Aim of the study** To compare the effects of pacifier versus non-pacifier use on breastfeeding. **Study dates** January 1998 to August 1999. **Source of funding** Medical Research Council of Canada.	**Characteristics** Age (years) - mean (±SD) Intervention: 31.6 (4.5); control: 31.5 (4.9) Birthweight (g) - mean (±SD) Intervention: 3457 (427); control: 3524 (415) Primiparous - % Intervention: 47.2; control: 47.3 **Inclusion criteria** • Women intending to breastfeed for at least 3 months; • Vaginal or caesarean delivery of healthy singleton newborns; • At least 37 weeks' gestational age; • Birthweight 2500g. **Exclusion criteria** Not stated.	breastfeeding. Both counselling interventions were provided by a research nurse trained in lactation counselling. Telephone calls by the research nurse reinforced the advice at 10 days and 3 weeks postpartum. Setting: Postpartum unit of a university teaching hospital in Montreal, Quebec.	whether they were still breastfeeding and use of pacifiers. **Analysis** 140 infants per intervention group were required. Analysis was undertaken on an intention-to-treat basis.		parity and, if multiparous, according to whether they had breastfed previously. Randomisation within each stratum was accomplished using computer-generated random numbers in blocks of 4.) Allocation concealment: Low risk (opaque envelopes) Baseline differences: Low risk (similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					from deviations from the intended interventions (effect of assignment to intervention): High risk DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (39% of mothers in the experimental group totally avoided pacifier use, compared with 16% in the control group) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Low risk (9% were lost to follow up in the intervention arm and 8% in the control arm)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from missing outcome data: Low risk DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (research assistant who was blinded to the intervention status of the mother) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Overall risk-of-bias judgement: Some concerns
Full citation Kronborg, H, Maimburg, R. D, Vaeth, M., Antenatal training to improve breast feeding: a randomised trial, Midwifery, 28, 784-790, 2012 **Ref Id** 1000615 **Country/ies where the study was carried out** Denmark **Study type** RCT **Aim of the study** To evaluate the impact of a breastfeeding focused antenatal training programme on knowledge, self-efficacy and problems relating to breasfeeding, and on	**Sample size** N=1193 randomised (Intervention: n=603; control: n=590) 2295 women were assessed for eligibility. 315 did not meet the inclusion criteria. 1980 were invited to participate. 478 did not reply, 172 refused to participate, 137 had an abortion. 1193 were randomised. 1138 women (95%) responded to questionnaire on baseline information, 1081 (91%) responded to questionnaire on breastfeeding status at 6 weeks, and 1077 (90%) responded to questionnaire at 1 year on duration of breastfeeding. 16 women in the intervention group (603 randomised) were lost to follow-up, leaving 587 women in the intervention group; 14 had an abortion and 2 had a late diagnosis of multiple pregnancy. 15 women in the control group (590 randomised) were lost to follow-up, leaving 575 women	**Interventions** Intervention: Structured antenatal training programme for 9 h attended between 30th and 35th weeks of pregnancy; partners were invited to participate. The programme, called 'Ready for Child programme' comprised 3 modules about 1. the birth process, pain relief, coping strategies 2. infant care and breast feeding 3. the parental role and the relationship between the woman and her partner. The maximum number of couples in each class was eight. The breastfeeding part was scheduled to take approximately 2 hours. The instructors were midwives. Control: Usual practice (no antenatal training programme). The existing antenatal care consisted of two consultations at the general practitioner, two ultrasound scans in early pregnancy, 4 to 5 midwifery consultations, and for	**Details** **Data collection** Data were collected through questionnaires sent via email or post, sent at weeks 24 and 26 of gestation and at 6 weeks and 1 year postpartum. Obstetric data were collected from the ongoing local birth cohort database. **Analysis** Categorical data were analysed using the chi-squared test and ordinal or continuous data were analysed using the Wilcoxon rank sum test of the Student's *t*-test. A Cox regression analysis was used to calculate a hazard ratio. Data were analysed according to the 'intention to treat' principle.	**Results** Breastfeeding within 2 hours after birth (extracted in the present review as breastfeeding initiation): intervention (n=587): 465 vs control (n=575): 438 (presented as baseline characteristic in paper) Any breastfeeding at 6 weeks: intervention group (n=587): 503 vs control (n=575): 478	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 Random sequence generation: Low risk (Randomisation was assigned by one staff midwife using a computer voice response system. Randomisation was based on an algorithm generated by a data manager. Ratio of 1:1) Allocation concealment: Low risk (Randomisation was assigned by one staff midwife using a computer voice response system) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between the groups)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
duration of breastfeeding. **Study dates** May 2006 to 2007 **Source of funding** Egmont Foundation, the Health Insurance Foundation, The National Board of Health, The Augustinus Foundation, and The Danish Midwifery Association.	in the control group. 8 had an abortion and 6 had a late diagnosis of multiple pregnancy. 1 had language problems. Across both groups (587+575), 90 women had missing data on breastfeeding within 2 hours after birth, and 102 women had missing data on any breast feeding 6 weeks postpartum. In the intervention group, 485 (80%) women attended the breastfeeding session. In the control group, 285 (50%) participated in an alternative antenatal course with a median number of lectures of 12 (range 1 to 22). **Characteristics** Maternal age (years) - mean (±SD) Intervention: 28.9 (3.7); control: 29.2 (3.7) BMI (kgm^2) - mean (±SD) Intervention: 23.0 (4.7); control: 23.1 (4.3) Gestational age at birth (week) - mean (±SD) Intervention: 39.7 (2.0); control: 39.6 (2.2) Birthweight (g) - mean (±SD) Intervention: 3429 (583.1); control: 3469 (560.0)	primiparous women a home visit by a health visitor. Women could seek additional support elsewhere. Setting: Aarhus Midwifery Clinic, a large clinic connected to a Danish university hospital in an urban area of Denmark.			**Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2 Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: Low risk (Postnatal midwives were blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): Some risk** Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria • Nullipara registered at the Aarhus Midwifery Clinic; • Older than 18 years of age at enrolment; • Singleton pregnancy; • Able to speak and understand Danish. **Exclusion criteria** Not stated.				(analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 Missing outcome data: Low risk (16/603 (3%) in intervention group and 15/590 (3%) of standard care group lost to follow-up) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (no

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					information is provided) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 Selective reporting: Some risk (Data not reported for all primary outcomes, but these outcomes are not relevant to our review question) **Judgement on risk of bias arising from selective reporting: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Kronborg,H, Vaeth,M, Olsen,J, Harder,I., Health visitors and breastfeeding support: influence of knowledge and self-efficacy, European Journal of Public Health, 18, 283-288, 2008	**Sample size** N randomised=109 health visitors, corresponding to 1595 women Intervention: n randomised=52 health visitors, corresponding to 780 women; n=654 women responded to the 2 questionnaires; n=52 reported on support at the end of follow-up.	**Interventions** Intervention: 1-3 home visits within the first 5 weeks covering topics on visit 1: technique and knowing the baby, visit 2: self-regulated breastfeeding and interpretation of baby's cues and visit 3: sufficient milk and interaction with the baby. Health visitors participated in	**Details** **Data collection** Data were collected from mothers to identify the influence of breastfeeding support, using self-administered questionnaires completed at the health visitors' first visit and 5 months postpartum. Outcomes	**Results** Comprehensible support (if the health visitor's information had been easy to comprehend) - mean score (±SD): intervention (n=52): 4.42 (0.24) vs control (n=57): 4.26 (0.34); p=0.01 Informational support (if the health visitor had talked to the woman about seven issues	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 1000617 **Country/ies where the study was carried out** Denmark **Study type** Cluster-RCT **Aim of the study** To assess the impact of a training course for health visitors on their practice. **Study dates** Health visitors in the intervention group participated in January 2004 in an 18 hour training course health visitors in the control group participated in March 2005. No other dates provided. **Source of funding** Danish Health Insurance Foundation,	Control: n randomised=57 health visitors, corresponding to 815 women; n=648 women responded to the 2 questionnaires; n=57 women reported on support at the end of follow-up. **Characteristics** <u>Maternal age (years) - number (%)</u> 15-24: Intervention (n=654): 61 (9); control (n=648): 66 (10) 25-32: Intervention (n=654): 432 (66); control (n=648): 411 (64) 33-46: Intervention (n=654) 160 (25); control (n=648): 161 (25) <u>Parity - number (%)</u> Primiparous: Intervention (n=654): 262 (40); control (n=648): 265 (41) Multiparous: Intervention (n=654): 392 (60); control (n=648): 381 (59) **Inclusion criteria** • Women living in the eligible municipalities; • Singleton birth;	an 18-hour training course on breastfeeding counselling. Information booklet given. Control: Standard care, which included 1 or more non-standardised visits by health visitors. Setting: 22 municipalities in Western Denmark.	were measured as mothers' perceptions on informational support provided by health visitors (scale of 0 to 7); instrumental support (yes or no); and comprehensible support (5-point Likert scale). **Analysis** Outcomes on informational, instrumental and comprehensible support were computed as the average value of the responses provided by the mothers whom she had visited.	related to breastfeeding practices) and instrumental support (if the health visitor had shown her how to breastfeed) were also reported but not extracted as considered too indirect proxies of women's satisfaction with intervention.	Allocation concealment: Low risk (not described, but as cluster RCT risk is likely to be low) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not described but assumed to be not blinded) Blinding of carers and people delivering the interventions: High risk (not described but assumed to be not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
the Lundbeck Foundation, and the Counties of Ribe and Ringkjobing in Denmark.	• Gestational age of at least 27 weeks. **Exclusion criteria** Not stated.				DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (missing values were excluded) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					(questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** The authors did not adjust for cluster design effect. ICC for breastfeeding cessation given in Kronborg 2007: ICC = 0.02
Full citation	**Sample size**	**Interventions**	**Details**	**Results**	**Limitations**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Labarere J, Bellin V, Fourny M, Gagnaire JC, Francois P, Pons JC. , Assessment of a structured in-hospital educational intervention addressing breastfeeding: a prospective randomised open trial. , BJOG: an international journal of obstetrics and gynaecology, 110:847–52., 2003 **Ref Id** 997273 **Country/ies where the study was carried out** France **Study type** RCT **Aim of the study** To assess the effects of a single one-to-one in-hospital education session on rates of breastfeeding at 17 weeks.	N randomised=210 Intervention: n randomised=106 Control: n randomised=104 Lost to follow-up: Intervention: n=13 women lost to follow-up; n=93 analysed. Control: n=7 lost to follow-up; n=97 analysed. **Characteristics** <u>Maternal age (years) - mean (±SD)</u> Intervention: 30.5 (4.6); control: 30.9 (4.2) <u>Parity - %</u> 0: Intervention: 52.7; control: 52.6 1: Intervention: 33.3; control: 40.2 ≥2: Intervention: 14.0; control: 7.2 <u>Gestation at birth (weeks) - mean (±SD)</u> Intervention: 39.9 (1.2); control: 40.1 (1.2) <u>Sex (female) - %</u> Intervention: 47.3; control: 54.6 <u>Infant birthweight (g) - mean (±SD)</u> Intervention: 3343 (396); control: 3360 (391) <u>Formula provision - %</u> Intervention: 37.6; control: 43.3	Intervention: In addition to standard care, women received a single (~30mins) one-to-one educational session delivered during the postpartum stay, and a leaflet containing key information in text and pictures. Control: Standard care which included verbal encouragement to maintain breastfeeding by maternity staff and a telephone number of a peer support group to call for help. Setting: Level 2 maternity hospital in France.	**Data collection** Data were collected during the postpartum hospital stay and mothers were sent a questionnaire by post when the infant was 17 weeks of age, relating to self-reported breastfeeding and exclusive breastfeeding. **Analysis** To achieve 80% power, 103 women were required for each treatment group. Data were analysed on an intention-to-treat basis.	Any breastfeeding at 17 weeks: intervention (n=93): 32 vs control (n=97): 39	Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (computer-generated random numbers in blocks of eight) Allocation concealment: Low risk (contained in consecutively numbered, sealed, opaque envelopes opened after the mother's consent was obtained) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates October to December 2001. **Source of funding** Not stated.	<u>Pacifier use - %</u> Intervention: 31.2; control: 30.9 **Inclusion criteria** • Women aged 18 years of age or older; • Able to speak French; • Employed outside of the home prenatally; • Gave birth to a healthy singleton baby of at least 37 weeks completed gestational age and of 2500 g birthweight; • In-hospital breastfeeding mothers; • Expected to complete follow-up. **Exclusion criteria** • Mother or newborn transferred to the intensive care unit; • Newborn died during the hospital stay.				Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Missing outcome data: Low risk (13/106 (12%) in intervention and 7/104 (7%) lost to follow up or incomplete questionnaire returned) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (postal questionnaires or if failed to respond, by phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (interviewer was blinded to mothers group allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from selection of the reporting result: Some risk **Overall risk-of-bias judgement:** **Other information** Breastfeeding defined as infant received any breast milk within the 24 hours prior to completion of the questionnaire. Exclusive breastfeeding defined as giving maternal milk s the only food source since the birth, with no other liquids (other than vitamins or medications) or foods given.
Full citation Labarere J, Gelbert-Baudino N, Ayral A S, Duc C, Berchotteau M, Bouchon N, et al. , Efficacy of breastfeeding support provided by trained clinicians during an early, routine, preventive visit: a prospective, randomized, open trial of 226 mother-infant	**Sample size** N randomised=231 Intervention: n randomised=116 Control: n randomised=115 Lost to follow-up: Intervention: n=92 attended routine preventive visit; n=4 excluded (unreachable or refused to participate); n=112 analysed. Control: n=107 received usual support; n=1 excluded (refused to participate); n=114 analysed.	**Interventions** Intervention: In addition to usual care, women were invited to an individual routine outpatient visit in a primary care physician's office within 2 weeks after birth (paediatrician or family physician). The physician had received 5-hour training on breastfeeding-related knowledge and counselling skills prior to the study. Control: Standard care including usual verbal encouragement to maintain	**Details** **Data collection** Mothers in the control and intervention groups completed postal questionnaires when infants reached 4 and 26 weeks of age, respectively. **Analysis** To achieve 85% power, accounting for ~5% loss to follow-up, 115 mother-infant pairs in each treatment group were required.	**Results** Breastfed within 1 hour after birth - number (%): intervention (n=11): 48 (41.4); control (n=115): 53 (46.1) Any breastfeeding at 12 weeks: intervention (n=112): 80 vs control (n=114): 72 Any breastfeeding at 24 weeks: intervention (n=112): 44 vs control (n=114): 30	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (random permuted blocks with a block size of 8, performed by a statistician) Allocation concealment: Low risk (concealed in

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
pairs. , Pediatrics, 115, e139–46, 2005 **Ref Id** 997096 **Country/ies where the study was carried out** France **Study type** RCT **Aim of the study** To assess the effect of pregnant women attending an early, routine, preventive, outpatient visits on breastfeeding outcomes. **Study dates** October 2001 to May 2002. **Source of funding** Grants from the Union Professionelledes Medecins Liberaux de la Region Rhone Alpes	**Characteristics** Maternal age (years) - mean (±SD) Intervention: 29.3 (4.1); control: 29.7 (4.8) Primiparous - number (%) Intervention: 58 (50.0); control: 63 (54.8) Infant sex (female) - number (%) Intervention: 56 (48.3); control: 53 (46.1) Gestational age at delivery (week) - mean (±SD) Intervention: 39.7 (1.3); control: 39.8 (1.2) Infant birthweight (g) - mean (±SD) Intervention: 3314 (441); control: 3325 (396) Expected duration of breastfeeding (months) - median (IQR) Intervention: 4 (3 to 6); control: 4 (3 to 6) **Inclusion criteria** • Women who gave birth to healthy, singleton infant;	breastfeeding by maternity ward staff, infant health and breastfeeding assessment by a paediatrician on the day of discharge, telephone number of a peer support group to call for help. Outpatient visits in a primary care physician's office at 1, 2, 3, 4, 5, and 6 months of age. Setting: Level 3 maternity facility in France.	Data were analysed on an intention-to-treat basis. Comparisons were undertaken using the Student's t-test for continuous data and the chi-square test or Fisher's exact test for categorical data. Multivariate analyses was performed, using logistic regression model to estimate the odds ratio of exclusive breastfeeding at 4 weeks associated with the intervention, after adjustment for variables such as maternal age.		consecutively numbered, sealed, opaque envelopes) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
and teh Delegation Regionale a la Recherche Clinique, Centre Hospitalier Universitaire. One author was supported by a grant from the Egide Foundation.	• Gestational age ≥37 weeks; • Breastfeeding on the day of hospital discharge. **Exclusion criteria** • Infant admitted to a neonatal unit; • Mother transferred to an intensive care unit; • Women ≤18 years of age; • Women living outside Chambery and its suburbs; • Unable to speak French; • Unlikely to complete follow-up monitoring because of psychosocial problems such as homelessness.				Non-adherence: High risk (79.3% of the intervention and 7% of the control group reported they attended the routine, preventive, outpatient visit) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Low risk (4/116 in intervention and 1/115 in control were lost to follow-up or refused to participate following enrolment) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (postal questionnaires and if not

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					returned, phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (investigators did not know allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Exclusive breastfeeding defined as giving maternal milk as the only food source, with no other liquids (other than vitamins or medications) or foods being given. Breastfeeding

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					defined as receipt by the infant of any breast milk.
Full citation Laliberte C, Dunn S, Pound C, Sourial N, Yasseen AS, Millar D, et al. , A randomized controlled trial of innovative postpartum care model for mother-baby dyads. , PLOS One , 11, e0148520, 2016 **Ref Id** 996996 **Country/ies where the study was carried out** Canada **Study type** RCT **Aim of the study** To assess the safety and efficacy of a newly established integrative postpartum community-based clinic providing support for mothers after discharge from	**Sample size** N=472 Intervention: n=315 Control: n=157 Lost to follow-up: Intervention: n=281 received intervention (n=34 did not attend clinic visit). At 12 weeks: lost to follow-up (n=20); mother withdrew (n=4); mother did not respond (n=16). Analysis at 12 weeks (primary outcome): n=295. Control: received control (n=157). At 12 weeks: lost to follow-up (n=23); mother withdrew (n=4); mother did not respond (n=19). Analysis at 12 weeks (primary outcome): n=134. **Characteristics** **Intervention (n=294); control (n=134)** <u>Maternal age (years) - number (%)</u> 15-19: Intervention: 1 (0.3); control: 1 (0.8) 20-24: Intervention: 16 (5.4); control: 6 (4.5) 25-29: Intervention: 67 (22.8); control: 28 (20.9)	**Interventions** Intervention: In addition to usual care, required to attend a postpartum pre-booked appointment scheduled 48hrs after discharge. Option to attend the clinic for further appointments at mothers' discretion up to 6 weeks following the birth of their baby. Control: Usual care – discharged according to hospital standards. Entitled to receive follow-up care and seek currently available breastfeeding support in the community. Setting: Two campuses of the Ottawa Hospital.	**Details** **Data collection** Baseline data were collected through chart review. Follow-up data were collected from all women at 2, 4, 12 and 24 weeks postpartum via a self-report web-based survey or a telephone interview. **Analysis** Accounting for 15% loss to follow-up, 230 participants per treatment group were required. Data were analysed on an intention-to-treat basis, the primary outcome (exclusive breastfeeding at 12 weeks) was also analysed on a per protocol basis. Logistic regression analyses were conducted to examine the effect of the intervention on 12 week exclusive breastfeeding rate; both adjusted and unadjusted models were used. Unadjusted and adjusted odds ratios and 95% confidence intervals were reported. Other	**Results** Any breastfeeding at 2 weeks: intervention (n=295): 278 vs control (n=140): 127 Exclusive breastfeeding at 2 weeks: intervention (n=295): 192 vs control (n=140): 82 Any breastfeeding at 12 weeks: intervention (n=295): 279 vs control (n=134): 124 Exclusive breastfeeding at 12 weeks: intervention (n=295): 195 vs control (n=134): 81 Any breastfeeding at 24 weeks: intervention (n=292): 242 vs control (n=138): 112 Satisfied with amount of information given by HCP, % very satisfied or satisfied (mean + SD): Intervention (n=295): 85.5 (68.8+19.7) vs control (n=134): 80.6 (42.5+38.1) Satisfaction with opportunities to ask questions, % very satisfied or satisfied (mean + SD): Intervention (n=295): 88.5	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (the randomisation list, which was generated using a permuted randomised block design, with permutation block sizes of 3, 6, and 9 units, by a statistician) Allocation concealment: Low risk (randomisation accessed from a data management system) Baseline differences: High risk (46.5% of the control group gave their baby supplements during the hospital stay compared to 35.9% of intervention group) **Judgement on risk of bias arising from the randomisation process: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
hospital on breastfeeding rates, readmission and mother's satisfaction. **Study dates** January to July 2014. **Source of funding** Ontario Ministry of Health and Long-Term Care.	30-34: Intervention: 105 (35.7); control: 60 (44.8) 35-39: Intervention: 76 (25.9); control: 32 (23.9) ≥40: Intervention: 21 (7.1); control: 5 (3.7) Missing: Intervention: 8 (2.7); control: 2 (1.5) **Intervention (n=315); control (n=157)** Primiparous - number (%) Intervention: 195 (61.9); control: 97 (61.8) Infant sex (male) - number (%) Intervention: 164 (52.1); control: 89 (56.7) **Inclusion criteria** • Women aged ≥18 years of age; • Women admitted to the birthing unit at either eligibility campus; • Birth of a healthy singleton infant at gestational age >36+6 weeks; • No diagnosed medical problems; • Women were breastfeeding their		outcomes were analysed using univariate tests, Pearson chi-squared or Student's *t*-tests based on the nature of the outcome.	(75.3+13.2) vs control (n=134): 62.7 (37.3+25.4) Satisfied with opportunities to give opinion, % very satisfied or satisfied (mean + SD): Intervention (n=295): 74.5 (60.3+14.2) vs control (n=134): 65.6 (44.0 +21.6) Satisfied with availability shown by HCP, % very satisfied or satisfied (mean + SD): Intervention (n=295): 88.2 (70.9+17.3) vs control (n=134): 76.2 (47.8+28.4) Satisfied with breastfeeding support received, % very satisfied or satisfied (mean + SD): Intervention (n=295): 87.5 (68.5+19.0) vs control (n=134): 64.2 (32.1+32.1) Satisfied with support received while transitioning from hospital to home, % very satisfied or satisfied (mean + SD): Intervention (n=295): 84.4 (62.7+21.7) vs control (n=134): 72.4 (38.8+33.6) Total general satisfaction score, (mean + SD): Intervention (n=295): 50.2 (6.9) vs control (n=134): 45.0 (8.4)	DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (10.8% of the intervention group did not attend the clinic) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	baby and continued upon discharge; • Could be contacted by phone or email after hospital discharge. **Exclusion criteria** • Women who did not speak English or French; • Unable to present to the clinic (transport not available); • Had given birth to multiples or preterm babies; • Had no plan or desire to breastfeed; • Were adoptive mothers; • Had breast surgery; • Women identified with a psychological risk that may impede their ability to attend the first clinic appointment; • Out-of-province women.				**from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (6.3% of the intervention and 14.6% of the control groups were lost to follow up) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (web-based survey or telephone interview - women's self-report on breastfeeding) Blinding of outcome assessors: High risk (not described clearly, likely not blinded) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 – reporting

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Selective reporting: Some risk (Data not reported for all primary outcomes, but these outcomes are not relevant to our review question) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Exclusive breastfeeding defined as the feeding of the infant's mother's breast milk only (including expressed breast milk).
Full citation Lavender, T, Baker, L, Smyth, R, Collins, S, Spofforth, A, Dey, P., Breastfeeding expectations versus reality: A cluster randomised controlled trial, BJOG: An International Journal of Obstetrics and Gynaecology, 112, 1047-1053, 2005	**Sample size** N=1312 randomised Randomised to intervention: n=679 Randomised to control: n=633 Of the 1649 women eligible for the study, 337 declined to participate: 163 in the intervention arm and 174 in the control arm. Reasons for declining were provided in the paper and included having breastfed successfully before,	**Interventions** Intervention: Standard antenatal care plus during third trimester attendance of a single antenatal education session on breastfeeding. The session involved up to 8 women and was facilitated by a qualified infant feeding coordinator. Midwives were trained for this intervention. Control: Standard antenatal care that included	**Details** **Data collection** Data on initial uptake of breastfeeding was gained from questionnaires completed immediately before discharge, and on maintenance of breastfeeding from postal questionnaires at 2, 4 and 6 weeks, and 4, 6 and 12 months postnatally. Women completed a semi-	**Results** Any breastfeeding at 2 weeks*: Intervention (n=644): 444 vs control (n=605): 389 Any breastfeeding at 6 weeks*: Intervention (n=644): 332 vs control (n=605): 297 Any breastfeeding at 6 months*: Intervention (n=644): 140 vs control (n=605): 138	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (Cluster RCT - not described)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 1000619 **Country/ies where the study was carried out** UK **Study type** Cluster-RCT **Aim of the study** 'To evaluate the effect of an antenatal education breastfeeding intervention on women's breastfeeding duration'. **Study dates** The study commenced on the 1st of July 1998. **Source of funding** Research and Development Fund grant from the Northwest Regional R&D Directorate.	not wanting to be part of research, not wanted to attend the workshop, or no reason given. Women in the intervention group (n=679) who attended the workshop: n=439; did not receive the intervention: n=240 Women in the control group (n=633) who received the intervention: n=5. A total of 1249 (95%) of women were available or analysis.* Women allocated in the intervention group (n=679) who provided main outcome data: n=644. Reasons for no response: 2 moved, 2 no live baby/withdrew; 31 data not available on breastfeeding status Women in the control group (n=633) who provided main outcome data: n=605. Reasons given for no response: 4 moved, 5 no live baby/withdrew, 19 data not available on breastfeeding status. **Characteristics** Age (years) - mean (±SD)	breastfeeding advice from clinic midwives. Setting: Teaching hospital in North West of England.	structured diary regarding their breastfeeding experiences. **Analysis** Unit of randomisation: 8 electoral wards in 1 county, pairs were matched according to Jarman Underprivileged area score (UPA). Within-pair randomised = 4 clusters each. Sample size calculation indicated that at least 1040 women were needed for a study power of 90% to detect an increase in breastfeeding of 15%. The authors adjusted for cluster design effect. ICC for breastfeeding cessation used: ICC=0.01. Analysis was conducted on an intention-to-treat basis. Multilevel models, accounting for the pair-matched cluster randomised design, were used to compare treatment arms.	The proportion of women feeling unprepared for the difficulties encountered while breastfeeding was provided* but was not extracted as it was considered a too indirect proxy of 'satisfaction with breastfeeding intervention' (outcome in protocol).	Allocation concealment: Low risk (opaque sealed envelopes) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (Some if women were blinded, but assumed not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Intervention: 29.6 (5.3); control: 29.7 (5.4) Primiparous - % Intervention: 49.7%; control: 53% Ethnic origin - % White: Intervention: 93.1%; control: 91.1% Deprivation score - mean (±SD) Intervention: 20.8 (2.6); control: 19.4 (5.9) Intention to breastfeed - number (%) 6 weeks up to 4 months Intervention: 37.4%; control: 34.1% in control group 4 months to 6 months Intervention: 23.4%; control: 28.9% 6 months up to 12 months Intervention: 18.1%; control: 15.8% >12 months Intervention: 4.3%; control: 3.9% **Inclusion criteria** • Women registered with a practice site/GP in one of the 8 electoral wards;				DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (n=5 of n=633 women assigned to the control group received the intervention and n=240 or n=679 women assigned to the intervention did not receive the intervention) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Low risk (28/633 (4%) in the intervention arm and 27/671 (4%) in the control arm did not provide outcome data)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Women who stated a desire to breastfeed. **Exclusion criteria** • Women with detected foetal abnormality at 20 week ultrasound scan.				**Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Statistician conducting the analysis was blinded) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some concerns**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Other information *Breastfeeding was defined as mothers giving babies any amount of breast milk, including expressed milk and those giving additional formulae feeds.
Full citation Lutenbacher, M., Elkins, T., Dietrich, M. S., Riggs, A., The Efficacy of Using Peer Mentors to Improve Maternal and Infant Health Outcomes in Hispanic Families: Findings from a Randomized Clinical Trial, Maternal and child health journal, 22, 92-104, 2018 **Ref Id** 929886 **Country/ies where the study was carried out** US **Study type** RCT	**Sample size** N=188 Intervention: n=94 Control: n=94 Lost to follow-up: Intervention: Prenatal (n=1 moved, n=2 preterm); 2 weeks (n=2 moved); 2 months (n=1 missed); 6 months (n=91). Control: Prenatal (n=4 preterm, n=2 moved, n=5 miscarriage); 2 weeks (n=1 missed), 2 months (n=1 missed), 6 months (n=87). **Characteristics** <u>Maternal age (years) - mean (±SD)</u> Intervention:30.4 (6.6); control: 28.7 (6.3) <u>Nation of origin - number (%)</u> Costa Rica: Intervention: 1 (1.1); control: 0 (0)	**Interventions** Intervention: Implementation of the Maternal Infant Health Outreach Worker (MIHOW) model – model stresses recognising family strengths and utilising those to address their own family needs. Monthly home visits (~1hr) and periodic group gatherings. Control: Minimal education intervention – distribution of printed educational materials about maternal and infant health. Setting: underserved communities in Tennessee.	**Details** **Data collection** Data were collected using interview guides at enrolment (≤26 weeks pregnant), approximately 35 weeks pregnant, and 2 weeks, 2 months and 6 months postpartum. Each data collection interview took approximately 1 hour. **Analysis** To achieve 80% power, 75 women per treatment group were required. Data were analysed on an intention-to-treat basis. Values of change in measured assessed more than once were summarised. Frequency distributions summarised nominal and ordinal distributions; means and	**Results** Breastfeeding initiation: intervention (n=91): 78 vs control (n=86): 71 Any breastfeeding at 2 weeks: intervention (n=90): 75 vs control (n=85): 68 Exclusive breastfeeding at 2 weeks: intervention (n=90): 19 vs control (n=85): 8 Any breastfeeding at 2 months: intervention (n=90): 61 vs control (n=85): 60 Exclusive breastfeeding at 2 months: intervention (n=90): 2 vs control (n=85): 1 Any breastfeeding at 6 months: intervention (n=90): 45 vs control (n=85): 42	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (generated by the study statistician via a computer-generated, permuted block program) Allocation concealment: Some risk (not described) Baseline differences: Some risk (Statistical difference between groups for employment status - 18.4% vs 1% full-time employed, 62.1% vs 84.6% unemployed / not looking)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess the effects of the Maternal Infant Health Outreach Worker (MIHOW) programme in Hispanic women on maternal and infant outcomes. **Study dates** July 2014 to September 2016. **Source of funding** Supported by the Affordable Care Act Maternal, Infant and Early Childhood Home Visiting Programme and the National Centre for Advancing Translational Sciences of the National Institutes of Health.	El Salvador: Intervention: 9 (9.9); control: 8 (9.2) Guatemala: Intervention: 9 (9.9); control: 3 (3.4) Honduras: Intervention: 11 (12.1); control: 17 (19.5) Mexico: Intervention: 60 (65.9); control: 59 (67.8) Peru: Intervention: 1 (1.1); control: 0 (0) Family income - number (%) <$10000: Intervention: 65 (71.4); control: 57 (65.5) $10001-$15000: Intervention: 23 (25.3); control: 27 (31.0) $15001-$40000: Intervention: 3 (3.3); control: 43 (3.4) **Inclusion criteria** • Women eligible to receive MIHOW programme; • Self-identified as Hispanic; • Written confirmation of pregnancy ≤26 weeks gestation; • Residing within 30 miles of study offices; • Willing to participate.		standard deviations summarised normal continuous distributions, median and inter-quartile range (IQR) skewed distributions. Effect sizes were generated for all comparisons using Cohen's d statistic.		**Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria • Women who had previously received MIHOW services; • Women with severe mental or physical disability; • Women aged <18 years of age.				(analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (85/94 for available for analysis from control vs 90/94 for intervention) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (home interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Data collectors were blinded to group assignment) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					measurement of the outcome: Low risk DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan provided - although reference to study protocol was made) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some riskOther information** $25 merchandise card given to all participants.
Full citation MacArthur, C, Jolly, K, Ingram, L, Freemantle, N, Dennis, C. L, Hamburger, R, Brown, J, Chambers, J, Khan, K., Antenatal peer support workers and initiation of breast feeding: cluster randomised controlled trial, BMJ (Clinical	**Sample size** See Jolly 2012 **Characteristics** See Jolly 2012 **Inclusion criteria** See Jolly 2012	**Interventions** See Jolly 2012	**Details** See Jolly 2012	**Results** See Jolly 2012	**Limitations** See Jolly 2012

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
research ed.), 338, b131, 2009 **Ref Id** 1000625 **Country/ies where the study was carried out** See Jolly 2012 **Study type** See Jolly 2012 **Aim of the study** See Jolly 2012 **Study dates** See Jolly 2012 **Source of funding** See Jolly 2012	**Exclusion criteria** See Jolly 2012				
Full citation Mattar CN, Chong YS, Chan YS, Chew A, Ta n P, Chan YH, et al. , Simple antenatal preparation to improve breastfeeding practice:	**Sample size** N=401 Intervention (1): n=123 Intervention (2): n=132 Control: n=146 Losses to follow-up at birth: intervention (1): 5 vs intervention (2): 6 vs control: 6	**Interventions** Intervention (1): Received an information booklet on breastfeeding, watched a 16 minute education video on breastfeeding, one 15 minute session with a lactation	**Details** **Data collection** Data on delivery and feeding practices were collected a day after delivery (before discharge from hospital) and 6 weeks postpartum either by	**Results** Exclusive or predominant breastfeeding at 2 weeks: intervention 1 (n=112): 61 vs intervention 2 (n=123): 60 vs control (n=135): 69 Exclusive or predominant breastfeeding at 3	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
a randomized controlled trial. , Obstetrics & Gynecology , 109, 73–80, 2007 **Ref Id** 996982 **Country/ies where the study was carried out** Singapore **Study type** RCT **Aim of the study** 'To address the impact of simple antenatal educational interventions on breastfeeding practice'. **Study dates** May 2002 to December 2004. **Source of funding** A grant from the National Healthcare Group, Singapore.	Losses to follow-up at 6 weeks postpartum in addition to the previous ones: intervention (1): 6 vs intervention (2): 3 vs control: 5 Losses to follow-up at 3 months postpartum in addition to the previous ones: intervention (1): 0 vs intervention (2): 3 vs control: 5 Total losses to follow-up at 3 months postpartum: intervention (1): 11 vs intervention (2): 12 vs control: 17 **Characteristics** <u>Age (less than 29 years old) - %</u> Intervention 1 (n=123): 50.4% vs intervention 2 (n=132): 56.1% vs control (n=146): 54.8% <u>Gestational age at birth (weeks) - mean (±SD)</u> Intervention 1 (n=123): 38.6 (1.6) vs intervention 2 (n=132): 38.7 (1.4) vs control (n=146): 38.7 (1.3) <u>Ethnicity - %</u> Chinese: intervention 1 (n=123): 28.5% vs intervention 2 (n=132): 26.5% vs control (n=146): 28.7% Malay: intervention 1 (n=123): 56.1% vs intervention 2	counsellor who examined the woman's nipples to assess adequacy for breastfeeding. Intervention (2): As for intervention 1 but no session with lactation counsellor. Control: Standard care Setting: National University Hospital (outpatient obstetric clinic), Singapore.	telephone interviews or in clinic conducted by research assistant. Follow-up questionnaires were administered via telephone at 3 and 6 months postnatally. **Analysis** To achieve 80% power for comparison between exclusive and predominant breastfeeding rates in intervention 1 and control, 134 participants in each group were required. Analysis was performed on an intention-to-treat basis. Associations between intervention groups and feeding practices were analysed using chi-square or Fisher exact tests, with odds ratios presented where applicable. Multiple comparisons were adjusted for using the Bonferroni correction.	months: intervention 1 (n=112): 27 vs intervention 2 (n=120): 21 vs control (n=130): 15 Any breastfeeding at 2 weeks*: intervention 1 (n=112): 106 vs intervention 2 (n=123): 111 vs control (n=135): 124 Any breastfeeding at 3 months*: intervention 1 (n=112): 64 vs intervention 2 (n=120): 66 vs control (n=130): 61 Any breastfeeding at 6 months*: intervention 1 (n=112): 48 vs intervention 2 (n=120): 39 vs control (n=129): 43 *Calculated by the NGA technical team by subtracting the number of women exclusively formula feeding to the number of women with available data.	Random sequence generation: Low risk (A computer-generated list was used to randomise the women into the 3 groups) Allocation concealment: Low risk (Each woman was allocated to the intervention group next on the list after written informed consent had been obtained) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: Low risk (The allocated group was concealed from the woman at the point of recruitment) Blinding of carers and people delivering the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	(n=132): 59.9% vs control (n=146): 58.9% Indian: intervention 1 (n=123): 13.0% vs intervention 2 (n=132): 12.1% vs control (n=146): 10.3% Others: intervention 1 (n=123): 2.4% vs intervention 2 (n=132): 1.5% vs control (n=146): 2.1% <u>Parity (multipara) - %</u> Intervention 1 (n=123): 61.8% vs intervention 2 (n=132): 61.4% vs control (n=146): 65.1% <u>Prior breastfeeding experience - %</u> Intervention 1 (n=123): 56.3% vs intervention 2 (n=132): 67.5% vs control (n=146): 58.0% **Inclusion criteria** • Singleton pregnancies; • Gestational age of at least 36 weeks at recruitment; • No uterine scar; • Absence of any obstetric complication that would				interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): Some risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (The discussion states: 'Contamination between groups was not strictly prevented, and women in the control group came to know about the interventions offered to the other groups simply by speaking to women in those groups. They were, however, not given access to the booklet or the video, which were available only at the clinic. It is unclear how much contamination there was and how it affected outcomes.) Analysis of participants in the group to which they were randomised: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	contraindicate a vaginal birth. **Exclusion criteria** Not stated.				(analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: low risk (Lost to follow up 11/123 (9%) for booklet, video + one lactation counsellor session; 12/132 (9%) for booklet and video; 17/146 (12%) for standard care) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (The second assistant collecting the data was blinded to the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					intervention however the investigators analysing the data were not blinded) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (trial registration reported and all outcomes included) **Judgement on risk of bias arising from selection of the reporting result: Low risk** **Overall risk-of-bias judgement: Low concerns** **Other information** Included in Cochrane review Lumbiganon 2016 Predominant breastfeeding (no formula; water allowed); exclusive breastfeeding (no formula or water); partial breastfeeding (feeding formula in addition to breast milk).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Maycock, B., Binns, C. W., Dhaliwal, S., Tohotoa, J., Hauck, Y., Burns, S., Howat, P., Education and support for fathers improves breastfeeding rates: a randomized controlled trial, Journal of human lactation: official journal of International Lactation Consultant Association, 29, 484-90, 2013 **Ref Id** 577781 **Country/ies where the study was carried out** Australia **Study type** RCT **Aim of the study** To assess the effects of an antenatal education session and postnatal support targeted at	**Sample size** N=699 couples Of the 385 men in the intervention group, 342 (89%) attended the antenatal sessions and 295 (86% responded to the 6-week questionnaire (no further details reported). **Characteristics** <u>Maternal age (years) - median (interquartile range)</u> Intervention: mothers: 27 (14 to 44); fathers: 29 (16 to 51); control: mothers: 27 (16 to 42); fathers: 29 (17 to 54) <u>Family income (fathers - $) - n (%)</u> <15000: Intervention: 7 (2.0); control: 4 (1.4) 15000-45000: Intervention: 50 (14.4); control: 43 (14.9) 45000-75000: Intervention: 97 (28.0); control: 87 (30.0) 75000-105000: Intervention: 110 (31.7); control: 80 (27.5) 105000-120000: Intervention: 90 (25.9); control: 80 (27.6) **Inclusion criteria**	**Interventions** Intervention: aimed at fathers - standard care plus a 2-hour antenatal education session led by a male facilitator and a postnatal support 6 week-package, which included promotional materials delivered at weekly intervals. Control: standard care consisting of antenatal classes and routine hospital and postnatal care. Setting: 8 public maternity hospitals in Perth, Western Australia.	**Details** **Data collection** To avoid contamination between intervention and control groups, a minimal period of 4 weeks was implemented. Questionnaires were completed during the antenatal period and postnatally at 6 weeks and 6 months. Baseline questionnaires were self-completion; follow-up self-completion questionnaires were administered by printed questionnaires or by telephone **Analysis** To achieve 80% power, assuming a loss to follow-up of 20%, a minimum of 368 participants in each group was required. Data were analysed on an intention-to-treat basis. Data were analysed as frequencies or medians (with interquartile range). Between group comparisons were made using logistic regression, both before and after adjustment for age, hospital, or socioeconomic	**Results** Any breastfeeding at 6 weeks*: intervention (n=354): 288 vs control (n=298): 224 Exclusive breastfeeding at 6 weeks*: intervention (n=354): 164 vs control (n=298): 133 *Denominators calculated by the NGA technical team based on numerators and percentages provided in the paper.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Random number generator) Allocation concealment: Some risk (no details) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
fathers on breastfeeding rates. **Study dates** Participants were originally recruited between May 2007 and July 2008; also states that the sample was recruited between May 2008 to June 2009. **Source of funding** Health promotion Foundation of Western Australia.	• Mothers who had enrolled for antenatal education and older than 18 years of age; • Fathers had to be contactable by telephone or email at home or in the community; • Fathers had to reside in Western Australia and intend to participate in the rearing of their child. **Exclusion criteria** Not stated.		status. Data were presented as odds ratios and their 95% confidence intervals for breastfeeding, full breastfeeding, and full formula feeding.		interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (To avoid contamination between intervention and control groups, a minimal washout period of 4 weeks was implemented. As the classes began at 33 weeks, the chance of overlap between a control and intervention class was there- fore remote and did not occur at any of the hospitals.) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					intended interventions (effect of adhering to intervention): Low risk DOMAIN 3 – missing data Missing outcome data: Low risk (data available on 593 of 699 (84.8%) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (printed questionnaires or by telephone based on preference) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (Data not reported for all primary outcomes, but

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					these outcomes are not relevant to our review question) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation McDonald SJ, Henderson JJ, Faulkner S, Evans SF, Hagan R., Effect of an extended midwifery postnatal support programme on the duration of breast feeding: a randomised controlled trial. , Midwifery , 26, 88-100, 2010 **Ref Id** 997145 **Country/ies where the study was carried out** Australia	**Sample size** N randomised=849 Intervention: n randomised=425 Control: n randomised=424 Lost to follow-up: Intervention: at 2 months (n=342), telephone follow-up (n=45); at 6 months (n=393), telephone follow-up (n=14) Control: at 2 months (n=300), telephone follow-up (n=66); at 6 months (n=389), telephone follow-up (n=22) **Characteristics** Maternal age (years) - number (%)	**Interventions** Intervention: Standard care plus individual educational session in hospital room and follow-up support at home by a midwife. Phone calls twice weekly and weekly home visits up to 6 weeks old. Control: Standard care, including one or more home visits by a midwife up to 7 days old, and access to outpatient lactation clinics. Breast-feeding promotional literature and access to an in-house video system to view videos on establishing breast feeding. Setting: large public teaching hospital in Australia.	**Details** **Data collection** Self-report postal questionnaires were completed at 2 and 6 months postpartum, including questions about breastfeeding status. Breastfeeding diaries were completed weekly until 2 months and then monthly until 6 months. **Analysis** To achieve 80% power, 850 women were required. Data were analysed on an intention-to-treat basis. Relative risks and 95% confidence intervals were calculated, and adjusted for	**Results** Initiation of breastfeeding (>4 hours after birth): Intervention (n=425): 149 vs control (n=424): 176 Any breastfeeding at 6 months: intervention (n=418): 267 vs control (n=421): 286. Adjusted risk ratio is provided.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Women were asked to select an envelope from a group of at least six. Envelops were replenished in blocks of 12) Allocation concealment: Low risk (sealed, opaque envelopes) Baseline differences: Low risk (no statistically

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type RCT **Aim of the study** To assess the effects of an extended midwife postnatal support programme on the duration of full breast feeding. **Study dates** March 2000 to October 2001. **Source of funding** Grants from Healthway, Women and Infants Research Foundation, and King Edward Memorial Hospital, Perth, Western Australia.	<25: Intervention: 94 (22.1); control: 92 (22.2) 25-34: Intervention: 246 (57.9); control: 245 (57.8) ≥35: Intervention: 85 (20.0); control: 86 (20.1) Low socio-economic status - number (%) Intervention: 137 (34.3); control: 148 (37.0) Intended to breastfeed >6 months - number (%) Intervention: 326 (76.7); control: 322 (75.9) Primiparous - number (%) Intervention: 213 (50.1); control: 215 (50.7) Gestational age (weeks) - median (range) Intervention: 39.0 (37.0 to 42.0); control: 40.0 (37.0 to 43.0) Birthweight (g) - median (range) Intervention: 3470 (3520 to 5170); control: 3483 (2500 to 5000) Baby SCBU admission - number (%) Intervention: 71 (16.7); control: 48 (11.3); p=0.029 **Inclusion criteria**		the stratification variables (parity, level of education completed), and tested using the Cochran-Mantel-Haenszel statistic. Logistic regression analysis was used to identify factors influencing stopping breastfeeding, full or any, by 6 months.		significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (93% of the intervention group received the education session and only

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Women who gave birth at King Edwards Memorial Hospital; • Women who intended to breastfeed. **Exclusion criteria** • Gestational age <36 weeks; • Multiple pregnancy; • Maternal age <18 years; • Insufficient English to complete questionnaires; • Women living outside the Perth area or who were not contactable by telephone.				7% did not receive a home visit) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (at 2 months 71.9% of control and 80.5% of intervention returned their questionnaires, whilst at 6 months 91.7% vs 92.5% respectively) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (postal questionnaire is no

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					response, then telephoned - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Full breastfeeding was defined as baby receiving breast milk alone with no additional fluids or solids apart from infrequent vitamins, water, juice or

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					ritualistic feeds; or any breastfeeding.
Full citation McKeever P, Stevens B, Miller KL , MacDonell K, Gibbins S, Guerriere D, et al. , Home versus hospital breastfeeding support for newborns: a randomized controlled trial., Birth 2002;29 (4):258–65., 2002 **Ref Id** 997077 **Country/ies where the study was carried out** Canada **Study type** RCT **Aim of the study** To compare the effects of breastfeeding support offered in hospital and home settings on breastfeeding outcomes.	**Sample size** N randomised =101 Intervention: n randomised=53 Control: n randomised=48 Women analysed: Intervention n=41, Control n=34 **Characteristics** <u>Maternal age at delivery (years, mean (SD))</u> Intervention: 32.0 (4.2) Control: 33.1 (4.4) <u>Primiparous (n (%))</u> Intervention: 20 (51.3) Control: 15 (45.5) <u>Multiparous (n (%))</u> Intervention: 19 (48.7) Control: 18 (54.5) <u>Breastfeeding status at discharge</u> Intervention: 87% Control: 83% **Inclusion criteria**	**Interventions** Intervention: Mother-newborn pairs in the experimental group were assessed at 24 to 36 hours postpartum and sent home if they met the same discharge criteria. Each mother-newborn pair in the experimental group was scheduled to receive up to 3 home visits from community nurses qualified as lactation consultants. Women were not evaluated until the end of the intervention, regardless of whether it consisted of 2 or 3 visits Control: Mother-newborn pairs in the standard care group were cared for in the hospital and were discharged using standard hospital criteria at approximately 48 to 60 hours postpartum. All: Mothers were made aware of the outpatient hospital breastfeeding clinic, and were encouraged to use a preexisting 24-hour telephone help line.	**Details** **Data collection** Assessed during a home visit scheduled at the mother's convenience from 5 to 12 days postpartum. The incidence and frequency of exclusive breastfeedings in the preceding 24 hours (defined as the mother feeding the newborn by breast, and excluding supplementation with expressed breast- milk or formula), and, second, the incidence and frequency of exclusive feeds of breastmilk in the preceding 24 hours (defined as the mother feeding the newborn by breast and/or by supplementing with expressed breastmilk, and excluding supplementation with formula). **Analysis** A sample of 40 home-based mother-infants pairs and 40 hospital-based mother-infant pairs would provide a power of 85 percent to detect a	**Results** On average, infants in the experimental group were discharged 7.1 hours earlier than infants receiving standard care At follow up (Intervention group mean 8.4 days (1.9); Control 7.8 days (1.4) Proportion of baby's feeds in the past 24hr that were exclusively breastfeeding: Intervention: mean 0.98 (range 0.50-1.00) vs Control mean 0.87 (range 0.00-1.00)	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Low risk (central randomisation procedures) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates July 1999 to December 2000 **Source of funding** Health Transition Fund, Health Canada, Ottawa and The Hospital for Sick Children Foundation, Toronto, Ontario, Canada	Women who had delivered a live, singleton infant within the preceding 12 hours, were at least 21 years of age, resided in the defined metropolitan area, had a telephone, intended to breastfeed, were breastfeeding at discharge, and would receive satisfactory support at home (determined by postpartum nurses who assessed mothers' circumstances). Newborns were eligible if they were 35 weeks' gestational age or greater, were breastfed at discharge, and did not have congenital anomalies or morbidities, including hyperbilirubinemia, blood group incompatibility, or sepsis. **Exclusion criteria** Women were excluded if they did not speak English and had experienced caesarean deliveries, postpartum complications, and morbidities such as fever and abnormal bleeding, chronic illnesses, or disabilities.		difference in cost equal to 0.67 standard deviations at the 0.05 level of significance using a two-tailed test. All quantitative data were double entered, logic checked, and corrected for errors. Two-sample t tests were used to compare normally distributed variables; nonparametric Wilcoxon rank sum tests were used to compare ordinal and skewed variables; and proportions were compared using the Fisher exact tests. Significance for all tests was set at 0.05, and all tests were two-tailed.		Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (15% of mothers 8/53 dropped out or were list to follow-up of the intervention arm and 15% from the control arm 7/48) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Missing outcome data: Some risk (9% of mothers 5/53 of the intervention arm and 13% from the control arm 6/48 were excluded from analysis) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (women self-report) Blinding of outcome assessors: High risk (Although they attempted to blind, women would reveal their allocations to interviewer) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from selection of the reporting result: Some risk **Overall risk-of-bias judgement: High risk** **Other information** Breastfeeding rates were assessed by determining, first, the incidence and frequency of exclusive breastfeedings in the preceding 24 hours (defined as the mother feeding the newborn by breast, and excluding supplementation with expressed breast- milk or formula).
Full citation McLachlan, H. L, Forster, D. A, Amir, L. H, Cullinane, M, Shafiei, T, Watson, L. F, Ridgway, L, Cramer, R. L, Small, R., Supporting breastfeeding In Local Communities (SILC) in Victoria, Australia: a cluster randomised	**Sample size** N randomised=9675 Home visit group (Intervention 1): n=3335 Home visit plus drop-in group (Intervention 2): n=2891 Control group: n randomised=3449	**Interventions** Intervention (1): Usual care plus home visit – Maternal and child health nurse (MCHN) early visit to bridge the gap (~7days) between a visit by a hospital-midwife and the typical first visit from a MCHN. Intervention (2): Usual care plus home visit and drop in – in addition to the extra	**Details** **Data collection** Baseline breastfeeding outcomes (3, 4 and 6 months) were collected for a period of 3 months before infants exposed to the interventions had their 4-month appointments. Data on the primary outcome (any breastfeeding at 4-	**Results** Any breast milk feeding at 3 months: intervention 1 (n=2991): 1890; intervention 2 (n=2530): 1475 vs control (n=2825): 1678 Any breast milk feeding at 6 months: intervention 1 (n=2527): 1261; intervention 2 (n=2450): 1110 vs control (n=2487): 1164	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Envelopes shuffled for cluster allocations)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
controlled trial, BMJ Open, 6, e008292, 2016 **Ref Id** 1000629 **Country/ies where the study was carried out** Australia **Study type** Cluster-RCT **Aim of the study** To assess the effects of early breastfeeding support at home, with or without access to breastfeeding assistance at drop-in centres, in breastfeeding maintenance in areas with low breastfeeding rates. **Study dates** The intervention ran for a 9-month period from July 2012 to March 2013. The first 2 months were a pilot phase.	Lost to follow-up: Intervention (1): 4 month visit: n=732 did not attend; n=6 infants <13 weeks, n=172 infants >22 weeks, n=144 primary outcome missing; 4 month infant feeding outcome: n=2281 women. Intervention (2): 4 month visit: n=382 did not attend; n=0 infants <13 weeks, n=93 infants >22 weeks, n=72 primary outcome missing; 4 month infant feeding outcome: n=2344 women. Control: 4 month visit: n=679 did not attend; n=0 infants <13 weeks, n=128 infants >22 weeks, n=228 primary outcome missing; 4 month infant feeding outcome: n=2414 women. **Characteristics** <u>Maternal age (years) - mean (±SD)</u> Intervention 1: 31.1 (5.0); intervention 2: 31.4 (5.1); control: 30.7 (5.3) <u>Gestational age (weeks) - mean (±SD)</u>	MCHN visit, a drop-in centre was made accessible to women. The centre was staffed by a MCHN and there was the opportunity to meet and learn from other mothers. Control: Usual care – hospital midwife visit(s) 1 to 2 days after discharge. MCHN home visit 10 days to 2 weeks after birth. Access to other community supports including 24hr helplines, support from GPs or other health professionals. Setting Local government authorities in Victoria, Australia - community-based maternal and child health centres.	month visit) was collected by asking women about feeding in the previous 24 hours. **Analysis** To achieve 80% power, 224 women in each intervention arm were required. Data were analysed using intention-to-treat. Proportions of women giving their baby any breast milk at 4 months were compared using logistic regression and both odds ratios and adjusted odds ratios. Women with infants <13 and >22 weeks were excluded from the analysis. Adjustments were made for clustering at the MCH centre level as well as baseline breastfeeding rates. Proportions of women giving their baby any breast milk at 3 and 6 months were compared using logistic regression. ICC: 0.03.		Allocation concealment: Low risk (Allocation using opaque envelopes) Baseline differences: Some risk (Significant differences in proportion of Australian-born women in across the groups' (73% in home-visiting plus drop-in centre LGAs;58% in home-visiting LGAs; 69% in control LGAs) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: Low risk (Women did not know whether their care was intervention or control - all told it was standard) Blinding of carers and people delivering the interventions: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding The Department of Education and Early Childhood Development, Victoria, Australia.	Intervention 1: 39.1 (1.6); intervention 2: 39.0 (1.5); control: 39.1 (1.) Primiparous - number (%) Intervention 1 (n=2425): 1001 (41.3); intervention 2 (n=2416): 1017 (42.1); control (n=2642): 1037 (39.3) Aboriginal or Torres Strait Islander mother - number (%) Intervention 1 (n=2425): 16 (1.0); intervention 2 (n=1084): 17 (1.6); control (n=2596): 35 (1.4) Baseline proportion of women breastfeeding (any) at 3 months - number (%) Intervention 1: 928 (66.6%); intervention 2: 639 (60.1); control: 721 (58.7) Baseline proportion of women breastfeeding (any) at 4 months - number (%) Intervention 1: 482 (63.3); intervention 2: 475 (57.1); control: 397 (54.1)				**Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): Some risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (20% of intervention received home visits as planned for the intervention group) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Some risk (Home visit 2281/3335 (68%), home visit + drop in group 2344/2891 (81%),

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	<u>Baseline proportion of women breastfeeding (any) at 6 months - number (%)</u> Intervention 1: 685 (53.6); intervention 2: 461 (44.5); control: 527 (45.6) **Inclusion criteria** • Local government areas in Victoria 'with a lower rate of any breastfeeding at discharge from hospital than the Victorian state average; and > 450 births per year. For the postal survey women were recruited on the basis of giving birth during the intervention time-frame' in all participating local government areas. **Exclusion criteria** • LGAs with breastfeeding initiatives similar to the proposed				2414/3449 (70%) of control group provided follow-up data at 4 months) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (Questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (assessor blinded to allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (Data not reported for all primary outcomes, but these outcomes are not relevant to our review question) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	interventions. Women living in participating. LGAs were not sent an invitation to take part in the postal survey if it was known that either they or the infant died, they had moved to another LGA since the birth or they were not enrolled in the Maternal and Child Health Service. Women were also excluded if their infant was <13 or >22 weeks of age at the time of the routine 4-month MCH visit.				**selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation McQueen KA, Dennis CL, Stremler R, Norman CD., A pilot randomized controlled trial of a breastfeeding self-efficacy intervention with primiparous mothers. , JOGNN: Journal of Obstetric, Gynecologic and Neonatal Nursing, 40, 35-46, 2011 **Ref Id** 997027 **Country/ies where the study was carried out**	**Sample size** N=150 Intervention: n=69 Control: n=81 Lost to follow-up: Intervention: n=1 withdrawal. At 4 weeks: lost to follow-up (n=4). At 8 weeks: lost to follow-up (n=3). Outcomes measured at 4 weeks (n=64), at 8 weeks (n=61). Control: At 4 weeks: lost to follow-up (n=3). At 8 weeks: lost to follow-up (n=5). Outcomes measured at 4 weeks (n=78), at 8 weeks (n=73).	**Interventions** Intervention: standard care plus self-efficacy intervention; first session within 24hrs of birth, second session within 24hr of the first session, third session via telephone within 1 week of discharge. Control: Standard care that included follow-up by a public health nurse post-hospital discharge. Setting: acute care hospital located in Northwestern Ontario, providing maternity care for the city and referral centre for the region.	**Details** **Data collection** Outcome data were collected by telephone at 4 and 8 weeks postpartum. The Infant Feeding Questionnaire was used to assess breastfeeding duration and exclusivity. **Analysis** No power analysis was performed. Means and standard deviations were calculated for continuous data and frequencies and percentages for categorical data.	**Results** Any breastfeeding at 8 weeks: intervention (n=61): 43 vs control (n=73): 48 Exclusive breastfeeding t 8 weeks: intervention (n=61): 31 vs control (n=73): 33 This paper provided some data on satisfaction with intervention but these were non-comparative data and so were not extracted.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (no details other than 'generated by an experienced researcher) Allocation concealment: Low risk (opaque sealed envelopes) Baseline differences: Low risk (no statistically significant differences in

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Canada **Study type** RCT **Aim of the study** To assess the feasibility, compliance, and acceptability of a newly developed intervention on breastfeeding self-efficacy, duration, and exclusivity. **Study dates** March 2008 to July 2008. **Source of funding** Not stated.	**Characteristics** Maternal age (years) - number (%) ≤19: Intervention: 12 (17.4); control: 8 (9.9) >19: Intervention: 57 (82.6); control: 73 (90.1) Ethnicity - number (%) White: Intervention: 57 (82.6); control: 65 (80.3) Aboriginal: Intervention: 9 (13); control: 12 (14.8) Other: Intervention: 3 (4.4); control: 4 (4.9) Income - number (%) <19999: Intervention: 15 (21.7); control: 21 (27.2) 20000-39999: Intervention: 10 (14.5); control: 11 (14.3) 40000-59999: Intervention: 10 (14.5); control: 14 (18.2) 60000-79999: Intervention: 11 (15.9); control: 15 (19.5) >80000: Intervention: 23 (33.3); control: 16 (20.8) Planned breastfeeding duration - number (%) Don't know: Intervention: 14 (20.3); control: 11 (13.6) <2 months: Intervention: 1 (1.5); control: 2 (2.5) 2-4 months: Intervention: 5 (7.3); control: 5 (6.2) >6 months: Intervention: 29 (42); control: 37 (45.7)		For between group differences, continuous data were analysed using an independent two-sample *t*-test. For dichotomous data, chi-square tests were used to assess between group differences.		baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (85.3% of mothers had the prescribed dose of intervention)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Inclusion criteria • English speaking women; • Primiparous women who gave birth to a single, health, term infant; • Planning on breastfeeding. **Exclusion criteria** • Women with a condition that could significantly interfere with breastfeeding, such as serious illness, an infant with a congenital anomaly, or an infant requiring special care that would not be discharged home with the mother.				Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (at 8 weeks follow up 8/81 in the control and 7/68 in the intervention were lost to follow up) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interview - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (assessor blinded to treatment allocation)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from measurement of the outcome: Low risk DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Exclusive breastfeeding (breast milk only); almost exclusive breastfeeding (breast milk and other fluids, but not formula); high breastfeeding (<1 bottle per day); partial breastfeeding (at least 1 bottle of formula per day); token breastfeeding (breast given to comfort baby, but not nutrition).
Full citation	**Sample size** N randomised=225	**Interventions** Intervention: Each woman, in addition to standard care,	**Details** **Data collection**	**Results**	**Limitations** Limitations were assessed using the revised Cochrane

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Muirhead, P. E, Butcher, G, Rankin, J, Munley, A., The effect of a programme of organised and supervised peer support on the initiation and duration of breastfeeding: a randomised trial, British Journal of General Practice, 56, 191-7, 2006 **Ref Id** 1000635 **Country/ies where the study was carried out** UK **Study type** RCT **Aim of the study** To assess the effect of an organised and supervised peer support programme on the initiation and/or duration of breastfeeding.	Intervention: n randomised=112 Control: n randomised=113 Lost to follow-up: Intervention: lost to follow-up after 56 days (n=1), after birth (n=1). At 16 weeks n=110 followed-up (received peer support: n=97; stopped breastfeeding before receiving any peer support: n=13). Control: lost to follow-up at 58 days (n=1), after 10 days (n=1), after birth (n=1). Followed up for 16 weeks (n=110). **Characteristics** <u>Maternal age (years) - mean (±SD)</u> Intervention: 28.5 (5.2); control: 27.8 (5.5) <u>Parity - number</u> 0: Intervention: 60; control: 60 1: Intervention: 37; control: 25 2: Intervention: 6; control: 21 3: Intervention: 3; control: 3 ≥4: Intervention: 6; control: 3 <u>Feeding intention - number</u> Breastfeed: Intervention: 57; control: 59	was assigned two peer supporters. Peer supporters visited the mother at least once during the antenatal period. Peer supporters contacted women at least every 2 days following discharge either by phone or personal visit up until 28 days. If requested, peer supporters could continue contact up to 16 weeks. Control: Standard care that included a community midwife for the first 10 days, health visitor after 10 days and breastfeeding support groups and workshops. Setting: general practice in Ayrshire, Scotland.	Questionnaires on stopping breastfeeding were completed along with solid start days and qualitative data on problems, solutions and types of support at 10 days, and 8 and 16 weeks. The 10-day questionnaire was completed in the presence of the health visitor. The 8-week and 16-week questionnaires were completed in the presence of a GP or practice nurse. **Analysis** To achieve 80% power to detect a 15% difference at 6 weeks, 160 women were required for each treatment group. Data were analysed on an intention-to-treat basis with four strata pooled (primigravida, previous formula feeder, previously breastfed <6 weeks, previously breastfed >6 weeks). The number and percentage of women breastfeeding in each treatment group at birth, 10 days, 6, 8 and 16 weeks, in addition to the difference between groups at each time point, were calculated	Initiated breastfeeding: Intervention (n=112): 61 vs control (n=113): 60 Any breastfeeding at 10 days: Intervention (n=111): 46 vs control (n=112): 46 Any breastfeeding at 6 weeks: Intervention (n=111): 35 vs control (n=111): 33 Exclusive breastfeeding* at 8 weeks: Intervention (n=111): 23 vs control (n=111): 16 Any breastfeeding at 16 weeks: Intervention (n=110): 26 vs control (n=110): 20	risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (computer generated in blocks of 10) Allocation concealment: Low risk (phone call to obtain the next allocation from the list) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates Recruitment took place between July 1997 and March 2002. **Source of funding** Ayrshire and Arran Health Board, and the Oxenward Surgery which was part of the Chief Scientist Office Research Practice Programme during 2000 to 2003.	Formula: Intervention: 35; control: 36 Undecided: Intervention: 20; control: 18 **Inclusion criteria** • Women at 28 weeks' gestation attending for antenatal care at a GP practice. **Exclusion criteria** Not stated.		along with 95% confidence intervals.		**Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (follow-up loss was very low in both groups (n =2 in one group and n=3 in the other)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from missing outcome data: Low risk DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (unclear, the questionnaire was completed in the presence of a health care professional, unclear if they knew group assignment) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Overall risk-of-bias judgement: Some risk **Other information** *Exclusive defined as no other feeding apart from breastfeeding.
Full citation Nilsson, I. M. S., Strandberg-Larsen, K., Knight, C. H., Hansen, A. V., Kronborg, H., Focused breastfeeding counselling improves short-and long-term success in an early-discharge setting: A cluster-randomized study, Maternal and Child Nutrition, 13, 2017 **Ref Id** 774911 **Country/ies where the study was carried out** Denmark **Study type** Cluster-RCT	**Sample size** N=3541 Intervention: n=2065 Control: n= 1476 Lost to follow-up/missing values: Intervention: 5 to 7 days postnatally: n=408; 1 month: n=619; 6 months postnatally: n=884. Hospitalisation >50 hours: n=768; total women <50 hours: n=1297. Complete case analysis (total women): 5 to 7 days: n=1657; 1 month: n=1446; 6 months: n=1181. Total women <50 hours: 5 to 7 days: n=921; 1 month: n=822; 6 months: n=698. Control: 5 to 7 days postnatally: n=333; 1 month: n=482; 6 months postnatally: n=662. Hospitalisation >50 hours: n=476; total women <50 hours: n=1000. Complete case analysis (total women): 5 to 7 days: n=1143; 1 month:	**Interventions** Intervention: New breastfeeding programme: Mothers were orally taught, which also included highlights on a postcard, handed out at recruitment. Supported postnatally according to the manual and a written pamphlet used during breastfeeding counselling. Encouraged adherence during the first 3 days or until the first home visit by the health visitor 3–5 days postnatally. The parents received a follow-up telephone call 24 hr after discharge. Control: Usual care. Setting: 9 maternity settings in Denmark.	**Details** **Data collection** Data relating to socio-demographics were collected at recruitment using a web-based self-administered questionnaire. Data on breastfeeding experiences, feeding status and related infant morbidity, use of the health care system, and general well-being were collected through 3 web-based self-administered questionnaires, completed at 5 to 7 days, 1 month and 6 months postnatally. **Analysis** To achieve 80% power, 79 mother-infant dyads were required in each cluster. Data were analysed using intention-to-treat (ITT), and complete-case analyses	**Results** Exclusive breastfeeding at 5 to 7 days, intervention (n=2065): 1682 vs control (n=1476): 1208	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (The hospitals were computer randomised to either the intervention or reference group) Allocation concealment: Some risk (cluster RCT design was used to 'minimise the risk for contamination between groups and to mirror the real-world implementation of the intervention', no further details provided)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess the effects of guidelines for breastfeeding counselling on maternal breastfeeding self-efficacy, infant readmission and breastfeeding duration in an early discharge hospital setting. **Study dates** April 2013 to August 2014. **Source of funding** Trygfonden and The Danish Nurses' Organisation.	n=994; 6 months: n=814. Total women <50 hours: 5 to 7 days: n=688; 1 month: n=620; 6 months: n=527. **Characteristics** Maternal age (years) - mean (±SD) Intervention: 29.7 (4.8); control: 29.7 (4.5) Ethnicity - number (%) Both parents Danish: Intervention: 1738 (84.2); control: 1252 (84.8) One or no parents Danish: Intervention: 185 (9.0); control: 116 (7.9) Missing: Intervention: 142 (6.9); control: 108 (7.3) Parity - number (%) Primiparous: Intervention: 825 (40.0); control: 579 (39.2) Multiparous: Intervention: 1097 (53.1); control: 788 (53.4) Missing: Intervention: 143 (6.9); control: 109 (7.4) BMI - number (%) <18.5: Intervention: 85 (4.1); control: 52 (3.5); p=0.02 18.5-24.9: Intervention: 1088 (52.7); control: 827 (56.0) 25-29.9: Intervention: 450 (21.8); control: 325 (22.0) 30-34.9: Intervention: 199 (9.6); control: 101 (6.8)		restricted to mothers and infants with available information on the specific outcomes. To account for cluster data, mixed models (logistic regression models for the binary outcomes, linear regression for modelling breastfeeding self-efficacy) with random effects for cluster were fitted. Adjustments were made for maternal BMI and mode of delivery. For the ITT analyses, missing data were handled by inverse probability weighting, with weights generated for each specific outcome using baseline information on maternal socioeconomic status, parity, smoking status and BMI, mode of delivery and length of admission. Missing baseline data were handled by single imputation.		Baseline differences: Some risk (significantly higher proportion of women gave birth via caesarean and less via vaginal delivery in the intervention group compared to control, more women with a BMI between 30-34.9 and less women with a BMI of 18.5-24.9 were in the intervention group) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: Some risk (mothers who agreed to participate were not informed whether their birth facility-provided breastfeeding support according to the intervention program or the usual practice) Blinding of carers and people delivering the interventions: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	≥35: Intervention: 100 (4.8); control: 62 (4.2) Missing: Intervention: 143 (6.9); control: 109 (7.4) Gestational age (weeks) - mean (±SD) Intervention: 39.6 (1.5); control: 39.6 (1.4) Birthweight (g) - mean (±SD) Intervention: 3588.3 (483.3); control: 3598.5 (484.3) **Inclusion criteria** • Singleton pregnancy; • Women intending to breastfeed; • Women able to read Danish; • Expected to be discharged within 50 hours postnatally due to pregnancy complications or clinical disease. **Exclusion criteria** Not stated.				**Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (study reports 'considerable loss to follow-up' yet data is only presented for those that

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					data was available for, so unknown the proportion of loss to follow up) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (web-based self-administered questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (all outcomes reported in NCT registry reported in paper) **Judgement on risk of bias arising from selection of the reporting result: Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Overall risk-of-bias judgement: Some risk **Other information** Exclusive breastfeeding defined as the infant receiving nothing other than milk from the mother and measured during the past 24 hours.
Full citation Noel-Weiss J, Rupp A, Cragg B, Bassett V, Woodend AK., Randomized controlled trial to determine effects of prenatal breastfeeding workshop on maternal breastfeeding self-efficacy and breastfeeding duration. , Journal of Obstetric, Gynecologic and Neonatal Nursing, 35, 616–24, 2006 **Ref Id** 996993 **Country/ies where the study was carried out** Canada	**Sample size** N=101 N randomised in each group not reported. Women retained in analysis: Intervention: n=47 Control: n=45 9 losses to follow-up, not specified in which group. Reasons: chose to drop out for personal reasons, did not remain in contact, or medical reasons. 6 women randomised to the intervention group did not attend the workshop, either due to personal reasons or because their baby was born before the workshop (these 6 women were included in intervention group for analysis purposes)	**Interventions** Intervention: Standard care plus 2.5hr prenatal breastfeeding workshop designed using a theory of self-efficacy and adult learning principles. The workshop involved the use of lifelike dolls, videos, and discussion. Control: Standard care Setting: Large tertiary hospital in Ontario, Canada.	**Details** **Data collection** A research assistant telephoned participants and completed a postpartum demographic questionnaire , the Breastfeeding Self-Efficacy Scale - Short Form (BSES-SF), and a breastfeeding duration questionnaire. At 8 weeks, the same research assistant telephoned each participant and completed a final BSES-SF and breastfeeding duration questionnaire. **Analysis** Analysis conducted on an intention-to-treat basis and using the actual workshop attendance (6 women in the intervention group did not attend the workshop).	**Results** Exclusive breastfeeding at 8 weeks: intervention (n=47): 34 vs control (n=45): 29 (numerators calculated by the NGA technical team based on this data: intervention: exclusively breastfeeding by breast: n=33, exclusive breastfeeding by breast with some expressed breastmilk: n=1, exclusively expressed breastmilk: n=0 vs control: exclusively breastfeeding by breast: n=26, exclusive breastfeeding by breast with some expressed breastmilk: n=0, exclusively expressed breastmilk: n=3) Any breastfeeding at 8 weeks: intervention (n=47): 40 vs control (n=45): 35 (numerators calculated by the NGA technical team based on this data: intervention:	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (No information provided) Allocation concealment: Low risk (Opaque envelopes used) Baseline differences: Low risk (No statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type RCT **Aim of the study** 'To determine the effects of a prenatal breastfeeding workshop on maternal breastfeeding self-efficacy and breastfeeding duration' **Study dates** Women with date of birth expected between August 2004 and February 2005. **Source of funding** Not stated.	**Characteristics** Age (years) - mean (range) 30.2 (17 to 42) Gestational age (weeks) - mean (range) 39.8 (36 to 42) Birthweight (g) - mean (range) 3437.62 (range 2183 to 5046) 68% received free formula, many from multiple sources including through the mail and at the hospital. No statistically significant differences between the two groups in relation to participant characteristics. Income: the majority had a family income in excess of $70.000 (% not reported) Intention to breastfeed: Prenatal goals for breastfeeding ranged from 3 to 18 months, and 87% of the participants had made the decision to breastfeed before getting pregnant. **Inclusion criteria** • Primiparous women with a singleton pregnancy; • Uncomplicated birth;		To achieve 80% power, 128 participants were required. Group comparisons were analysed using t-test for continuous data and Pearson chi-squared test for categorical data.	exclusive breastfeeding as per calculation above: n=34, almost exclusive breastfeeding: n=0, high breastfeeding: n=2, partial breastfeeding: n=4, token breastfeeding: n=0 vs control: exclusive breastfeeding as per calculation above: n=29, almost exclusive breastfeeding: n=0, high breastfeeding: n=5, partial breastfeeding: n=1, token breastfeeding: n=0)	DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Planning to breastfeed; • Women had to read and write in English and have a telephone to complete the postpartum questionnaires. To remain in the study, a mother and her infant had to be discharged at the same time and be able to breastfeed without restriction. **Exclusion criteria** Not stated.				**from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: High risk (n randomised to each group not reported so intention to treat analysis could not be carried out for the present review, only women not lost to follow-up were included in the denominators; the authors state that they present an intention to treat analysis when in fact the denominators exclude losses to follow-up; 8.9% (9/101) losses to follow-up; not reported how these were distributed across groups) **Judgement on risk of bias arising from missing outcome data: High risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Blinding of outcome assessors: Low risk (Research assistant was blinded to participants group assignment) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some concerns** **Other information** This study was included in the Cochrane review Lumbiganon 2016 Exclusive breastfeeding meaning the only fluid the infant receives is breastmilk; exclusive by breast with some

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					expressed breast milk by bottle; expressed breastmilk by bottle only.
Full citation Paul, I. M, Beiler, J. S, Schaefer, E. W, Hollenbeak, C. S, Alleman, N, Sturgis, S. A, Yu, S. M, Camacho, F. T, Weisman, C. S., A randomized trial of single home nursing visits vs office-based care after nursery/maternity discharge: the Nurses for Infants Through Teaching and Assessment After the Nursery (NITTANY) Study, Archives of pediatrics & adolescent medicine, 166, 263-70, 2012 **Ref Id** 1000640 **Country/ies where the study was carried out** US **Study type** RCT	**Sample size** N randomised=1154 women, corresponding to 1169 newborns Intervention: n randomised=576 women, corresponding to 583 newborns Control: n=578 women, corresponding to 586 newborns At two weeks, 1065/1154 women participated in the phone interview, corresponding to 1080 newborns with available data (545 newborns in intervention, 535 in control group). At 2 months, data was available for 1013 newborns (516 newborns in intervention group and 497 in control group). **Characteristics** Ethnicity: White/non-Hispanic*: 84.3% in intervention group, 84.4% in control group; Black/non-Hispanic: 6.1% in intervention group, 4.8% in control group; Asian: 3.3% in intervention group, 5.4% in	**Interventions** Intervention: 1 home nurse visit scheduled to occur within 48hrs of discharge, additional office visit 1 week after first visit. Control: Typical office based care – timing of visit determined by newborn physician.	**Details** **Data collection** Telephone interviews were conducted by the study coordinators blinded to study group with the mothers at 2 weeks, 2 months, and 6 months after childbirth **Analysis** ITT analysis was used. The primary analysis comparing unplanned health care utilisation in the first 14 days after delivery between study groups was conducted using the Mantel-Haenszel test to account for randomisation stratification by delivery type and was quantified using relative risks (RRs). Secondary out- comes of surveys at 2 weeks, 2 months, and 6 months were analysed using analysis of covariance models that	**Results** Breastfeeding at 2 weeks*: intervention (n=545): 503 vs control (n=535): 474 Breastfeeding at 2 months*: intervention (n=516): 372 vs control (n=497): 330 Breastfeeding at 6 months*: intervention (n=516): 257 vs control (n=497): 243 Satisfaction with Maternal and Newborn Care scale score at 2 weeks, mean difference between intervention (n=535) and control group (n=527): 0.39 (-0.45 to 1.22) Satisfaction with Maternal and Newborn Care scale score at 2 months, mean difference between intervention (n=509) and control group (n=484): 0.25 (-0.6 to 1.14) * Numerators calculated based on denominators and percentages provided in the paper. Denominators at 6 months unavailable so denominators at 2 months were used	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Computer-generated randomisation sequence) Allocation concealment: Some risk (not described) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To compare office-based care with a care model using a home nursing visit as the initial post discharge encounter for "well" breastfeeding newborns and mothers. **Study dates** Recruitment occurred between September 12, 2006 and August 1, 2009. **Source of funding** The project was supported by grant R40 MC 06630 from the Maternal Child Health Bureau (Title V, Social Security Act), Health Resources and Services Administration, Department of Health and Human Services. Additional support was provided by the Children's Miracle Network	control group; White, Hispanic: 4.9% in intervention group, 3.6% in control group; Black, Hispanic: 0.5% in intervention group, 0.9% in control group. Age under 20 years: 5.0% in intervention group, 3.5% in control group Single*: 11.5% in intervention group, 11.3% in control group. Education, postgraduate training*: 19.1% in intervention group, 21.6% in control group. Insurance type, Medicaid*: 11.9% in intervention group, 14.8% in control group. Annual income, < $25000*: 8.5% in intervention group, 8.5% in control group. Primiparous*: 48.6% in intervention group, 46.4% in control group. Planned feeding mode, exclusively breastfeeding*: 78.8% in intervention group, 76.0% in control group. Mode of birth*: unassisted vaginal birth: 63.7% in intervention group, 64.2% in control group; vaginal with forceps and/or vacuum: 4.9% in intervention group, 4.8% in control group; caesarean section: 31.4% in intervention group, 31.1% in control group.		included 2 predictors: randomized group and baseline score (where available).		Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Twin birth*: 1.2% in intervention group, 1.4% in control group. Late preterm birth, 34 to <37 weeks*: 4.8% in intervention group, 6.5% in control group. **Inclusion criteria** 'Singletons and twins born after at least 34 weeks' gestation to English speaking mothers attempting to breastfeed during the maternity stay and with intent to continue breastfeeding after discharge' **Exclusion criteria** [A]typical stays characterised by: '1) a 2-night or longer stay after a vaginal delivery; 2) a 4-night stay or longer after a caesarean section; 3) a hospital course with atypical complications (e.g. ambiguous genitalia, endometritis); or 4) newborn hyperbilirubinemia requiring phototherapy during the nursery stay. Mothers were also excluded for major morbidities and/or pre-existing conditions that would affect postpartum care, lack of a telephone number, previous				Missing outcome data: Low risk (Follow-up at 2 weeks, data received from 92.3% and similar between both groups; at 2 months 86.7%) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (assessors blinded to study group allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (Data not reported for all outcomes, but these outcomes are not relevant to our review question)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	study participation, residence outside the coverage region of the Visiting Nurse Association of Central Pennsylvania, or if a home nursing visit was specifically requested by a hospital social worker or child protective services owing to social concerns'.				**Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Petrova A, Ayers C, Stechna S, Gerling JA, Mehta R. , Effectiveness of exclusive breastfeeding promotion in low-income mothers: a randomized controlled study., 2009 **Ref Id** 997114 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To evaluate the effectiveness of a	**Sample size** N randomised=104 Intervention: n randomised=52 Control: n randomised=52 **Characteristics** Singleton pregnancy. Planning to breastfeed. Age at enrolment mean (SD): intervention arm 24.8 (5.6), control 25.6 (5.6) Ethnicity: White (5.8% intervention, 5.8% control), Black (1.9% intervention, 9.6% control), Hispanic (90.4% intervention, 84.6% control), Asian (1.9% intervention, 0% control) Unemployed: 82.7% intervention, 88.2% control. **Inclusion criteria**	**Interventions** Intervention: standard care plus additional breastfeeding education and support from a lactation consultant antenatally (two one-to-one face-to-face 15-20 min sessions) and post-birth (in hospital or by phone after discharge, again at the end of the first or second week and of the first and second month). Control: standard breastfeeding education and support during pregnancy and postpartum. Hospital lactation consultant services were available for all postpartum women if any breastfeeding problems arose during the hospital stay	**Details** **Data collection** Data were collected through a combination of surveys and telephone interviews. **Analysis** The primary analysis was based on the intention-to-treat principle with all participants being included in their as-signed group. Exclusive breastfeeding and any breastfeeding (defined as exclusive or partial breastfeeding) were identified, respectively, as the primary and secondary outcomes and were analysed in the women who actually received the assigned breastfeeding education and support. Three women whose age was less than 18 years at time of recruitment were	**Results** Exclusive breastfeeding at 1 week: intervention (n=44): 20 vs control (n=38): 11 Any breastfeeding at 3 months*: intervention (n=36): 28 vs control (n=38): 24 Exclusive breastfeeding at 3 months: intervention (n=36): 5 vs control (n=38): 4 *Numerators calculated by the NGA technical team based on denominators from table 4 and percentages provided within text.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (computer-generated random numbers) Allocation concealment: Some risk (not clearly described) Baseline differences: High risk (Intervention group had a higher proportion of women who had previously breastfed (93% compared to control 68%)) **Judgement on risk of bias arising from the randomisation process: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
breastfeeding promotion in the Women, Infant and Children (WIC) Supplemental Nutrition Program participants. **Study dates** Recruitment from March 2006-December 2006 **Source of funding** The study was supported by CDC/AAMC grant MM00841-05/05.	Low-income inner-city population. Pregnant women in third trimester who qualify for Women, Infants and Children Special Supplemental Nutrition Programme. **Exclusion criteria** Pregnant women with HIV, cancer or history of illegal drug use.		excluded from the final analysis. Difference in the rate of breastfeeding between the intervention and control group was assessed by the calculation of the adjusted odds ration and 95% confidence interval in regressional model.		DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					from deviations from the intended interventions (effect of adhering to intervention): Low risk DOMAIN 3 – missing data Missing outcome data: Some risk (35/52 (67%) in the intervention group and 38/52 (73%) in control reported outcome data) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Pisacane, A., Continisio, G. I., Aldinucci, M., D'Amora, S., Continisio, P., A controlled trial of the father's role in breastfeeding promotion, Pediatrics, 116, e494-8, 2005 **Ref Id** 807136 **Country/ies where the study was carried out** Italy **Study type** RCT	**Sample size** N randomised=280 Intervention: n randomised=140 Control: n randomised=140 **Characteristics** Maternal age in years n (%) <20: intervention 6(4); control 4(3) 20-35: intervention 118(84); control 116(83) >35: intervention 16(11); control 20(14) First pregnancy n (%) intervention 64(46); control 62(44) Type of delivery n (%) Vaginal: intervention 64(46); control 59(42)	**Interventions** Intervention: Fathers were offered a face-to-face, 40-minute session about infant feeding by a midwife who was trained through the WHO-UNICEF 40-hour course. The session focused on potential difficulties and complications and on the father's role in supporting breastfeeding. A leaflet with the main points of the session was provided to fathers. Control: Fathers were offered a face-to-face, 40-minute session about child care, such as accident prevention and vaccination. The session focused on the benefits of breastfeeding but not on the	**Details** **Data Collection** Fathers allocated to study groups according to infant's month of birth (October and November allocated intervention, December and January allocated control group). This was done to minimise contamination bias i.e. avoiding communication between the two groups. The mothers were interviewed by telephone at 6 and 12 months after birth using a questionnaire recommended by the WHO	**Results** Any breastfeeding at 6 months*: intervention (n=140): 75 vs control (n=140): 62 *Numerators calculated by adding full and complementary breastfeeding.	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: High risk (Cluster RCT, no description on how randomisation was performed: 'we allocated the 2 study groups into 2 consecutive blocks of time, after having randomly paired the 2 study groups with the 2 blocks of time')

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To investigate whether supporting fathers to recognise the relevance of their role in successful breastfeeding and teaching them how to prevent/manage common lactation problems would result in more women breastfeeding. **Study dates** 1 October 2002 to 31 January 2003 **Source of funding** Not reported.	Caesarean: intervention 76(54); control 81(58) Maternal education n (%) ≤8: intervention 55(39); control 56(40) >8: intervention 85(61); control 84(60) Planned return to outside employment after childbirth n (%) intervention 33(24); control 37(26) Maternal smoking n (%) Before pregnancy: intervention 49(35); control 46(33) During pregnancy: intervention 19(14); control 25(18) After birth: intervention 33(24); control 37(26) Father's education n (%) ≤8: intervention 64(46); control 66(47) >8: intervention 76(54); control 73(53) Father's smoking n (%) intervention 69(49); control 64(46) Previous children breastfed n (%) intervention 66/76(87); control 62/78(79) Mother's breastfed during infancy n (%) intervention 111(79); control 109(78) Father's breastfed during infancy n (%) intervention 103(74); control 94(67)	management of breastfeeding. A leaflet with the main points of the session was provided to fathers. Support and advice about breastfeeding was provided to all mothers, regardless of which group the father was allocated to.	to obtain information on breastfeeding. **Data Analysis** Comparison between groups was performed by means of the X2 test. The relative risk with 95% confidence intervals was used to compare the incidence of breastfeeding between the groups.		Allocation concealment: Some risk (allocation was based on blocks of time) Baseline differences: Low risk (no obvious differences between groups) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (Parents were unaware of the objectives of the organisation of the study but were not blinded to their treatment) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Early (<2hr) mother-new-born contact after delivery n (%) intervention 2(1); control 0(-) Rooming in n (%) intervention 140(100); control 140(100) **Inclusion criteria** Mother and father dyads of healthy, full term, normal birth weight infants who were born between October 1, 2002 and January 31, 2003. **Exclusion criteria** Unmarried mothers Women deciding to bottle feed Parents whose infant's had to be admitted to ICU.				DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (None reported) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (assessors were blinded to the study hypothesis and allocation of participants) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Predominant breastfeeding = exclusive or predominant Complementary breastfeeding = any consumption of breast milk after the introduction of other fluids and solid foods.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Pollard, D. L., Impact of a Feeding Log on Breastfeeding Duration and Exclusivity, Maternal and Child Health Journal, 1-6, 2010 **Ref Id** 986301 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To evaluate a breastfeeding log intervention and its influence on self-efficacy or confidence in breastfeeding. **Study dates** 6 month recruitment period but no dates reported.	**Sample size** N randomised=86 Intervention: n randomised=43 Control: n randomised=43 **Characteristics** Mean age in years (SD): intervention 26.7 (4.7); control 25.2 (4.7) Race (%): White (95.3 intervention, 97.7 control); other (4.7 intervention, 2.3 control). Marital status (%): Married (88.4 intervention, 72.1 control); single (11.6 intervention, 27.9 control). Mode of delivery (%): Vaginal (72.1 intervention, 76.7 control); Caesarean (27.9 intervention, 23.3 control). Presently employed (%): 74.4 intervention; 44.2 control. WIC enrolment (%): 34.9 intervention; 46.5 control. **Inclusion criteria** Postpartum, primiparous mothers:	**Interventions** Intervention: women were directed to complete a daily breastfeeding log for 6 weeks. The log had 9 columns that addressed areas such as length of feeding, urine and stool output, use of supplement or pumping, and women's feelings. Women received instructions on use of the log and weekly phone calls at 1, 2, 3 weeks to remind them to return the logs to the researcher. This group also received a videotaped educational session before randomisation. Control: usual care (no details) plus videotaped educational session before randomisation.	**Details** **Data Collection** Began in first 12-48 hours following delivery and extended to 6 months postpartum. The Personal Data Form (PDF), Breastfeeding Experience Instrument (BEI) and the Hughes Breastfeeding Support Scale (HBSS) were instruments completed at the first data point in the hospital and the BEI and HBSS were repeated at the 6 month data collection point. An additional instrument used at 6 months was the Feeding and Weight Pattern Instrument. Daily Breastfeeding Log was investigator generated form to record mother's breastfeeding experiences. **Data Analysis** Subjects who completed the log for 3 or more weeks were considered to meet the protocol of the intervention. Data analysis based on 84 subjects (97.7% of initial sample) who finished the study (43	**Results** Any breastfeeding at 12 weeks: intervention (n=41): 23 vs control (n=43): 18 Any breastfeeding at 24 weeks: intervention (n=41): 15 vs control (n=43): 14	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: low risk (permuted block within strata randomisation using mode of delivery and return to work/school as stratifying factors) Allocation concealment: some risk (sealed envelope, not described if it was opaque or not) Baseline differences: High risk (significant difference for presently employed - 74.4% or experimental group vs 44.2% in control group) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Not reported.	• Between ages of 18 and 40 • Delivered a healthy infant greater than 37 weeks gestation • Planning to breastfeed • Have initiated breastfeeding within 24 hours of delivery • Able to read, write and speak English • Have attended prepared childbirth classes. **Exclusion criteria** Mothers with infants unable to breastfeed due to medical condition.		in control group, 41 in intervention group). Descriptive statistics were computed for the demographic variables and nonparametric inferential statistics were used for the hypothesis testing procedures, specifically survival analyses techniques that included log rank test, Cox proportional hazards regression, and Kaplan–Meier estimation. For categorical variables, the chi-square test or the Fisher's Exact test was used to conduct two-tailed testing of the differences in the proportions between the groups.		Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					DOMAIN 3 – missing data Missing outcome data: Low risk (2.3% were lost from intervention group, none were lost from control group) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (no details provided) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from selection of the reporting result: Some risk **Overall risk-of-bias judgement: Some risk**
Full citation Pugh L, Milligan R, Frick K, Spatz D, Bronner Y., Breastfeeding duration, costs, and benefits of a support program for low-income breastfeeding women., Birth, 29, 95-100, 2002 **Ref Id** 1000642 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To evaluate a community health nurse/peer counsellor intervention designed to	**Sample size** N number = 41 Intervention n = 21 Usual care n = 20 **Characteristics** Mother's mean age years (SD): intervention 20.86 (3.58); 22.35 (4.98). African American (5): intervention 95.2; usual care 90.0 Education ≥ 12 yr (%): intervention 81.0; usual care 88.9 Single (%): intervention 81.0; usual care 100.00 Mean infant birthweight in g (SD): intervention 3089.6 (417.9); usual care 3387.2 (424.4) Breastfeeding goals in weeks (SD): intervention 30.7 (17.2); usual care 29.4 (17.8)	**Interventions** Usual care: breastfeeding support from hospital nurses, assistance by means of a telephone ‘‘warm line,’’ and one hospital visit by a lactation consultant if the participant delivered on a weekday. Intervention: mother's received supplementary visits from the community health nurse/peer counsellor team. These included daily visits during hospitalisation, and visits at home during weeks 1, 2, and 4 (and at the team’s discretion). Peer counsellors provided telephone support twice weekly through to week 8 and then weekly through to month 6 (even if the mother stopped breastfeeding). Setting: large academic medical centre in the mid-Atlantic region of the US	**Details** **Data Collection** Interviews were conducted in the client’s hospital room or home. Infant data outcomes were collected in person at months 3 and 6, and by telephone at postpartum weeks 1, 2, 3, 4, and 6, and month 4. **Data Analysis** None reported	**Results** Exclusive breastfeeding at 3 months: intervention (n=21): 9 vs control (n=20): 5 Any breastfeeding at 36 months: intervention (n=21): 9 vs control (n=20): 7	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Some risk (sealed envelope, not described if it was opaque or not) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
increase the duration of breastfeeding among low-income, predominately minority women during the first 6 months postpartum. **Study dates** April 1999 to February 2000 **Source of funding** The National Institute of Nursing Research, Bethesda, Maryland, funded this study (R55 NR04958).	**Inclusion criteria** Low income women (receiving financial medical support). **Exclusion criteria** Not reported.				DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					intended interventions (effect of adhering to intervention): Low risk DOMAIN 3 – missing data Missing outcome data: Some risk (not described) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (both in person and phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from selection of the reporting result: Some risk **Overall risk-of-bias judgement: Some risk**
Full citation Pugh LC, Milligan RA., Nursing intervention to increase the duration of breastfeeding. , Applied Nursing Research, 11, 190-4, 1998 **Ref Id** 997031 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To test the hypothesis that subjects in the intervention programme would have more positive outcomes (less fatigue and increased	**Sample size** N randomised=60 Intervention: n randomised=30 Control: n randomised=30 **Characteristics** Mean age in years = 24.4 Married n(%) = 47(78) White n(%) = 55(93) Completed high school n(%) = 58(97) Income ≤ $20,000 n(%) = 13(22) **Inclusion criteria** Primiparous women • Vaginal delivery • Full term pregnancy **Exclusion criteria** Not stated.	**Interventions** Intervention: Two home visits by community health nurse (once 3-4 days after birth using a structured protocol and again after 12 days) and telephoned by lactation consultant (between two nurse visits). Before 2nd visit, the nurse telephoned mothers to include their structuring in the context of the visit. Control: Standard care including a home visit at 3 to 4 days Setting: community hospital with diverse socioeconomic status.	**Details** **Data Collection** At recruitment, demographic information and information about fatigue, depressive symptoms and anxiety. The same questionnaire was administered by telephone at day 7, day 14, and in the 6th week. Subjects continuing to breastfeed were telephoned monthly until duration of breastfeeding was determined. **Analysis** Stepwise regression conducted with duration of breastfeeding as the outcome.	**Results** Any breastfeeding at 6 months*: intervention (n=30): 15 vs control (n=30): 8 *Numerators calculated by the NGA technical team based on percentages provided in the paper	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Some risk (not described) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
duration of breastfeeding) than subjects in the routine care group. **Study dates** Not stated. **Source of funding** Funded by Mead Johnson Perinatal nutritionals through Sigma Theta Tau.					Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					DOMAIN 3 – missing data Missing outcome data: Low risk (No missing data) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Overall risk-of-bias judgement: Some risk
Full citation Pugh LC, Serwint JR, Frick KD, Nanda JP, Sharps PW, Spatz DL, et al., A randomized controlled community-based trial to improve breastfeeding rates a mong urban low-income mothers. , Academic Pediatrics , 10, 14-20, 2010 **Ref Id** 997002 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess whether providing a breastfeeding support team results in higher breastfeeding rates at 6,	**Sample size** N randomised=328 Intervention: n randomised=168 Control: n randomised=160 **Characteristics** *Participant Characteristics* <u>Age in years n(%)</u> 13-17: total 33(10.1); intervention 20(11.9); control 13(8.1) 18-19: total 56(17.1); intervention 26(15.5); control 30(18.8) 20-24: total 137(41.8); intervention 70(41.7); control 67(41.9) 25-34: total 91(27.7); intervention 48(28.6); control 43(26.9) 35-43: total 11(3.4); intervention 4(2.4); control 7(4.4) Mean age in years (SD): total 23.1(5.3); intervention 23.1(5.3); control 23.2(5.3) <u>Race/ethnicity n(%)</u> African American: total 286(87.2); intervention 150(89.3); control 136(85.0)	**Interventions** Intervention: Breastfeeding support and education for 24 weeks postpartum. Including daily hospital visits, twice at home in week 1 and again in week 4 (home visits lasted 45-60 mins) by community nurse and peer counsellor. Scheduled telephone calls by peer counsellor at least every 2 weeks through to week 24. Contact number for nurse 24hrs. Control: Standard care including inpatient visit by lactation consultant. Lactation consultant was also available via an answering machine checked at least every 24 hours and office visit with lactation consultant could be requested.	**Details** **Data Collection** Baseline data from the mother-infant dyads were collected by the community nurse before randomization. Longitudinal data were collected by telephone or during home visits. After recruitment, staff were no longer masked to group assignment. Breastfeeding was a dichotomous variable (no = 0, yes = 1) identified in relation to data points at 6 weeks, 12 weeks, and 24 weeks postpartum. **Analysis** At baseline, intervention and usual-care group differences in sociodemographic, behavioural, and health characteristics were compared by X2 statistics for categorical measures. Analysis of variance was	**Results** Any breastfeeding at 12 weeks*: intervention (n=168): 83 vs control (n=160): 65 Any breastfeeding at 24 weeks*: intervention (n=168): 49 vs control (n=160): 45 Adjusted odds ratios are provided. *The study authors used last contact date to input breastfeeding status for losses to follow-up	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (SPSS generated randomisation by a statistician) Allocation concealment: Some risk (sealed envelope, not described if it was opaque or not) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
12 and 24 weeks postpartum among urban low-income mothers. **Study dates** October 2003-December 2005 **Source of funding** Research was supported by a grant (1RO1NR007675) from the National Institute of Health-National Institute of Nursing Research.	White: total 15(4.6); intervention 7(4.2); control 8(5.0) Latina: total 13(4.0); intervention 5(3.0); control 8(5.0) Other: total 14(4.3); intervention 6(3.6); control 8(5.0) Education n(%) Less than high school: total 87(26.5); intervention 49(29.2); control 38(23.8) High school/GED: total 121(36.9); intervention 59(35.1); control 62(38.8) Some college: total 83(25.3); intervention 47(28.0); control 36(22.5) College graduate/graduate degree: total 37(11.3); intervention 13(7.7); control 24(15.0) Marital status n(%) Married: total 56(17.1); intervention 33(19.6); control 23(14.4) Single: total 261(79.6); intervention 129(76.8); control 132(82.5) Separated/divorced/widowed: total 11(3.4); intervention 6(3.6); control 5(3.1) Employment and school status during pregnancy n(%)		used to test differences in means. Breastfeeding rates at the 3 follow-up periods were also compared with the evaluated group differences by X2 statistics. Bivariate analysis X2 statistics) compared breastfeeding rates with covariates. Finally, multiple logistic regression, adjusting for individual covariates at baseline, was used to assess the relationship between the intervention and breastfeeding at 6, 12, and 24 weeks postpartum. The decision to include covariates in the multiple regression was based on a significant association of the covariate with breastfeeding rate (P <.05) or covariates that are traditionally associated with breastfeeding initiation rates and were gathered as study variables. Setting: Postpartum units of 2 urban hospitals in Baltimore, Maryland.		Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (7% in each arm did not receive hospital or home visit) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Employed and in school: total 72(22.0); intervention 35(20.8); control 37(23.1) Employed, not in school: total 139(42.4); intervention 70(41.7); control 69(43.1) In school, not employed: total 60(18.3); intervention 33(19.6); control 27(16.9) Not employed, not in school: total 57(17.4); intervention 30(17.9); control 27(16.9) Parity and breast feeding experience n(%) Primapara, no experience: total 166(50.6); intervention 82(48.8); control 84(52.5) Multipara, no experience: total 56(17.1); intervention 32(19.0); control 24(15.0) Multipara, with experience: total 106(32.3); intervention 54(32.1); control 52(32.5) Delivery type n(%) Vaginal: total 241(73.5); intervention 122(72.6); control 119(74.4) Caesarean, no experience: total 87(26.5); intervention 46(27.4); control 41(25.6) *Participant Characteristics* Mean gestational age in weeks (SD): total 38.9(1.2); intervention 38.8(1.2); control 39.1(1.2) Mean 1-minute Apgar score (SD): total				DOMAIN 3 – missing data Missing outcome data: Low risk (not data was missing) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (in person or phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: High risk (not blinded) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	8.0(1.4); intervention 8.1(1.3); control 7.8(1.6) Mean 5-minute Apgar score (SD): total 8.9(0.4); intervention 8.9(0.4); control 8.9(0.4) **Inclusion criteria** • Singleton infant of at least 37 weeks' gestation • Breastfeeding intention by the mother • English-speaking mother • WIC eligible family (determined by maternal self-report using the WIC questions regarding financial information) • Telephone access • Address within 25 miles of the birth hospital **Exclusion criteria**				**Overall risk-of-bias judgement: Some risk** **Other information** Breastfeeding: mothers had to have breastfed at least once within the previous 24 hours. NB. Most infants were fed formula in the hospital nursery before enrolment so there was no opportunity to establish exclusive breastfeeding

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Craniofacial abnormalities in the infant • Positive drug screen for mother or infant • NICU admission immediately after birth				
Full citation Quinlivan JA, Box H, Evans SF. , Postnatal home visits in teenage mothers: a randomised controlled trial., Lancet, 361, 893-900, 2003 **Ref Id** 997024 **Country/ies where the study was carried out** Australia **Study type** RCT **Aim of the study** Ascertain whether a post-natal home visiting	**Sample size** N randomised=136 Intervention: n randomised*=71 Control: n randomised*=65 *This paper reports different numbers in the abstract, in figure 1 and in the table. Data has been extracted as reported in the table. **Characteristics** <u>Indigenous Australian ethnicity n(%):</u> Intervention group 21(30); control group 12(18) <u>Mean age in years (SD):</u> Intervention group 16.4(0.96); control group 16.6(0.90) <u>Low/destitute socioeconomic status score n(%):</u> Intervention group 62(88); control group 55(85)	**Interventions** Intervention: standard care plus home visits by a nurse-midwife at week 1, 2 weeks, 1 month, 2 months, 4 months, and 6 months after birth. Each visit lasted 1–4 h. Control: routine postnatal support, counselling, and information services provided by the hospital, including access to routine hospital domiciliary home-visiting services	**Details** **Data Collection** Participants completed antenatal questionnaire with the assistance of a midwife. Responses were written down verbatim at the time and later scored on a pre-defined scale by researcher. These were repeated at 6 months postnatal. Scores for knowledge of the benefits of breastfeeding were allocated as three points for an answer suggesting that it is best for the baby, two points each for indicating that breastfeeding is best for the mother, that is encourages bonding, and that it gives immunity. One point answers were indication that breastfeeding is	**Results** Initiation of breastfeeding*: intervention (n=71): 51 vs control (n=65): 49 Any breastfeeding at 12 weeks*: intervention (n=71): 27 vs control (n=65): 24 Any breastfeeding at 24 weeks*: intervention (n=71): 16 vs control (n=65): 16 *This paper reports different numbers in the abstract, in figure 1 and in the table. Denominators have been extracted as reported in the table.	**Limitations** This paper reports different numbers in the abstract, in figure 1 and in the table Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Computer generated) Allocation concealment: Low risk (sealed opaque envelopes) Baseline differences: High risk (Higher proportion of women in the intervention were of indigenous Australian origin, had

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
service for teenage mothers younger than age 18 years could reduce the frequency of adverse neonatal outcomes and improve knowledge of contraception, breastfeeding and infant vaccination schedules in this parent group. **Study dates** July 1998 to December 2000 **Source of funding** The work was foundered by the Innovative Funding for Homeless Youth Support Services Grants Schemes administered by the Health Department of Australia through its state branches.	Positive antenatal Edinburgh depression score (>13) n(%): Intervention group 19(27); control group 16(24) Father does plan to have ongoing involvement with either the mother or child n(%): Intervention group 53(74); control group 41(63) Social isolation n(%): Intervention group 46(65); control group 36(56) Homeless n(%): Intervention group 13(18); control group 7(11) Experience of Domestic Violence n(%): Intervention group: 23(33); control group 13(21) Main source of perpetrator - family: Intervention group 9(13); control group 7(11) Main source of perpetrator - partner: Intervention group 14(20); control group 6(10) Type - physical: Intervention group 17(24); control group 10(15) Type - sexual: Intervention group 6(9); control group 5(8) Type - other: Intervention group 13(19); control group 5(8) Smoking Status n(%) Smoker smoked throughout pregnancy: Intervention group 43(61); control group 36(56)		convenient or cheaper. Maximum score was 11. Agreement between methods of assessment of knowledge of breastfeeding was 83% (Cohens K 0.62, 95% CI 0.35-0.92). **Analysis** Analysis was done by intention-to-treat. Univariate and multivariate statistical techniques. Numerical variables were compared with the t-test or Wilcoxon's rank sum test as appropriate if variables were not normally distributed. Group testing of categorical data were compared with X2 test of Mantel-Haenszel X2 test for linear association of ordinal variables, with Taylor-series relative risks applied. Difference between groups in duration of breastfeeding were calculated using Kaplan-Meier survival analysis with the log rank test. Setting: Australian public-care teenage pregnancy clinic for first time mothers.		fathers involved, reported domestic violence and stopped smoking when pregnant) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Ceased when became pregnant: Intervention group 22(31); control group 14(21) Alcohol n(%) Drank alcohol throughout pregnancy: Intervention group 22(31); control group 16(25) Ceased alcohol when became pregnant: Intervention group 34(48); control group 29(44) Illegal Drugs n(%) Used illegal drugs throughout pregnancy: Intervention group 21(30); control group 14(21) • Marijuana: Intervention group 18(25); control group 11(17) • Heroin: Intervention group 4(5); control group 3(5) • Amphetamines: Intervention group 1(3); control group 5(8) • Other(LSD, solvents): Intervention group 5(7); control group 4(6) Ceased illegal drugs while pregnancy: Intervention group 22(31); control group 19(30)				Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (data obtained from 62/65 in intervention and 62/71 in control) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Marijuana: Intervention group 18(25); control group 16(25) • Heroin: Intervention group 6(8); control group 1(2) • Amphetamines: Intervention group 9(13); control group 3(5) • Other(LSD, solvents): Intervention group 3(4); control group 3(5) Mean gestational age in weeks when pregnancy diagnosed (SD): Intervention group 11.9(7.2); control group 12.2(6.4) Mean gestational age in weeks when pregnancy diagnosed (SD): Intervention group 19.9(6.0); control group 21.0(5.4) Kessner score to quantify antenatal care n(%) High: Intervention group 31(43); control group 32(49) Medium: Intervention group 20(28); control group 21(32) Low: Intervention group 20(28); control group 12(19)				**Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Mean total days of antenatal admissions (SD): Intervention group 4.7(4.1); control group 2.6(1.8) Mean gestational age in weeks at delivery (SD): Intervention group 39.1(2.4); control group 38.6(3.5) Method of Delivery n(%) Spontaneous vaginal delivery: Intervention group 58(82); control group 48(74) Assisted vaginal delivery: Intervention group 11(16); control group 13(20) Elective Caesarean section: Intervention group 1(1); control group 1(2) Emergency Caesarean section: Intervention group 1(1); control group 2(3) Breech or twin delivery: Intervention group 0(-); control group 1(2) Male sex of infant n(%): Intervention group 41(57); control group 29(45) Mean newborn biometry (SD) Birthweight in grams: Intervention group 3288(475); control group 3091(786)				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Head circumference in cms: Intervention group 34.0(1.5); control group 33.4(3.1) Length in cms: Intervention group 48.8(2.3); control group 48.4(4.3) Median Apgar score of baby (IQR) 1 min: Intervention group 9(7,9); control group 8(6,9) 5 min: Intervention group 9(9,10); control group 9(8,9) Neonatal problems n(%): Intervention group 43(60); control group 38(59) Jaundice: Intervention group 11(15); control group 16(24) Feeding difficulties: Intervention group 9(13); control group 9(14) Temperature: Intervention group 23(33); control group 21(33) Admission to ICU: Intervention group 4(5); control group 3(5) Other: Intervention group 15(21); control group 16(25) Maternal puerperal problems n(%): Intervention group 39(55); control group 35(54) Social crisis: Intervention group 18(26); control group 19(29)				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Depression: Intervention group 9(13); control group 11(17) Fever: Intervention group 17(24); control group 10(15) Antibiotics prescribed: Intervention group 17(24); control group 7(11) **Inclusion criteria** • Primiparous teenagers attending their first antenatal appointment • Under 18 years old • Speak English • Intention to continue with pregnancy **Exclusion criteria** • Residence more than 150 km from hospital • Known foetal abnormality				
Full citation	**Sample size** N number = 50 Targeted care group = 25	**Interventions** Targeted care: Women in this group received a more	**Details** **Data Collection**	**Results** Breastfeeding initiation: BIBS1 intervention (n=20): 20 vs	**Limitations** Limitations were assessed using the revised Cochrane

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Rasmussen, K. M., Dieterich, C. M., Zelek, S. T., Altabet, J. D., Kjolhede, C. L., Interventions to increase the duration of breastfeeding in obese mothers: the Bassett Improving Breastfeeding Study, Breastfeeding Medicine: The Official Journal of the Academy of Breastfeeding Medicine, 6, 69-75, 2011 **Ref Id** 420264 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To ascertain whether increased breastfeeding support is a feasible, effective intervention to improve breastfeeding in obese women.	Control group = 25 **Characteristics** Mean pre-pregnancy weight in kgs (SD): targeted care 103.8(21.0); usual care 96.3(13.9) Mean height in cm (SD): targeted care 165.0(7.1); usual care 166.6(7.2) Mean pre-pregnancy BMI in kg/m2 (SD, range): targeted care 38.1(6.9, 29.6-57.7); usual care 34.7(4.3, 29.3-47.7) Mean gestational weight gain in kgs (SD): targeted care 13.0(9.5); usual care 10.6(8.2) Mean BMI at delivery in kg/m2 (SD, range): targeted care 42.9(7.9, 31.2-66.2); usual care 38.5(5.6, 31.5-56.1) Mean age in years (SD): targeted care 27.3(8.6); usual care 26.6(9.1) Caesarean delivery (%): targeted care 31.6; usual care 40.0 Parous (%): targeted care 45.0; usual care 61.1 Previous breastfeeding experience (%): targeted care 50.0; usual care 42.1 Married (%): targeted care 72.2; usual care 75.0	detailed pre-partum phone call, reviewing practical points about breastfeeding. Post-partum, nurses encouraged to move, as well as managing visitation in such a way as to minimise disruption to breastfeeding schedule. Two further telephone calls from lactation consultant were scheduled at 24 and 72 hours after discharge. Usual care: All women roomed-in with their new-born and a breastfeeding session is observed at least once per 8 hour shift. Pre-partum call received from lactation consultant.	Data was collected using telephone questionnaires before delivery, every day up to 7 days postpartum, one at 30 days postpartum and final one at 90 days postpartum. **Data Analysis** Differences between treatment groups in participants' perinatal characteristics were tested using X2 and t tests or analysis of variance. Both studies first analysed by intention to treat. Proportion of participants who were breastfeeding were compared using X2. Total durations of exclusive and any breastfeeding were pampered by two-sided Wilcoxon rank sums test. Adjustment of breastfeeding duration for maternal BMI at delivery was performed using logistic regression. Women in the targeted-care group were compared to those in the usual-care group. Unfortunately, BIBS 1 was not implemented as planned, so additional analyses were conducted to explore whether the	BIBS1 control (n=19): 19 vs BIBS2 electric intervention (n=12): 13 vs BIBS2 control (n=12): 12 vs BIBS2 manual intervention (n=9): 7Exclusive breastfeeding at 7 days: BIBS1 intervention (n=20): 13 vs BIBS1 control (n=19): 16 vs BIBS2 electric intervention (n=12): 4 vs BIBS2 control (n=12): 3 vs BIBS2 manual intervention (n=9): 5Any breastfeeding at 90 days: BIBS1 intervention (n=20): 6 vs BIBS1 control (n=19): 12 vs BIBS2 electric intervention (n=12): 3 vs BIBS2 control (n=12): 8 vs BIBS2 manual intervention (n=9): 5	risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (no details available) Allocation concealment: Some risk (no details available) Baseline differences: Some risk (BMI was not evenly distributed between groups) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates May 2006 to February 2007 **Source of funding** Research supported by USDA/Hatch grant NYC-399430.	Mean education in years (SD): targeted care 14.0(2.4); usual care 13.7(1.9) Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and/or Prenatal Care Assistance Program (PCAP) participation (%): targeted care 44.4; usual care 60.0 Smoked during pregnancy (%): targeted care 21.1; usual care 15.8 Mean breastfeeding goal in weeks (SD): targeted care 29.2(19.1); usual care 30.1(19.3) Mean infant birth weight in kgs (SD): targeted care 3.61(0.48); usual care 3.51(0.44) Infant fed formula in hospital (%): targeted care 26.3; usual care 22.2 **Inclusion criteria** Women at least 19 years old with a pre-pregnancy BMI > 29 kg/m2 and who intended to breastfeed. No history of breast surgery. Singleton pregnancy, as least 35 weeks at time of enrolment. Resided near hospital where study was based.		intervention as actually received by the participants improved breastfeeding outcomes. To do this, all analyses were repeated using a dataset restricted to those who had received the prespecified calls (n=11 usual care, n=11 targeted care).		**intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (Three women in the control group requested and received manual pumps at discharge, one woman in the electric group did not receive any pump, two women randomised to the manual group received electric pumps, and one woman in the electric pump refused the hospital-grade pump and used her own battery-powered one.) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Not reported				Missing outcome data: Some risk (drop out around 20% but in both groups) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Research assistants did not know the assigned treatment groups) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					selection of the reporting result: Some risk **Overall risk-of-bias judgement: High risk** **Other information** Successful initiation of breastfeeding: still breastfeeding on day 4 after delivery. Exclusive breastfeeding: difference between date after hospital discharge and when the infant was first given anything other than breastmilk Paper reports findings from 2 RCTs - BIBS1 and BIBS2. BIBS2 investigated the intervention of breast pumps on duration of breast feeding in obese women. Data from this trial was not extracted.
Full citation Redman S, Watkins J, Evans L, Lloyd D. , Evaluation of an Australian intervention to encourage breast feeding in primiparous women., Health Promotion International, 10, 101-13, 1995	**Sample size** N number = 238 Intervention n = 120 Control = 115 **Characteristics** NB. Questionnaire only completed by 200 participants (95 control, 105 intervention)	**Interventions** Intervention group - consisted of: • 3 hr teaching sessions at 24-28 weeks for mothers and support persons. Semi-structured discussions,	**Details** **Data Collection** Participants were mailed an introductory letter and a pre-test questionnaire to assess knowledge and attitudes towards breast feeding and demographic characteristics. A 6 week postpartum follow-up questionnaire sent out. In	**Results** Breastfeeding initiation: intervention (n=83): 81 vs control (n=81): 77 Any breastfeeding at 6 weeks: intervention (n=83): 68 vs control (n=81): 64 Any breastfeeding at 4 months (17 weeks): intervention (n=77): 45 vs control (n=75): 42	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: High risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 997092 **Country/ies where the study was carried out** Australia **Study type** RCT **Aim of the study** To develop and evaluate the effect of an intensive, structured programme on the maintenance of breast feeding in a representative sample of primiparous women. **Study dates** August 1989 - November 1989 **Source of funding** Research supported by a grant from the New South Wales Department of Health.	<u>Age in years (%)</u> 18-25: intervention 47; control 54 26-35 intervention 53; control 46 <u>Marital status (%)</u> Single/separated/divorced: intervention 14; control 16 Married/living as married: intervention 86; control 84 <u>Education (%)</u> Some high school: intervention 20; control 22 Completed high school/tech: intervention 69; control 62 University: intervention 11; control 16 <u>Mode of delivery (%)</u> Normal vaginal: intervention 62; control 63 Caesarean/forceps with general anaesthetic: intervention 15; control 18 Forceps/vacuum extraction: intervention 23; control 19 <u>Length of labour (%)</u> ≤8 hour: intervention 71; control 55 ≥8 hour: intervention 24; control 39 **Inclusion criteria** Primiparous women who intended to breastfeed.	demonstrations of correct breastfeeding position and breast pumps, 5 min instructional video and printed information pack. • Postnatal hospital visit by breastfeeding consultant who observed a feeding. Second information pack provided. • Phone call at 2-3 weeks postpartum. • Postnatal discussion group at 6-8 weeks for mother's, babies and support persons. postnatal information package provided. • Phone call 3 months after the birth • Calls to consultant and home visits were available on request. Individual sessions were provided after the birth of the baby, allowing them to be	the event of non-response, a telephone interview was conducted. Second follow-up questionnaire was sent 4 months postpartum. **Analysis** Intent-to-treat analysis basis, assuming those lost to follow-up were not breastfeeding at 4 months. X2 analysis performed. Settings: Newcastle Western Suburbs Hospital		(based on odd or even numbered consent forms) Allocation concealment: Low risk (women or staff were unaware of the code for allocation) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Not previously given birth to live baby • Aged between 18-35 • Advised the hospital of their expected delivery date ('booked in') before 20 weeks gestation • Live in a 25km radius of the hospital and not intending to move before baby was 4 months old **Exclusion criteria** Women under the care of independent midwife.	tailored to the needs of individual women. Group sessions offered the opportunity for social support from other attenders. Control group - received the usual advice about breastfeeding from their doctor, the hospital staff and from the Antenatal/Preparation for Parenthood classes.			DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): risk** DOMAIN 3 – missing data Missing outcome data: Some risk (pretest questionnaire completed by 200/245 (81%), 6 week followup by 166/245 (68%) and 155/245 for 4 month (63%)) **Judgement on risk of bias arising from missing outcome data: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Reeder JA, Joyce T, Sibley K, Arnold D, Altindag O., Telephone peer counseling of	**Sample size** N=1948 randomised. Assigned to high-frequency peer counselling: n=645. Assigned to low-frequency peer counselling: n=646.	**Interventions** High-frequency telephone peer counseling group: women were scheduled to receive 4 calls as per the low frequency group, and 4	**Details** **Data collection** Outcomes were reported by mothers to WIC staff who were not part of the study team.	**Results** Exclusive breastfeeding for at least 3 months, unadjusted RR: 1.10 (95% CI 0.97 to 1.26) adjusted RR: 1.09 (95% CI 0.95 to 1.24) * (N with non-	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
breastfeeding among WIC participants: a randomized controlled trial. , Pediatrics , 134, e700–e709, 2014 **Ref Id** 996976 **Country/ies where the study was carried out** US **Study type** RCT with 3 study arms **Aim of the study** **Study dates** Women attending a new pregnancy appointment for WIC between July 2005 and July 2007. **Source of funding** The research 'was supported by the US Department of Agriculture, Food and Nutrition Service, WIC Special Project Grant	Assigned to control group: n=657. 63 women miscarried or left the state, leaving 1885 women out of the 1948 randomised. In the high-frequency group (n=645), 12 had an infant or pregnancy lost and 8 were lost to follow-up, so data was available for 625 women. In the low-frequency group (n=646), 13 had an infant or pregnancy lost and 8 were lost to follow-up, so data was available for 625 women. In the control group, n=21 had an infant or pregnancy lost and 1 was lost to follow-up, so data was available for 635 women. Out of these 1885 women, breastfeeding duration was unknown for 12 in the high frequency group, 17 in the low frequency group and 26 in the control group. Exclusive breastfeeding duration was unknown for 6 in the high frequency group, 11 in the low frequency group and 12 in the control group. **Characteristics** WIC clients - low-income	additional calls at months 1, 2, 3, and 4. Low-frequency telephone peer counseling group: Women were scheduled to receive 4 planned, peer-initiated contacts: the first after initial prenatal assignment, the second 2 weeks before the expected due date, and the third and 4th at 1 and 2 weeks postpartum. For the analysis two treatment arms were combined because there was no difference in the distribution of peer contacts. Control: Standard WIC breastfeeding promotion and support (no contact with a peer counsellor)	**Analysis** Sample size calculation indicated that 523 mother-infant pairs per group would be needed to detect a 10 percentage point difference in breastfeeding. Analysis was by intention-to-treat A one-way analysis of variance was used to test for balance across the 3 study arms with continuous characteristics of mothers and x2 tests of independence for categorical measures. For each dichotomous breastfeeding outcome, logistic regression was used to estimate the relative risk (RR) and risk difference associated with peer counseling.	missing data: see sample size section) *Estimate adjusted for age, education, race, language, marital status, month in pregnancy enrolled, family income, caesarean section, and local WIC agency.* Nonexclusive breastfeeding was also reported but this was not extracted for the present review. The results were also presented stratified by English-speaking women and Spanish-speaking women, however no data stratified by language was extracted for the present review. Breastfeeding initiation is not reported in primary paper but is reported in Cochrane.	DOMAIN 1 - randomisation Random sequence generation: Low risk (Computer generated random numbers) Allocation concealment: Some risk (Not described) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
WISP-04-OR-01 and grant R03 HD072991-01 from the National Institutes of Child Health and Human Development to the Research Foundation of the City University of New York. Funded by the National Institutes of Health (NIH)'	Spanish speaker: 47% in high-frequency group, 45% in low frequency group, 43% in control group. (Percentages based on n=1885) * Married or with a partner: 65% in high-frequency group, 69% in low-frequency group, 64% in control group (Percentages based on n=1827)* High school diploma: 57% in high-frequency group, 59% in low-frequency group, 59% in control group. (Percentages based on n=1813)* Monthly family income,$: 1420 in high-frequency group, 1451 in low-frequency group, 1390 in control group. (Average based on n=1847)* Caesarean birth: 26% in high-frequency group, 31% in low-frequency group, 30% in control group (Percentages based on n=1676) **Inclusion criteria** WIC clients recruited during pregnancy who intended to breastfeed or were considering breastfeeding. **Exclusion criteria**				**(effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: High risk (Both treatment arms combined in analysis) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Low risk (Analysis conducted on 635/657 in control, 625/646 in low frequency counselling and 625/645 in high frequency counselling)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	There were no exclusions on the basis of age, multiple gestations, or previous birth history.				**Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (Interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Assessors blinded to group allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (all outcomes reported as indicated by NCT registration) **Judgement on risk of bias arising from selection of the reporting result: Low risk** **Overall risk-of-bias judgement: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Relton, C., Strong, M., Thomas, K. J., Whelan, B., Walters, S. J., Burrows, J., Scott, E., Viksveen, P., Johnson, M., Baston, H., Fox-Rushby, J., Anokye, N., Umney, D., Renfrew, M. J., Effect of financial incentives on breastfeeding a cluster randomized clinical trial, JAMA Pediatrics, 172 (2) (no pagination), 2018 **Ref Id** 807210 **Country/ies where the study was carried out** UK **Study type** Cluster-RCT **Aim of the study** To evaluate the effects of an area-level financial incentive intervention on breastfeeding rates at 6	**Sample size** N=92 areas (10,010; 9207 women included in analysis, but analysis was based on areas, not women) Intervention: n=46 areas (5398 women) Control: n=46 areas (4612 women) Loss to follow-up: Intervention: 425 infants lost to follow-up; areas included in primary outcome analysis: 46 (4973 mother-infant dyads) Control: 378 infants lost to follow-up; areas included in primary outcome analysis: 46 (4234 mother-infant dyads) **Characteristics** White population (%) - median (interquartile range; IQR) Intervention: 97.5 (96.0 to 98.0); control: 97.9 (97.0 to 98.3) Women aged 16 to 44 years - mean (±SD) Intervention: 36.2 (3.0); control: 37.4 (3.6) Baseline 6 to 8 week breastfeeding prevalence (%) - mean (±SD) Intervention: 28.7 (6.5); control: 27.4 (7.3)	**Interventions** Intervention: Usual care plus financial incentives - shopping vouchers worth £40 (US$50) 5 times based on infant age: 2 days, 10 days, 6 to 8 weeks, 3 months, and 6 months (i.e., up to £200/US$250 in total). Vouchers were exchangeable at supermarkets and other retail shops with no restriction on allowable purchases. Control: Usual care. Setting: Electoral ward areas situated in 5 local government areas in the north of England.	**Details** **Data collection** Breastfeeding data were collected at 6 to 8 weeks postpartum by those delivering routine infant feeding services (midwives, health visitors, and primary care physicians). **Analysis** To achieve 80% power, 47 areas per intervention group were required. Primary analysis was conducted on an intention-to-treat basis. Primary outcome data were analysed using a weighted multiple linear regression model, controlling for baseline breastfeeding prevalence and local government area. Infants with missing outcome data were not included in the analysis.	**Results** Breastfeeding initiation: intervention (n=46 areas) vs control (n=46 areas): adjusted mean difference in prevalence: 2.9 percentage points (-0.4 to 6.2) Any breastfeeding at 6 to 8 weeks: intervention (n=46 areas)vs control (n=46 areas): adjusted mean difference in prevalence: 4.5 percentage points (1.5 to 7.5) Exclusive breastfeeding at 6 to 8 weeks: intervention (n=46 areas) vs control (n=46 areas): adjusted mean difference in prevalence: 2.3 percentage points (-0.2 to 4.8)	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (cluster random allocation sequence with stratification at local government area level) Allocation concealment: Low risk (Cluster RCT where each clinic was allocated a particular treatment at the same time) Baseline differences: Some risk (Limited participant characteristics, population larger (and therefore more births) in the intervention arm) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
to 8 weeks postpartum in areas with historically low breastfeeding rates. **Study dates** April 2015 to March 2016. **Source of funding** Medical Research Council. Funding for the costs of the intervention for the trial was supported by Public Health England.	**Inclusion criteria** • Estimated or actual infant birth date fell between February 2015 and February 2016; • Mother aged 16 years or older; • Living within an intervention electoral ward area. **Exclusion criteria** Not stated.				Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					DOMAIN 3 – missing data Missing outcome data: Low risk (425/5398 (8%) lost to follow up in the intervention arm and 378/4612 (8%) lost to follow-up in the control arm) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: High risk (Interview - women's self-report on breastfeeding: 'Receipt of vouchers was conditional on mothers signing a form stating that “my baby is receiving breast milk” and a countersignature from a clinician for the statement “I have discussed breastfeeding with mum today.”') Blinding of outcome assessors: Some risk (no information is provided) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					measurement of the outcome: Some risk DOMAIN 5 – reporting Selective reporting: Some risk (Not all outcomes reported as per trial registration, however none of the missing outcomes were relevant to this review question) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** The authors stated that they adjusted for cluster design effect. ICC from Fleiss and Cuzick (ICC for breastfeeding prevalence: 0.024; ICC for breastfeeding initiation prevalence: 0.039; ICC for exclusive breastfeeding prevalence: 0.018).
Full citation	**Sample size**	**Interventions** Intervention: Best Start programme which included	**Details** **Data collection**	**Results**	**Limitations** Limitations were assessed using the revised Cochrane

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ryser FG., Breastfeeding attitudes, intention, and initiation in low-income women: the effect of the best start program., Journal of Human Lactation, 20, 300–5, 2004 **Ref Id** 997189 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To determine the effect of the Best Start breastfeeding educational programme on breastfeeding attitudes, intention and initiation in a sample of urban women of low socioeconomic status. **Study dates** Not stated.	N=54 • Intervention: n=26 • Control: n=28 **Characteristics** Age (years) - mean (±SD) Intervention (n=26): 25.3 (5.6) vs control (n=28): 22.6 (4.6). No statistically significant difference in age between groups. Parity - mean (±SD; range) Intervention: 1.4 (1.1; 0 to 3); control: 1.0 (1.2; 0 to 5). No statistically significant difference in parity between groups. Feeding intention, undecided at initial interview - number Intervention (n=26): 23 vs control (n=28): 14 Feeding intention, planned to use formula at initial interview - number Intervention (n=26): 2 vs control (n=28): 14 Feeding intention, planned to use both formula and breastfeeding at initial interview - number Intervention (n=26): 1 vs control (n=28): 0 Differences in breastfeeding intention were statistically significant.	counselling, viewing videos, reading written materials. Given to women during each of the 4 prenatal visits. Control: Standard care (no details provided). Setting: private, urban physician's (obstetrician and gynaecologist) office in the southwestern United States.	Data from the Breastfeeding Attrition Prediction Tool (BAPT) collected during the initial contact and again during the last month of gestation. BAPT uses a 6-point rating scale to assess 4 domains associated with breastfeeding decisions. Telephone contact made within 1 week postnatally by researcher using the Postpartum Infant Feeding Telephone Survey. **Analysis** Treatment group (intervention vs control) by time (pre-test vs post-test) repeated measures analysis of variance was performed to assess group and time interactions on outcomes.	Any breastfeeding at 1 week*: intervention (n=23): 18 vs control (n=27): 10 Exclusive breastfeeding at 1 week*: intervention (n=23): 14 vs control (n=27): 4 *Numerators and denominators above calculated by the NGA technical team based on the following information provided in the paper: intervention group: 14 women breastfeeding, 5 using formula, 4 doing both; control group: 4 women breastfeeding, 17 formula feeding, 6 doing both).	risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (Subjects select a sealed envelope to determine their assignment to either the experimental group or the control group) Allocation concealment: Low risk (Sealed envelope) Baseline differences: High risk (statistically significant differences in baseline characteristics between groups for intention to breastfeed or formula feed: 'During the initial interview, nearly 68% (n = 37) of subjects (23 and 14 in experimental and control groups, respectively) were undecided about feeding method. Nearly 30% (n = 16) of subjects (2 and 14 in experimental and control groups, respectively) had planned to use formula.') **Judgement on risk of bias arising from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding Received the John W Carter Research Award from the Texas Woman's University, Texas.	**Inclusion criteria** • At least 18 years of age; • English speaking; • Able to read and write; • Pregnant, with gestation allowing time for 4 points of contact; • Receiving prenatal care; • Low income (eligible for Medicaid); • Having access to a telephone; • Stating the intention to bottle feed or undecided about feeding method. **Exclusion criteria** • Women who intended to breastfeed at initial contact.				**randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk DOMAIN 3 – missing data Missing outcome data: Low risk (Data reported for 88.5% (23/26) in the intervention group and 96.4% (27/28) in the control group) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: High risk (The researcher was not blinded to group allocation, as all contact with the groups was performed by the researcher to increase standardisation of communication)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from measurement of the outcome: Some risk DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some concerns** **Other information** This study was included in the Balogun and Lumbiganon Cochrane reviews.
Full citation Sandy JM, Anisfeld E, Ramirez E., Effects of a prenatal intervention on breastfeeding initiation rates in a Latina	**Sample size** N=238 Intervention: n=137 Control: n=101	**Interventions** Intervention: Weekly antenatal home visits from family support worker. Visits involved providing women with information about pregnancy, prenatal care,	**Details** **Data Collection** Family support workers obtained information from mothers about current infant feeding method during postpartum stay at	**Results** Any breastfeeding at 1 week: intervention (n=137): 118 vs control (n=101): 79 Exclusive breastfeeding at 1 week: intervention (n=137): 44 vs control (n=101): 20	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
immigrant sample. , Journal of Human Lactation, 25, 404–11, 2009 **Ref Id** 997106 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To evaluate the effectiveness of a prenatal health education intervention aimed at increasing breastfeeding rates in an urban, low-income, predominately Dominican immigrant sample. **Study dates** Not stated. **Source of funding**	**Characteristics** First time mothers (%): 48.3 Aged between 15-19 years at child's birth (%): 16.4 At least a high school diploma/GED (%): 43.5 No one contributing to household income (%): 43.4 Biological father residing in the home (%): 39.9 Biological father as target child's 2nd primary caregiver (%): 27.3 Mother born outside US (%): 88 Predominately urban Latina immigrant population Ethnicity (%): Dominican 87; Puerto Rican: 4; Mexican 2; Salvadoran 2; other Latin American ethnicity 6; African American <0.5 Primiparous and multiparous **Inclusion criteria** Inclusion criteria for Best Beginnings • Resided in 1 of 2 census tracts in Washington Heights, an impoverished, mostly Latino immigrant	childbirth preparation, infant-feeding methods, child health and safety. Visit by family support worker in hospital and then weekly at home. Home visit by paediatric resident, in part to motivate women to breastfeed. Control: 1 or 2 visits during prenatal period, information about community services, educational booklets and pamphlets covering childbirth, child rearing and infant feeding methods but no discussion on the booklets content	the hospital or during first home visit. It was recorded whether a mother was currently exclusively bottle feeding, exclusively breastfeeding, or breast and bottle feeding. Consistent with prior studies, for data analytic purposes this 3-level variable was later recoded into 2 dichotomous "dummy" variables, 1 for any breastfeeding (exclusively breastfeeding or breast and bottle feeding = 1, exclusively bottle feeding = 0), and another for exclusive breastfeeding (exclusively breastfeeding = 1, breast and bottle feeding or exclusively bottle feeding = 0). **Analysis** The Pearson x2 statistic was used to test for associations between mothers' exposure to the prenatal intervention and 2 breastfeeding outcomes. A series of		DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Some risk (not described) Baseline differences: Some risk (not reported for each arm, therefore cannot tell) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not described but assumed to be not blinded) Blinding of carers and people delivering the interventions: High risk (not described but assumed to be not blinded) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Research was received from the New York State Office of Children and Family Services, New York State Department of Health, US Department of Health and Human Services Children's Bureau's Abandoned Infants Assistance Programme, and the Smith Richardson Foundation.	neighbourhood in New York City. • Pregnant or who had a baby 3 months or younger. • Reported psychosocial risk factors for caregiving difficulties Study inclusion criteria • Enrolled in Best Beginnings prenatally • Didn't drop out of Best Beginnings prior to infants birth • Singleton pregnancy • Infant who was placed in a well-baby nursery after birth (as opposed to NICU) • Valid mother report data on infant feeding practices **Exclusion criteria** Not stated.		Pearson x2 tests and t tests for independent samples were used to identify any significant associations between each breastfeeding outcome and the 8 putative correlates of breastfeeding listed earlier. Variables found to be significant correlates of breastfeeding in univariate analyses were included in subsequent multivariate analyses for prediction of breastfeeding outcomes. Binary logistic regression analysis was used to identify predictors of each breastfeeding outcome in a multivariate context. Statistical significance was defined as P < .05 for all analyses presented here. Settings: Best Beginnings participants approached in community prenatal clinics and Special Supplemental Nutrition Program for Women, Infants and Children sites operated by New York Presbyterian Hospital, 2 further hospital sites in the local community and community agencies and gatherings.		**intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (adherence to protocol was 100%, though this could be based on the way the analysis was conducted) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (no missing data, though this could be based on the way the analysis was conducted, possibly not ITT)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from missing outcome data: Some risk DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: High risk (not blinded) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Other information 238 families were a subsample of the 588 families participating in Best Beginnings, a primary prevention home visitation programme.
Full citation Schlickau J, Wilson M. , Development and testing of a prenatal breastfeeding education intervention for Hispanic women., Journal of Perinatal Education, 14, 24-35, 2005 **Ref Id** 997163 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effect of a prenatal breastfeeding education intervention	**Sample size** N randomised*=30 Intervention (1): n randomised*=10 Intervention (2): n randomised*=10 Control: n randomised*=10 *Calculated based on the following information provided in the paper: 'seven participants in the control group (data missing for three)'; 'nine participants in [intervention (1)] (data missing for one)'; 'nine participants who received [intervention (2)] (data missing for one)'. 5 women could not be contacted at 6 to 7 weeks postpartum. **Characteristics** Age (years) - mean (range) 22 (16 to 45) All women came from a stable family and were not planning to work outside the home for 6	**Interventions** Intervention (1): 1hr teaching session on breastfeeding (presented by Spanish language interpreter), including information on the benefits of breastfeeding, supply-and-demand concepts, and practising holding and positioning with a doll. Intervention (2): after completing teaching session as per intervention(1), additional teaching session on breastfeeding and baby quarantine (nothing enters the baby's mouth, expect the mother's breast, for at least 40 days after birth); the benefits of avoiding bottles, pacifiers and supplementation to promote establishment of breastfeeding were reinforced; breastfeeding commitment was	**Details** **Data collection** At 6 to 7 weeks postpartum (approximately 45 days), telephone interviews were conducted with women to determine status of infant feeding (breast only, partially breastfeeding, or bottle only). **Analysis** Data were analysed using *t*-tests and one-way analysis of variance.	**Results** Any breastfeeding at 45 days*: intervention (1) (n=9): 3 vs intervention (2) (n=9): 5 vs control (n=7): 2 *Numerators calculated by the NGA technical team based on percentages provided in the paper *Denominators calculated by the NGA technical team based on the number of women with missing data in each group	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (Not described) Allocation concealment: Some risk (Not described) Baseline differences: Some risk (No baseline characteristics provided) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
on breastfeeding duration among Hispanic women. **Study dates** Not stated. **Source of funding** Not stated.	months. 85% of women had emigrated from Mexico in the past 7 years. **Inclusion criteria** • Hispanic women in their third trimester of pregnancy; • Low-risk, nulliparous. **Exclusion criteria** Not stated.	encouraged with the use of a checklist. Control: Standard care of breastfeeding information which included offering advice and handouts. Setting: Sedgwick County Department of Health's Mother and Infant Clinic, Kansas, US.			Blinding of participants: High risk (not described but assumed to be not blinded) Blinding of carers and people delivering the interventions: High risk (not described but assumed to be not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): Some risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					(effect of adhering to intervention): Low risk DOMAIN 3 – missing data Missing outcome data: High risk (1/10 (10%) in the intervention had missing data whilst 3/10 (30%) in control arm had missing data) **Judgement on risk of bias arising from missing outcome data: High risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (Not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some concerns**
Full citation Schubiger G, Schwarz U, Tonz O. , UNICEF/WHO baby-friendly hospital initiative: Does the use of bottles and pacifiers in the neonatal nursery prevent successful breastfeeding?. , European Journal of Pediatrics, 156, 874–7, 1997 **Ref Id** 996971 **Country/ies where the study was carried out** Switzerland **Study type** RCT	**Sample size** N= 602 Intervention: n=294 Control: n=308 Protocol violations (1st week): Intervention: 114; control 17 Lost to follow-up: Intervention: 23; control: 13 **Characteristics** Maternal age (years) - mean (±SD) Intervention: 30.8 (4); control: 31.0 (4) Birthweight (g) - mean (±SD) Intervention: 3367 (319); control: 3404 (348) Gestational age (weeks) - mean (±SD) Intervention: 39.9 (1.4); control: 39.9 (1.2) Parity - mean (±SD)	**Interventions** Intervention: supplements, if medically indicated, were administered by cup or spoon; bottles, teats and pacifiers were strictly forbidden. Control: supplements were conventionally offered by bottle after breastfeeding; pacifiers were offered to all infants without restriction. Setting: 10 Swiss hospitals.	**Details** **Data collection** Frequency of breastfeeding was recorded daily for 5 days. Questionnaires were sent to mothers at 2, 4, and 6 months to request feedback on breastfeeding, introduction of supplementary nutrition and use of pacifiers. **Analysis** To achieve 95% power, 235 infants per treatment group were required. Between group comparisons were analysed using Student's *t*-test and Mann-Whitney *U*-test. Pearson's chi-square tests was used for categorical data.	**Results** Any breastfeeding at 2 months*: intervention (n=271): 238 vs control (n=291): 255 Any breastfeeding at 6 months*: intervention (n=271): 160 vs control (n=291): 161 Any breastfeeding at 5 days and exclusive breastfeeding at 5 days data were not extracted because the outcome data were not based on an intention to treat analysis. For the intervention group, the denominator was calculated by the NGA technical team, subtracting losses to follow-up from the number of 'involved mother-child pairs' provided in table 1. The numerator was calculated by the NGA technical team using the percentages in the paper that refer to an analysis that included infants who had used	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (Not described) Allocation concealment: Low risk ('Sealed protocol forms were centrally randomised') Baseline differences: Some risk (Some baseline characteristics differences e.g. more boys were born to the intervention arm,) **Judgement on risk of bias arising from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess the effects of using bottles and pacifiers on breastfeeding. **Study dates** Not stated. **Source of funding** Not stated.	Intervention: 1.7 (0.7); control: 1.8 (0.8) **Inclusion criteria** • Healthy full-term infants (>37 weeks of gestation); • Weight 2750 to 4200 g; • Mothers intended to stay in hospital for 5 days postpartum; • Planned to breastfeed for 3 months or more. **Exclusion criteria** Not stated.			a pacifier (as per an intention to treat approach). For the control group, intention to treat percentages were not provided, so percentages based on the denominator 291 were used, as this was considered to be close enough to 295 (the denominator that would be obtained by subtracting losses to follow-up from the number of 'involved mother-child pairs' provided in table 1).	**randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (114/294 (39%) protocol violations in intervention arm vs 17/308 (6%) protocol violations in the control arm) Analysis of participants in the group to which they were randomised: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					(analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: low risk (23/294 (8%) lost to follow-up in intervention arm compared to 13/308 (4%) in control arm) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (no information is provided)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from measurement of the outcome: Low risk DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some concerns** **Other information** Infant formula was allowed only from day 4 to 5 if the baby had lost >8% of his/her birthweight and if there was evidence of insufficient lactogenesis. Fully breast-fed meant feeding with breast milk only or with breast milk and nutritionally insignificant amounts of water-based liquids according to WHO definitions; partially breast-fed meant feeding predominantly with breast

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					milk with additional formula or beikust.
Full citation Sciacca, J. P., Phipps, B. L., Dube, D. A., Ratliff, M. I., Influences on breast-feeding by lower-income women: An incentive-based, partner-supported educational program, Journal of the American Dietetic Association, 95, 323-328, 1995 **Ref Id** 807351 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effects of partner-supported, incentive-based educational interventions on	**Sample size** N=68 Intervention: n=34 Control: n=34 Loss to follow-up: Intervention: n=2 births before attendance; n=6 did not attend any intervention sessions. N=26 women received the intervention. Control: n=5 left the area before giving birth. N=29 control group **Characteristics** <u>Ethnicity - number (%)</u> White: Intervention: 16 (61.5); control: 20 (69.0) Non-white: Intervention: 10 (38.5); control: 9 (31.0) <u>Age - number (%)</u> 21 years or older: Intervention: 13 (50.0); control: 19 (65.5) 21 years or younger: Intervention: 13 (50.0); control: 10 (34.5) **Inclusion criteria**	**Interventions** Intervention: Usual WIC breastfeeding education plus 2-hr expectant couples breastfeeding class, where gifts were given to the woman and her partner. Standard five 1-hr sessions on childbirth preparation as the control group, but the intervention group received incentives for attending at least 3 of 5 sessions (incentives included a coupon for a free haircut, lunch or breakfast for two, a gift certificate for $15 from a clothing store, an infant carrier, video coupons, or stuffed animals). Women were encouraged to contact the peer counsellor through the incentive of a box of baby wipes, which was brought over by the peer counsellor at the first visit. Women who reported any breastfeeding at 3 months received a bag of diapers. Women who reported breastfeeding at least half of the time at hospital discharge, at 6 weeks and at 3 months gained entry into a	**Details** **Data collection** Data regarding infant feeding were collected from mothers at the time they were discharged from the hospital and at 2 weeks, 6 weeks, and 3 months postpartum. **Analysis** Feeding outcome data were analysed using binomial proportional analysis.	**Results** Any breastfeeding at 2 weeks: intervention (n=26): 25 vs control (n=29): 16 Exclusive breastfeeding at 2 weeks: intervention (n=26): 21 vs control (n=29): 10 Any breastfeeding at 3 months: intervention (n=26): 16 vs control (n=29): 7 Exclusive breastfeeding at 3 months: intervention (n=26): 11 vs control (n=29): 5	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Some risk (not described) Baseline differences: High risk (Participant demographics for ethnicity, education and age were significantly different between groups) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
breastfeeding rates and duration. **Study dates** March to December 1992. **Source of funding** Food and Nutrition Service, US Department of Agriculture.	• Primiparous pregnant women who attended the 2 WIC clinics; • Expected due date between May 1992 and December 1992; • An interest in, expressed on the infant feeding questionnaire, in participating in the programme with the baby's father or significant other. **Exclusion criteria** • Multiparous women.	raffle. Raffled incentives were higher for exclusive breastfeeding and included: a $40 dinner for two, an electric drill, $100 of groceries, a 52-piece tool set, a trip for two on the Grand Canyon Railway. Raffled incentives for breastfeeding at least half of the time but not exclusively included: a free haircut, lunch for two, a compact disc, a car wash, $5 of gasoline. Control: Standard breastfeeding education. This included five 1-hr sessions on childbirth preparation, promotion of breast pump rental service, optional 15 minute breastfeeding group class, 1 prenatal and 3 postnatal contacts from peer supporters. Setting: 2 WIC clinics in Flagstaff, US.			Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): Some risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (6/34 (18%) in treatment arm did not attend intervention session) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Missing outcome data: High risk (8/34 (24%) in the treatment arm and 5/34 (15%) in the control arm were lost to follow up /not included in the follow-up data collection) **Judgement on risk of bias arising from missing outcome data: High risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					selection of the reporting result: Some risk **Overall risk-of-bias judgement: High risk**
Full citation Serwint JR, Wilson MEH, Vogelhut JW, Repke JT, Seidel HM. , A randomized controlled trial of prenatal pediatric visits for urban low income families. , Pediatrics , 98, 1069–75, 1996 **Ref Id** 996995 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study**	**Sample size** N= 156. Intervention: n=81 Control: n=75 161 women were approached for the study, 5 did not enrol (2 had not decided where they would take their infant for care, 2 did not wish to participate, 1 was moving away). By the time of birth, 74 women remained in the intervention group (losses between randomisation and birth: 1 miscarriage, 6 transferred to care out of state) and 70 in the control group (losses between randomisation and birth: 1 miscarriage, 4 transferred care). By 2 weeks, 68 women were in the intervention group (losses between birth and 2 weeks: 6 transferred care) and 60 in the control group (losses between birth and 2 weeks: 9	**Interventions** Intervention: In addition to routine care, women received an antenatal visit at a hospital-based paediatric clinic with the infant's future paediatrician. During the visit, parents-to-be received counselling on feeding options and advantages of breastfeeding, as well as on infant car safety, circumcision and access to paediatric health care and appropriate utilisation. Control: Usual care; no antenatal paediatric visit. Setting: Hospital-based paediatric continuity clinic in an urban academic medical centre.	**Details** **Data collection** Outcome data were collected through interviews at enrolment, at infant's 2-month visit, and by review of the infant's nursery chart. Breastfeeding measures included prenatal intention to breastfeed, changes to feeding during pregnancy subsequent to enrolment, and initiation and duration as of 30 and 60 days of age. **Analysis** To achieve 80% power, 125 participants in each intervention group was required. Data were analysed on an intention-to-treat basis, using chi-squared, Fisher's exact test, and Student's *t*-test.	**Results** Initiated breastfeeding: intervention (n=74): 31 vs control (n=70): 22 Any breastfeeding at 60 days: intervention (n=54): 8 vs control (n=51): 6 Women's satisfaction, measured after a 2-month visit, by response to question 'How satisfied have you been with the medical care your doctor has given your baby?' on a 1-5 Likert scale from strongly disagree to strongly agree: intervention (n=54): 52 vs control (n=51): 49 (Data not extracted in the analysis for the present review as interpretation of this data is unclear).	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (a random number table with blocks of 10 was used for random assignment) Allocation concealment: Some risk (not reported) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To assess whether antenatal paediatric visits would have an impact on breastfeeding decisions, healthcare behaviours, health care utilisation, and the doctor-patient relationship. **Study dates** February 1992 through July 1993. **Source of funding** The research was supported in part by a grant from the General Research Center Unit, Johns Hopkins University.	transferred care, 1 remained hospitalised). By 2 months, 54 women were in the intervention group (losses between 2 weeks and 2 months: 12 transferred care, 2 not interviewed) and 51 in the control group (losses between 2 weeks and 2 months: 5 transferred care, 4 not interviewed). Protocol violations: 46/81 women in the intervention group had a prenatal visit. Of the other 35, 7 were lost to follow-up (1 due to miscarriage, 6 due to transfer of care) and 6 had a premature birth. Reason for protocol violation not reported for the other 22 women. **Characteristics** Singleton pregnancies except for 1 woman who had twins (only twin A included in the study). Low-income families. <u>Maternal age (years) - mean (±SD)</u> Intervention (n=81): 20.2 (2.1) vs control (n=75): 20.7 (2.5) <u>Infant gestational age, mean (±SD)</u> Intervention (n=81): 38.6 (1.8) vs control (n=75): 37.5 (5.2)				DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: High risk (35/81 (43%) in the intervention arm did not keep their prenatal appointment) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Maternal race African-American: intervention (n=81): 91% vs control (n=75): 91% Intention to breastfeed before the prenatal visit: Intervention (n=74): 36% vs control (n=70): 45% *Paper does not specify if data refer to mean and SD, it was assumed so by the NGA technical team. No statistically significant differences between groups based on characteristics above. **Inclusion criteria** • Primiparous women; • Aged 18 years or older; • Gestational age of 28 weeks or less; • Not yet selected a paediatrician or wanted their infant to receive paediatric care at the hospital-based paediatric clinic.				**intended interventions (effect of adhering to intervention): Some risk** DOMAIN 3 – missing data Missing outcome data: Some risk (27/81 (33%) in the intervention arm and 24/75 (32%) had missing data at the 2 month outcome) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not reported) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria • Women admitted to prenatal drug use; • Women with recognised psychiatric illness; • Women with HIV.				risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some concerns** **Other information** The authors had to terminate the study before reaching their estimated sample size, but this was not included in the risk of bias assessment because there is an imprecision domain (separate from the risk of bias domain) in the GRADE assessment. Included in Balogun, Lumbiganon and Whitford Cochrane reviews.
Full citation Simonetti V, Palma E, Giglio A, Mohn A, Cicolini G., A structured telephonic counselling to promote the exclusive	**Sample size** N randomised=114 Intervention: n=55 Control: n=59	**Interventions** Intervention: prenatal Ten Steps to Successful Breastfeeding teaching as per control group plus structured telephonic counselling from midwife at	**Details** **Data Collection**	**Results** Any breastfeeding at 3 months: intervention (n=55): 50 vs control (n=59): 47 Exclusive breastfeeding at 3 months: intervention (n=55):30 vs control (n=59): 17	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
breastfeeding of healthy babies aged zero to six months: a pilot study, 2012 **Ref Id** 996980 **Country/ies where the study was carried out** Italy **Study type** RCT **Aim of the study** To test the effectiveness of structured telephonic counselling (STC) in increasing duration of exclusive breastfeeding (EB) on primiparous women. **Study dates** February 2009 - March 2009 **Source of funding** Not stated.	**Characteristics** Mean mother's age in years (SD): intervention 32.18(3.796); control 31.54(3.807) Level of education n(%): Lower secondary: intervention 31(56.4); control 41(69.5) Upper secondary: intervention 24(43.6); control 18(30.5) Work after childbirth n(%): Yes: intervention 41(74.5); control 32(54.2) No: intervention 14(25.5); control 27(45.8) Mean gestation in weeks (SD): intervention 39.69(1.153); control 39.47(1.150) Mean infant weight in grams (SD): intervention 3452.18(338.56); control 3323.73(426.92) **Inclusion criteria** Healthy primiparous women who explicitly declared intention to breastfeed. • Women without breastfeeding problems • Infant born full term (37-41 weeks) and	least once a week over the first 6 weeks after birth and able to call the WHO-UNICEF licensed midwife as necessary Control: Standard care included the prenatal Ten Steps to Successful Breastfeeding teaching programme antenatally and conventional counselling - consisting of programmed periodical visits with the physician at 1, 3 and 5 months after delivery. Able to call the WHO-UNICEF licensed midwife as necessary	Participants were interviewed by telephone at discharge, 1 month postpartum, 3 months postpartum and 5 months after delivery. **Analysis** Demographic data were analysed using Student's t-tests and chi-square test to check if comparison between groups was appropriate. A statistical significance level of 0.05 was used for all statistical tests. Data about mother's age, gestational period's length and newborn's weight were analysed using a Student's t-test and a homogeneity of variance test; a P-value < 0.01 was considered significant. Demographic data such as mother's age, gestational age and baby's birth weight were analysed. A chi-square test was used to further describe the two groups, in terms of level of education, work after childbirth, formula administration, use of baby bottle, pacifier and breastfeeding observation.	Any breastfeeding at 5 months: intervention (n=55): 37 vs control (n=59): 30	Random sequence generation: Some risk (not described) Allocation concealment: Some risk (not described) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not described but assumed to be not blinded) Blinding of carers and people delivering the interventions: High risk (not described but assumed to be not blinded) **Judgement on risk of bias arising**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	weighing more than 2.5 kg **Exclusion criteria** • Multiparous women • Infant born before 37 weeks • Infant born with a low birth weight (under 2.5 kg) • Infant admitted to the ICU or transferred to another hospital • Infants who suffer from a disease that temporarily or permanently contraindicates breastfeed, including acute tuberculosis, psychosis, acute phase hepatitis A and B, positivity to hepatitis C or HIV • Women who don't speak Italian • Couldn't be contacted by telephone		Settings: one public Italian maternity ward.		**from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (No missing data) **Judgement on risk of bias arising from missing outcome data: Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Srinivas GL, Benson M, Worley S, Schulte E. , A clinic-based	**Sample size** N randomised: 120. N randomised to each group not reported. N analysed=103	**Interventions** Intervention: Standard care plus contact from a peer counsellor, initially between 28 weeks gestation and 1	**Details** **Data Collection** Baseline survey and questionnaire was completed with	**Results** Breastfeeding initiation: intervention (n=50): 43 vs control (n=53): 41	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
breastfeeding peer counselor intervention in an urban, low-income population: Interaction with breastfeeding attitude. , Journal of Human Lactation , 31, 120-8, 2015 **Ref Id** 997176 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To evaluate the effectiveness of a model of peer counsellor contact on breastfeeding rates in low-income urban mothers. **Study dates** January 2011 - June 2012	Intervention: n=50 Control: n=53 **Characteristics** Low-income Attitude to breastfeeding Positive (IIFAS score > 57) n(%): intervention 34(68); control 33(62) Mean IIFAS score (SD): intervention 60.7(7.1); control 60.8(8.9) Ethnicity n(%) White: intervention 22(44); control 22(42) African American: intervention 13(26); control 15(28) Hispanic: intervention 9(18); control 18(34) Other (including Arabic/Southeast Asian/unrecorded): intervention 6(12); control 1(2) Insurance n(%) Public: intervention 41(82); control 46(87) Private/uninsured/not recorded: intervention 9(18); control 7(14) Occupation n(%) Not recorded: intervention 21(42); control 29(55) Service/blue collar/clerical: intervention 17(34); control 11(21)	week prior to birth. Then contact from peer counsellor in person during clinic visits or via telephone within 3 to 5 days after birth, weekly to 1 month, every 2 weeks up to 3 months, and once at 4 months. Control: Usual care including access to lactation consultants in hospital and outpatient lactation support from paediatricians and nutritionist.	demographic information, prior breastfeeding experience, and the IIFAS and received a $10 incentive. The IIFAS score was used to stratify to positive (IIFAS score ≥ 58) or negative (IIFAS score ≤ 57) breastfeeding attitude, and study participants were randomised within these strata in blocks of 4 participants in a 1:1 ratio to intervention or control group. The Primary Carer, who was blinded to attitude and self-efficacy scores, initiated contact with women in the intervention group between 28 weeks' gestation and 1 week prior to delivery, with additional contacts at the mother's request. Mothers who initiated breastfeeding in hospital were administered the postnatal survey containing the BSES-SF and asked to state their intended breastfeeding duration in months. If this survey was not completed prior to discharge, the study coordinator administered the survey by telephone or in clinic within 5 days of delivery. Women in the	Any breastfeeding at 6 months: intervention (n=50): 4 vs control (n=53): 4 Women felt that breastfeeding support was very respectful*: intervention (n=41): 30 vs control (n=46): 11 Women felt that standard care was sufficient*: intervention (n=41): 7 vs control (n=46): 28 *Numerators calculated by the NGA technical team based on denominators and percentages provided in the paper	DOMAIN 1 - randomisation Random sequence generation: Some risk (not clear, randomised in blocks of 4 participants in a 1-1 ratio) Allocation concealment: Some risk (not described) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Source of funding The study was funded by a Project Implementation Grant from the AAP Community Access To Child Health p=Project Implementation Grant Program, and a CareSource Foundation Responsive Grant.	Homemaker: intervention 6(12); control 7(13) Education level < High school/completed High school or GED n(%): intervention 27(54); control 34(64) Currently employed n(%): intervention 22(44); control 17(32) Plan to return to work/school: intervention 42(84); control 35(66) Return to work at ≤6 weeks (n=77) n(%): intervention 26(62); control 20(57) Second or subsequent pregnancy n(%): intervention 26(52); control 31(58) Prior breastfeeding experience (n=57) n(%): intervention 19(73); control 22(71) Longest duration of prior breastfeeding (n=41) n(%) Less than 6 months: intervention 15(100); control 13(76) 9 months: intervention 0(-); control 1(6) 1 year or more: intervention 0(-); control 3(18) **NB: Numbers reported do not add up to 41 for this section.** **Inclusion criteria** Women ≥ 28 weeks gestation		control group who initiated breastfeeding also completed the postnatal survey within 5 days and were then contacted monthly by the study coordinator to assess breastfeeding status. The study coordinator administered the exit interview to both groups either after the mother stopped breastfeeding or after 6 months of breastfeeding, to confirm breastfeeding status as well as perceptions on peer counselling or usual care. **Data Analysis** Study groups were described using means and standard deviations for continuous outcome variables and counts and percentages for categorical outcome variables. The homogeneity of the ORs for the effect of the intervention on breastfeeding rate across breastfeeding attitude strata was assessed using the Breslow-Day test. Groups were compared on		**Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (66% had prenatal contact in the intervention group, those who initiated breastfeeding 41/43 continued to have contact) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (85% provided follow-up data)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Exclusion criteria Women under 18 years old Non-English speakers Diagnosis that is a permanent contra-indication of breastfeeding, including HIV/AIDS, herpes simplex on the breast, tuberculosis lesions on the breast.		breastfeeding rate (exclusive or not exclusive), adjusting for strata at 1 month, 6 weeks, and 6 months using Mantel-Haenszel chi-square tests, and the common success rate ratios were estimated with their 95% confidence intervals. The main effects of, and interactions between, maternal attitudes and study group were assessed in linear regression models with weeks of breastfeeding as the outcome, and in logistic regression models with breastfeeding at 1 and 6 weeks as outcomes. Post-hoc comparisons of study groups on exit interview responses and of attitude strata on outcomes were performed using chi-square, Fisher exact, or Cochran-Armitage trend tests as appropriate. The Kaplan-Meier was used to plot breastfeeding rates over time. Sample sizes for individual variables reflect missing data.		**Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: High risk (not clear, assumed not) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** Breastfeeding initiation was defined as any

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			All analyses were performed on a complete-case basis. Setting: Westown Physician Center, hospital affiliated urban clinic		breastfeeding attempts after birth Exclusive breastfeeding was defined as only breastfeeding or breast milk feeding since birth. Participants completing baseline questionnaire received a $10 incentive.
Full citation Steel O'Connor, K. O., Mowat, D. L., Scott, H. M., Carr, P. A., Dorland, J. L., Young Tai, K. F., A randomized trial of two public health nurse follow-up programs after early obstetrical discharge: an examination of breastfeeding rates, maternal confidence and utilization and costs of health services, Canadian Journal of Public Health. Revue Canadienne de Sante Publique, 94, 98-103, 2003 **Ref Id** 775553	**Sample size** N number = 733 Telephone screen n = 380 Home visit n = 353 Site A = 358 Site B = 375 **Characteristics** <u>Mean age of mother in years (SD):</u> Telephone screen, Site A 27.0 (5.2); Telephone screen, Site B 27.9 (5.0); Home visit, Site A 26.3 (5.4); Home visit, Site B 28.1 (4.8). <u>Mother's Education (%)</u> Less than high school: Telephone screen, site A 13.2; Home visit Site A 16.2; Telephone screen, site B 13.5; Home visit, site B 12.5. Completed high school: Telephone screen, site A 7.5; Home visit Site A 7.8; Telephone screen, site B 10.4; Home visit, site B 10.7.	**Interventions** Telephone screen: telephone call to the new mother first working day following discharge from hospital. Home visit was made if either the mother or PHN identified a need. Also, referrals to other support services provided by the Health Unit, primary medical care or community support services were made if a need identified. Otherwise, no further contact was initiated by the PHN, although the mother was provided with the Health Unit telephone number and encouraged to call if she wished for further support. Home visit: 2 home visits by a PHN. Mothers allocated to this group were telephoned on the first working day following discharge, and arrangements were made for	**Details** **Data Collection** Baseline data was collected through personal interviews at intake. Outcome data was collected through telephone interviews at 2 weeks, 4 weeks and 6 months post-partum. **Data Analysis** All analyses were conducted using intent-to-treat approach. Mothers who were not breast feeding at discharge were excluded from the analysis of breastfeeding outcomes. Cox regression used to test for differences in the duration of breastfeeding by allocation, controlling for site and other potential confounders.	**Results** Any breastfeeding at 2 weeks: intervention home visit (n=339): 271 vs intervention telephone screen (n=370): 292 Any breastfeeding at 4 weeks: intervention home visit (n=336): 258 vs intervention telephone screen (n=266): 266 Any breastfeeding at 6 months: intervention home visit (n=248): 146 vs intervention telephone screen (n=262): 149 NB site A and site B combined for data reporting	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Sequential set of sealed envelopes, prepared in advance by the research associate, containing allocations determined by random numbers) Allocation concealment: Some risk (sealed envelope, not described if it was opaque or not) Baseline differences: Low risk (groups were well matched on the baseline characteristic variables)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Canada **Study type** RCT **Aim of the study** To determine whether the outcomes of routine home visiting by public health nurses (PHN) after early obstetrical discharge differ from those of a screening telephone call designed to identify mothers who need further intervention **Study dates** 27 January 1997 - 31 January 1999 **Source of funding** Funding from The Physicians' Services Incorporated Foundation.	Some post secondary: Telephone screen, site A 16.1; Home visit Site A 14.4; Telephone screen, site B 7.8; Home visit, site B 9.5. Completed post secondary: Telephone screen, site A 63.2; Home visit Site A 61.7; Telephone screen, site B 68.4; Home visit, site B 67.3. First pregnancy (%) Telephone screen, site A 74.2; Home visit Site A 82.0; Telephone screen, site B 77.6; Home visit, site B 68.2. Male sex (%): Telephone screen, site A 40.9; Home visit Site A 50.0; Telephone screen, site B 46.1; Home visit, site B 47.8. Gestational Age in weeks (%) 35-37: Telephone screen, site A 7.8; Home visit Site A 4.1; Telephone screen, site B 6.0; Home visit, site B 8.0. 38: Telephone screen, site A 9.5; Home visit Site A 12.4; Telephone screen, site B 20.3; Home visit, site B 13.6. 39: Telephone screen, site A 26.3; Home visit Site A 21.3; Telephone screen, site B 22.0; Home visit, site B 29.6. 40: Telephone screen, site A 29.6; Home visit Site A 37.9; Telephone screen, site B 32.4; Home visit, site B 30.9.	the first PHN visit as soon as possible. The second visit was scheduled to take place within 10 days of discharge. Each visit included a thorough infants and postpartum assessment. Referrals to other support services, primary medical care or community support services were made if needs for these services were identified by the mother or PHN.			**Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	41-42: Telephone screen, site A 26.8; Home visit Site A 24.3; Telephone screen, site B 19.2; Home visit, site B 17.9. **Inclusion criteria** Primiparous Singleton pregnancy, delivered vaginally and discharged within 2 days of birth Resided in areas served by the local Community Care Access Centre Able to understand and give informed consent in English **Exclusion criteria** Not reported.				**Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (Loss to follow-up was 3.3% between intake and two weeks and 1.8% between two and four weeks and between four weeks and six months 2.1%) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (all data collected by research assistants who were blind

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					to the allocation of the mothers) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Stockdale J, Sinclair M, Kernohan G, Keller JM, Dunwoody L, Cunningham JB, et al. , Feasibility study to test Designer Breastfeeding: a randomised controlled trial. , Evidence Based Midwifery, 6, 76–82, 2008 **Ref Id**	**Sample size** N number = 182 ITT N number = 144 Randomised intervention group n = 93 ITT intervention group n = 69 Randomised control group n = 89 ITT control group n = 75 **Characteristics** Crude data not reported.	**Interventions** Intervention: motivationally enhanced instruction provided at 4 time points during antenatal and postnatal care. These were an antenatal infant-feeding class at 32-36 weeks gestation, breastfeeding information book provided in antenatal phase, breastfeeding CD-ROM, and a postnatal instructional support provided by	**Details** **Data Collection** Data about infant-feeding was collected from all women in the trial at 1-2 hours prior to discharge as a structured interview and at 3-4 weeks postnatal by telephone. Prior to discharge, women who started breastfeeding were asked to provide data	**Results** Breastfeeding initiation: intervention (n=69): 57 vs control (n=75): 53	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Computer generated random assignment) Allocation concealment: Some risk (not described)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
997086 **Country/ies where the study was carried out** UK **Study type** RCT **Aim of the study** To test the effectiveness of a motivationally-enhanced version of midwife instruction as a means of increasing women's expectancy for successful breastfeeding, compared to best practice. **Study dates** December 2005 - August 2006 **Source of funding** The development and testing of Designer Breastfeeding™ was funded by the Research	**Inclusion criteria** • Primiparous • Women who intended to have their baby within the Trust • Attended the routine 20-week antenatal appointment during recruitment (December 2005-March 2006) **Exclusion criteria** • Women who did not speak English or did not have the interpretation services available • Women who experienced infant-maternal separation • Infants with newborn abnormalities that require additional feeding support	midwives (up to 3 weeks postnatal) and additional lactation consultancy on request. Control: usual care (details not reported)	relating to the primary outcomes (motivational persistence) and data relating to the secondary outcomes (initiation, duration and exclusivity of breastfeeding). Secondary outcomes were recorded again at 3-4 weeks postnatal by telephone. Likewise, women who never gave any breast milk – defined as non-initiation – were interviewed on discharge concerning their infant-feeding decision and again at 3-4 weeks postnatal (as it is possible to initiate breastfeeding after leaving hospital). Follow-up for all participants ended in August 2006. **Analysis** Likert items that represented a negative statement, such as 'I hate breastfeeding' were re-coded. Composite scores were created for the 3 motivational components		Baseline differences: High risk (Higher attendance at antenatal class (70%) in the intervention group compared to control (53%)) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: Low risk (participants were blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
and Development Office of Northern Ireland.			(total value, total perceived midwife support and total expectancy for success). Preliminary analyses described the sample demography, confirmed the accuracy of the entries and the random occurrence of missing values (<5%). The primary outcome measures of motivation from the BMIMS (total value, total perceived midwife support and total expectancy for success) were compared using independent t-tests for unequal variances, with group membership as a selection variable. Secondary outcomes (initiation and duration rates) were analysed using chi-square analysis on an intention to treat basis. Setting: not reported		Non-adherence: Some risk (12/69 in the intervention and 22/75 did not initiate the study) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (36/69 in the intervention and 15/75 in the control provided three week data) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk** **Other information** To enable the accurate evaluation of the motivationally-designed instruction to increase persistence, the conceptualisation of 'exclusive' breastfeeding was applied as defined in the Infant Feeding Survey (2005) – the baby is being exclusively breastfed and

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					has been for a minimum of 48 hours.
Full citation Su LL, Chong YS, Chan YH, Chan YS, Fok D, Tun KT, et al., Antenatal education and postnatal support strategies for improving rates of exclusive breast feeding: randomised controlled trial., BMJ, 335, 596, 2007 **Ref Id** 1000648 **Country/ies where the study was carried out** Singapore **Study type** RCT **Aim of the study** To compare the effects of antenatal breastfeeding education versus postnatal lactation support or routine hospital care on	**Sample size** N randomised=450 Intervention (1): n randomised=150 Intervention (2): n randomised=149 Control: n randomised=151 Loss to follow-up: Intervention (1): Withdrawn (n=2); delivered in another hospital (n=3). 1-2 weeks: lost to follow-up (n=0); dropped out (n=7). 6-8 weeks: lost to follow-up (n=2). 3 months: lost to follow-up (n=2). 6 months: lost to follow-up (n=8). Completed follow-up at 6 months (n=126). Intervention (2): delivered in another hospital (n=1). 1-2 weeks: lost to follow-up (n=7); dropped out (n=5). 6-8 weeks: lost to follow-up (n=5). 3 months: lost to follow-up (n=5); dropped out (n=1). 6 months: lost to follow-up (n=5). Completed at 6 months (n=122). Control: withdrawn (n=5); delivered in another hospital (n=2); could not be contacted (n=1). 1-2 weeks: lost to follow-up (n=3); dropped out (n=12). 6-8 weeks: lost to	**Interventions** Intervention (1): One session of antenatal breastfeeding education – including a 16 minute educational video, handouts and opportunities to talk to lactation counsellor for ~15 minutes Intervention (2): two ~30 minute sessions of postnatal lactation support, once before discharge, once during their first routine postnatal visit one to two weeks after birth. Visit by lactation consultant within the first 3 postnatal days before discharge, printed guides on breastfeeding, handouts. Control: Standard care that included optional antenatal classes that addressed infant feeding and postnatal visits by a lactation consultant should problems arise.	**Details** **Data collection** Interviews were conducted at discharge from hospital, at 2 and 6 weeks (in clinic or during home visits), and at 3 and 6 weeks postpartum (via telephone). Mothers were also given an infant feeding diary. **Analysis** To achieve 90% power, 450 women were required for randomisation. Data were analysed on an intention-to-treat basis. Pairwise comparisons between different intervention groups on rates of breastfeeding were analysed using modified Cox regression analysis to provide adjusted relative risks and 95% confidence intervals. Sensitivity analyses were performed where necessary.	**Results** Exclusive breastfeeding at 2 weeks: antenatal intervention (n=133): 36 vs postnatal intervention (n=128): 48 vs control (n=136): 28 Exclusive breastfeeding at 3 months: antenatal intervention (n=127): 31 vs postnatal intervention (n=122): 29 vs control (n=134): 17 Any breastfeeding at 2 weeks: antenatal intervention (n=133): 126 vs postnatal intervention (n=128): 126 vs control (n=136): 127 Any breastfeeding at 3 months: antenatal intervention (n=127): 73 vs postnatal intervention (n=122): 71 vs control (n=134): 65 Any breastfeeding at 6 months: antenatal intervention (n=122): 52 vs postnatal intervention (n=119): 48 vs control (n=126): 43	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk ('The unit generated and maintained a list of random codes for participants, corresponding to the two interventions and the control assignment groups.') Allocation concealment: Low risk ('The clinical project coordination department of the Clinical Trials and Epidemiology Research Unit randomised women by means of telephone calls. Unit personnel would then log on to the password protected website to obtain the randomisation number and assign the study group. Backup envelopes were used if website randomisation failed.')

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
exclusive breastfeeding rates. **Study dates** February 2004 to September 2005. Follow-up May 2006. **Source of funding** National Medical Research Council.	follow-up (n=5); dropped out (n=1). 3 months: lost to follow-up (n=6). 6 months: lost to follow-up (n=3). Completed 6 months (n=119). **Characteristics** <u>Age (years) - mean (±SD)</u> Intervention 1: 29.5 (5.2); intervention 2: 29.9 (6); control: 28.6 (5.8) <u>Parity - number (%)</u> Primiparous: Intervention 1: 59 (39); intervention 2: 59 (40); control: 60 (40) Multiparous: Intervention 1: 91 (61); intervention 2: 90 (60); control: 91 (60) <u>Ethnicity - number (%)</u> Chinese: Intervention 1: 62 (41); intervention 2: 65 (44); control: 46 (31) Malay: Intervention 1: 65 (43); intervention 2: 69 (46); control: 82 (54) Indian: Intervention 1: 20 (13); intervention 2: 12 (8); control: 16 (11) Other: Intervention 1: 3 (2); intervention 2: 3 (2); control: 7 (5) <u>Gestational age (weeks) - mean (±SD)</u> Intervention 1 (n=138): 39.2 (1.2); intervention 2 (n=134):	Setting: Tertiary hospital in Singapore.			Baseline differences: Low risk (Similar baseline participant demographic characteristics except for ethnicity where one arm had a higher Chinese population - this is not thought to affect the outcomes) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	39.4 (1.3); control (n=138): 39.1 (1.3) Birthweight (g) - mean (±SD) Intervention 1 (n=138): 3171 (429); intervention 2 (n=134): 3171 (411); control (n=138): 3194 (439) **Inclusion criteria** • Healthy pregnant women; • >34 weeks' gestation at time of delivery; • Expressed an intention to breastfeed; • No illness that would contraindicate breastfeeding or severely compromise success. **Exclusion criteria** • High risk pregnancy; • Multiple pregnancy.				DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (Data for 6 months completed by 122/150 (19% missing) in the one antenatal education session arm, 119/149 (20% missing) in the two postnatal sessions arm and 126/151 (17% missing) in control arm)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from missing outcome data: Some risk DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (Not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (trial registration reported and all outcomes included) **Judgement on risk of bias arising from selection of the reporting result: Low risk** **Overall risk-of-bias judgement: Some concerns**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Other information Exclusive breastfeeding: only breast milk given to baby. Medicines, vitamins, and oral rehydration solution may be given but no formula or water. Predominant breastfeeding: breast milk and water, sweetened water, and juices given without formula.
Full citation Vidas M, Folnegovic-Smalc V, Catipovic M, Kisic M. , The application of autogenic training in counseling center for mother and child in order to promote breastfeeding. , Collegium Antropologicum, 35, 723-31, 2011 **Ref Id** 997197 **Country/ies where the study was carried out** Croatia	**Sample size** N number = 100 Intervention n = 50 Control n = 50 **Characteristics** Not stated but following was noted 'The sociodemographic characteristics of mothers of both groups (experimental and control) were in a very high correlation/very tight relationship, so that groups were similar to each other (r=0.989).' **Inclusion criteria**	**Interventions** Autogenic training - 6 basic exercises of autogenic training taught in small groups (up to 10 mothers). Mothers practiced a new exercise every two weeks, for 12 weeks. Training techniques were easy to adopt, while warning of problems and experiences during training. Exercises focused on building a strong mother-infant relationship. Mothers were encouraged to practice at home 3 times daily. After mothers have learned all the exercises of autogenic training, they were encouraged to continue the	**Details** **Data Collection** Breastfeeding questionnaire administered to mothers at the start of study and again at the end, when infant was 6 months old. Also assessed postpartum psychological symptoms due to the negative impact on breastfeeding and the relationship between mother and child. Treatment group mothers also participated in a survey to assess satisfaction with the intervention. **Analysis**	**Results** Any breastfeeding at 6 months: intervention (n=50): 47 vs control (n=50): 35 Satisfaction of mothers was graded on a scale from 0 (very dissatisfied) to 10 (extremely satisfied) 'Satisfaction with the healthcare of mothers and children support to breastfeed': During pregnancy: intervention (n=50): 8.1 vs control (n=50): 8.08 In the maternity ward: intervention (n=50): 8.26 vs control (n=50): 8.24 Upon arriving home -visiting nursing: intervention (n=50): 8.4 vs control (n=50): 8.42	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Some risk (not described) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type RCT **Aim of the study** To investigate whether the USge of autogenic training with advice on breastfeeding effect on the decision and the duration of breastfeeding, increasing maternal confidence and support. **Study dates** Throughout 2010 **Source of funding** Not stated.	• Mother was breastfeeding an infant. • Infant was at least 2 months old (exact term used was 'infant had up to two months') **Exclusion criteria** Not stated	practice until their child was at least 6 months old. Control - usual care (details not stated)	Differences in mean results presented for: • measurements before and after the intervention • measurements in intervention versus control group Setting: Counseling Center for Mother and Child in a paediatric practice in Bjelovar, Croatia.	Upon arriving home - gynaecological clinic: intervention (n=50): 8.1 vs control (n=50): 8.08 Upon arriving home -paediatric clinic/counselling: intervention (n=50): 8.44 vs control (n=50): 8.48	**randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not described but assumed not blinded) Blinding of carers and people delivering the interventions: High risk (not described but assumed not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					(analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (none reported missing) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (questionnaire - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Wallace LM, Dunn OM, Alder EM, Inch S, Hills RK, Law SM. , A randomised-controlled trial in England of a postnatal midwifery intervention on breast-feeding duration. , Midwifery, 22:262–73. , 2006 **Ref Id** 997289 **Country/ies where the study was carried out** UK **Study type**	**Sample size** N randomised=370 women. Intervention: n randomised=188 Control: n randomised=182 **Characteristics** Age in years (number) <20: intervention 10; control 11 20-29: intervention 94; control 95 30-39: intervention 81; control 72 40+: intervention 3; control 4 Hospital Site (number)	**Interventions** Intervention: Advice about initiation of feeding, positioning and attachment. Verbal-only care was advised to ensure the mother was able to attach the baby herself. A leaflet explained this information and also reminded mothers that their baby needed only breast milk until at least 4 months post-partum. Midwives attended a 4-hour long workshop covering the rationale and skills of a 'hands-off' approach to care at first feed. Control: Control midwives received at least an hour of breast-feeding policy update. Routine care followed each	**Details** Data Analysis Data on breast feeding were collected using diaries to record feed patterns daily (occurrence and type of feed in three time blocks per day) to 6 weeks and then a single record per week of the type of feed up to 17 weeks. These data were augmented by information from infant-feeding interviews at 6 (home visit with questions covering infant breastfeeding) and 17 weeks (telephone consultation including questions on breastfeeding duration) post-partum. The care given by the trial	**Results** Any breastfeeding at 6 weeks*: intervention (n=172): 111 vs control (n=167): 114 Exclusive breastfeeding at 6 weeks*: intervention (n=172): 42 vs control (n=163): 37 Any breastfeeding at 17 weeks*: intervention (n=173): 64 vs control (n=167): 66 *Numerators calculated by the NGA technical team based on number of women stopping breastfeeding or stopping exclusive breastfeeding	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Allocation was initially by telephone randomisation using a balanced block design stratified by ward and time of day; later randomisations used computers installed in each ward) Allocation concealment: Low risk (as above)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
RCT **Aim of the study** Determine whether postnatal 'hands off' care by midwives on positioning and attachment of the newborn baby improves breast-feeding duration. **Study dates** 2001-2002 **Source of funding** Sponsored by the Department of Health Infant Feeding Initiative, UK. **Inclusion criteria**	The Horton: intervention 46; control 47 The John Radcliffe: intervention 38; control 36 South Warwick General: intervention 40; control 41 Walsgrave Hospitalisation: intervention 64; control 58 Method of randomisation (number) Paper: intervention 88; control 80 Computer: intervention 100; control 102 Grade of midwife (number) F and above (high): intervention 87; control 91 E (low): intervention 101; control 91 Delivery type (number) Spontaneous vaginal delivery: intervention 133; control 128 Forceps: intervention 39; control 40 Caesarean under local anaesthetic: intervention 16; control 14 Prior feed in delivery suite (number) Yes : intervention 124; control 118 No: intervention 63; control 64 NB data missing for this variable.	maternity unit's policy, which did not stipulate advice about positioning, attachment nor verbal-only care. Additional breast-feeding advice leaflets were available to mothers and staff in line with the local policy. However, the trial protocol required that this care was delivered by a midwife, which was not required by local maternity unit policies at this time.	midwife was recorded by her in a bespoke intervention checklist. This was developed alongside the intervention protocol to record aspects of the experimental protocol (i.e. a feed initiated by the baby, the mother in a supported upright position out of bed, baby positioned across mother's lap or under her arm, absence of physical help from the midwife, demand feeding, avoidance of supplemental feeds, breast milk expression, and the midwife present for the duration of the first postnatal ward feed). The mothers' self-reported experience of care and support were assessed by interview. Answers were written by the researcher during the interview on a proforma. All quantitative data were coded by researchers blind to allocation and analysed in SPSS. Data were combined from diary and interview sources, allowing for reliability checks. Analysis		Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: Low risk (Mothers were blind to treatment allocation) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): Some risk** DOMAIN 2b – deviations from intended interventions (adherence)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Primiparous • Gestational age of baby > 37 weeks • Mothers intending to breastfeed • Able to sit out of bed at the time of first feed • Both mother and baby well at time of randomisation **Exclusion criteria** • Babies delivered by Caesarean section under general anaesthetic		Trial designed to recruit 600 mothers, based on power calculations. Slow recruitment resulted in closure after 370 mothers were recruited. Data were analysed using intention to treat, standard Log-rank techniques and heterogeneity tests. Analyses adjusting for possible clustering by midwife showed similar results. Setting: 8 postnatal wards of 4 maternity hospitals in English Midlands not currently accredited to Baby Friendly Initiative standards.		Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (342/370 provided data at 6 weeks and 347/370 at 17 weeks - split similar between groups) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					(interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (assessors were blinded) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Wambach KA, Aaronson L, Breedlove G, Domian EW, Rojjanasrirat W, Yeh	**Sample size** N number = 289 (of these 289, only 201 (69.5%) were followed after hospital discharge as the other 30.5% did not initiate breastfeeding)	**Interventions** Intervention group: Prenatal, in-hospital, and postnatal education and support, delivered by lactation consultant and trained peer	**Details** **Data Collection** The Breastfeeding Attrition Prediction Tool (BAPT) was designed to identify postpartum breastfeeding	**Results** Breastfeeding initiation: intervention (n=97): 77 vs control (n=102): 64 vs attention control (n=90): 59	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2).

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
HW. , A randomized controlled trial of breastfeeding support and education for adolescent mothers. , Western Journal of Nursing Research, 33, 486–505, 2011 **Ref Id** 996997 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** Test the hypotheses that education and counselling interventions provided by a lactations consultant-peer counsellor tea would increase breastfeeding initiation and duration up to 6 months postpartum.	Intervention group n = 97 Attention control group n = 90 Usual care group n = 102 **Characteristics** Mean age in years: 17, SD 0.9, range 15-18 Primiparous; Majority were African American (61%); of low income (75% of those who knew their family incomes reported incomes less than $25,000/ year); were single, living with their families (74%); in school (71%); and planning to continue school after the baby's birth (93%). 81.8% were not employed at all and only 5% were employed full-time. The only significant difference among the three study groups on these demographic factors was for plans to continue school (p = .04). More teens in the experimental group planned to return to school than in the usual care and attention control group (97% vs. 87.5% and 93%, respectively). **Inclusion criteria**	counsellor, through 4 weeks postpartum. Two prenatal classes (1.5 and 2 hr in length), co-taught by the lactation consultant and peer counsellor, focused on the benefits of breastfeeding for mother and baby, decision making, and the "how to" of breastfeeding as well as managing breastfeeding after return to work and/or school. Participants were required to attend at least one class, or they were dropped from the study. Peer counsellor telephone calls were made before Class 1 and after both Class 1 and 2. The in-hospital experimental intervention was a face-to-face visit from the peer counsellor who provided encouragement and support for early breastfeeding efforts. Those teens choosing to breastfeed, or leaning toward doing so, also received a lactation consultant visit. Postpartum telephone contact with the lactation consultant and/or peer counsellor occurred at 4, 7, 11, and 18 days and 4 weeks for those experimental participants who initiated breastfeeding, unless they	women at risk for premature weaning and measures all breastfeeding behaviour antecedents except intentions to breastfeed. The item used for analysis in this report was a 6-point rating scale querying the respondent on plans to breastfeed (1 = definitely not breastfeed to 6 = definitely breastfeed). Breastfeeding knowledge was measured in a 30-item questionnaire which combined items from Knowledge of Breastfeeding Scale and the Breastfeeding Knowledge Questionnaire. The resultant measure includes multiple-choice and true–false items on components of breast milk, colostrum, weaning and breastfeeding techniques. Both measures were administered at baseline and following the second intervention class for the experimental and attention control groups, and at a comparable time for the usual care group. Post hospital discharge data were collected by telephone at 3 and 6	Study authors say that numbers of women initiating breastfeeding correspond to 79%, 66% and 63% of women analysable, respectively, so the NGA technical team used the number of women initiating breastfeeding to calculate the number of women analysable.	DOMAIN 1 - randomisation Random sequence generation: Some risk (unclear, 'using a list of random codes generated by the study bio-statistician') Allocation concealment: Some risk (not described) Baseline differences: Some risk (More teens in the experimental group planned to return to school than in the usual care and attention control group (97% vs. 87.5% and 93%, respectively).) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates October 2003 - June 2007 **Source of funding** This study was funded by the National Institutes for Health/National Institute of Nursing Research, ROI NR007773.	• Mothers aged between 15-18 years • Primiparous • Second trimester pregnancy • Planning to keep newborn • ability to speak and read English • Access to telephone for contact **Exclusion criteria** • Multiple-gestation pregnancy • Preterm labour and birth • Mothers treated for significant complications during labour and birth that prohibited breastfeed or delayed it beyond 48 hours • Mothers with conditions that are contra-indicated for breastfeeding e.g HIV, Hepatitis C • Infant possessing any of the following: cleft	ceased breastfeeding before 4 weeks. Experimental group participants received a double-set-up electric breast pump at no charge on an as-needed basis. Attention control group: paralleled the experimental group interventions in the amount of content and timing and included two prenatal education classes on healthy pregnancy behaviours and birth Provided by advanced-practice nurse and trained peer counsellor team. The attention control intervention did not focus on breastfeeding. As with the experimental group, attention control participants were required to attend at least one class or they were dropped from the study. They also received peer counsellor prenatal telephone support and an in-hospital peer counsellor visit. Postdischarge, only those who breastfed received postpartum telephone interventions by peer counsellors. Like the attention control prenatal intervention classes, these	weeks, 3 and 6 months postpartum from all participants who initiated breastfeeding, regardless of group, and continued until breastfeeding ceased if that occurred before 6 months. Breastfeeding status was monitored by telephone between these formal data collection times at least monthly. Breastfeeding initiation and continuation to 6 weeks was validated with postpartum clinic medical record checks from the 6-week postpartum check-up. **Analysis** Analyses were based on intention to treat. Descriptive statistics were computed for demographic factors; timing of feeding decision; breastfeeding knowledge; intention to breastfeed; and BAPT's positive and negative breastfeeding sentiment, social and professional support, and breast feeding control subscales prior to and after the prenatal educational intervention. To confirm group equivalence after randomization, the preintervention variables		**Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (Comparable loss to follow-up between groups, study design only followed women who continued to

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	lip/palate; congenital heart defects; Down syndrome; neural tube defects; or other conditions that warranted admission to NICU	calls were intended to mimic the breastfeeding intervention. Usual care group: received standard prenatal and postpartum care at respective clinic with varying provider types and birth settings. No controls were placed on level or content of care, or on educational or social support services for usual care group participants.	were compared across groups by ANOVA, chi-square/Fisher's exact tests, and Kruskal-Wallis tests. Chi-square analysis identified the crude group effect on breastfeeding initiation and exclusive breastfeeding in the hospital, and multivariate logistic regression determined factors predictive of breastfeeding initiation. The Kaplan-Meier estimate for the median duration of breastfeeding was obtained for each group and survival analysis compared the study groups on breastfeeding duration. Theory of Planned Behaviours variables also were compared across study groups at baseline. Positive breastfeeding sentiment and social and professional support were significantly different, with higher values in the experimental group. However, the Consolidated Standards of Reporting Trials recommends simple unadjusted analyses to compare groups unless baseline adjustment is predetermined based on		breastfeed, so low outcome rates a factor of the study design) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			hypothesized relationships with the outcome variable. Because we hypothesized that the impact of these factors would be indirect through their effect on intention, we adjusted for them even though we did not expect a direct effect on breastfeeding initiation. Setting: bistate metropolitan area in Midwestern US. Sites were chose based on volume of services to low-income adolescent mothers and a lack of full-time lactation consultant support.		**Overall risk-of-bias judgement: Some risk** **Other information** Breastfeeding initiation: initiating breastfeeding in the hospital with intention to provide at least half of the infant's feedings at the breast or with pumped breast milk and was measured by self-report in all three groups. Breastfeeding duration: total number of days the mother breastfed or provided breast milk. Participants received between $10 and $20 following enrolment, attendance at each intervention session, and completion of each data collection period, with specific amounts identified for each event.
Full citation Washio, Y., Humphreys, M., Colchado, E., Sierra-Ortiz, M., Zhang, Z., Collins, B. N., Kilby, L. M., Chapman, D. J., Higgins, S. T., Kirby, K.	**Sample size** N=36 Intervention: n=18 Control: n=18 Lost to follow-up: Intervention: lost to follow-up (n=0); discontinued	**Interventions** Intervention: In addition to standard care a financial incentive of $20 at the end of the first month and increased by $10 every month until the end of 6 months. Maximal	**Details** **Data collection** Interviews were conducted at study entry with questions on sociodemographic characteristics, attitude toward breastfeeding,	**Results** Any breastfeeding at 3 months*: intervention (n=18): 16 vs control (n=17): 3 Any breastfeeding at 6 months*: intervention (n=18): 13 vs control (n=17): 0	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
C., Incentive-based intervention to maintain breastfeeding among low-income Puerto Rican mothers, Pediatrics, 139 (3) (no pagination), 2017 **Ref Id** 807720 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To assess the effects of financial incentives on breastfeeding among low-income Puerto Rican mothers. **Study dates** February 2015 to February 2016. **Source of funding**	intervention (n=0). Included in analysis: n=18. Control: relocated, changed phone number/lost to follow-up (n=1); discontinued intervention (n=0). Included in analysis: n=18. **Characteristics** Age (years) - mean (±SD) Intervention: 24.1 (4.7); control: 23.0 (4.6) Primiparous - number (%) Intervention: 7 (39); control: 8 (44) Infant birthweight (g) - mean (SD) Intervention: 3110.3 (712.3); control: 3236.9 (885.9) **Inclusion criteria** • Puerto Rican or of Puerto Rican descent; • Able to read or speak Spanish or English; • Currently living in the area and planning to stay through 6 months postpartum; • Enrolled in a WIC programme;	potential earning was $270 for breastfeeding for 6 months. Control: Standard breastfeeding services from women and infant centre programme. Services included on-site lactation consultation, bilingual peer counselling, weekly peer support meetings, free breast pump, enhanced food package for breastfeeding mothers. Setting: urban hospital near WIC offices, Philadelphia.	history, support, and self-efficacy of breastfeeding, maternal and infant health, acculturation, and postnatal depression. Modified questionnaires were repeated at 1, 3, and 6 months postpartum. **Data Analysis** Data were analysed on an intention-to-treat basis. Continuous and categorical data were analysed using Pearson chi-squared test of Wilcoxon rank-sum tests, respectively. Fisher's exact test was used when a cell count was <5. The Cochran-Armitage Trend test was used to examine the trend of breastfeeding at 1 to 6 months postpartum.	Numerators calculated by the NGA technical team based on denominators and percentages provided in the paper	Random sequence generation: Low risk (Blocks of 2 by a statistician) Allocation concealment: Some risk (not described) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
National Institutes of Health.	• Initiate breastfeeding. **Exclusion criteria** • Ongoing illicit drug use; • Current active suicidal thoughts or a past suicide attempt; • Untreated HIV (breastfeeding contraindicated); • Postpartum medical problems (e.g. postpartum haemorrhage, infections, and serious jaundice requiring exchange transfusion).				**(effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (All women received their designated intervention) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (No missing data reported) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Method of measuring the outcome: High risk (Breastfeeding was visually verified by observation of a feed) Blinding of outcome assessors: High risk (not blinded) **Judgement on risk of bias arising from measurement of the outcome: High risk** DOMAIN 5 – reporting Selective reporting: High risk (Satisfaction survey listed as a secondary outcome on the NCT registry but missing from results) **Judgement on risk of bias arising from selection of the reporting result: High risk** **Overall risk-of-bias judgement: High concerns**
Full citation Wen LM, Baur LA, Simpson JM, Rissel C,	**Sample size** N randomised=667 Intervention: n randomised=337	**Interventions** Intervention: 6 home visits from community nurse – once at 30-36 weeks	**Details** Data Collection Baseline assessments conducted during home	**Results** Any breastfeeding at 6 months*: intervention (n=278): 117 vs control (n=283): 91	**Limitations** Limitations were assessed using the revised Cochrane

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Flood VM., Effectiveness of an early intervention on infant feeding practices and " tummy time": a randomized controlled trial., Archives of Pediatrics and Adolescent Medicine, 165, 701-7, 2011 **Ref Id** 1000652 **Country/ies where the study was carried out** Australia **Study type** RCT **Aim of the study** To assess the effectiveness of a home-based early intervention on infant feeding practices and "tummy time" for infants in the first year of life. **Study dates**	Control: n randomised=330 **Characteristics** <u>Mothers age in years, number(%)</u> ≤ 24: intervention 144(42.7); control 135(41.0); lost to follow up 78(55.7) 25-29: intervention 112(33.2); control 114(34.5); lost to follow up 43(30.7) ≥ 30: intervention 81(24.1); control 81(24.5); lost to follow up 19(13.6) <u>Marital status, number(%)</u> Married/de facto partner: intervention 286(85.6); control 296(90.0); lost to follow up 113(81.9) Never married: intervention 48(14.4); control 33(10.0); lost to follow up 25(18.1) <u>Mother's employment status, number(%)</u> Employed/paid and unpaid maternity leave: intervention 177(52.7); control 186(56.4); lost to follow up 60(42.9) Unemployed: intervention 76(22.6); control 62(18.8); lost to follow up 44(31.4) Home duties/student/other: intervention 83(24.7); control 82(24.8); lost to follow up 36(25.7)	gestation and then after birth at 1, 3, 5, 9, 12 months. Each visit lasted 1-2hrs Control: usual care to include one nurse home visit within 1 month of birth if needed.	visits by research nurses in a face-to-face interview (20-30 mins), before randomisation. The outcome data were collected at 6 months of age by telephone and at 12 months of age by face-to-face interview in the home. **Analysis** Analysis were by intention to treat. Proportions were compared between intervention and control groups using Pearson X2 tests or Mantel-Haenszel X2 tests for trend when appropriate. Survival analysis was used to compare breastfeeding duration for the intervention and control groups. Kaplan-Meier curves were used to estimate median breastfeeding time and were compared between the groups using the log-rank test. The estimated hazard ratio for stopping breastfeeding in the intervention group compared with the control group was calculated using Cox proportional hazards regression. To test whether	*Numerators calculated by the NGA technical team based on denominators and percentages provided in the paper	risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk (Computer generated random numbers) Allocation concealment: Low risk (Opaque sealed envelopes) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not described but assumed blinded) Blinding of carers and people delivering the interventions: High risk (not described but assumed blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
1 January 2007 - December 31 2010 **Source of funding** This study is part of the Healthy Beginnings Trial funded by the Australian National Health and Medical Research Council (ID number: 393112).	Mothers income in Australian $, number(%) ≤39,999: intervention 106(31.5); control 103(30.9); lost to follow up 61(43.6) 40,000-79,999: intervention 113(33.5); control 102(30.9); lost to follow up 47(33.6) ≥80,000: intervention 118(35.0); control 126(38.2); lost to follow up 32(22.8) Mother's educational level, n(%) Up to school certificate: intervention 66(19.6); control 71(21.6); lost to follow up 44(31.7) Higher School Certificate to Technical and Further Education certificate/diploma: intervention 180(53.6); control 184(56.1); lost to follow up 69(49.6) University: intervention 90(26.8); control 73(22.3); lost to follow up 26(18.7) Mother's country of birth, n(%) Australia: intervention 213(63.4); control 216(65.7); lost to follow up 89(63.6) Other: intervention 123(36.6); control 113(34.3); lost to follow up 51(36.4) Language spoken at home, number(%)		the effect of the intervention differed between subgroups, we added an interaction between treatment group and subgroup to this Cox model. Setting: antenatal clinics of Liverpool and Campbeltown Hospitals in southwestern Sydney, Australia (both socially and economically disadvantaged areas)		**Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (278/337 (82%) of the intervention and 283/330 (86%) provided 6 month data)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	English: intervention 303(90.2); control 289(88.1); lost to follow up 125(89.3) Other: intervention 33(9.8; control 39(11.9); lost to follow up 15(10.7) Timing of recruitment, number(%) Before giving birth: intervention 208(61.7); control 201(60.9); lost to follow up 72(51.4) After giving birth: intervention 129(38.3); control 129(39.1); lost to follow up 68(48.6) **Inclusion criteria** • 16 years or older • Primiparous • Between 24-34 weeks gestation • Able to communicate in English • Lived in the local area **Exclusion criteria** • Mothers with a severe medical condition as				**Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (assessors unaware of treatment allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (trial registry number given, but could not be identified on registry to check, therefore had to assume no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	evaluated by their physician				**Overall risk-of-bias judgement: Some risk** **Other information** Breastfeeding: child receiving breast milk regardless of whether other solid foods or liquids are also being received. Exclusive breastfeeding: child receiving only breast milk and no other liquids or solid foods, with the exception of drops i.e. syrups of vitamins, mineral supplements, or medicines. This trail forms part of the Healthy Beginnings Trial, a study designed to test the effectiveness of an early childhood obesity intervention in the first 2 years.
Full citation Wilhelm, S. L., Stepans, M. B., Hertzog, M., Rodehorst, T. K., Gardner, P., Motivational interviewing to promote sustained breastfeeding, Journal of obstetric,	**Sample size** N number = 73 Intervention group = 37 Control group = 36 **Characteristics**	**Interventions** Motivational interviewing (MI) has 4 principles: 1. express empathy, reflecting what the client is saying; 2. create discrepancy, which includes gaining an	**Details** **Data Collection** Data collected for both groups at baseline via questionnaire. Home visit on day 2-4, 2 weeks, 6 weeks and 6 months. Mothers reported date of last date of sustained breastfeeding	**Results** Any breastfeeding at 6 months (180 days) *: Intervention (n=37): 12 or 32% vs control (n=35): 9 or 25% *Numerators calculated by the NGA technical team based on denominators and percentages provided in the paper	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
gynecologic, and neonatal nursing: JOGNN / NAACOG, 35, 340-348, 2006 **Ref Id** 807759 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To explore the feasibility of using motivational interviewing to promote sustained breastfeeding by increasing intent to breastfeed and increasing breastfeeding self-efficacy. **Study dates** Not reported **Source of funding**	Race/ethnicity White 88.9%; Hispanic 6.9%; Native American 1.4%; Asian 2.8% Age (years) mean 25.1; SD 4.5 Marital status married 75.3% Education Less than high school 6.8%; high school 35.6%, some college associate degree 26.0%; Bachelor's degree or higher 31.5% Income <$10,000 8.3%; $10,000-$19,000 16.7%; $20,000-$40,000 29.2%, >$40,000 45.8% Employment Stay at home mom 16.7%; part time 37.9%; full time 45.5% Gestational age (weeks) mean 39.3; SD 1.1 Birthweight (g) mean 3,272.8; SD 418.4 **Inclusion criteria** Primiparous breastfeeding mothers. **Exclusion criteria** Mothers with infants who: • were admitted to NICU,	understanding of values and beliefs and clarifying important goals; 3. roll with resistance to hear the reasons for ambivalence; 4. support self-efficacy by emphasizing the client's abilities and resource availability Initial MI intervention conducted at days 2-4. Brief MI booster sessions performed at outpatient visits in week 2 and week 6. Usual care also provided. Usual care: breastfeeding assessment and a lactation consultant troubleshooting problems during the hospital stay and at each visit.	(breastfeeding during a 24 hour period). Intent to breastfeed for 6 months was measured using 7 point Likert scale and Breastfeeding Self-Efficacy Scale used to measure self-efficacy at each visit. **Data Analysis** Duration of breastfeeding in the groups was compared in two ways: a t test of the mean number of days of breastfeeding during the first 6 months (defined as 180 days) and Kaplan-Meier survival analysis of length of time until breastfeeding ended. Final duration for mothers still breastfeeding at 6 months was unknown. Survival analysis takes this censoring of the data into account, accommodates the two cases deleted from the t test, and allows comparison of the groups across the entire period.		(randomly assigned to either the MI or usual care group using a predetermined randomisation schedule created using Excel random number generation function) Allocation concealment: Some risk (not described) Baseline differences: High risk (Mothers in the comparison group were more likely to work outside the home (94% vs. 72% in the intervention group) and to hold full- time positions (59% vs. 31%)) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
UW College of Health Sciences: BRIN RR16474, Regional West Medical Center Foundation, and Medela Equipment Grant.	• were born before 37 weeks, • weighed less than 2.5 kg at birth • had bilirubin level over 15 mg/dl.				**Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (follow-up contact in 62 of 73 mothers (84.9%))

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Judgement on risk of bias arising from missing outcome data: Low risk DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (home interview - women's self-report on breastfeeding) Blinding of outcome assessors: High risk (not blinded) **Judgement on risk of bias arising from measurement of the outcome: Some risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Wilhelm L, Aguirre M, Koehler E, Rodehorst TK., Evaluating motivational interviewing to promote breastfeeding by rural Mexican-American mothers: the challenge of attrition. , Issues in Comprehensive Pediatric Nursing , 38, 7–22, 2015 **Ref Id** 997094 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To evaluate the effectiveness of a motivational interviewing intervention by comparing intent to breastfeed, breastfeeding self-	**Sample size** N randomised = 53 mother-infant dyads Motivational interviewing (MI) group randomised= 26 Attention control (AC) group randomised = 27 High levels of attrition – (69%/n=18 in MI group, 63%, n=17 in AC group) **Characteristics** Mothers tended to be young, had limited income and limited education. <u>Age of mother (years)</u> Majority (58%) aged 20-25. Mean (±SD) 24(5.9); range 15-44. <u>Annual household income (%)</u> <$10,000 58%; $10,000-19,000 32%	**Interventions** Intervention – motivational interviewing (MI) sessions were delivered by certified practitioner, and focused on the importance of breastfeeding in the first 6 months and a mother's confidence in ability to breastfeed. Initial intervention session delivered during visit on day 3 postpartum, with 2 booster sessions during week 2 and week 6 postpartum visits. Written algorithm used to ensure uniform delivery of the intervention throughout the study. Control – attention control (AC) sessions were concerning infant safety and were delivered on the same time scale as the intervention. Information was provided on topics such as fall prevention, burns, drowning, choking/aspiration and car seat safety. Spanish language research materials and an interpreter were available as needed for all assessments, MI	**Details** <u>Data Collection</u> Data on demographic and medical history collected at baseline using self-reported questionnaire. Intention to breastfeed for 6 months was measured using a single intent question and scored using a 7-point Likert-type scale. Breastfeeding assessment included questions about problems with breastfeeding, frequency of breastfeeding, and plans to return to work. Assessment questionnaires administered at each of the 3 postpartum visits (day 3, week2 and week 6) and a final telephone assessment administered at 6 months postpartum. <u>Analysis</u> Descriptive statistics were used to summarize demographic variables. Independent t-tests and Mann Whitney U non-parametric tests used to evaluate differences	**Results** Any breastfeeding at 6 months: intervention (n=23): 5 vs control (n=27): 6	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (limited description - provided by statistician) Allocation concealment: Some risk (not described) Baseline differences: Some risk (demographics not reported for each group so cannot tell) **Judgement on risk of bias arising from the randomisation process: Some risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
efficacy, and duration of breastfeeding. **Study dates** Recruitment between December 2008 and March 2010 **Source of funding** Study conducted with the support of a Small Dean's Grant from the University of Nebraska Medical Center, College of Nursing	Education level n(%): less than high school 36(68); completed high school 13(25); college education 4(7) 96% mothers had no formal prenatal childbirth or breastfeeding instruction. 98% infants born ≥ 37 weeks (full term) and 81% delivered vaginally. **Inclusion Criteria** • Self-identified Mexican-American mothers • Age between 15-50 • Breastfeeding at the time of recruitment **Exclusion criteria** • Mother admitted to ICU • Multiple-gestation pregnancy • Infant born with congenital abnormalities	interventions and AC sessions.	between groups at 6 weeks postpartum. Setting: Regional acute care hospital serving the rural areas of western US.		interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Some risk (69% of intervention and 63% of

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Infant admitted to NICU after birth				control failed to provide 6 week data) **Judgement on risk of bias arising from missing outcome data: Some risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (Both in person and telephone interview - women's self-report on breastfeeding) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					Other information Incentives - mothers received manual breast at study onset and box of diapers upon study completion.
Full citation Wolfberg AJ, Michels KB, Shields W, O'Campo P, Bronner Y, Bienstock J., Dads as breastfeeding advocates: results from a randomized controlled trial of an educational intervention., American Journal of Obstetrics and Gynecology , 191, 708-12, 2004 **Ref Id** 1000655 **Country/ies where the study was carried out** US **Study type** RCT	**Sample size** N=59 couples Intervention: n=27 mothers; n=27 fathers Control: n=32 mothers; n=30 fathers Attrition: refused to participate (24% women); loss to follow-up during prenatal period (36% women); women's lack of involvement with father (8%); father's refused to participate (11%); fathers' failure to attend the study class (9%). Data were collected for 57 of 59 fathers and all women whose partners attended classes, with the exception of 2 who were lost to follow-up after discharge from hospital. **Characteristics** Ethnicity/race (women) - number (%)	**Interventions** Intervention: 2hr classes on infant care and breastfeeding promotion from peer educator. Classes held approximately every 2 weeks. Control: 2hr classes on infant care only from peer educator. Classes held approximately every 2 weeks In both groups, expectant fathers who completed the class received a $25 stipend. Setting: John Hopkins Hospital.	**Details** **Data collection** Data were collected from expectant mothers at enrolment, either in person or by telephone, and by telephone at 2, 4 and 8 weeks postnatally. Data were collected from expectant fathers by telephone at enrolment and via self-administered questionnaires when attending classes. **Analysis** To achieve 80% power, 230 women were required. Initiation and duration of breastfeeding were compared between groups using chi-squared test. Adjusted chi-squared statistics were obtained by logistic regression models.	**Results** Initiation of breastfeeding: intervention (n=27): 20 vs control (n=32): 13 Any breastfeeding at 8 weeks: intervention (n=26): 9 vs control (N=31): 6	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Some risk (not described) Allocation concealment: Some risk (not described) Baseline differences: Low risk (Similar baseline participant demographic characteristics) **Judgement on risk of bias arising from the randomisation process: Some risk**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To assess the effect of an education intervention teaching expectant fathers how to work with their partner to achieve successful breastfeeding. **Study dates** March 2001 to August 2002. **Source of funding** Training grant from the Centres for Disease Control and Prevention.	Black: Intervention (n=27): 23 (85); control (n=32) 27 (84) Ethnicity/race (fathers) - number (%) Black: Intervention (n=27): 23 (85); control (n=30): 24 (80) Received public assistance (women) - number (%) Intervention (n=27): 6 (22); control (n=32): 5 (16) **Inclusion criteria** • Expectant fathers of women seeking prenatal care at John Hopkins Hospital. **Exclusion criteria** Not stated.				DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence) Non-adherence: Low risk (9% of fathers failed to attend the study class after enrolling) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					(effect of adhering to intervention): Low risk DOMAIN 3 – missing data Missing outcome data: Low risk (Data was collected on 57/59 fathers (3% missing) who attended educational classes) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (interviews - women's self-report on breastfeeding, fathers were also interviewed) Blinding of outcome assessors: Some risk (not described) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Some risk (no information on trial

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					registration or pre-specified analysis plan) **Judgement on risk of bias arising from selection of the reporting result: Some risk** **Overall risk-of-bias judgement: Some risk**
Full citation Wong KL, Fong DYT, Lee ILY, Chu S, Tarrant M., Antenatal education to increase exclusive breastfeeding. A randomized controlled trial. , Obstetrics & Gynecology, 124, 961–8, 2014 **Ref Id** 997198 **Country/ies where the study was carried out** Hong Kong **Study type** RCT	**Sample size** N=469 Intervention: n=233 Control: n=236 Of the 469 participants, 15 (3.2%) had no follow-up after recruitment, 11 (2.3%) had partial follow-up, and 443 (94.5%) completed all follow-up to 6 months postpartum or until weaned. All loss to follow-up was the result of failure to contact participants by telephone. No participants withdrew from the study after recruitment. **Characteristics** Age (years) - mean (±SD)	**Interventions** Intervention: standard care and one 20-30 minute one-to-one antenatal breastfeeding support and education session plus 10-15 mins for questions and hand-outs. Control: Standard antenatal care with optional large-group breastfeeding classes. Setting: 2 public hospitals in Hong Kong.	**Details** **Data collection** Data were collected at baseline using self-administered questionnaires. Follow-up breastfeeding data were collected via telephone at 6 weeks, 3 months and 6 months postpartum or until weaned. **Analysis** To achieve 80% power, accounting for loss to follow-up, 200 participants were intervention group were required. Outcome data were analysed using the chi-squared test. Participants who were lost to follow-up	**Results** Any breastfeeding at 3 months: intervention (n=233): 116 vs standard care (n=236): 131 Exclusive breastfeeding at 3 months: intervention (n=233): 62 vs standard care (n=236): 61 Any breastfeeding at 6 months: intervention (n=233): 87 vs standard care (n=236): 96	**Limitations** Limitations were assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB 2). DOMAIN 1 - randomisation Random sequence generation: Low risk ('block randomisation procedures and random block sizes of two, four, and six. An independent researcher who did not participate in participant recruitment or data collection generated the allocation sequence using the statistical software')

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Aim of the study To evaluate the effects of an antenatal education and support intervention on breastfeeding rates **Study dates** January 2013 to June 2013, with follow-up in December 2013. **Source of funding** University of Hong Kong.	Intervention: 31.4 (4.3); control: 31.5 (4.3) Gestational age (weeks) - mean (±SD) Intervention: 39.3 (1.12); control: 39.2 (1.15) Birthweight (g) - mean (±SD) Intervention: 3165.5 (396.7); control: 3132.2 (380.7) Intention to exclusively breastfeed - number (%) Intervention: 177 (76); control: 190 (80.5) Monthly family income (HK$) - number (%) 14,999 or less: Intervention: 27 (11.7); control: 32 (13.8) 15,000-29,999: Intervention: 75 (32.6); control: 68 (29.3) 30,000 or more: Intervention: 128 (55.7); control: 132 (56.9) **Inclusion criteria** • Aged 18 years or older; • Cantonese-speaking; • Primiparous; • At least 35 weeks of gestation; • Singleton pregnancy; • No serious medical or obstetric complications;		were treated as weaned at the point of last contact and all randomised participants were included in the analysis. Odds ratios were calculated for any and exclusive breastfeeding at each follow-up timepoint using logistic regression while adjusting for one baseline variable that showed differences between treatment groups.		Allocation concealment: Low risk (opaque, sealed envelopes) Baseline differences: Low risk (no statistically significant differences in baseline characteristics between groups) **Judgement on risk of bias arising from the randomisation process: Low risk** DOMAIN 2a – deviations from intended intervention (assignment) Blinding of participants: High risk (not blinded) Blinding of carers and people delivering the interventions: High risk (not blinded) **Judgement on risk of bias arising from deviations from the intended interventions (effect of assignment to intervention): High risk** DOMAIN 2b – deviations from intended interventions (adherence)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	• Intending to breastfeed; • Planning to stay in Hong Kong for at least 6 months postpartum. **Exclusion criteria** • Women not entitled to health benefits in Hong Kong; • Not Hong Kong resident.				Non-adherence: Some risk (no details available on non-adherence or crossovers) Analysis of participants in the group to which they were randomised: Low risk (analysis based on random assignment) **Judgement on risk of bias arising from deviations from the intended interventions (effect of adhering to intervention): Low risk** DOMAIN 3 – missing data Missing outcome data: Low risk (11/223 (5%) in the intervention arm and 15/236 (6%) in control arm were lost to follow-up) **Judgement on risk of bias arising from missing outcome data: Low risk** DOMAIN 4 – outcome measurement Method of measuring the outcome: Low risk (phone

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
					interviews - women's self-report on breastfeeding) Blinding of outcome assessors: Low risk (Research assistant was blinded to the participants' group allocation) **Judgement on risk of bias arising from measurement of the outcome: Low risk** DOMAIN 5 – reporting Selective reporting: Low risk (trial registration reported and all outcomes included) **Judgement on risk of bias arising from selection of the reporting result: Low risk** **Overall risk-of-bias judgement: Some concerns**

AC: Attention control: ANOVA: analysis of variance; BAPT: Breastfeeding Attrition Prediction Tool; BEI: Breastfeeding experience instrument; BMI: body mass index; BMIMS: breastfeeding motivational instructional measurement scale; BSES-SF: Breastfeeding Self-Efficacy Scale - Short Form; CI: Confidence intervals; CSQ-8: client satisfaction questionnaire; EP: Electronic prompts; GP: general practitioner; HBSS: Hughes Breastfeeding Experience Instrument; ICC: Interclass correlation coefficient; ICU: intensive care unit; IIFAS: Iowa Infant Feeding Attitude Scale; ITT: intention to treat; IQR: Inter-quartile range; LATCH: Latch on, Audible swallow, Type of nipple, Comfort and Help LC: lactation consultant; LGAs: Local Government Areas; MCH: Maternal and child health; MCHN: Maternal and child health nurse; MI: motivational interviewing; MIHOW: Maternal Infant Health Outreach Worker; N: number; NCT: National clinical trials; NGA: National Guideline Alliance; NICU: newborn intensive care unit; NTI: nipple trauma index; OR: odds ratio; PCT: primary care trust; Personal Data Form: PDF; PHN: public health nurse; RCT: randomised controlled trials; RoB: Risk of Bias; RR: risk ratio; SBFPC: Specialised breastfeeding peer counselling; SCBU: special care baby unit; SD: Standard Deviation; SIMD: Scottish Index of Multiple Deprivation; VAS: visual analogue scale; vs: versus; WIC: Women, Infants and Children; WHO: World Health Organisation