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Draft for consultation

Postnatal Care

[P] Breastfeeding interventions

NICE guideline tbc

Evidence reviews

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Draft for consultation

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

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ISBN:

Contents

Breastfeeding interventions

This evidence review supports recommendations 1.5.2, 1.5.4, 1.5.10, 1.5.11 and 1.5.12.

Review question

This evidence report contains information on two review questions relating to breastfeeding interventions:

- What interventions are effective in starting and maintaining breastfeeding (single births)?
- What interventions are effective in starting and maintaining breastfeeding (twins or triplets)?

Introduction

Breastfeeding is known to have benefits for women and babies, when compared with formula feeding, including lower rates of infection in the babies and reduced risk of breast cancer in the women. Some women choose bottle feeding while others struggle to establish satisfactory breastfeeding. It is important to encourage women to start and to make effort to help them establish effective breastfeeding. Such help might be in the form of specific interventions initiated by healthcare professionals. The aim of this review is to identify what interventions are effective in starting and maintaining breastfeeding.

Summary of the protocol

Please see Table 1 for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO table)

Population	Pregnant women and women who have given birth to a healthy baby at term (or to healthy twins or triplets), from the birth of the baby to 8 weeks after birth, and their partners.

Intervention	Intervention 1
	• Education, advice or support from peer* or professional provided antenatally, for example:
	  ○ One to one
	  ○ Group classes
	  ○ Professional or peer* breastfeeding support
	  ○ Provision of self-help or educational material, including digital
	
	Intervention 2
	• Education, advice or support from peer* or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth; for example:
	  ○ One to one
	  ○ Group classes
	  ○ Professional or peer* breastfeeding support
	  ○ Provision of self-help or educational material
	
	Intervention 3

	• Avoidance of foreign objects (for example dummies, teats for formula milk) to baby's mouth in first four weeks of life Intervention 4 • Financial incentives
Comparison	Comparison 1 • Standard care • Different kinds of intervention 1 compared against each other Comparison 2 • Standard care • Different kinds of intervention 2 compared against each other Comparison 3. • Using foreign objects (for example dummies, teats for formula milk) to baby's mouth in first four weeks of life Comparison 4. • Standard care • Different kinds of intervention 4 compared against each other Studies will be included if the intervention being evaluated is a combination of any of the above for example 1 and 3 versus nothing. Where data allow, active interventions will also be compared with each other, including those provided antenatally versus. those provided postnatally.
Outcomes	**Critical** • Proportion of women initiating breastfeeding (any) up to 48 hours following birth) • Proportion of women breastfeeding at 3-14 days (any and exclusive) • Proportion of women breastfeeding at 6-12 weeks (any and exclusive) • Proportion of women breastfeeding at 16 – 26 weeks (any breastfeeding) **Important** • Women's satisfaction with breastfeeding interventions

*denotes that the person has undergone specific training related to the provision of information and support for breastfeeding.

For further details see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual 2014. Methods specific to this review, including meta-regression, are described in the review protocol in appendix A and appendix M, and in Supplement 1: Methods.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy until March 2018. From April 2018 until June 2019, declarations of interest were recorded according to NICE's 2018 conflicts of interest policy. From July 2019 onwards, the declarations of interest were recorded according to NICE's 2019 conflicts of interest policy. Those interests declared before July 2019 were reclassified according to NICE's 2019 conflicts of interest policy (see Register of Interests).

Clinical evidence

Included studies

Overall 83 studies on different breastfeeding interventions were included in this review, reported in over 92 publications. Eighty three studies were randomised controlled trials (RCTs) of which 13 were cluster RCTs. More information is given below of the studies included in each intervention type and about whether the studies recruited women who had had a single baby, twins or triplets.

For interventions 1, 2 and 3, most studies were identified from Cochrane systematic reviews and literature searches were conducted to top up from the dates of the Cochrane searches. In addition, a search was conducted to identify studies on financial incentives (intervention 4) and a search was conducted to identify studies on breastfeeding interventions for caesarean births. For these the date cut-off was 1995 as this was when the Baby Friendly Initiative (BFI) was introduced into the UK.

Education, advice or support from peer or professional provided antenatally (Intervention 1)

Sixteen RCT were identified for this review of interventions that started and finished antenatally. Fourteen RCTs reported in 15 publications (Bonuck 2014, Duffy 1997, Finch 2002, Forster 2004, Kellams 2016 & Kellams 2018, Kronborg 2012, Mattar 2007, Noel-Weiss 2006, Ryser 2004, Schlickau 2005, Serwint 1996, Su 2007, Wolfberg 2004 and Wong 2014) and two cluster RCTs (Caulfield 1998 and Lavender 2005). The included studies are summarised in Table 2. Moreover, two Cochrane systematic reviews (Balogun 2016 and Lumbiganon 2016) were used to identify relevant studies and to extract information relating to protocol registration and selective reporting bias.

Of the sixteen studies, eight specifically recruited women who were expecting a single baby (Bonuck 2014, Caulfield 1998, Kellams 2016 & Kellams 2018, Kronborg 2012, Mattar 2007, Noel-Weiss 2006, Su 2007, Wong 2014), seven studies did not report whether they recruited women expecting single or multiple babies (Duffy 1997, Finch 2002, Forster 2004, Lavender 2005, Ryser 2004, Schlickau 2005 and Wolfberg) and one study recruited both women who were expecting single or multiple babies, this study included one family who had twins (Serwint 1996). No studies were identified that specifically recruited women expecting twins or triplets.

The scope of this guideline was for all breastfeeding questions to cover both the antenatal and postnatal periods.

Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2)

Sixty-two RCT were identified for this review of interventions that started antenatally or postnatally and finished postnatally. Fifty-two RCTs were reported in 60 publications (Abbass-Dick 2015 & 2018, Ahmed 2016, Anderson 2005 & 2007, Bonuck 2005 & 2006, Bonuck 2014, Brent 1995, Bunik 2010, Carlsen 2013, Chan 2016, Chapman 2004 & 2004, Chapman 2013, Curro 1997, Dennis 2002 & 2002, Edwards 2013, Efrat 2015, Ekstrom 2006 & 2012, Gagnon 2002, Graffy 2004 & 2005, Gross 2016, Harari 2018, Henerson 2001, Hoddinott 2012, Labarere 2003, Labarere 2005, Laliberte 2016, Lutenbacher 2018, Maycock 2013, McDonald 2010, McQueen 2011, Muirhead 2006, Paul 2012, Petrova 2009, Pollard 2010, Pugh 1998, Pugh 2002, Pugh 2010, Quinlivan 2003, Ramsussen 2011, Redman 1995, Reeder

2014, Sandy 2009, Simonetti 2012, Srinivas 2015, Steel O'Connor 2003, Stockdale 2008, Su 2007, Vidas 2011, Wallace 2006, Wambach 2011, Wen 2011, Wilhelm 2006 and Wilhelm 2015) and 10 cluster RCTs reported in 13 publications (Caulfield 1998 & Gross 1998, Elliott-Rudder 2014, Fu 2014, Hoddinott 2009 & 2010, Jolly 2012 & MacArthur 2009, Kools 2005, Kronborg 2008, McLachlan 2016, Nilsson 2017 and Pisacane 2005).

Of the 62 studies, 33 specifically recruited women who were expecting a single baby (Abbass-Dick 2015 & 2018, Ahmed 2016, Anderson 2005 & 2007, Bonuck 2014, Bunik 2010, Carlsen 2013, Caulfield 1998 & Gross 1998, Chapman 2004 & 2004, Chapman 2013, Dennis 2002 & 2002, Edwards 2013, Efrat 2015, Ekstrom 2006 & 2012, Gagnon 2002, Gross 2016, Henerson 2001, Kronborg 2008, Labarere 2003, Labarere 2005, Laliberte 2016, McDonald 2010, McQueen 2011, Nilsson 2017, Petrova 2009, Pugh 2002, Pugh 2010, Ramsussen 2011, Sandy 2009, Simonetti 2012, Steel O'Connor 2003, Su 2007, Wambach 2011 and Wilhelm 2015), 24 studies did not report whether they recruited women expecting single or multiple babies (Brent 1995, Chan 2016, Curro 1997, Elliott-Rudder 2014, Fu 2014, Graffy 2004 & 2005, Harari 2018, Hoddinott 2009 & 2010, Jolly 2012 & MacArthur 2009, Kools 2005, Lutenbacher 2018, Maycock 2013, McLachlan 2016, Muirhead 2006, Pisacane 2005, Pollard 2010, Pugh 1998, Redman 1995, Srinivas 2015, Stockdale 2008, Vidas 2011, Wallace 2006, Wen 2011 and Wilhelm 2006) and five studies recruited both women who were expecting single or multiple babies (Bonuck 2005 & 2006, Hoddinott 2012, Paul 2012, Quinlivan 2003 and Reeder 2014). No studies were identified that specifically recruited women expecting twins or triplets.

Moreover, one Cochrane systematic review (McFadden 2017) was used to identify relevant studies and to extract information relating to protocol registration and selective reporting bias.

Due to the large volume of included studies for this comparison and the variability of the interventions across the studies, meta-regression was conducted in addition to the pair-wise meta-analysis. Meta-regression allows for the analysis of the effectiveness of the different variables that made up each study's intervention and would determine what component of an intervention was effective irrespective of all other components that made up the intervention.

For the purpose of the meta-regression analysis, each study under this intervention category was categorised using the following variables:

- number of contact visits – 0, 1, 2-3, 4-8 and 9+
- how delivered – face-to-face on an individual basis, face-to-face in a group, remote, self-help
- duration of contact – contact with the intervention lasted less than 8 weeks, contact with the intervention lasted more than 8 weeks
- where the intervention was delivered – at the woman's home, in a healthcare setting or a combination of both home and healthcare setting.

More details on the methods can be found in Supplement 1: Methods. The WinBUGS code used and the results of the analysis can be found in appendix M.

Avoidance of foreign objects (Intervention 3)

Four RCTs were identified for this review of interventions involving the avoidance of foreign objects (Jenik 2009, Kramer 2001, Schlickau 2005 and Schubiger 1997).

Of the 4 studies, 1 specifically recruited women who were expecting a single baby (Kramer 2001), whilst 3 studies did not report whether they recruited women

expecting single or multiple babies (Jenik 2009, Schlickau 2005 and Schubiger 1997). No studies were identified that specifically recruited women expecting twins or triplets.

One Cochrane systematic review (Jaafar 2016) was used to identify relevant studies and to extract information relating to protocol registration and selective reporting bias.

Financial incentives (Intervention 4)

Three RCTs were identified for this review of interventions involving financial incentives. Two were RCTs (Sciacca 1995 and Washio 2017) and 1 was a cluster RCT (Relton 2018). All studies used financial incentives as a reward for maintaining breastfeeding to certain milestones.

Of the 3 studies, 1 specifically recruited women who were expecting a single baby (Sciacca 1995), 1 study did not report whether they recruited women expecting single or multiple babies (Washio 2017) and 1 study recruited both women who were expecting single or multiple babies, this study included families who had had multiple babies (Relton 2018). No studies were identified that specifically recruited women expecting twins or triplets.

Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus Education, advice or support from peer or professional provided antenatally (Intervention 1)

Three studies reported more than 1 intervention where 1 was relevant to intervention 1 and the other was relevant to intervention 2 (Bonuck 2014, Caulfield 1998 & Gross 1998 and Su 2007), so these were compared against each other as well as against the control arm. In these cases, the same control arm was used. This is not a duplication of data given that interventions 1 and 2 were analysed separately.

Stratification by intention to breastfeed

A post-hoc exploratory stratified analysis was conducted to explore whether the mother's intention to breastfeed would alter the effect of an intervention. This analysis was not set out a priori in the protocol but was conducted post-hoc. The categorisation of a woman's intention to breastfeed was split into three groups: (i) the study recruited women who had a pre-established desire to breastfeed or were considering breastfeeding before entering the study, (ii) the study recruited women regardless of their intention to breastfeed or did not report the breastfeeding intention of the women and (iii) in the case of the outcomes that were looking at maintaining breastfeeding, whether the study recruited women that had already established breastfeeding. The results of these analyses are presented in the forest plots in appendix E. As these were exploratory post-hoc analyses not set a priori in the protocol, the reporting of this and the assessment of the quality of the evidence was not done as per usual process. However, the results were included in the clinical evidence statements and the forest plots for transparency.

The included studies grouped by their interventions are summarised in Table 2..

See the literature search strategy in appendix B and study selection flow chart in appendix C.

Excluded studies

Studies not included in this review are listed, and reasons for their exclusion are provided in appendix K.

Summary of studies included in the evidence review

Summaries of the studies that were included in this review are presented in Table 2.

Table 2: Summary of included studies

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
Education, advice or support from peer or professional provided antenatally (Intervention 1)				
Bonuck 2014 RCT US	N=313 women • Intervention (1): n=236 women • Control: n=77 women Characteristics: Single pregnancies Nulliparous and multiparous Over half Hispanic women (>55%) Primarily low-income women Approximately 37% women obese (BMI ≥30 kg/m^2) Mix of feeding intentions Nulliparous and multiparous	Intervention (1): Electronic prompts in medical records during 5 prenatal visits. Included 2-3 brief open-ended questions that portrayed breastfeeding as the norm, sought to clarify knowledge about breastfeeding, and elicited information on social network support. Control: Standard care – no explicit breastfeeding promotion or support This publication reported on 2 RCTs, called BINGO and PAIRINGS. Only the BINGO RCT focused on an antenatal intervention (as well as on 2 additional interventions performed across the antenatal and postnatal period, which are reported in the section of this table that focuses on intervention 2). The PAIRINGS RCT is only reported in the section of this table focusing on intervention 2.	• Initiation of breastfeeding • Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months • Any breastfeeding at 6 months	Source: Cochrane McFadden Exclusive breast-feeding was defined as feeding only breast milk or vitamin supplements, with no water, juice, formula, or solid foods
Caulfield 1998; Gross 1998 Cluster RCT US	N=121 women • Intervention (1): n=64 women • Control: n=57 women Characteristics: Single pregnancies Nulliparous and multiparous	Intervention (1): Breastfeeding motivational video played in waiting area plus standard care (posters, pamphlets and counselling from service provider). Control: Standard Women Infant and Children infant-feeding education, including individualised	• Initiation of breastfeeding • Any breastfeeding at 7-10 days	Source: Cochrane Balogun The authors did not adjust for cluster design effect. Intraclass correlation coefficient (ICC) for

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Approximately 30% women aged less than 18 years Predominately African-American women (>90%) Low-income 43% intended to breastfeed at enrolment	encouragement and support, and written materials. This study had 4 arms and also looked at 2 additional interventions performed across the antenatal and postnatal period; these are reported in the section of the table that focuses on intervention 2.		breastfeeding cessation from Lavender 2005 was used: ICC=0.01.
Duffy 1997 RCT Western Australia	N=75 women • Intervention: n=37 women • Control: n=38 women Characteristics: Nulliparous women >36 weeks pregnant, who intended to breastfeed 70% with low income	Intervention: Standard care plus 1 hour antenatal group session on position and attachment of the baby on the breast by a lactation consultant. Control: Standard educational programme of the study hospital.	• Any breastfeeding at 6 weeks	Source: Cochrane Lumbiganon
Finch 2002 RCT US	N=60 women • Intervention: n=30 women • Control: n=30 women Characteristics: Predominately African-American (approximately 67%) Approximately 31% aged less than 19 years of age Mostly minority population with the highest poverty level in New York City	Intervention: Breastfeeding education by a trained counsellor plus small group 'truth or myth' activity, followed by discussion and hand-outs. Control: Standard antenatal education regarding general benefits and barriers to breastfeeding. Women in both groups were offered educational materials and support.	• Breastfeeding initiation	Source: Cochrane Lumbiganon 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

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	69% intended to breastfeed			breastfed exclusively for at least 2 months were also eligible to receive a $25 gift certificate.
Forster 2004 RCT Australia	N=984 women • Intervention (1): n=327 women • Intervention (2): n=329 women • Control: n=328 women Characteristics: Nulliparous Pension/benefit primary family income – 7% to 16% women	Intervention (1): Standard care plus a 1.5 hour group session focused on practical breastfeeding skills, using teaching aids (partners not included). Intervention (2): Standard care plus two 1 hour group sessions that focused on changing attitudes to breastfeeding (included partners or significant others). Control: Standard care which included formal breastfeeding education, peer support from community breastfeeding groups, lactation consultant support, breastfeeding information evenings, videos or education on breastfeeding presented in the postnatal ward, 24 hour telephone counselling support, postnatal home visit by a midwife.	• Any breastfeeding 2-4 days • Any breastfeeding 6 months • Women's satisfaction with intervention	Source: Cochrane Lumbiganon and Balogun
Kellams 2016; Kellams 2018 RCT US	N=522 women • Intervention: n=263* women • Control: n=259* women Characteristics: Single pregnancies Nulliparous and multiparous	Intervention: 25 minute educational breastfeeding video viewed during the prenatal period. Control: 20 minute educational video about nutrition during pregnancy.	• Initiation of breastfeeding	Source for Kellams 2016: Cochrane Balogun and Lumbiganon Source for Kellams 2018: update search

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Average of 25 years old Predominately White or black non-Hispanic – approximately 87% Low-income women 11% of babies were born preterm; 17% of babies in intervention group and 12% in control group were admitted to the intermediate care nursery (ICN) or the neonatal intensive care unit (NICU) *extracted from Kellams 2018	Videos were viewed in waiting room/examination room while the participant waited to be seen by the physician or nurse practitioner.		Even if some babies were preterm or admitted to NICU, not considered as indirect evidence because the percentage was relatively small.
Kronborg 2012 RCT Denmark	N=1193 women • Intervention: n=603 women • Control: n=590 women Characteristics: Single pregnancies Nulliparous women	Intervention: 'Ready for Child programme' that consists of 3 modules: focusing on birth and pain relief, infant care and breastfeeding, parental role and the relationship between the woman and her partner. Delivered in a group session lasting 3 hours between 30-35th week of pregnancy. This was classified as 2 to 3 contacts for the present review. Partners invited to participate. Control: Standard care – no antenatal training programme. Women could seek additional support elsewhere.	• Initiation of breastfeeding within 2 hours after birth (extracted as breastfeeding initiation for the present review). • Any breastfeeding at 6 weeks.	Source: Cochrane Lumbiganon
Lavender 2005 Cluster RCT	N=1312 women	Intervention: Normal antenatal care plus a single antenatal breastfeeding education session	• Any breastfeeding at 2 weeks	Source: Cochrane McFadden

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
UK	• Intervention: n=679 women • Control: n=633 women Characteristics: Nulliparous and multiparous Majority White origin (>90%) Women who stated a desire to breastfeed.	during third trimester. Each session involved up to 8 women and was facilitated by a qualified infant feeding coordinator. Control: Standard care that included breastfeeding advice from attending clinic midwives.	• Any breastfeeding at 6 weeks • Any breastfeeding at 6 months	Excluded Studies and Lumbiganon The authors adjusted for cluster design effect. ICC for breastfeeding cessation used: ICC=0.01.
Mattar 2007 RCT Singapore	N=401 women • Intervention (1): n=123 women • Intervention (2): n=132 women • Control: n=146 women Characteristics: Single pregnancies; women at low risk Nulliparous and multiparous Mostly aged between 20-39 years Predominately of Malay origin Majority lived in subsidised government housing (income <US $3000 per month)	Intervention (1): An information booklet on breastfeeding, a 16 minute education video on breastfeeding, one 15 minute session with a lactation 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 (no details provided)	• Any breastfeeding at 2 weeks • Exclusive and predominant breastfeeding at 2 weeks • Any breastfeeding at 3 months • Exclusive and predominant breastfeeding at 3 months • Any breastfeeding at 6 months	Source: Cochrane Lumbiganon Predominant breastfeeding meant no formula (water allowed). The study only provided merged data for exclusive and predominant breastfeeding. For the analysis in the present review, these outcome data were considered as exclusive breastfeeding.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
Noel-Weiss 2006 RCT Canada	N randomised=101 women N randomised to each group not reported. N included in the analysis=92 women • Intervention: n=47 women • Control: n=45 women Characteristics: Single pregnancies Nulliparous Aged between 17-42 years (mean 30 years) Majority completed postsecondary education and had a family income >$70,000 Women planning to breastfeed	Intervention: Standard care plus 2.5 hour prenatal breastfeeding workshop that involved the use of lifelike dolls plus videos, and discussion. Control: Standard care (no details provided)	• Exclusive breastfeeding at 8 weeks • Any breastfeeding at 8 weeks	Source: Cochrane Lumbiganon Exclusive breastfeeding meaning the only fluid the infant receives is breastmilk; exclusive by breast with some expressed breast milk by bottle; expressed breastmilk by bottle only.
Ryser 2004 RCT US	N=54 women • Intervention: n=26 women • Control: n=28 women Characteristics: Aged between 18-40 years Nulliparous and multiparous women	Intervention: Best Start programme: counselling, viewing videos, reading written materials. The educational strategy focused on identifying the women's concerns in order to provide carefully targeted educational messages. Given to women during each of the 4 prenatal visits. Control: Standard care (no details provided).	• Any breastfeeding at 1 week • Exclusive breastfeeding at 1 week	Source: Cochrane Balogun and Lumbiganon Definition of exclusive breastfeeding not given

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Low income women – approximately 90% women eligible for Medicaid benefits Intention to bottle feed or undecided about feeding method			
Schlickau 2005 RCT US	N=20 women • Intervention (1): n=10 women • Control: n=10 women Characteristics: Nulliparous Mean age 22 years (range 16-45 years Hispanic women Low-risk women	Intervention (1): 1 hour 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. Control: Standard care of breastfeeding information which included offering advice and hand-outs This study was a three-arm trial and had an additional arm where, in addition to education on breastfeeding, there was a teaching session on avoiding bottles and pacifiers. Moreover, as part of this session a checklist for breastfeeding commitments was used. This third intervention was classified as intervention 3 and is presented in the section of the table focusing on intervention 3.	• Any breastfeeding at 45 days	Source: Cochrane Lumbiganon
Serwint 1996 RCT US	N=156 women • Intervention: n=81 women • Control: n=75 women	Intervention: Routine care and an antenatal visit at a 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,	• Initiated breastfeeding • Any breastfeeding at 60 days	Source: Cochrane Whitford, Balogun and Lumbiganon

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Characteristics: Single pregnancies except for 1 woman who had twins (only twin A included in the study) Nulliparous women 91% African-American Low-income	circumcision and access to paediatric healthcare and appropriate utilisation. Control: Standard care; no antenatal paediatric visit		
Su 2007 RCT Singapore	N=301 women • Intervention (1): n=150 women • Control: n=151 women Characteristics: Single pregnancies Nulliparous and multiparous women Ethnicity: 38% Chinese, 48% Malay, 11% Indian, 3% other Women who stated an intention to breastfeed	Intervention (1): One session of antenatal breastfeeding education – including a 16 minute educational video, hand-outs and opportunities to talk to lactation counsellor for ~15 minutes. Control: Standard care that included optional antenatal classes that did address infant feeding and postnatal visits by a lactation consultant should problems arise. This study had 3 arms and also looked at a postnatal intervention. This is reported in the section of the table that focuses on category 2 interventions.	• Any breastfeeding at 2 weeks • Exclusive breastfeeding at 2 weeks • Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months • Any breastfeeding at 6 months	Source: Cochrane McFadden 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.
Wolfberg 2004 RCT US	N=59 couples • Intervention: n=27 mothers; n=27 fathers	Intervention: 2 hour group classes aimed at expectant fathers on infant care and breastfeeding promotion from peer educator. Classes held approximately every 2 weeks.	• Initiation of breastfeeding • Any breastfeeding at 8 weeks	Source: Cochrane McFadden and Lumbiganon

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	• Control: n=32 mothers; n=30 fathers Characteristics: Expectant fathers and mothers 84% of Black ethnicity 19% of women received public assistance	Control: 2 hour classes aimed at expectant fathers 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. In both groups, mothers who completed survey at 8 weeks received a $25 stipend.		
Wong 2014 RCT Hong Kong	N=469 women • Intervention: n=233 women • Control: n=236 women Characteristics: Single pregnancies Women who planned to breastfeed Nulliparous women	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	• Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months • Any breastfeeding at 6 months	Source: Cochrane Lumbiganon Exclusive breastfeeding was defined as the infant receives breast milk as the only source of food.
Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2)				
Abbass-Dick 2015; Abbass-Dick 2018 RCT Canada	N=214 couples (intervention aimed at mothers and fathers) • Intervention: n=107 couples • Control: n=107 couples Characteristics:	Intervention: Standard 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.	• Any breastfeeding at 12 weeks • Exclusive breastfeeding at 12 weeks	Source: Cochrane McFadden Exclusive breastfeeding defined as no food or liquid other than breast milk given to infant in the last 24 hours and

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Single pregnancies Nulliparous women Women who planned to breastfeed for at least 12 weeks Women living with partner	Control: Standard care, which included standard in-hospital breastfeeding support and any breastfeeding assistance that was proactively sought in the community.		included feeding expressed breast milk and undiluted drops or syrups consisting of vitamins, minerals, supplements, or medicines.
Ahmed 2016 RCT US	N=141 women • Intervention: n=84 women • Control: n=57 women Characteristics: Single pregnancies Nulliparous and multiparous women. Predominately White (>65%) Women with an intention to continue breastfeeding after discharge	Intervention: Standard care and an interactive breastfeeding monitoring system. Breastfeeding data was inputted along with 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: Standard care including breastfeeding support and education prior to discharge, one phone call within the first week after discharge and advice of community breastfeeding resources. A thank-you letter with a $30 gift card was sent to 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.	• Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months	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.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
Anderson 2005; Anderson 2007 RCT US	N=182 women • Intervention: n=90 women • Control: n=92 women Characteristics: Single pregnancies Nulliparous and multiparous women. Mean age 25 years (range 18-39) Predominantly Latina women, majority of these Puerto Rican Low-income – income level below 185% federal poverty level Women who were considering breastfeeding	Intervention: Standard care plus 3 prenatal home visits, daily in-hospital visits after birth and 9 postpartum home visits from a trained peer counsellor until 6 weeks after birth. Control: Standard care, certified Baby-Friendly Hospital, hands-on breastfeeding support on maternity ward, 24hr support telephone line Analyses to examine the role of ethnicity on outcomes was also conducted and reported in Anderson 2007.	• Initiated breastfeeding by hospital discharge • Any breastfeeding by hospital discharge • Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months	Source: Cochrane McFadden >25% lost to follow-up 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?).
Bonuck 2014 RCT US	BINGO RCT N randomised=666 women, N analysed=628 women • Intervention (1): n=236 women • Intervention (2): n=77 women • Intervention (3): n=238 women • Control: n=77 women	Intervention (1) (BINGO): Electronic prompts in the medical records during 5 prenatal visits. Included 2-3 brief open-ended questions for providers to ask that portrayed breastfeeding as the norm. (This data is presented as part of Intervention 1 – antenatal advice) Intervention (2) (BINGO): Lactation consultant that held 2 prenatal sessions with the woman, a hospital visit, telephone calls for up to 3 months	• Initiation of breastfeeding • Any breastfeeding at 1 month • Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months • Any breastfeeding at 6 months • Exclusive breastfeeding at 6 months	This study reports on 2 RCTs, BINGO and PAIRINGS. Source: Cochrane McFadden Free nursing bras and pumps to lactation consultant groups Exclusive breastfeeding: only breastmilk or vitamin

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	PAIRINGS RCT N randomised=275 women, N analysed=262 women • Intervention (3): n=129 women • Control: n=133 women Characteristics: Single pregnancies Nulliparous and multiparous Majority Hispanic women (>55%) and non-Hispanic Black women (approximately 28%) Approximately 37% women obese (BMI ≥30 kg/m^2) Low risk BINGO RCT: Primarily low-income women (approximately 60% participating in Special Supplemental Nutrition Program for Women, Infants, and Children, WIC) PAIRINGS RCT: Economically diverse	postpartum. Nursing bras, breast pumps and home visits provided as needed. Intervention (3) (BINGO and PAIRINGS): Lactation consultant and electronic prompts Control: Standard care – no explicit breastfeeding promotion or support		supplements. No water, juice, formula or solid foods during the past week.
Bonuck 2005; Bonuck 2006	N=382 women	Intervention: 2 individual meetings with a lactation consultant prenatally and 1 postpartum	• Any breastfeeding at 2 weeks	Source: Cochrane McFadden

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
RCT US	• Intervention: n=188 women • Control: n=194 women Characteristics: Twin or single pregnancies Nulliparous and multiparous Mean age 25 years Primarily Hispanic (55%) and/or black women (37%) Low income (56% in receipt of Medicaid)	hospital and/or 1 home visit and was available for telephone consultation up to 12 months. Meetings were for 60-90 minutes each. Free nursing bra and pump. Control: Health centre standard care. No established protocol for breastfeeding education or support so variation in levels of breastfeeding education or support. Contact with lactation consultant was prohibited. Participants were compensated (no further details provided).	• Exclusive breastfeeding at 2 weeks • Any breastfeeding at 6 weeks • Exclusive breastfeeding at 6 weeks • Any breastfeeding at 26 weeks	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.
Brent 1995 RCT US	N=115 women • Intervention: n=58 women • Control: n=57 women Characteristics: Nulliparous Predominately White origin (approximately 71%) 90% with low income (eligible for Special Supplemental Nutrition Program for Women, Infants, and Children, WIC) Choice of breastfeeding at first prenatal visit <40%	Intervention: 2-4 prenatal sessions with a lactation consultant (10 min-15 min each); daily inpatient rounds after birth; telephone call 48 h after discharge; visit to lactation clinic at 1 week postpartum and contact with lactation consultant at each health supervision visit until weaning or 1 year Control: Women were offered optional prenatal breastfeeding classes as well as postpartum breastfeeding instruction and outpatient follow-up by nurses and physicians in the paediatric ambulatory department	• Initiation of breastfeeding • Any breastfeeding at 2 weeks • Any breastfeeding at 2 months • Any breastfeeding at 6 months	Source: Cochrane McFadden and Balogun

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
Bunik 2010 RCT US	N=341 women • Intervention: n=161 women • Control: n=180 women Characteristics: Single pregnancies Nulliparous Low income (>60% participating in Special Supplemental Nutrition Program for Women, Infants, and Children, WIC) Majority White Hispanic Willing to consider breastfeeding	Intervention: Standard care plus daily telephone calls by a nurse starting on the day of discharge and continuing daily for the first 2 weeks postpartum. Telephone calls were scripted and developed to be culturally appropriate to target population. Control: Standard care – including healthcare visit at 3 to 5 days and 2 weeks at the clinic, as well as formula company discharge bags. Both groups received hand-outs on breastfeeding, a hand breast pump and lanolin cream, and a water bottle.	• Any breastfeeding at 3 months • Any breastfeeding at 6 months	Source: Cochrane McFadden Data were not extracted for predominant breastfeeding as this was defined as feeding 4 oz or less of formula per day.
Carlsen 2013 RCT Denmark	N=226 women • Intervention: n=108 women Control: n=118 women Characteristics: Single pregnancies Women who had participated in the 'Treatment of Obese Pregnant Study' (pre-	Intervention: Standard care plus telephone - based advisory support service from a lactation consultant for first 6 months postpartum. Starting within the first week (~20min call) followed by a minimum of 8 follow-up calls (~5-10mins). Control: Standard care (no details provided) All women had contact with a health visitor (paediatric nurse) who makes home visits during the first 18 months of the child's life.	• Exclusive breastfeeding at 2 weeks • Exclusive breastfeeding at 3 months • Any breastfeeding* at 6 months *Defined in the paper as partial breastfeeding	Exclusive breastfeeding defined according to WHO criteria of breastfeeding only supplemented with vitamins, mineral supplements, and water. Partial breastfeeding defined as breastfeeding supplemented with

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	pregnancy BMI ≥30 kg/m^2) Women intended to breastfeed Nulliparous and multiparous			formula milk or solid food.
Caulfield 1998; Gross 1998 Cluster RCT US	N=242 women • Intervention (1): n=64 women • Intervention (2): n=55 women • Intervention (3): n=66 women • Control: n=57 women Characteristics: Single pregnancies Nulliparous and multiparous Predominately African-American women (>90%) Approximately 30% women aged less than 18 years Low-income (participating in Special Supplemental Nutrition Program For Women, Infants, And Children, WIC)	Intervention (1): Video intervention. A breastfeeding motivational video addressing the benefits and barriers to breastfeeding, played in waiting area plus posters, pamphlets and counselling from service provider. Largely a prenatal intervention (study also reported as part of Intervention 1 – interventions in the antenatal period). Intervention (2): Peer-counselling activities to include talking to the woman pre- and postnatally, holding one-to-one and group support sessions and follow-ups 3 or more times during pregnancy for women interested in breastfeeding. Follow-ups performed weekly up to 16 weeks postpartum. Contact was made at home, at the clinic or by phone. Intervention (3): Video and peer counselling activities. Co-ordination of interventions was through use of a breastfeeding promotion record. Control: Standard Women Infant and Children infant-feeding education (included all nutrition education and breastfeeding promotion activities	• Initiation of breastfeeding • Any breastfeeding at 7-10 days	Source: Cochrane Balogun The authors did not adjust for cluster design effect. ICC for breastfeeding cessation from Lavender 2005 was used: ICC=0.01.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
		as required by regulations, plus written materials and pamphlets available).		
Chan 2016 RCT Hong Kong	N=71 women • Intervention: n=35 women • Control: n=36 women Characteristics: Nulliparous Primarily Chinese women >65% intended to breastfeed for more than 12 weeks	Intervention: Standard care plus a 2.5 hour small group breastfeeding workshop at 28–38 weeks of gestation involving a 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 breastfeeding support provided by midwives in the hospital, access to a lactation consultant, and post-partum follow-up by midwives or doctors).	• Initiation of breastfeeding • Any breastfeeding at 2 weeks • Exclusive breastfeeding at 2 weeks • Any breastfeeding at 8 weeks • Exclusive breastfeeding at 8 weeks • Any breastfeeding at 6 months	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 breastfeeding defined as an infant receiving at least one bottle of artificial milk each day.
Chapman 2004a; Chapman 2004b RCT US	N=219 women • Intervention: n=113 women • Control: n=106 women Characteristics: Single pregnancies Nulliparous and multiparous Primarily (80%) Latina women with majority of these Puerto Rican Low income (recipient of food stamps, Special Supplemental Nutrition Program For Women,	Intervention: Standard care plus breastfeeding peer counselling services including at least 1 prenatal home visit, daily in-hospital perinatal visits, at least 3 postpartum home visits, and participants could contact the peer counsellor by pager. 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.	• Initiation of breastfeeding • Any breastfeeding at 3 months • Any breastfeeding at 6 months	Source: Cochrane McFadden and Balogun 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

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Infants, And Children, WIC participant, household income less than 180% of federal poverty level) Women who were considering breastfeeding			women in the control group.
Chapman 2013 RCT US	N=206 women • Intervention: n=103 women Control: n=103 women Characteristics: Single pregnancies Primarily (>80%) Hispanic women Low income (income less than 185% of federal poverty level) Overweight or obese (BMI ≥27 kg/m^2) Women considering breastfeeding	Intervention: Standard care plus specialised breastfeeding peer counselling intervention promoting exclusive breastfeeding. Intervention included access to 3 prenatal visits, daily in-hospital visits after birth, and up to 11 postpartum home visits during the first 6 months postpartum. Manual breast pump issued before discharge. This intervention replaced the optional breastfeeding support from Breastfeeding: Heritage and Pride Peer Counsellors (BHP PC) available to control group Control: Routine breastfeeding support from hospital personnel, including lactation consultants able to call hospital's 'warm line', Also optional breastfeeding support from BHP PC. This consisted of prenatal breastfeeding education during routine clinic appointments, written education materials and an electric breast pump loaned on request.	• Any breastfeeding at 2 weeks • Exclusive breastfeeding at 2 weeks • Exclusive breastfeeding at 3 months	Source: Cochrane McFadden and Balogun (identified as Chapman 2013 in Balogun) Exclusive breastfeeding defined as infants not receiving water, formula, juice, tea or any other solids/liquids in previous 24 hours.
Currò 1997 RCT Italy	N=200 women • Intervention: n=103 women	Intervention (1): 10 minutes verbal counselling session on breastfeeding. Additional booklet with instructions for practical breastfeeding management and with information on	• Any breastfeeding (defined as complementary breastfeeding) at 6 months	

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	• Control: n=97 women Characteristics: Primiparous Women who were exclusively breastfeeding at recruitment (10-20 days after birth)	advantages of exclusive breastfeeding, particularly if prolonged for the first 6 months of life. Control: 10 minutes verbal counselling session only		
Dennis 2002a; Dennis 2002b RCT Canada	N=258 women • Intervention: n=132 women • Control: n=126 women Characteristics: Single births Nulliparous women Women breastfeeding	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 breastfeeding clinic managed by lactation consultants, a telephone breastfeeding support line managed by hospital nursing staff, and support services provided by public health nurses at the local regional community health department and by community-based physicians and paediatricians.	• Any breastfeeding at 12 weeks • Exclusive breastfeeding at 12 weeks • Maternal satisfaction	Source: Cochrane McFadden Exclusive breastfeeding defined as breast milk only; almost exclusive (breast milk and other fluids (for example 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); bottle-feeding (no breast milk).

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
Edwards 2013 RCT US	N=248 women • Intervention: n=124 women • Control: n=124 women Characteristics: Low-income Women aged 21 and under, mean age 18.3 (SD 1.7) African-American women Predominately nulliparous (~88%) Approximately 62% considering breastfeeding	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, visited during the first 3 months postpartum (average 10-12 home visits) and were available by phone 24 hours. Breast pumps were provided for women who were returning to work or school. Control: Standard care (no details provided)	• Initiation of breastfeeding • Any breastfeeding at 6 weeks • Any breastfeeding at 4 months	Source: Cochrane McFadden Excludes and Balogun
Efrat 2015 RCT US	N=289 women • Intervention: n=146 women • Control: n=143 women Characteristics: Single births Low-income Hispanic women Nulliparous and multiparous	Intervention: Standard care plus 4 prenatal and 17 postpartum phone calls with a lactation educator until 6 months after birth. Lactation educators' phone number available to the mothers. Control*: Standard care – including routine breastfeeding education and support offered by the local health corporation. *1 baby in the control group reported to have birth defects.	• Any breastfeeding at 3 days • Exclusive breastfeeding at 3 days • Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months • Any breastfeeding at 6 months	Source: Cochrane McFadden and Balogun 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,

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
				formula, folk remedies or another food.
Ekstrom 2006; Ekstrom 2012 Cluster RCT Sweden	N=540 women • Intervention: n=206 women • Control (1): n=162 women • Control (2): n=172 women Characteristics: Single pregnancies Nulliparous women	Intervention: A process-oriented training in breastfeeding counselling and continuity of care at the antenatal and child health centre Control: Standard care – included attending family classes. Control (2): Second control group with differing data collection time points	• Breastfeeding initiation • Women's satisfaction with 'where to ask if any problems with baby or breastfeeding' and 'breastfeeding information' at 3 days and 3 months	Source: Cochrane McFadden The authors did not adjust for cluster design effect. ICC for breastfeeding cessation from Lavender 2005 was used: ICC = 0.01.
Elliott-Rudder 2014 Cluster RCT Australia	N=15 clusters, corresponding to N=330 women • Intervention: 8 clusters, corresponding to n=154 women • Control: 7 clusters, corresponding to n=176 women Characteristics: Women breastfeeding 12% low family income Nulliparous and multiparous Continued breastfeeding to at least 8 weeks	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 but would commonly asked whether the woman had any problems	• Any breastfeeding at 6 months	Source: Cochrane McFadden The authors did not adjust for cluster design effect. ICC for breastfeeding cessation from Lavender 2005 was used: ICC = 0.01.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
Fu 2014 Cluster RCT Hong Kong	N=724 women • Intervention (1): n=191 women • Intervention (2): 269 women • Control: n=264 women Characteristics: Intending to breastfeed Nulliparous	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 (20-30 mins) 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 consultant, one-on-one assistance with breastfeeding if problems arose and time permitted, post discharge follow-up, information on available peer-support groups.	• Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months • Any breastfeeding at 6 months	Source: Cochrane McFadden Excludes 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 giving only breast milk without food or other liquids, with the exception of vitamins or medications.
Gagnon 2002 RCT Canada	N=586 women • Intervention (1): n=292 women • Intervention (2): n=294 women Characteristics: Single pregnancies Breastfed at least once in the hospital	Intervention (1) home contact: Nurse telephone contact at 48 hours post birth and a nurse visit at 3-4 days postpartum in the woman's home Intervention (2) clinic contact: Nurse telephone contact at 48 hours post birth and a nurse visit at 3-4 days' postpartum in the hospital clinic	• Any breastfeeding** at 2 weeks • Exclusive breastfeeding* at 2 weeks • Service satisfaction	Source: Cochrane McFadden *Breast milk only **Mixed (breast milk plus breast milk and formula or water)

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Approximately 89% planning to breastfeed exclusively Nulliparous and multiparous			
Graffy 2004; Graffy 2005 RCT UK	N=720 women • Intervention: n=363 women • Control: n=357 women Characteristics: Women considering breastfeeding who had not breastfed a previous child for 6 weeks Mixed breastfeeding intentions Nulliparous and multiparous	Intervention: 1 antenatal visit from a trained breastfeeding counsellor, who offered postnatal support by telephone or further home visits if requested after the birth Control: Standard care (no details provided)	• Breastfeeding initiation • Any breastfeeding at 6 weeks • Exclusive breastfeeding at 6 weeks • Any breastfeeding at 4 months	Source: Cochrane McFadden and Whitford 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. Exclusive breastfeeding implied that infants received no other liquids or solid foods
Gross 2016 RCT US	N=533 women • Intervention: n=266 women • Control: n=267 women Characteristics: Single pregnancies Low-income	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 3 years old. Consisting of individual 45-60 minutes counselling sessions in the prenatal and newborn periods; nutrition and	• Breastfeeding initiation • Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months	Exclusive breastfeeding defined as breast milk only versus formula only, both formula and breast milk, or ever giving complementary foods or liquids.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Hispanic families Nulliparous and multiparous 29% pre-pregnancy obesity	parenting support groups over the 3 years, handouts and DVDs Control: Standard care to include prenatal visits with obstetrician or nurse midwife, initial individual consultation with a nutritionist. Offered antenatal group childbirth and breastfeeding classes; 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.		
Harari 2018 RCT US	N=58 women • Intervention: n=32 women • Control: n=26 women Characteristics: 75% Hispanic population, 17% African American, 6% White Nulliparous and multiparous Women who intended to breastfeed	Intervention: Breastfeeding peer counselling support programme with texting. Automated text messages that provided breastfeeding education, in addition, texts could be sent to peer counsellor and would be replied to between 8am and 5pm Monday to Friday Control: Breastfeeding peer counselling support programme without texting	• Exclusive breastfeeding at 2 weeks	Source: Cochrane McFadden excluded studies list Participants received $25 for taking part Exclusive breastfeeding defined as the intake of only breastmilk in prior 48 hours, no solids, no water and no other liquids
Henderson 2001 RCT Australia	N=160 women • Intervention: n=80 women • Control: n=80 women Characteristics:	Intervention: Standard care plus postpartum positioning and attachment education (~30mins) provided on a one-to-one basis within the first 24 hours; on each subsequent day in the hospital, the woman's positioning and attachment	• Breastfeeding at 3 months • Breastfeeding at 6 months	Source: Cochrane McFadden excluded studies list

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Single pregnancies Nulliparous women Women who planned to breastfeed	technique was assessed and immediate feedback given Control: Standard postpartum breastfeeding care from hospital midwives (variation in support provided by midwives, often midwives attached the infant for the woman, formal education and assessment of positioning and attachment were not a usual focus)		
Hoddinott 2009; Hoddinott 2010 Cluster RCT UK	N=14 areas, corresponding to N=18858 women • Intervention: n=7 areas, corresponding to n=9747 women • Control: n=7 areas, corresponding to n=9111 women Characteristics: No reported	Intervention: A local area policy that 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.	• Initiation of breastfeeding • Any breastfeeding at 5 to 7 days • Any breastfeeding at 6 to 8 weeks • Satisfaction with intervention	Source: Cochrane McFadden, Balogun Interclass correlation coefficient: 0.003. Breastfeeding initiation defined as having given baby breast milk at least once.
Hoddinott 2012 RCT UK	N=69 women • Intervention (1), proactive calls: n=35 women • Intervention (2), reactive calls: n=34 women Characteristics: Single births	Intervention (1): Proactive telephone calls daily for 1 week following 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	• Any breastfeeding at 6 to 8 weeks • Exclusive breastfeeding at 6 to 8 weeks • Satisfaction with help at home	Source: Cochrane McFadden, Whitford Exclusive breastfeeding defined as no other liquids (except medicines) within the previous 24 hours.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Women living in disadvantaged areas Women initiating breastfeeding Nulliparous and multiparous	proactive calls stopped 14 days after hospital discharge. Intervention (2): 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		
Jolly 2012; MacArthur 2009 Cluster RCT UK	N=2724 women • Intervention: n=1267 women • Control: n=1457 women Characteristics: Nulliparous and multiparous Multi-ethnic, socio-economically disadvantaged population	Intervention: Standard care plus antenatal peer support, and postnatal peer support for women who initiated breastfeeding. Antenatal support was aimed to be 2 support sessions. The support workers were informed when the women were discharged from hospital so that they could contact and visit them within 24-48 hours. 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-based), which included breastfeeding advice. Health visitors also saw women postnatally from 10-14 days, sometimes at home, and gave breastfeeding advice as appropriate. Breastfeeding advice was also available from midwives and peer supporters in the hospital.	• Breastfeeding initiation • Any breastfeeding at 10 to 14 days • Exclusive breastfeeding at 10 to 14 days • Any breastfeeding at 6 weeks • Exclusive breastfeeding at 6 weeks • Any breastfeeding at 6 months • Maternal satisfaction	Source: Cochrane McFadden, Balogun and Lumbigan Exclusive breastfeeding defined in relation to milk, in the absence of any artificial milk feeding. ICC: 0.05 for any breastfeeding at 10 to 14 days); 004 for exclusive breastfeeding at 10 to 14 days; 0.23 for any breastfeeding at 6 weeks; 0.22 for exclusive breastfeeding at 6 weeks; 0.17 for any breastfeeding at 6 months.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
Kools 2005 Cluster RCT Netherlands	N=781 women • Intervention: n=408 women • Control: n=373 women Characteristics: 69% women intended to breastfeed Nulliparous and multiparous	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. Control: Not specified	• Initiation of breastfeeding • Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months • Women's satisfaction with feeding advice	Source: Cochrane McFadden and Lumbigan 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.
Kronborg 2008 Cluster RCT Denmark	N=109 health visitors, corresponding to 1595 women • Intervention: n=52 health visitors, corresponding to 780 women	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. Information booklet given to women.	• Women's satisfaction with intervention	Source: Cochrane McFadden The authors did not adjust for cluster design effect. ICC for breastfeeding

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	• Control: n=57 health visitors, corresponding to 815 women Characteristics: Single pregnancies Nulliparous and multiparous	Control: Standard care, which included 1 or more non-standardised visits by health visitors		cessation given in Kronborg 2007: ICC = 0.02
Labarere 2003 RCT France	N=210 women • Intervention: n=106 women • Control: n=104 women Characteristics: Single pregnancies Nulliparous and multiparous In-hospital breastfeeding mothers	Intervention: Standard care and 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.	• Any breastfeeding at 17 weeks	Source: Cochrane McFadden Excluded Studies
Labarere 2005 RCT France	N=231 women • Intervention: n=116 women • Control: n=115 women Characteristics: Single pregnancies Breastfeeding on the day of discharge Nulliparous and multiparous	Intervention: Standard care and an individual routine outpatient visit in a primary care physician's office within 2 weeks after birth (paediatrician or family physician). Control: Standard care including verbal encouragement to maintain 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	• Initiation of breastfeeding • Any breastfeeding at 12 weeks • Any breastfeeding at 24 weeks	Source: Cochrane McFadden

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
		visits in a primary care physician's office monthly to 6 months of age.		
Laliberte 2016 RCT Canada	N=472 women • Intervention: n=315 women • Control: n=157 women Characteristics: Single pregnancies Women breastfeeding their baby and continued to do so upon discharge Nulliparous and multiparous	Intervention: In addition to standard care, required to attend a postpartum pre-booked appointment scheduled 48 hours after discharge. Option to attend the clinic for further appointments at woman discretion up to 6 weeks following the birth of their baby. Control: Standard care – discharged according to hospital standards. Entitled to receive follow-up care and seek currently available breastfeeding support in the community.	• Any breastfeeding at 2 weeks • Exclusive breastfeeding at 2 weeks • Any breastfeeding at 12 weeks • Exclusive breastfeeding at 12 weeks • Any breastfeeding at 24 weeks • Women's satisfaction	Source: Cochrane McFadden Exclusive breastfeeding defined as the feeding of the infant's mother's breast milk only (including expressed breast milk).
Lutenbacher 2018 RCT US	N=188 women • Intervention (1): n=94 women • Intervention (2), control: n=94 women Characteristics: Self-identified Hispanic women Mean age 30 years Low income – eligible to participate in Maternal Infant Health Outreach Worker programme Approximately 97%	Intervention (1): Implementation of model of care that stresses recognising family strengths and utilising those to address their own family needs. Visits run from pregnancy through to 6 months, consisting of monthly home visits (~1hr) and periodic group gatherings. Intervention (2): Minimal education intervention – distribution of printed educational materials about maternal and infant health. $25 merchandise card given to all participants at the end of each interview.	• Initiation of any breastfeeding • Any breastfeeding at 2 weeks • Exclusive breastfeeding at 2 weeks • Any breastfeeding at 2 months • Exclusive breastfeeding at 2 months • Any breastfeeding at 6 months	$25 merchandise card given to all participants Exclusive breastfeeding not defined

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	reported annual income ≤$15,000			
Maycock 2013 RCT Australia	N=699 couples • Intervention: n=385 couples • Control: n=314 couples Characteristics: Nulliparous and multiparous Over 18 years	Intervention: Aimed at fathers - standard care plus a 2 hour antenatal education small-group session led by a male facilitator and a postnatal social support 6 week-package. The package included printed and promotional materials delivered at weekly intervals. Antenatal education provided information on benefits of breastfeeding, common difficulties breastfeeding mothers may encounter, and the support fathers can offer. Control: Standard care consisting of antenatal education classes and routine hospital and postnatal care	• Any breastfeeding at 6 weeks • Exclusive breastfeeding at 6 weeks	Exclusive breastfeeding defined as full breastfeeding was defined as baby receiving breast milk alone with no additional fluids or solids apart from infrequent vitamins, water, juice or ritualistic feeds; or any breastfeeding
McDonald 2010 RCT Australia	N=849 women • Intervention: n=425 women • Control: n=424 women Characteristics: Single pregnancies Women who intended to breastfeed ~36% low socio-economic status Nulliparous and multiparous	Intervention: 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. Breastfeeding promotional literature and access to an in-house video system to view videos on establishing breastfeeding.	• Initiation of breastfeeding • Any breastfeeding at 6 months	Source: Cochrane McFadden
McLachlan 2016	N=9675 women	Intervention (1): Standard care plus home visit – Maternal and child health nurse (MCHN) early visit to bridge the gap (~7days) between a visit	• Any breastfeeding at 3 months	Source: Cochrane McFadden

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
Cluster RCT Australia	• Intervention (1): n=3335 women • Intervention (2): n=2891 women • Control: n=3449 women Characteristics: Nulliparous and multiparous	by a hospital-midwife and the typical first visit from a MCHN. Intervention (2): Standard care plus home visit and drop in – in addition to the extra 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: Standard care – hospital midwife visit/s 1-2 days after discharge. MCHN home visit 10 days to 2 weeks after birth. Access to other community supports including 24 hour helpline, support from GPs or other health professionals.	• Any breastfeeding at 6 months	The authors adjusted for cluster design effect. ICC = 0.03
McQueen 2011 RCT Canada	N=150 women • Intervention: n=69 women • Control: n=81 women Characteristics: Single pregnancies ~14% women aged 19 years or less Women planning to breastfeed Nulliparous	Intervention: Standard care plus self-efficacy intervention; first session within 24 hours of birth, second session within 24 hour 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	• Any breastfeeding at 8 weeks • Exclusive breastfeeding at 8 weeks	Source: Cochrane McFadden 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

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
				given to comfort baby, but not nutrition).
Muirhead 2006 RCT UK	N=225 women • Intervention: n=112 women • Control: n=113 women Characteristics: Mix of feeding intentions (breastfeeding, formula and undecided) Nulliparous and multiparous	Intervention: Standard care and assigned two peer supporters. Peer supporters visited the mother at least once during the antenatal period and 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.	• Initiation of breastfeeding • Any breastfeeding at 10 days • Any breastfeeding at 6 weeks • Exclusive breastfeeding at 8 weeks • Any breastfeeding at 16 weeks	Source: Cochrane McFadden and Balogun Exclusive defined as no other feeding apart from breastfeeding.
Nilsson 2017 Cluster RCT Denmark	N=3541 women • Intervention: n=2065 women • Control: n=1476 women Characteristics: Single pregnancies Intention to breastfeed Nulliparous and multiparous	Intervention: Mothers were verbally taught breastfeeding techniques along with highlights on a postcard. Mothers were supported postnatally according to the manual and a written pamphlet used during each 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 hour after discharge. Control: Standard care (no details provided)	• Exclusive breastfeeding at 5-7days	Exclusive breastfeeding defined as the infant receiving nothing other than milk from the mother and measured during the past 24 hours.
Paul 2012 RCT US	N=1154 women and 1169 newborns • Intervention: n=576 women, 583 newborns	Intervention: 1 home nurse visit scheduled to occur within 48 hours of discharge (typically 3-5 days postpartum). Additional office visit	• Any breastfeeding at 2 weeks • Any breastfeeding at 2 months	Source: Cochrane McFadden, Whitford

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	• Control: n=578 women, 586 newborns Characteristics: Single and twin pregnancies Nulliparous and multiparous Mean age 25 years Majority non-Hispanic Whites (>80%) 5.6% of babies were late preterm (34 to <37 weeks) Women attempting to breastfeed during the maternity stay and with intent to continue breastfeeding after discharge	scheduled for 1 week after first home visit (typically 5-14 days postpartum). Control: Typical office based care – timing of visit determined by newborn physician.	• Any breastfeeding at 6 months	
Petrova 2009 RCT US	N=104 women • Intervention: n=52 women • Control: n=52 women Characteristics: Single pregnancies Nulliparous and multiparous Low-income – Special Supplemental Nutrition Program For Women,	Intervention: Standard care plus additional breastfeeding education during the pregnancy and post-delivery support. A lactation consultant provided two one-to-one (in person 15-20 min) sessions prenatally. Post-birth, education and support was provided in hospital or by phone after discharge, again at the end of the first or second week and of the first and second month. Women were also asked to contact the lactation consultant if problems arose. Educational material translated into Spanish was also provided.	• Exclusive breastfeeding at 1 week • Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months	Source: Cochrane McFadden Exclusive breastfeeding: breastmilk only or breastmilk and vitamins.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Infants, And Children, WIC participants Primarily Hispanic (88%)	Control: Standard breastfeeding education and support during pregnancy and postpartum, including access to lactation consultant services if any breastfeeding problems arose during the hospital stay.		
Pisacane 2005 RCT Italy	N=280 mother-father dyads • Intervention: n=140 mother-father dyads • Control: n=140 mother-father dyads Characteristics: Mothers and fathers of healthy, full-term infants, considering breastfeeding Nulliparous and multiparous	Intervention: Fathers were offered a face-to-face, 40-minute session about infant feeding by a midwife. 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 health benefits of breastmilk but not on the management of breastfeeding. A leaflet with the main points of the session was provided to fathers.	• Any breastfeeding at 6 months	This intervention was targeted at the fathers of infants, training them to manage commonly-reported breastfeeding complications. Infant feeding was measured in the previous 24 hour period.
Pollard 2011 RCT US	N=86 women • Intervention (1): n=43 women • Control: n=43 women Characteristics: Postpartum women who planned to breastfeed and initiated	Intervention (1): 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.	• Any breastfeeding at 12 weeks • Any breastfeeding at 24 weeks	

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	breastfeeding within 24 hours of birth Primiparous mothers over 6 months postpartum Age range 18-40 years Primarily White origin (>95%)	Control: Standard care (no details provided) All participants had a videotaped educational session before randomisation, which included information on effective breastfeeding practice, infant feeding patterns, use of breast pumps and common barriers to breastfeeding.		
Pugh 1998 RCT US	N=60 women • Intervention: n=30 women • Control: n=30 women Characteristics: Primiparous, postpartum women Diverse socioeconomic status Mean age 24 years Majority White origin (93%)	Intervention: Two home visits by community health nurse (once 3-4 days postpartum and again 12 days postpartum). The first visit followed a structured protocol, the second visit was structured to the specific needs of the mother (about 2 hours). Telephone conversation with lactation consultant between these two nurse visits. Control: Standard care including a home visit at 3 to 4 days	• Any breastfeeding at 6 months	Source: Cochrane McFadden
Pugh 2002 RCT US	N=41 • Intervention: n=21 • Control: n=20 Characteristics: Low income (receiving financial medical assistance support) Predominately (>90%) African American women	Intervention: Standard care plus supplementary visits from community health nurse or peer counsellor team daily in hospital and home visits during weeks 1, 2 and 4 at the team's discretion. Peer counsellors provided telephone support twice weekly through to week 8 and weekly thought to month 6. Control: Standard care that included support from hospital nurses, telephone ''warm line,'' and	• Exclusive breastfeeding at 3 months • Any breastfeeding at 6 months • Exclusive breastfeeding at 6 months	Source: Cochrane McFadden Exclusive breastfeeding not defined.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
		one hospital visit by a lactation consultant if the participant delivered on a weekday		
Pugh 2010 RCT US	N=328 women • Intervention: n=168 women • Control: n=160 women Characteristics: Single pregnancies Nulliparous and multiparous Mean age 23 years Predominantly African American (approximately 87%) Low-income (participating in Special Supplemental Nutrition Program For Women, Infants, And Children, WIC) Currently breastfeeding with intention to continue	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 (calls lasted 20 mins on average). Contact number for nurse 24hrs. Additional home visits or telephone support provided if decided by community nurse Control: Standard care including inpatient visit by lactation consultant. Post-discharge, lactation consultant was also available via an answering machine checked at least every 24 hours and office visit with lactation consultant could be requested.	• Any breastfeeding at 12 weeks • Any breastfeeding at 24 weeks	Source: Cochrane McFadden
Quinlivan 2003 RCT Australia	N=136 women • Intervention: n=71 women • Control: n=65 women Characteristics: Nulliparous Adolescent women (younger than 18 years)	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 followed a structured protocol and lasted 1–4 hours. Midwives were able to contact the clinic obstetrician if urgent advice was needed, and make referrals.	• Initiation of breastfeeding • Any breastfeeding at 12 weeks • Any breastfeeding at 24 weeks	Source: Cochrane McFadden

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
		Control: Routine postnatal support, counselling, and information services provided by the hospital, including access to routine hospital domiciliary home-visiting services		
Rasmussen 2011 RCT US	N=50 women • Intervention: n=25 women • Control: n=25 women Characteristics: Single pregnancies Obese women (pre-pregnancy BMI >29 kg/m2) Aged at least 19 years Intention to breastfeed	Intervention: Phone call from lactation consultant before birth and at 24 to 72 hours after discharge. The lactation consultant asked questions, reviewed practical points about breastfeeding, addressed any issues and was able to book a face-to-face visit if needed. Scripts were followed. After birth, nurses encouraged women to get up and move and asked visitors to leave to allow the mother privacy to breastfeed and bond with the infant. Control: Standard care and a phone call from the lactation consultant before birth to thank women for their participation and asking if they had any questions	• Initiation of breastfeeding • Duration of exclusive breastfeeding • Exclusive breastfeeding at 7 days • Duration of any breastfeeding • Any breastfeeding at 30 days • Exclusive breastfeeding at 30 days • Any breastfeeding at 90 days	Data on additional comparison, receiving a breast pump versus no pump, not to be extracted Exclusive breastfeeding defined as the duration between the infant's data of birth / or data of discharge from hospital and the data when the infant was first given anything other than breastmilk
Redman 1995 RCT Australia	N=235 women • Intervention: n=120 women • Control: n=115 women Characteristics: Nulliparous Aged between 18-35 years Women intending to breastfeeding	Intervention: Both group and individual sessions delivered by a nurse with midwife and lactation qualifications to include 3 hours teaching session at 24-28 weeks gestation, postnatal hospital visit, phone call at 2-3 weeks, home visit if requested, discussion group at 6-8 weeks postpartum, phone call at 3 months, access to consultant at any point. Control: Standard advice about breastfeeding from their doctor, the hospital staff and from the Antenatal/Preparation for Parenthood classes.	• Any breastfeeding at 6 weeks • Any breastfeeding at 4 months	Source: Cochrane McFadden

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
Reeder 2014 RCT US	N=1948 women • Intervention (1): n=646 women • Intervention (2): n=645 women • Control: n=657 women Characteristics: Nulliparous or multiparous Low-income (participating in Special Supplemental Nutrition Program for Women, Infants, and Children, WIC) Intended to breastfeed or were considering breastfeeding	Intervention (1): Low frequency telephone peer counselling– 4 planned, peer-initiated calls. One after the initial prenatal assignment, another 2 weeks before due date. Final two are at 1 and 2 weeks postpartum Intervention (2): High frequency telephone peer counselling – 8 planned, peer-initiated calls, two prenatally and one at 1 and one at 2 weeks postpartum. Remaining four scheduled for months 1, 2, 3 and 4. Control: Standard breastfeeding promotion and support. No contact with a peer counsellor.	• Exclusive breastfeeding at 3 months	Source: Cochrane Balogun and Whitford For the analysis two treatment arms were combined because there was no difference in the distribution of peer contacts. Exclusive breastfeeding was derived from the first time that the mother reported she had stopped breastfeeding or introduced formula.
Sandy 2009 RCT US	N=238 women • Intervention: n=137 women • Control: n=101 women Characteristics: Single pregnancies Low income 16% were young women, mean age 26 years (range 16-41)	Intervention: Weekly antenatal home visits from family support worker. Visits involved providing women with information about pregnancy, prenatal care, childbirth, explanation of breastfeeding mechanics and provision of written information on breastfeeding. Written information was provided in Spanish and English Visit by family support worker in hospital to assist initiation of breastfeeding and then weekly visits at home. Home visit by paediatric resident, in part to motivate women to breastfeed. Family support workers could refer mothers to local lactation clinic.	• Any breastfeeding at 1 week • Exclusive breastfeeding at 1 week	Source: Cochrane Balogun Participants for this study were a subsample of families participating in Best Beginnings, a primary prevention home visitation programme. Exclusive breastfeeding not defined.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Predominately urban Latina immigrant population, 88% born outside US Nulliparous and multiparous	Control: 1 or 2 visits during prenatal. Provided with information about community services, educational booklets and pamphlets covering childbirth, child rearing and infant feeding methods but no discussion on the booklets content or active promotion of breastfeeding.		
Sciacca 1995 RCT US	N=68 women • Intervention: n=34 women • Control: n=34 women Characteristics: Low income (participating in Special Supplemental Nutrition Program for Women, Infants, and Children, WIC) Predominately White (approximately 65%) Nulliparous women Participating in study with partner	Intervention: Standard care and a 2 hour couples breastfeeding class, where gifts were given to the woman and her partner. In addition, the standard five 1 hour sessions on childbirth preparation as the control group, but the intervention group received incentives for attending at least 3 of 5 sessions. Additional incentives were given for making contact with peer supporter and maintaining breastfeeding. 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, a box of baby wipes, a bag of diapers. 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 given at clinics. This include five 1 hour sessions on childbirth preparation, promotion of breast pump rental service, optional 15 minute breastfeeding	• Any breastfeeding at 2 weeks • Exclusive breastfeeding at 2 weeks • Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months	Exclusive breastfeeding not defined.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
		group class, 1 prenatal and 3 postnatal contacts (at 2 days, 2 weeks and 2 months postpartum) from peer supporters		
Simonetti 2012 RCT Italy	N=114 women • Intervention: n=55 women • Control: n=59 women Characteristics: Nulliparous women Intending to breastfeed	Intervention: Prenatal Ten Steps to Successful Breastfeeding teaching as per control plus structured telephonic counselling from midwife at least once a week over the first 6 weeks after birth. Able to call the 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 midwife as necessary	• Exclusive breastfeeding at 3 months • Exclusive breastfeeding at 5 months	Source: Cochrane McFadden Exclusive breastfeeding: baby received breastmilk as it's only source of nutrition
Srinivas 2015 RCT US	N randomised=120 women N randomised to each group not reported N analysed=103 women • Intervention: n=50 women • Control: n=53 women Characteristics: Nulliparous and multiparous Majority non-White origin Low income – participating in Special Supplemental Nutrition Program for Women, Infants, and Children, WIC and	Intervention: Standard care plus contact from a peer counsellor, initially between 28 weeks gestation and 1 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: Standard care including access to lactation consultants in hospital and outpatient lactation support from clinic paediatricians and nutritionist.	• Initiation of breastfeeding • Any breastfeeding at 6 months • Satisfaction with intervention	Source: Cochrane McFadden and Balogun $10 incentive for taking part in demographic survey

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	majority on public insurance 82% planning to breastfeed			
Steel O'Connor 2003 RCT Canada	N=733 women • Intervention (1), home visits: n=353 women • Intervention (2), telephone screen: n=380 women Characteristics: Single pregnancies Nulliparous Discharged within 2 days of birth	Intervention (1): Two structured home visits by public health nurse, scheduled on the first working day following discharge. One home visit was scheduled as soon as possible, the other one within 10 days of discharge. Referrals to other support services were made if need identified by mother or nurse. Intervention (2): Screening telephone call by public health nurse on the first working day following discharge. A home visit or referrals followed if a need was identified. Otherwise women were provided with a phone number to call if they wished further support	• Any breastfeeding at 2 weeks • Any breastfeeding at 4 weeks • Any breastfeeding at 6 months	The interventions were not only focused on breastfeeding but breastfeeding was among the main aims of the interventions
Stockdale 2008 RCT Northern Ireland	N=182 women • Intervention: n=93 women • Control: n=89 women Characteristics: Nulliparous	Intervention: Infant feeding class (32-36 weeks gestation), antenatal breastfeeding information book, breastfeeding CD-ROM and postnatal instructional support provided by midwives up to 3 weeks postnatally and additional lactation consultancy on request Control: Standard care (no details provided)	• Initiation of breastfeeding • Exclusive breastfeeding at 3 weeks	Source: Cochrane McFadden Exclusive breastfeeding: baby is being exclusively breastfed and has been for previous 48 hours
Su 2007 RCT Singapore	N=450 women • Intervention (1): n=150 women • Intervention (2): n=149 women	Intervention (1): One session of antenatal breastfeeding education – including a 16 minute educational video, printed handouts and opportunities to talk to lactation counsellor for	• Any breastfeeding at 2 weeks • Exclusive breastfeeding at 2 weeks	Source: Cochrane McFadden Exclusive breastfeeding: only

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	• Control: n=151 women Characteristics: Single pregnancies. Nulliparous and multiparous Women who stated an intention to breastfeed Ethnicity: 38% Chinese, 48% Malay, 11% Indian, 3% other	~15 minutes. Subsequently received routine intrapartum and postnatal obstetric care. Intervention (2): Two sessions ~30 minutes 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 when they were also given printed handouts on breastfeeding. Control: Standard care that included optional antenatal classes that did address infant feeding and postnatal visits by a lactation consultant should problems arise	• Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months • Any breastfeeding at 6 months	breast milk given to baby. Medicines, vitamins, and oral rehydration solution may be given but no formula or water.
Vidas 2011 RCT Croatia	N=100 women • Intervention: n=50 women • Control: n=50 women Characteristics: Currently breastfeeding Child had up to 2 months breastfeeding	Intervention: Autogenic training. Every two weeks mothers practiced a new exercise. The 6 basic exercises of autogenic training were taught for 12 weeks in small groups. Mothers were encouraged to practice three times a day at home, until child was 6 months old. Control: Standard care (no details provided)	• Intervention satisfaction • Duration of breastfeeding • Any breastfeeding at 6 months	Source: Cochrane McFadden
Wallace 2006 RCT UK	N=370 women • Intervention: n=188 women • Control: n=182 women Characteristics:	Intervention: Verbal advice about initiation of feeding, positioning and attachment, delivered at the first postnatal ward feed, by a trained midwife. A leaflet explained this information and also reminded mothers that their baby needed only breast milk until at least 4 months post-partum.	• Any breastfeeding at 6 weeks • Exclusive breastfeeding at 6 weeks • Any breastfeeding at 17 weeks	Slow recruitment meant that trial only reached 370 participants, rather than the 600 suggested by power

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Intended to breastfeed Nulliparous	Control: Standard care followed each maternity unit's policy, which did not stipulate advice about positioning, attachment nor verbal-only care. Additional breastfeeding advice leaflets were available to mothers and staff in line with the local policy.		calculations. Mainly due to staffing issues. Exclusive breastfeeding defined as those who only gave breastmilk
Wambach 2011 RCT US	N=390 women • Intervention: n=128 women • Control (1): n=134 women • Control (2): n=128 women Characteristics: Single pregnancies Nulliparous Aged between 15-18 years Low income (family income <$25,000 per year) Breastfeeding initiated within first 48 hours postpartum	Intervention: Lactation consultant and trained peer counsellor provided education support prenatally (two classes 1.5 and 2 hours in length), in-hospital visit from the peer counsellor and postnatal education through to 4 weeks postpartum. Mothers were encouraged to bring partners along with them to the classes. Telephone calls from peer counsellor and/or lactation consultant before class 1 and following class 2 and also at 4, 7, 11, 18 days and 4 weeks. Free electric breast pump provided as needed. Control (1): Standard care – received standard prenatal and postpartum care at respective clinic with varying provider types and birth settings Control (2): Attention control group – used to control for nonspecific effects of treatment. Same treatment pattern as intervention with prenatal education classes, but focused on healthy pregnancy and birth preparation and maternal transition and postpartum adaptations. All control mothers received peer counsellor prenatal support and in-hospital peer counsellor	• Initiation of breastfeeding	Source: Cochrane McFadden and Balogun (Wambach 2011 in Balogun) Participants received $10-$20 following enrolment, attendance at each intervention session and completion of each data collection period.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
		visit but only mother's breastfeeding on discharge received postpartum telephone calls from peer counsellors. These were provided on the same schedule as intervention.		
Wen 2011 RCT Australia	N=667 women • Intervention: n=337 women • Control: n=330 women Characteristics: Nulliparous Mean age 26 years (range 16-47)	Intervention: Staged intervention lasting one year. 6 home visits from community nurse – once at 30-36 weeks gestation and then after birth at 1, 3, 5, 9, 12 months. Each visit lasted 1-2 hours and addressed infant feeding practices and infant nutrition. Control: Standard care to include one nurse home visit within 1 month of birth if needed.	• Any breastfeeding at 6 months	Source: Cochrane McFadden Breastfeeding: child receiving breastmilk regardless of whether other solid foods or liquids are also being received.
Wilhelm 2015 RCT US	N=53 women • Intervention: n=26 women • Control: n=27 women Characteristics: Single pregnancies Self-identified Mexican-American women Mean age 24 years (range 15-50) Majority low income – 91% had annual income <$20,000, 58% <$10,000 Currently breastfeeding at recruitment stage	Intervention: Motivational interviewing delivered during home visit at 3 days and booster sessions delivered during visits at 2 weeks and 6 weeks postpartum. Control: Attention control - Mothers given educational information about different aspects of infant safety during the 3 visits. Includes information on fall prevention, poisoning, drowning and car seat safety. Spanish language research materials and an interpreter were available as needed for all sessions.	• Mean breastfeeding duration • Any breastfeeding at 6 months	Source: Cochrane McFadden

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
		All mothers received a manual breast pump at the beginning of the study and a box of diapers at the end of the study as incentives.		
Wilhelm 2006 RCT US	N=73 women • Intervention: n=37 women • Control: n=36 women Characteristics: Primiparous Currently breastfeeding at recruitment Mean age 25 years (range 19-38) Primarily White origin (approximately 89%)	Intervention: Standard care plus motivational interviewing. Initial intervention delivered at days 2-4. 2 booster sessions were delivered during 2 and 6 week outpatient visits Control: Standard care, consisting of breastfeeding assessment plus a lactation consultant troubleshooting problems. Provided during hospital stay and subsequent visits	• Any breastfeeding at 6 months	
Avoidance of foreign objects (Intervention 3)				
Jenik 2009 RCT Argentina	N=1021 women • Intervention: n=493 women • Control: n=528 women Characteristics: Postpartum women who intended to breastfeed for at least 3 months Women had no preferences regarding the use (or not) of pacifiers. Infants exclusively breastfed until	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. Pacifiers were avoided by all for the first two weeks	• Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months • Any breastfeeding at 4 months	Source: Cochrane Jaafar Infants exclusively breastfed received breast milk only. No other liquids (other than vitamins or medications) or solid foods were given. Partially breastfed infants received formula or semisolids in addition to breast

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	recruitment at 2 weeks old.			milk. Any breastfeeding included both the above.
Kramer 2001 RCT Canada	N=281 women • Intervention: n=140 women • Control: n=141 women Characteristics: Single pregnancies Postpartum women who intended to breastfeed for at least 3 months Primiparous and multiparous	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 also received a 45-minute session and information sheet on 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.	• Exclusive breastfeeding at 3 months	Source: Cochrane Jaafar Exclusive breastfeeding not defined.
Schlickau 2005 RCT US	N=20 women • Intervention (1): n=10 women • Intervention (2): n=10 women Characteristics: Primiparous women Mean age 22 years (between 16-45) Hispanic women Low risk	Intervention (1): 1 hour teaching session on breastfeeding, 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 on breastfeeding as per intervention (1), additional teaching session on breastfeeding and baby quarantine (nothing enters the baby's mouth, except the mother's breast, for at least 40 days after birth); the benefits of avoiding bottles, pacifiers and supplementation to	• Any breastfeeding at 45 days	Source: Cochrane Lumbiganon

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
		promote establishment of breastfeeding were reinforced; breastfeeding commitment was encouraged with the use of a checklist. This study also included an additional standard care arm which is presented in the section of the table focusing on Intervention 1.		
Schubiger 1997 RCT Switzerland	N= 602 women • Intervention: n=294 women • Control: n=308 women Characteristics: Primiparous and multiparous Postpartum women who intended to breastfeed for 3 months or more	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. Breastfeeding was actively encouraged in both groups.	• Any breastfeeding at 2 months • Any breastfeeding at 6 months	Source: Cochrane Jaafar 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 milk with

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
				additional formula or beikost.
Financial incentives (Intervention 4)				
Relton 2018 Cluster RCT UK	N=92 areas, corresponding to n=9207 women included in the analysis (analysis was based on areas, not women) • Intervention: n=46 areas, corresponding to n=4973 women analysed • Control: n=46 areas, corresponding to n=4234 women analysed Characteristics: Predominately White (>95%) population The mean area-level deprivation scores were higher (more deprived) than the mean for England	Intervention: Standard 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. A web-app postal address checker and a booklet detailing the scheme were distributed to children centres and other public places. Control: Standard care (no details provided)	• Initiation of breastfeeding • Any breastfeeding at 6-8 weeks • Exclusive breastfeeding at 6-8 weeks	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). Exclusive breastfeeding not defined.
Sciacca 1995 RCT US	N=68 women • Intervention: n=34 women • Control: n=34 women	Intervention: Standard care and a 2 hour couples breastfeeding class, where gifts were given to the woman and her partner. In addition, the standard five 1 hour sessions on childbirth preparation as the control group, but the	• Any breastfeeding at 2 weeks • Exclusive breastfeeding at 2 weeks	Exclusive breastfeeding not defined.

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Characteristics: Nulliparous women interested in participating with infant's father or other supportive partner Predominately White Low income – enrolled in Special Supplemental Nutrition Program for Women, Infants, and Children, WIC programme	intervention group received incentives for attending at least 3 of 5 sessions. Additional incentives were given for making contact with peer supporter and maintaining breastfeeding. 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, a box of baby wipes, a bag of diapers. 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 given at clinics. This include five 1 hour sessions on childbirth preparation, promotion of breast pump rental service, optional 15 minute breastfeeding group class, 1 prenatal and 3 postnatal contacts (at 2 days, 2 weeks and 2 months postpartum) from peer supporters	• Any breastfeeding at 3 months • Exclusive breastfeeding at 3 months	
Washio 2017 RCT US	N=36 women • Intervention: n=18 women • Control: n=18 women Characteristics: Primiparous and multiparous women	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 potential earning was $270 for breastfeeding for 6 months Control: Standard breastfeeding services from women and infant centre programme. Services	• Any breastfeeding at 3 months • Any breastfeeding at 6 months	

Study	Population (n randomised)	Intervention and comparator	Outcomes	Comments
	Self-identified Puerto Rican women Low-income – enrolled in Special Supplemental Nutrition Program for Women, Infants, and Children, WIC programme Currently breastfeeding	included on-site lactation consultation, bilingual peer counselling, weekly peer support meetings, free breast pump, enhanced food package for breastfeeding mothers. All participants in both study groups were compensated $25 per assessment, regardless of breastfeeding status. This equalled a total potential earning of $100 for completing follow-up.		

BMI: Body Mass Index; ICC: intraclass correlation coefficient; MCHN: Maternal and child health nurse; RCT: Randomised controlled trial; WHO: World Health Organisation; WIC: Women, Infant and Children

See the full evidence tables in appendix D and the forest plots in appendix E.

Quality assessment of studies included in the evidence review

See the clinical evidence profiles in appendix F.

Economic evidence

Included studies

Five economic studies were identified which were relevant to this question (Anokye 2020, Frick 2012, Hoddinott 2009 & 2012, Stevens 2006).

A single economic search was undertaken for all topics included in the scope of this guideline. See the literature search strategy in appendix B and economic study selection flow chart in appendix G.

Excluded studies

Six studies were reviewed at full text and excluded from this review. Economic studies not included in this review are listed, and reasons for their exclusion are provided, in appendix K.

Summary of studies included in the economic evidence review

Anokye 2020

Anokye (2020) conducted an economic analysis alongside a cluster RCT (Relton 2018) to assess the cost-effectiveness of financial incentives on breastfeeding provided to women with newborn healthy babies living in areas with low breastfeeding prevalence (<40% at 6-8 weeks) in England. Up to five vouchers (£40 each) were offered to women if their baby was receiving breastmilk at the following ages: 2 days, 10 days, 6 weeks, 3 months and 6 months. The comparator was standard care, where no financial incentives were offered.

The study sample comprised 10,010 woman-baby dyads. The analysis adopted a healthcare perspective and considered intervention costs only, comprising set up and voucher delivery costs. National unit costs and further administrative cost data were used. The primary outcome of the trial was the proportion of any breastfeeding at 6-8 weeks postpartum.

The RCT showed a higher proportion of women breastfeeding at 6-8 weeks postpartum in the intervention group compared with standard care, a difference that was statistically significant (0.06 risk difference, p<0.001). The mean intervention cost per woman in the intervention group was £91.45 (2016 prices). The cost per additional baby breastfed at 6–8 weeks was £974. The authors estimated that at a cost-effectiveness threshold of £20,000/quality-adjusted life-year (QALY) or £30,000/QALY, an additional breastfed baby would need to show a lifetime total QALY gain to the baby and/or woman of 0.05 or 0.03, respectively, to justify the intervention cost. The probability of the intervention being cost-effective was 0.54 at a cost-effectiveness threshold of £1,000 per additional baby breastfed at 6-8 weeks; 0.94 at a cost-effectiveness threshold of £1,500; and 0.99 at a cost-effectiveness threshold of £2,000.

The study is partially applicable to the NICE decision-making context because although it was conducted in England, the measure of benefit was not the QALY and

therefore further judgments are required in order to draw conclusions on the cost-effectiveness of the intervention. The study is characterised by potentially serious limitations including the short time horizon and the consideration of intervention costs only.

Hoddinott 2009

Hoddinott (2009) conducted an economic analysis alongside a cluster RCT (Hoddinott 2009 & 2012) to assess the cost-effectiveness of the implementation of new breastfeeding groups set up to provide population coverage in Scotland. The comparator was standard care, where women were not offered additional group support. The groups were aimed at pregnant or breastfeeding women registered with general practices in relatively deprived areas of Scotland. Group meetings, which were run weekly, were facilitated by a health professional and aimed at promoting initiation and maintenance of breastfeeding; at least 50% of the group meeting time was social and interactive.

Fourteen localities in Scotland that routinely collected breastfeeding outcome data participated in the trial. These served 18,603 eligible women (pregnant or breastfeeding); 1,310 women attended the breastfeeding groups in total, of whom 74 attended from nonparticipating general practices, and 138 attended from control locality general practices. At randomisation, both intervention and control localities had 10 breastfeeding groups each; after implementation of the policy, intervention localities increased breastfeeding groups from 10 to 27, whereas control localities remained unchanged with 10 groups.

The analysis adopted a healthcare perspective and considered intervention costs only, exclusively relating to staff time, including travel time. The source of unit costs was unclear, but it is likely that national unit costs were used. The primary outcome of the trial was the proportion of any breastfeeding at 6-8 weeks postpartum, measured at locality level two years before intervention and two years after the policy was implemented.

The RCT did not show any statistically significant differences in outcomes between the practices implementing the policy and those that maintained standard care. At baseline (2 years before intervention), the proportion of any breastfeeding in practices implementing the policy was 0.27, which was reduced to 0.26 at 2 years after implementation. In control practices, the proportion of any breastfeeding was 0.29 at 2 years before intervention and increased at 0.30 at trial endpoint (2 years after implementation of policy). This translated into a difference of -0.017 (p=0.08), adjusted for pre-trial proportions. Each woman of those attending a breastfeeding group did so with a median of 4 times. The mean intervention cost was £13,400 per locality annually or £143 per woman attending the group intervention (2005/06 prices).

The results suggest that a policy for providing increased coverage for breastfeeding groups in relatively deprived areas is not cost-effective, as it does not improve breastfeeding rates at 6-8 weeks. The study is directly applicable to the NICE decision-making context as it was conducted in Scotland, where the healthcare setting is very similar to that of England, and although the measure of benefit was not the QALY, lack of estimation of QALYs had no impact on the interpretation of the results since the two arms of the RCT had very similar outcomes (so, in effect, the study was a cost-minimisation analysis). The study is characterised by potentially serious limitations. The most important limitation is the fact that the control localities also offered the intervention (breastfeeding groups), albeit to a more limited extent, which may have contaminated the results. The study findings may indicate that the

level of coverage of breastfeeding groups at baseline was adequate to engage women in relatively deprived areas who intend to start/maintain breastfeeding, leading to optimal breastfeeding rates for this intervention (breastfeeding groups), and therefore increasing the number of established breastfeeding groups has no further impact on breastfeeding rates. Another limitation of the study is the consideration of intervention costs relating to staff time only. It is possible that women attending breastfeeding groups have less contact with healthcare and other community services, resulting in cost-savings elsewhere in the care pathway. Moreover, no sensitivity analysis was conducted around costs and no uncertainty in costs was reported.

Hoddinott 2012

Hoddinott (2012) conducted an economic analysis alongside an RCT (Hoddinott 2012, N=69; completers n=59) to assess the cost-effectiveness of proactive and reactive telephone support versus reactive only telephone support at home for up to 14 days after hospital discharge, in women living in disadvantaged areas of Scotland who breastfed at hospital discharge. The analysis adopted a healthcare perspective and considered intervention costs only, exclusively relating to staff time (telephone ward contact and case note /discussion time). The source of unit costs was unclear, but it is likely that national unit costs were used. The primary outcome of the trial was the proportion of any breastfeeding at 6-8 weeks postpartum.

At 6-8 weeks postpartum, the proportion of any breastfeeding was 0.69 for the intervention and 0.46 for control, a difference that did not reach statistical significance (risk ratio [RR] 1.49, 95%CI 0.92 to 2.40). The staff time cost per woman was £41.25 for the intervention group and £21.13 for the control group, a difference of £20.12 (likely 2010 prices). This translates into an incremental cost-effectiveness ratio (ICER) of £87 per additional woman breastfeeding at 6-8 weeks postpartum. Costs were sensitive to service organisation, that is, the type of staff providing the intervention and the time and hours of coverage during the day.

The study is partially applicable to the NICE decision-making context because, although it was conducted in Scotland, it did not use the QALY as the measure of outcome, which makes the interpretation of the ICER and the judgement of the cost-effectiveness of the intervention difficult. It is also characterised by potentially serious limitations, mainly the small size of the study sample, the high attrition rate and the fact that the attrition rate differed between the two groups. Another limitation of the study is the consideration of intervention costs relating to staff time only, and its short time horizon, both of which may have not allowed estimation of potential cost-savings further and elsewhere in the care pathway. Moreover, the uncertainty around the ICER was not reported.

Frick 2012

Frick (2012) conducted an economic analysis alongside an RCT (Pugh 2010, N=328; completers at 6 weeks postpartum=280; at 24 weeks postpartum=243) to assess the cost-effectiveness of an intervention aimed at promoting breastfeeding versus treatment as usual for low-income breastfeeding women of full-term babys in the US. The intervention comprised provision of a prescribed programme of support and education for the first 24 weeks postpartum, which included daily postpartum hospital visits by a breastfeeding support team until discharge, three 45-60 minute home visits in the first 4 postpartum weeks, telephone support through a scheduled telephone call by the peer counsellor at least every two weeks until 24 weeks postpartum, and 24-hour pager access over 24 weeks postpartum. If in the

community nurse's professional judgment the woman warranted more support than prescribed, additional home visits or telephone support were provided. Treatment as usual comprised access to an inpatient visit by a lactation consultant (LC) for breastfeeding women, a hospital-based LC available post-discharge via a telephone "warm-line" (an answering machine checked at least every 24 hours), and access to a post-discharge office visit with the LC upon request. The analysis adopted a healthcare perspective and considered intervention costs only, exclusively relating to staff time including travel/mileage, although data on wider healthcare resource use were collected. National unit costs were used. The primary outcome of the trial was the proportion of any breastfeeding at 6, 12 and 24 weeks postpartum.

At 6 weeks postpartum, the proportion of any breastfeeding was 0.67 for the intervention and 0.57 for treatment as usual, a statistically significant difference (odds ratio [OR] 1.71, 95% CI 1.07 to 2.76, p=0.05); at 12 and 24 weeks postpartum there were no statistically significant differences between intervention and treatment as usual (0.49 versus 0.41, p=0.07 at 12 weeks; 0.29 versus 0.28, p=0.46 at 24 weeks postpartum). The mean intervention cost per woman was $296.45 (range from $274.12 to $320.97) in 2009 US$. This translates into an estimated ICER of: $3,025 per additional woman breastfeeding at 6 weeks postpartum; $3,369 at 12 weeks postpartum; and $26,950 at 24 weeks postpartum. Healthcare resource use was similar for the intervention and treatment as usual groups; where there were statistically significant differences between the two groups, the intervention group used fewer resources.

The study is partially applicable to the NICE decision making context as it was conducted in the US and the measure of outcome was not the QALY, which makes the interpretation of the ICER and the judgement of the cost-effectiveness of the intervention difficult. It is also characterised by potentially serious limitations, mainly the consideration of intervention costs relating to staff time and travel only, which may have not allowed estimation of potential cost-savings elsewhere in the care pathway. However, measurement of resource use indicated use of fewer resources (other than the intervention) by the intervention group, although the study was not powered to detect cost differences. Another limitation of the study is that the ICER was not reported (it was estimated based on reported cost and outcome data), and therefore the uncertainty around the ICER was also not reported.

Stevens 2006

Stevens (2006) conducted an economic analysis alongside an RCT (McKeever 2002, N=138, 101 term and 37 near term babies; n=102 completers, 75 term and 27 near-term babies) to assess the cost-effectiveness of early hospital discharge (24-36 hours postpartum) combined with home-based support (2-3 visits) from certified nurse lactation consultants versus standard hospital discharge (48-60 hours postpartum) combined with hospital-based support by nurse lactation consultants in women with term or near-term (35-37 weeks gestational age) babys in Canada. The analysis adopted a healthcare and family perspective (the latter assessing out-of-pocket expenses and time costs of unpaid caregivers); healthcare and family costs were reported separately. Healthcare costs were measured from birth and up to 7 days postpartum and included hospitalisation, ambulatory and home-based appointments with healthcare professionals, medication, laboratory testing, equipment and supplies provided by the hospital, emergency visits, telephone calls to the 24-hour help line, and visits and telephone calls to the breastfeeding clinic or to community practitioners. National unit costs were used. The primary outcome of the trial was the proportion of exclusive breastfeeding at follow-up (5-12 days postpartum).

The proportion of exclusive breastfeeding at follow-up for term babies was 0.95 for the intervention group and 0.74 for the control group (p=0.02); for near-term babies it was 0.73 for the intervention group and 0.68 for the control group (p=1.00). Regarding costs, for term babies the mean cost of hospitalisation for giving birth was $2,529 for the intervention group and $2630 for the control group (p=0.22) in 2002 Canadian dollars; the mean post-discharge healthcare cost was $179 for the intervention group and $61 for the control group (p<0.0001). For near-term babies the mean cost of hospitalisation for giving birth was $2,692 for the intervention group and $2,686 for the control group (p=0.73); and the mean post-discharge healthcare cost was $223 for the intervention group and $538 for the control group (p=0.57). Based on these results, the estimated ICER was $81 per additional term baby exclusively breastfeeding; for near-term babies the intervention was the dominant option, since it was overall less costly (regarding total healthcare costs) and more effective. Results were characterised overall by high uncertainty, especially in the near-term baby sub-group, due to the low number of study participants.

The study is partially applicable to the NICE decision-making context as it was conducted in Canada and the measure of outcome was not the QALY, which makes the interpretation of the ICER and the judgement of the cost-effectiveness of the intervention difficult. It is also characterised by potentially serious limitations, mainly due to the small study sample, especially for the near-term baby sub-group, which resulted in lack of statistical power. Moreover, the time horizon of the analysis was very short for the measurement of both costs and outcomes. Another limitation of the study is that the ICER was not reported (it was estimated based on reported cost and outcome data), and therefore the uncertainty around the ICER was also not reported.

See the economic evidence table in appendix H and the economic evidence profile in appendix I.

Economic model

A decision-analytic model was developed to assess the cost-effectiveness of an intervention for women, initiated antenatally or in the first 8 weeks after birth, aiming at starting and/or maintaining breastfeeding. The intervention was provided in addition to standard care and was compared with standard care alone. Details of the economic modelling are provided in appendix J. This section provides a summary of the methods employed and the results of the economic analysis.

Overview of economic modelling methods

The characteristics of the intervention assessed in the economic analysis, in terms of effectiveness and resource use (number of sessions, format, people delivering the intervention, etc.), were determined by the findings of the guideline systematic review and meta-regression undertaken to inform the review questions (described in appendix M), supplemented by the committee's expert opinion on patterns of routine practice regarding postnatal care in the UK. The intervention comprised education, advice or support from a peer or professional provided postnatally and was initiated either antenatally or within the first eight weeks after birth. Standard care in the RCTs that informed the economic analysis ranged from no intervention, through written materials and peer breastfeeding support, to availability of breastfeeding educational programmes of variable intensity in-hospital or in the community. In the UK NHS, standard care is also variable and may include provision of written material, antenatal breastfeeding educational programmes, and postnatal breastfeeding support groups run by peers and/or health professionals; in some settings breastfeeding information

and support is provided by midwives and/or health visitors as part of routine postnatal care visits.

The relative effect (RR) of the intervention added onto standard care versus standard care alone on any breastfeeding at 16-26 weeks after birth was 1.19 (95% CI 1.01 to 1.29). The intervention consisted of 6 face-to-face contacts, comprising 4 individual and 2 group sessions. The first two individual sessions were assumed to be provided by a health professional in NHS England Agenda for Change Band 5, while the remaining sessions were assumed to be provided by a volunteer trained peer supporter.

A hybrid decision-analytic model consisting of a decision-tree followed by 3 further decision trees and 2 Markov models, each representing a clinical condition that has been associated with breastfeeding, was constructed to evaluate the relative cost-effectiveness of the breastfeeding intervention in the long term. The time horizon of the analysis ranged from 1 year to lifetime, depending on the clinical condition modelled. The structure of the economic model was based, for the majority of the assessed outcomes, on a UK modelling study that estimated long-term benefits and cost-savings associated with breastfeeding that was commissioned by UNICEF UK. Effectiveness data on the protective effect of breastfeeding in women and babies were derived from published systematic reviews and meta-analyses, identified from a systematic review undertaken for the guideline, most of which reported results adjusted for known confounders. Epidemiological data utilised in the model, including baseline breastfeeding rates (that is, breastfeeding rates under standard care) were derived from national statistics and large administrative databases. Utility data were estimated based on national UK norms and a published systematic review and meta-analysis. Cost data were taken from national sources and other published literature.

The clinical conditions considered in the model were determined by the availability of relevant clinical data on the protective effect of breastfeeding in women and babies, as identified from the systematic review that was undertaken for this purpose. The following clinical conditions were modelled:

- clinical conditions in babies:
  - gastrointestinal infection
  - respiratory tract infection
  - acute otitis media
  - mortality due to infectious diseases
  - mortality due to SIDS (sudden infant death syndrome)
- clinical conditions in women:
  - breast cancer.

According to the model structure, hypothetical cohorts of women who are pregnant or have given birth to healthy babies at term were either initiated on a breastfeeding intervention in addition to standard care, or received standard care only. Following care received, women either breastfed or they did not breastfeed at 16-26 weeks after birth. Women and their babies were subsequently followed for a period of time that ranged from 1 year after birth to lifetime, depending on the clinical condition assessed, to estimate their outcomes and costs associated with each of the clinical conditions considered, resulting from the women and babies' breastfeeding status at 16-26 weeks after birth.

The economic analysis adopted the perspective of the NHS and personal social services (PSS). Costs consisted of the intervention cost (healthcare professional time) and costs associated with breastfeeding outcomes that are incurred in

community, primary or secondary healthcare or personal social service settings. The cost year was 2018. The primary measure of outcome was the QALY. Other secondary measures of outcome were determined by the clinical conditions considered in the economic analysis.

Both deterministic and probabilistic analyses were conducted. Moreover, a two-way sensitivity analysis was carried out, by changing concurrently the mean effect (RR) and cost of the intervention, to explore the impact of changes on the cost-effectiveness results. The ranges tested were from 1.05 to 2.00 for the intervention effect; and from £20 to £100 for the intervention cost.

The result of the analysis was expressed as an ICER, estimated as the difference in costs divided by the difference in QALYs between the intervention added on standard care and standard care alone.

Overview of economic modelling results and conclusions

The ICER of the intervention added on standard care compared with standard care alone was £51,946/QALY, which is well above the NICE upper cost-effectiveness threshold of £30,000/QALY, suggesting that the intervention is not cost-effective.

Results of the two-way sensitivity analysis suggested that the cost-effectiveness of the intervention improved as its effectiveness increased and its intervention cost decreased. At the base-case effect (RR) of 1.19 (any breastfeeding at 16-26 weeks after birth), the intervention was cost-effective (<£20,000/QALY) if its cost per woman receiving the intervention fell at approximately £40-£45. On the other hand, at the base-case cost of £84, the intervention was cost-effective if its effectiveness (in terms of breastfeeding rates), when added on to standard care, was at least 35%-40% higher than the effectiveness of standard care alone (that is, if the RR reached 1.35-1.40).

Details of the methods employed in the economic analysis and full results are provided in appendix J.

Evidence statements

Clinical evidence statements

Education, advice or support from peer or professional provided antenatally (Intervention 1)

Comparison 1.1. Education, advice or support from peer or professional provided antenatally versus standard care

Critical outcomes

Initiation of breastfeeding

- Low quality evidence from 6 RCTs (n=2,157 women) showed no clinically important difference in the proportion of women initiating breastfeeding between those receiving an antenatal breastfeeding promotion intervention and the comparative arm (typically standard care).
- Low quality evidence from 1 RCT (N=59 women) showed a clinically important higher proportion of women initiating breastfeeding among families where the fathers had received an antenatal breastfeeding promotion intervention compared to fathers who did not.

Any breastfeeding between 3 and 14 days

- Very low quality evidence from 6 RCTs, (of which 2 RCTs were three arm trials, N=2,178 women) on antenatal breastfeeding promotion interventions showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 3 to 14 days after birth between those receiving an antenatal breastfeeding promotion intervention and the comparative arm (typically standard care). The results showed high heterogeneity and therefore subgroup analyses were carried out.
  - The first subgroup analysis separated interventions implemented in different ways (face-to-face as a group, face-to-face as an individual, digital or self-help), with no clinically important difference between intervention and control found in any of the three groups (low to very low quality evidence).
  - The second subgroup analysis separated interventions based on number of contacts with peer or professional supporters or educators. The results are provided below.
    - Very low to low quality evidence showed no clinically important difference between intervention and control for interventions with 0-3 contacts.
    - Low quality evidence from 1 RCT (N=50 women) involving 4 to 8 contacts showed a clinically important higher proportion of women breastfeeding (any) across the time period of 3 to 14 days after birth in the intervention group compared to standard care
  - The third subgroup analysis divided interventions based on whether the population was a general population or a low-income population. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
    - Low quality evidence showed no clinically important difference between intervention and control in the general population.
    - Low quality evidence from 2 RCTs (N=126 women) on low-income women showed a clinically important higher proportion of women breastfeeding (any) across the time period of 3 to 14 days after birth in the intervention group compared to the comparative arm (typically standard care)

NB. all interventions were delivered in a healthcare setting.

With regards to the test for subgroup differences, the subgroups of interventions implemented in different ways (face-to-face in a group setting, face-to-face and one-to-one, and digital/self-help) were not clinically different (p=0.63), the subgroups of interventions with different number of contacts were clinically important (p=0.02) and the subgroup for whetherthe population was general or from a low-income backgroup was clinically important (p=0.001).

Exclusive breastfeeding between 3 and 14 days

- Very low quality evidence from 4 RCTs (of which 2 RCTs were three arm trials, N=1,613 women) on antenatal breastfeeding promotion interventions showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 3 to 14 days after birth between those receiving an antenatal breastfeeding promotion intervention and the comparative arm (typically standard care). The results showed high heterogeneity and therefore subgroup analyses were carried out.
  - The first subgroup analysis separated interventions implemented in different ways (face-to-face as a group, face-to-face as an individual, digital or self-help), with no clinically important difference between intervention and control found in any of the three groups (very low to low quality evidence).

- The second subgroup analysis separated interventions based on number of contacts with peer or professional supporters or educators. The results are provided below.
  - Low quality evidence showed no clinically important difference between intervention and control for interventions with 0-3 contacts.
  - Low quality evidence from 1 RCT (N=50 women) involving 4 to 8 contacts showed a clinically important higher proportion of women exclusively breastfeeding across the time period of 3 to 14 days after birth in the intervention group compared to standard care
- The third subgroup analysis divided interventions based on whether the population was a general population or a low-income population. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
  - Low quality evidence showed no clinically important difference between intervention and control in the general population.
  - Low quality evidence from 1 RCT (N=50 women) on low-income women showed a clinically important higher proportion of women exclusively breastfeeding across the time period of 3 to 14 days after birth in the intervention group compared to standard care.

NB. all interventions were delivered in a healthcare setting.

With regards to the test for subgroup differences, the subgroups of interventions implemented in different ways (face-to-face in a group setting, face-to-face and one-to-one, and digital/self-help) were not clinically important (p=0.31). The subgroups of interventions with different number of contacts were clinically important (p=0.04) and the general population subgroup was clinically important from the low-income subgroup (p=0.004),

Any breastfeeding between 6 and 12 weeks

- Low quality evidence from 10 RCTs (N=3,338 women, of which 2 RCTs were three arm trials) on antenatal breastfeeding promotion interventions showed a clinically significant higher proportion of women breastfeeding (any) across the time period 6 to 12 weeks after birth among those receiving an antenatal breastfeeding promotion intervention compared to the comparative arm (typically standard care). There was high heterogeneity in the results therefore subgroup analyses were carried out.
  - The first subgroup analysis separated interventions implemented in different ways (face-to-face as a group, face-to-face as an individual, digital or self-help), with no clinically important difference between intervention and control found in any of the three groups (very low to low quality evidence).
  - The second subgroup analysis separated interventions based on number of contacts with peer or professional supporters or educators, with no clinically important difference between intervention and control found in any of the four groups (very low to low quality evidence).
  - The third subgroup analysis divided interventions based on whether the population was a general population or a low-income population, with no clinically important difference between intervention and control found in any of the two groups (very low to low quality evidence). General population in this case means any study that was relevant to this outcome but not classified within another subgroup.

NB all interventions were delivered in a healthcare setting.

With regards to the test for subgroup differences, the subgroups of interventions implemented in different ways (face-to-face in a group setting, face-to-face and one-to-one, and digital/self-help) were not clinically important (p=0.66), subgroups of interventions with different number of contacts were not clinically important (p=0.42) and the general population subgroup was not clinically important from the low-income subgroup (p=0.18)

- Low quality evidence from 1 RCT (N=57 women) showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 6 to 12 weeks after birth between families where the fathers had received an antenatal breastfeeding promotion intervention and fathers who did not.

Exclusive breastfeeding between 6 and 12 weeks

- Moderate quality evidence from 5 RCTs (of which one RCT was a three arm trial, N=1,485 women) showed a clinically important higher proportion of women exclusively breastfeeding across the time period of 6 to 12 weeks after birth among those receiving an antenatal breastfeeding promotion intervention compared to the comparative arm (typically standard care).

Any breastfeeding between 16 and 26 weeks

- Low quality evidence from 6 RCTs (of which two RCTs were three arm trials N=2,757 women) showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 16 to 26 weeks after birth between those receiving an antenatal breastfeeding promotion intervention and the comparative arm (typically standard care).

Important outcome

Maternal satisfaction of the intervention

No evidence was identified for this outcome.

Comparison 1.2. One-contact antenatal intervention focusing on practical skills without partners versus two-contact antenatal intervention focusing on attitudes and involving partners

Critical outcomes

Initiation of breastfeeding

No evidence was identified for this outcome.

Any breastfeeding between 3 and 14 days

- Low quality evidence from 1 RCT (N=614 women) showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 3 to 14 days after birth between those receiving an antenatal one-contact breastfeeding promotion intervention focusing on practical skills and those receiving an antenatal two-contact breastfeeding promotion intervention focusing on attitudes and involving partners.

Exclusive breastfeeding between 3 and 14 days

- Low quality evidence from 1 RCT (N=614 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 3 to 14 days after birth between those receiving an antenatal one-contact breastfeeding promotion intervention focusing on practical skills and those receiving an antenatal two-contact breastfeeding promotion intervention focusing on attitudes and involving partners.

Any breastfeeding between 6 and 12 weeks

No evidence was identified for this outcome.

Exclusive breastfeeding between 6 and 12 weeks

No evidence was identified for this outcome.

Any breastfeeding between 16 and 26 weeks

- Low quality evidence from 1 RCT (N=590 women) showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 16 to 26 weeks after birth between those receiving an antenatal one-contact breastfeeding promotion intervention focusing on practical skills and those receiving an antenatal two-contact breastfeeding promotion intervention focusing on attitudes and involving partners.

Important outcome

Maternal satisfaction with the intervention

- Moderate quality evidence from 1 RCT (N=422 women) showed no difference in satisfaction with the intervention between those receiving an antenatal one-contact breastfeeding promotion intervention focusing on practical skills and those receiving an antenatal two-contact breastfeeding promotion intervention focusing on attitudes and involving partners, in relation to the following aspects: whether the class was enjoyable, whether the women learnt anything new, whether there were sufficient opportunities to ask questions, whether the class leader was able to answer questions, whether women felt uncomfortable participating in the classes, whether the time and place of the class was convenient, whether they would recommend the class to other women. In relation to whether the class was useful for deciding how to feed the baby, women in the practical skills 1-contact group had a median score of 5 on a Likert scale from 1 (disagree strongly) to 5 (agree strongly), while women in the attitudes 2-contact group had a median score of 4. The clinical importance and imprecision of the satisfaction outcomes could not be assessed due to insufficient data.

Comparison 1.3. Antenatal provision of booklet plus video plus one contact versus antenatal provision of booklet and video only

Critical outcomes

Initiation of breastfeeding

No evidence was identified for this outcome.

Any breastfeeding between 3 and 14 days

- Low quality evidence from 1 RCT (N=235 women) showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 3 to 14 days after birth between those receiving an antenatal intervention involving a booklet, a video and one contact with a professional and those receiving booklet and video only.

Exclusive breastfeeding between 3 and 14 days

- Low quality evidence from 1 RCT (N=235 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 3 to 14 days after birth between those receiving an antenatal intervention involving a booklet, a video and one contact with a professional and those receiving booklet and video only.

Any breastfeeding between 6 and 12 weeks

- Low quality evidence from 1 RCT (N=232 women) showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 6 to 12 weeks after birth between those receiving an antenatal intervention involving a booklet, a video and one contact with a professional and those receiving booklet and video only.

Exclusive breastfeeding between 6 and 12 weeks

- Low quality evidence from 1 RCT (N=232 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 6 to 12 weeks after birth between those receiving an antenatal intervention involving a booklet, a video and one contact with a professional and those receiving booklet and video only.

Any breastfeeding between 16 and 26 weeks

- Low quality evidence from 1 RCT (N=232 women) showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 16 to 26 weeks after birth between those receiving an antenatal intervention involving a booklet, a video and one contact with a professional and those receiving booklet and video only.

Important outcome

Maternal satisfaction of the intervention

No evidence was identified for this outcome.

Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2)

Comparison 2.1. Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth versus standard care

Critical outcomes

Initiation of breastfeeding

- Very low quality evidence from 19 RCTs (N=4,873 women) showed a clinically important higher proportion of women initiating breastfeeding having received a breastfeeding intervention that finished postnatally compared to those receiving standard care. There was however high heterogeneity, therefore a meta-regression analysis was conducted. See Meta-Regression section.
- The following subpopulations were analysed separately: general population, low-income population, obese women or young women. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
    - Very low quality evidence from 9 RCTs among women from a low income population found a clinically important improvement in breastfeeding initiation rate among those who received the intervention compared to those who received standard care.
    - Low quality evidence from 1 RCT among young women from a low income population found a clinically important improvement in breastfeeding initiation rate among those who received the intervention compared to those who received standard care.

  - Very low quality evidence from 8 RCTs among the general population found no clinically important improvements in breastfeeding initiation rate among those who received the intervention compared to those who received standard care.
  - Very low quality evidence from 3 RCTs among obese women found no clinically important improvements in breastfeeding initiation rate among those who received the intervention compared to those who received standard care.
  - Very low quality evidence from 2 RCTs among young women found no clinically important improvements in breastfeeding initiation rate among those who received the intervention compared to those who received standard care.
  - Very low quality evidence from 1 RCT among obese women from a low income population found no clinically important improvements in breastfeeding initiation rate among those who received the intervention compared to those who received standard care.
- Low quality evidence from 1 RCT (N=480 women) showed no clinically important difference in the proportion of women initiating breastfeeding among families where the healthcare professionals had received additional training compared to those being treated by healthcare professionals who had not received additional training.

Any breastfeeding between 3 and 14 days

- Very low quality evidence from 14 RCTs (N=4,268 women) showed a clinically important higher proportion of women breastfeeding across the time period of 3 to 14 days in those who had received an intervention that finished postnatally compared to those receiving standard care. There was however high heterogeneity, therefore a meta-regression analysis was conducted. See Meta-Regression section.
- The following subpopulations were analysed separately: general population, low-income population or obese women. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
  - Moderate quality evidence from 6 RCTs among women from the general population found a clinically important improvement in any breastfeeding at 3 to 14 days among those who received the intervention compared to those who received standard care.
  - Very low quality evidence from 7 RCTs among women from a low income population found a clinically important improvement in any breastfeeding at 3 to 14 days among those who received the intervention compared to those who received standard care.
  - Very low quality evidence from 1 RCT among obese women from a low income population found no clinically important improvements in any breastfeeding at 3 to 14 days among those who received the intervention compared to those who received standard care.
- Low quality evidence from 1 RCT (N=10 areas) showed no clinically important difference in the proportion of women breastfeeding across the time period of 3 to 14 days between the areas providing additional breastfeeding groups compared to areas providing standard care. NB N=10 areas corresponds to N=19411 women but unit of analysis is the areas that were randomised.

Exclusive breastfeeding between 3 and 14 days

- Very low quality evidence from 15 RCTs (N=5,023 women) showed a clinically important higher proportion of women exclusively breastfeeding across the time period of 3 to 14 days in those who had received an intervention that finished postnatally compared to those receiving standard care. There was however high

heterogeneity, therefore a meta-regression analysis was conducted. See Meta-Regression section.

- The following subpopulations were analysed separately: general population, low-income population or obese women. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
  - Very low quality evidence from 6 RCTs among women from a low income population found a clinically important improvement in exclusive breastfeeding at 3 to 14 days among those who received the intervention compared to those who received standard care.
  - Very low quality evidence from 5 RCTs among the general population found no clinically important improvements in exclusive breastfeeding at 3 to 14 days among those who received the intervention compared to those who received standard care.
  - Very low quality evidence from 4 RCTs among obese women found no clinically important improvements in exclusive breastfeeding at 3 to 14 days among those who received the intervention compared to those who received standard care.
  - Very low quality evidence from 1 RCT among obese women from a low income population found no clinically important improvements in exclusive breastfeeding at 3 to 14 days among those who received the intervention compared to those who received standard care.

Any breastfeeding between 6 and 12 weeks

- Low quality evidence from 35 RCTs (N=13,447 women) showed a clinically important higher proportion of women breastfeeding across the time period of 6 to 12 weeks in those who had received an intervention that finished postnatally compared to those receiving standard care. See Meta-Regression section.
- Moderate quality evidence from 1 RCT (N=593 women) showed a clinically important higher proportion of women breastfeeding across the time period of 6 to 12 weeks among families where the fathers had received a breastfeeding promotion intervention compared to fathers who did not.
- Low quality evidence from 1 cluster RCT (N=10 areas) showed no clinically important difference in the proportion of women breastfeeding across the time period of 6 to 12 weeks between the areas providing additional breastfeeding groups compared to areas providing standard care. NB N=10 areas corresponds to N=17,970 women but unit of analysis is the areas that were randomised.

Exclusive breastfeeding between 6 and 12 weeks

- Low quality evidence from 23 RCTs (N=7,928 women) showed a clinically important higher proportion of women breastfeeding across the time period of 6 to 12 weeks in those who had received an intervention that finished postnatally compared to those receiving standard care. There was however high heterogeneity, therefore a meta-regression analysis was conducted. See Meta-Regression section.
- The following subpopulations were analysed separately: general population, low-income population or obese women. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
  - Very low quality evidence from 16 RCTs among women from the general population found a clinically important improvement in breastfeeding initiation rate among those who received the intervention compared to those who received standard care.

  - Low quality evidence from 10 RCTs among women from a low income population found a clinically important improvement in exclusive breastfeeding at 6 to 12 weeks among those who received the intervention compared to those who received standard care.
  - Low quality evidence from 1 RCT among obese women found a clinically important improvement in exclusive breastfeeding at 6 to 12 weeks among those who received the intervention compared to those who received standard care.
  - Very low quality evidence from 1 RCT among obese women from a low income population found no clinically important improvements in exclusive breastfeeding at 6 to 12 weeks among those who received the intervention compared to those who received standard care.
- Moderate quality evidence from 1 RCT (N=593 women) showed a clinically important higher proportion of women exclusively breastfeeding across the time period of 6 to 12 weeks among families where the fathers had received a breastfeeding promotion intervention compared to fathers who did not.

Any breastfeeding between 16 and 26 weeks

- Low quality evidence from 36 RCTs (N=13,534 women) showed a clinically important higher proportion of women breastfeeding across the time period of 16 to 26 weeks in those who had received an intervention that finished postnatally compared to those receiving standard care. See Meta-Regression section.
- Very low quality evidence from 1 RCT (N=118 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 16 to 26 weeks among families where the fathers had received a breastfeeding promotion intervention compared to fathers who did not.

Important outcome

Maternal satisfaction with the intervention

- Low to very low-quality evidence from 1 RCT (range of responses for each question from N=101 to 616 women) showed no difference in satisfaction with the feeding advice given by the hospital nurse, general practitioner (GP), paediatrician, child healthcare nurse, child healthcare physician, or lactation consultant between the intervention group and those receiving standard care. In addition, there were no differences in satisfaction with whether the aforementioned healthcare professionals take into account the womans' own opinion. Likewise, there were no differences in the satisfaction with the reach or extent of the caregivers input. There was however a statistical difference in whether women felt they received contradictory feeding advice, with women in the intervention group rating lower (that is, they did not feel they received contradictory feeding advice) compared to women receiving standard care.
- Low quality evidence from 1 RCT (N=993 women) showed no difference in the womans satisfaction with maternal and new-born care between the intervention and standard care.
- Low quality evidence from 1 RCT (N=572 women) showed no difference in whether women felt the received less advice and help from services than they wanted between the intervention and standard care.
- Low quality evidence from 1 RCT (N=109 women) showed woman reported informational support, instrumental support and comprehensible support were all rated as higher (better) in the intervention group compared to standard care.
- Low quality evidence from 1 RCT (N=429 women) showed no differences in woman rating of their satisfaction with the amount of information given by

healthcare professionals and opportunities to give opinion between the intervention group and standard care. Whilst moderate quality evidence from the same 1 RCT showed significantly more woman rated they were satisfied or very satisfied with the opportunities to ask questions, availability of the healthcare professional, breastfeeding support received and support with the transition from hospital to home in the intervention arm compared to standard care. In addition, woman general satisfaction score was higher in the intervention group compared to standard care.

- Low quality evidence from 1 RCT (N=87 women) showed woman reported their breastfeeding support was significantly more respectful in those receiving the intervention compared to those receiving standard care. In addition, from the same RCT, low quality evidence indicated that significantly less women in the intervention group felt that standard care was enough support compared to the standard care group.
- Low quality evidence from 1 cluster RCT (N=10 areas) showed no difference in women rating on a social support scale, between those receiving the intervention and those with standard care.
- Low quality evidence from 1 RCT (N=192 women) showed no difference in woman satisfaction with knowing where to ask if any problems with the baby or breastfeeding arose nor their satisfaction with the breastfeeding information provided between those receiving care from healthcare professionals who had received an intervention to those receiving care from healthcare professionals who had not received an intervention.

Comparison 2.2 Education, advice or support from peer or professional provided antenatally (Intervention 1) versus education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2)

Critical outcomes

Initiation of breastfeeding

- Very low quality evidence from 2 RCTs (N=637 women) showed no clinically important difference in the proportion of women initiating breastfeeding among women who had received a breastfeeding intervention that ended antenatally compared to those who had received an intervention that ended postnatally.

Any breastfeeding between 3 and 14 days

- Very low quality evidence from 2 RCTs (N=376 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 3 to 14 days among women who had received a breastfeeding intervention that ended antenatally compared to those who had received an intervention that ended postnatally.
- The following subpopulations were analysed separately: general population or low-income population. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
    - Very low quality evidence from 1 RCT among women from the general population found no clinically important improvements in any breastfeeding at 3 to 14 days among those who received the intervention postnatally or antenatally and postnatally compared to those who received the intervention antenatally only.
    - Very low quality evidence from 1 RCT among women from a low income population found no clinically important improvements in any breastfeeding at 3

to 14 days among those who received the intervention postnatally or antenatally and postnatally compared to those who received the intervention antenatally only.

Exclusive breastfeeding between 3 and 14 days

- Very low quality evidence from 1 RCT (N=261 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 3 to 14 days among women who had received a breastfeeding intervention that ended antenatally compared to those who had received an intervention that ended postnatally.

Any breastfeeding between 6 and 12 weeks

- Low quality evidence from 2 RCTs (N=777 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 6 to 12 weeks among women who had received a breastfeeding intervention that ended antenatally compared to those who had received an intervention that ended postnatally.
  - The following subgroup analysis divided interventions based on whether the population was a general population or from a low-income. General population in this case means any study that was relevant to this outcome but not classified within another subgroup. A clinically important difference was found between intervention 2 that improved breastfeeding rates in low-income women more so, than intervention 1. No clinically important difference between intervention1 and intervention 2 were found for the women who were from the general population.
- The following subpopulations were analysed separately: general population or low-income population. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
  - Low quality evidence from 1 RCT among women from a low income population found a clinically important improvement in any breastfeeding at 6 to 12 weeks among those who received the intervention postnatally or antenatally and postnatally compared to those who received the intervention antenatally only.
  - Very low quality evidence from 1 RCT among women from the general population found no clinically important improvements in any breastfeeding at 6 to 12 weeks among those who received the intervention postnatally or antenatally and postnatally compared to those who received the intervention antenatally only.

Exclusive breastfeeding between 6 and 12 weeks

- Very low quality evidence from 2 RCTs (N=775 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 6 to 12 weeks among women who had received a breastfeeding intervention that ended antenatally compared to those who had received an intervention that ended postnatally.
- The following subpopulations were analysed separately: general population or low-income population. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
  - Low quality evidence from 1 RCT among women from a low income population found a clinically important improvement in exclusive breastfeeding at 6 to 12 weeks among those who received the intervention postnatally or antenatally and postnatally compared to those who received the intervention antenatally only.
  - Very low quality evidence from 1 RCT among women from the general population found no clinically important improvements in exclusive

breastfeeding at 6 to 12 weeks among those who received the intervention postnatally or antenatally and postnatally compared to those who received the intervention antenatally only.

Any breastfeeding between 16 and 26 weeks

- Very low quality evidence from 2 RCTs (N=773 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 16 to 26 weeks among women who had received a breastfeeding intervention that ended antenatally compared to those who had received an intervention that ended postnatally.
- The following subpopulations were analysed separately: general population or low-income population. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.
  - Very low quality evidence from 1 RCT among women from the general population found no clinically important improvements in any breastfeeding at 16 to 26 weeks among those who received the intervention postnatally or antenatally and postnatally compared to those who received the intervention antenatally only.
  - Very low quality evidence from 1 RCT among women from a low income population found no clinically important improvements in any breastfeeding at 16 to 26 weeks among those who received the intervention postnatally or antenatally and postnatally compared to those who received the intervention antenatally only.

Important outcome

Maternal satisfaction of the intervention

No evidence was identified for this outcome.

Comparison 2.3. Counselling session + booklet versus counselling session

Critical outcomes

Initiation of breastfeeding

No evidence was identified for this outcome.

Any breastfeeding between 3 and 14 days

No evidence was identified for this outcome.

Exclusive breastfeeding between 3 and 14 days

No evidence was identified for this outcome.

Any breastfeeding between 6 and 12 weeks

No evidence was identified for this outcome.

Exclusive breastfeeding between 6 and 12 weeks

No evidence was identified for this outcome.

Any breastfeeding between 16 and 26 weeks

- Very low quality evidence from 1 RCT (N=200 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 16 to 26 weeks among women who had received both a counselling

session and an educational booklet compared to those who had received just the counselling session.

Important outcome

Maternal satisfaction of the intervention

No evidence was identified for this outcome.

Comparison 2.4. Video + keeping a log book versus video

Critical outcomes

Initiation of breastfeeding

No evidence was identified for this outcome.

Any breastfeeding between 3 and 14 days

No evidence was identified for this outcome.

Exclusive breastfeeding between 3 and 14 days

No evidence was identified for this outcome.

Any breastfeeding between 6 and 12 weeks

- Very low quality evidence from 1 RCT (N=84 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 6 to 12 weeks among women who had watched the educational video and been instructed to keep a breastfeeding log compared to those who had just watched the educational video.

Exclusive breastfeeding between 6 and 12 weeks

No evidence was identified for this outcome.

Any breastfeeding between 16 and 26 weeks

- Very low quality evidence from 1 RCT (N=84 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 16 to 26 weeks among women who had watched the educational video and been instructed to keep a breastfeeding log compared to those who had just watched the educational video.

Important outcome

Maternal satisfaction of the intervention

No evidence was identified for this outcome.

Comparison 2.5. Two home visits versus a telephone call on day of discharge

Critical outcomes

Initiation of breastfeeding

No evidence was identified for this outcome.

Any breastfeeding between 3 and 14 days

- Very low quality evidence from 1 RCT (N=709 women) showed no clinically important difference in the proportion of women breastfeeding across the time

period of 3 to 14 days among women who received two home visits compared to those who had a telephone call.

Exclusive breastfeeding between 3 and 14 days

No evidence was identified for this outcome.

Any breastfeeding between 6 and 12 weeks

No evidence was identified for this outcome.

Exclusive breastfeeding between 6 and 12 weeks

No evidence was identified for this outcome.

Any breastfeeding between 16 and 26 weeks

- Very low quality evidence from 1 RCT (N=510 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 16 to 26 weeks among women who received two home visits compared to those who had a telephone call.

Important outcome

Maternal satisfaction of the intervention

No evidence was identified for this outcome.

Comparison 2.6. Regular home visits versus printed educational materials

Critical outcomes

Initiation of breastfeeding

- Very low quality evidence from 1 RCT (N=177 women) showed no clinically important difference in the proportion of women initiating breastfeeding among women who had received regular home visits compared to those who had received educational materials.

Any breastfeeding between 3 and 14 days

- Very low quality evidence from 1 RCT (N=175 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 3 to 14 days among women who had received regular home visits compared to those who had received educational materials.

Exclusive breastfeeding between 3 and 14 days

- Low quality evidence from 1 RCT (N=176 women) showed a clinically important higher proportion of women exclusively breastfeeding across the time period of 3 to 14 days among women who had received regular home visits compared to those who had received educational materials.

Any breastfeeding between 6 and 12 weeks

- Very low quality evidence from 1 RCT (N=175 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 6 to 12 weeks among women who had received regular home visits compared to those who had received educational materials.

Exclusive breastfeeding between 6 and 12 weeks

- Very low quality evidence from 1 RCT (N=176 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 6 to 12 weeks among women who had received regular home visits compared to those who had received educational materials.

Any breastfeeding between 16 and 26 weeks

- Very low quality evidence from 1 RCT (N=175 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 16 to 26 weeks among women who had received regular home visits compared to those who had received educational materials.

Important outcome

Maternal satisfaction of the intervention

No evidence was identified for this outcome.

Comparison 2.7. Home contact versus Clinic contact

Critical outcomes

Initiation of breastfeeding

No evidence was identified for this outcome.

Any breastfeeding between 3 and 14 days

- Low quality evidence from 1 RCT (N=513 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 3 to 14 days among women who had received a contact visit at home compared to those who had contact visit at a clinic.

Exclusive breastfeeding between 3 and 14 days

- Low quality evidence from 1 RCT (N=513 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 3 to 14 days among women who had received a contact visit at home compared to those who had contact visit at a clinic.

Any breastfeeding between 6 and 12 weeks

No evidence was identified for this outcome.

Exclusive breastfeeding between 6 and 12 weeks

No evidence was identified for this outcome.

Any breastfeeding between 16 and 26 weeks

No evidence was identified for this outcome.

Important outcome

Maternal satisfaction of the intervention

- Low quality evidence from 1 RCT (N=512 women) showed no difference in the client satisfaction questionnaire between women who had received a contact visit at home compared to those who had contact visit at a clinic.

Comparison 2.8. Proactive phone calls versus reactive phone calls

Critical outcomes

Initiation of breastfeeding

No evidence was identified for this outcome.

Any breastfeeding between 3 and 14 days

No evidence was identified for this outcome.

Exclusive breastfeeding between 3 and 14 days

No evidence was identified for this outcome.

Any breastfeeding between 6 and 12 weeks

- Very low quality evidence from 1 RCT (N=64 women) showed no clinically important difference in the proportion of women breastfeeding across the time period of 6 to 12 weeks among women who received phone calls (proactive) compared to those who were given a number to call if necessary (reactive).

Exclusive breastfeeding between 6 and 12 weeks

- Very low quality evidence from 1 RCT (N=58 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 6 to 12 weeks among women who received phone calls (proactive) compared to those who were given a number to call if necessary (reactive).

Any breastfeeding between 16 and 26 weeks

No evidence was identified for this outcome.

Important outcome

Maternal satisfaction of the intervention

- Very low quality evidence from 1 RCT (N=58 women) showed no difference in woman satisfaction with help at home between women who received phone calls (proactive) compared to those who were given a number to call if necessary (reactive).

Meta-regression results for the evidence on education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus standard care

Critical outcomes

Initiation of breastfeeding

- Very low quality evidence from 20 RCTs (N=5,066 women) showed that the interventions involving 9+ contacts and interventions delivered using a combination of both at home and in a healthcare setting improved breastfeeding initiation rates. Other variables showed no effect in breastfeeding initiation rates.

Any breastfeeding between 3 and 14 days

- Very low quality evidence from 16 RCTs (N=5,465 women) showed that the interventions involving delivery in a group setting and interventions delivered using a combination of both at home and in a healthcare setting improved the proportion of any breastfeeding between 3 and 14 days. Other variables showed no effect on the proportion of any breastfeeding between 3 and 14 days.

Exclusive breastfeeding between 3 and 14 days

- Very low quality evidence from 16 RCTs (N=5,512 women) showed no variables were significantly important on improving the proportion of women exclusively breastfeeding between 3 and 14 days.

Any breastfeeding between 6 and 12 weeks

- Very low quality evidence from 37 RCTs (N=13,500 women) showed that the interventions involving delivery in a group setting improved the proportion of any breastfeeding between 6 and 12 weeks. Other variables showed no effect on the proportion of any breastfeeding between 6 and 12 weeks.

Exclusive breastfeeding between 6 and 12 weeks

- Very low quality evidence from 27 RCTs (N=8,456 women) showed that the interventions that were delivered remotely improved the proportion of exclusive breastfeeding between 6 and 12 weeks. Other variables showed no effect on the proportion of exclusive breastfeeding between 6 and 12 weeks.

Any breastfeeding between 16 and 26 weeks

- Very low quality evidence from 39 RCTs (N=14,229 women) showed that the interventions involving delivery in a group setting improved the proportion of any breastfeeding between 16 and 26 weeks. Other variables showed no effect on the proportion of any breastfeeding between 16 and 26 weeks.

Exploratory post-hoc analysis: stratification according to breastfeeding intention

Initiation of breastfeeding

Evidence from studies with women with mixed intentions to breastfeed showed a significantly improved rate of initiation of breastfeeding in the intervention group compared to standard care whilst evidence from studies with women with intention to breastfeed showed no difference in the initiation of breastfeeding rate between intervention and standard care.

Any breastfeeding 3 to 14 days

Evidence from studies with women with mixed intentions to breastfeed or who had already initiated breastfeeding did not show a difference in breastfeeding rate at 3 to 14 days between intervention and standard care whilst evidence from studies with women with intention to breastfeed showed a significant improvement in breastfeeding rate at 3 to 14 days in the intervention group compared to standard care.

Exclusive breastfeeding 3 to 14 days

Evidence from studies with women with mixed intentions to breastfeed or who had already initiated breastfeeding did not show a difference in exclusive breastfeeding rate at 3 to 14 days whilst evidence from studies with women with intention to breastfeed showed a significant improvement in exclusive breastfeeding rate at 3 to 14 days in the intervention group compared to standard care.

Any breastfeeding 6 to 12 weeks

Evidence from studies with women with mixed intentions to breastfeed or who had already initiated breastfeeding did not show a difference in breastfeeding rate at 6 to 12 weeks whilst evidence from studies with women with intention to breastfeed showed a significant improvement in breastfeeding rate at 6 to 12 weeks in the intervention group compared to standard care.

Exclusive breastfeeding 6 to 12 weeks

Evidence from studies with women who had already initiated breastfeeding did not show a difference in exclusive breastfeeding rate at 6 to 12 weeks whilst evidence from studies with women with mixed intentions to breastfeed and those who had intention to breastfeed showed a significant improvement in exclusive breastfeeding rate at 6 to 12 weeks in the intervention group compared to standard care.

Breastfeeding 16 to 24 weeks

Evidence from studies with women who had already initiated breastfeeding did not show a difference in breastfeeding rate at 16 to 24 weeks whilst evidence from studies with women with mixed intentions to breastfeed and those who had intention to breastfeed showed a significant improvement in breastfeeding rate at 16 to 24 weeks in the intervention group compared to standard care.

Foreign objects (Intervention 3)

Comparison 3: Foreign objects versus standard care

Critical outcomes

Initiation of breastfeeding

No evidence was identified to for this outcome.

Any breastfeeding between 3 and 14 days

No evidence was identified to for this outcome.

Exclusive breastfeeding between 3 and 14 days

No evidence was identified to for this outcome.

Any breastfeeding between 6 and 12 weeks

- Very low quality evidence from 3 RCTs (N=1,550 women) showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 6 to 12 weeks after birth between those advised to avoid foreign objects use (pacifiers or bottles/teats) and those not receiving this advice.

Exclusive breastfeeding between 6 and 12 weeks

- Low quality evidence from 2 RCTs (N=1,228 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 6 to 12 weeks after birth between those advised to avoid foreign objects use (pacifiers or bottles/teats) and those not receiving this advice.

Any breastfeeding between 16 and 26 weeks

- Very low quality evidence from 2 RCTs (N=1,515 women) showed no clinically important difference in the proportion of women breastfeeding (any) across the time period of 16 to 26 weeks after birth between those advised to avoid foreign objects use (pacifiers or bottles/teats) and those not receiving this advice. The results showed high heterogeneity, therefore a subgroup analysis was carried out separating the 2 RCTs (although both had been carried out in a general population, one was on a self-help intervention and the other on a 1-contact face-to-face and one-to-one intervention), with no clinically important difference in any of the 2 RCTs. General population in this case means any study that was relevant to this outcome but not classified within another subgroup.

Important outcome

Maternal satisfaction of the intervention

No evidence was identified to for this outcome.

Financial incentives (Intervention 4)

Comparison 4: Financial incentives versus standard care

Critical outcomes

Initiation of breastfeeding

- Low quality evidence from 1 cluster RCT (N=92 areas) showed no clinically important difference in the proportion of women initiating breastfeeding between the areas where financial incentives were provided to initiate breastfeeding and the areas with standard care. NB N=92 areas corresponds to N=9207 women but unit of analysis is the areas that were randomised.

Any breastfeeding between 3 and 14 days

- Very low quality evidence from 1 RCT (N=55 women) showed a clinically important higher proportion of women breastfeeding (any) across the time period of 3 to 14 days among those receiving financial incentives for breastfeeding compared to standard care

Exclusive breastfeeding between 3 and 14 days

- Very low quality evidence from 1 RCT (N=55 women) showed a clinically important higher proportion of women exclusively breastfeeding across the time period of 3 to 14 days among those receiving financial incentives for breastfeeding compared to standard care.

Any breastfeeding between 6 and 12 weeks

- Very low quality evidence from 2 RCTs (N=90 women) showed a clinically important higher proportion of women breastfeeding (any) across the time period of 6 to 12 weeks after birth among those receiving financial incentives for breastfeeding compared to standard care.
- Moderate quality evidence from 1 RCT (N=92 areas) showed a clinically important higher proportion of women breastfeeding (any) across the time period of 6 to 12 weeks after birth in the areas providing financial incentives for breastfeeding compared to areas providing standard care. NB N=92 areas corresponds to N=9,207 women but unit of analysis is the areas that were randomised.

Exclusive breastfeeding between 6 and 12 weeks

- Very low quality evidence from 1 RCT (N=55 women) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 6 to 12 weeks between those receiving financial incentives for breastfeeding and standard care.
- Low quality evidence from 1 cluster RCT (N=92 areas) showed no clinically important difference in the proportion of women exclusively breastfeeding across the time period of 6 to 12 weeks between in the areas providing financial incentives for breastfeeding and areas providing standard care. NB N=92 areas corresponds to N=9,207 women but unit of analysis is the areas that were randomised.

Any breastfeeding between 16 and 26 weeks

- Very low quality evidence from 1 RCT (N=35 women) showed a clinically important higher proportion of women breastfeeding (any) across the time period of 16 to 26 weeks after birth among those receiving financial incentives to maintain breastfeeding compared to standard care.

Important outcome

Maternal satisfaction of the intervention

No evidence was identified to for this outcome.

Economic evidence statements

- Evidence from an English study conducted alongside a cluster RCT (N=10,010 women) suggests that providing financial incentives to women breastfeeding in areas with low breastfeeding rates (<40% at 6-8 weeks) is cost-effective if the lifetime total QALY gain to the baby and/or the mother for every additional breastfeed baby reaches 0.03-0.05. The study is partially applicable to the NICE decision-making context as it has not used the QALY as the outcome measure and is characterised by potentially serious limitations.
- Evidence from a Scottish study conducted alongside a cluster RCT (N=14 areas; N=18,603 eligible women) suggests that implementation of new breastfeeding groups set up to provide population coverage in pregnant or breastfeeding women in relatively deprived areas is not cost-effective compared with standard care that already provides breastfeeding group activity. The study is directly applicable to the NICE decision-making context but is characterised by potentially serious limitations.
- Evidence from a Scottish study conducted alongside an RCT (N=69; completers n=59) suggests that proactive and reactive telephone support versus reactive only telephone support at home provided for up to 14 days after hospital discharge to women living in disadvantaged areas who breastfed at hospital discharge has an increased cost but it also tends to improve breastfeeding rates. The study is partially applicable to the NICE decision-making context because the lack of use of QALY as the measure of outcome makes interpretation of findings and judgement of the cost-effectiveness of the intervention difficult. The study is also characterised by potentially serious limitations.
- Evidence from a US study conducted alongside an RCT (N=328; completers at 6 weeks postpartum n=280; at 24 weeks postpartum n=243) suggests that an intervention aimed at promoting breastfeeding, which includes provision of a prescribed program of support and education in hospital and for the first 24 weeks postpartum for low-income breastfeeding women of full-term babys improves breastfeeding rates at 6 weeks, but not at 24 weeks postpartum and has an increased cost compared with standard routine practice. The study is partially applicable to the NICE decision-making context as it was conducted in the US; moreover, the lack of use of QALY as the measure of outcome makes interpretation of findings and judgement of the cost-effectiveness of the intervention difficult. The study is also characterised by potentially serious limitations.
- Evidence from a Canadian study conducted alongside an RCT (N=138; n=102 completers) suggests that early hospital discharge combined with home-based support from certified nurse lactation consultants results in improved breastfeeding rates in term and near-term babies compared with standard hospital discharge combined with hospital-based support from nurse lactation consultants; it also leads to higher healthcare costs in term babies but lower healthcare costs in near-term babies. The study is partially applicable to the NICE decision-making context as it was conducted in Canada; moreover, the lack of use of QALY as the measure of outcome makes interpretation of findings and judgement of the cost-effectiveness of the intervention difficult. The study is also characterised by potentially serious limitations.

- Evidence from the guideline economic analysis suggests that providing an intervention aimed at promoting breastfeeding, which comprises education, advice or support from a peer or professional, in addition to standard care, is unlikely to be cost-effective compared with standard care alone. The study is directly applicable to the NICE decision-making context but is characterised by potentially serious limitations.

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee rated the initiation of breastfeeding as a critical outcome because for a woman to maintain breastfeeding, she first needs to initiate it. Improving the initiation rate of breastfeeding is the first hurdle in any intervention aiming to increase overall breastfeeding rates. The committee also rated the maintenance of breastfeeding as a critical outcome because knowing whether an intervention improved breastfeeding over time was paramount to recommending breastfeeding interventions. The committee were interested in both any breastfeeding and exclusive breastfeeding. The committee grouped the assessment timepoints for breastfeeding maintenance into the following: 3 to 14 days, 6 to 12 weeks and 16 to 26 weeks. The committee felt that 3 to 14 days would capture successful start to breastfeeding, it is also considered a time when many women would give up breastfeeding. Assessing breastfeeding at 6 to 12 weeks would capture established breastfeeding whilst breastfeeding at 16 to 26 weeks would capture those women who continued to breastfeed for the recommended duration of 6 months. Although there are obvious gaps between the follow-up time periods, the committee did not wish to bridge the gaps by extending time points because they believed this would result in pooling data that are too wide apart to be meaningful for the purpose of drafting recommendations.

Maternal satisfaction was rated as an important outcome because the committee wanted to know whether women found receiving an intervention beneficial and acceptable when compared to not receiving an intervention and whether women were more satisfied with one intervention or another.

No evidence was identified for maternal satisfaction for interventions 1 (education, advice or support from peer or professional provided antenatally), intervention 3 (avoiding foreign objects) and intervention 4 (financial incentives). In addition, no evidence was identified for intervention 3 (foreign objects) for the outcomes of initiation of breastfeeding, any breastfeeding at 3 to 14 days and exclusive breastfeeding at 3 to 14 days. It is likely that avoiding foreign objects would not show much of a difference between the intervention and comparator group so early on in the infants life.

The quality of the evidence

The quality of the included data ranged from very low to moderate. This was true for both the meta-analysis results and the meta-regression.

Typically, there were serious risks of bias in the studies. There were concerns with selective reporting, randomisation and missing data. Most studies did not do blinding, which was unsurprising given the nature of the interventions. All studies relating to an intervention that involved financial incentives or gifts as a result of achieving certain breastfeeding milestones were thought to have serious limitations regarding

'measurement' of outcomes. This was because there were concerns that the financial incentives for demonstrating or reporting maintenance of breastfeeding may encourage inaccurate reporting from the women, therefore the results may not accurately reflect the true breastfeeding status of the women. For the most part, there were no concerns over inconsistency despite the heterogeneous nature of the studies. Relatively few outcomes had concerns over indirectness. There were serious or very serious concerns with imprecision on a number of outcomes.

The main issue with the included studies were the heterogeneous nature of the interventions, with no two interventions the same, making pooling of the studies questionable. Examples of the differences between study interventions include:

- how they were delivered: face-to-face, in a group (large or small groups), as a video playing in a waiting room or a DVD to take home, telephone contacts, or a telephone number to contact and also a combination of different delivery styles
- how many contacts the women received, whether there was an open access line of communication to ask for help, typically if the intervention involved many contacts some would be face-to-face and some would be over the phone
- where the intervention was delivered: at home, in hospital, in a specific breastfeeding clinic or combination of places
- duration of overall contact, some interventions were short and were finished by hospital discharge, whilst others maintained contact with the women up to 6 months
- who they were delivered by and whether additional breastfeeding training had been given: peer supporter, lactation consultant, midwife, health visitor or combination of teachers
- whether incentives were given, for example a breast pump, or nursing bra
- whether the intervention actively encouraged fathers, specially recruited only fathers or was focused on just the woman
- the proportion of women recruited to the intervention who already intended to breastfeed before they were recruited, likewise the proportion of women who had no intentions to breastfeed
- the definition used to describe any brestfeeding and exclusive breastfeeding.

It was noted that in some examples, when conducting subgroup analysis to investigate the high hetrogenity observed in the meta-analysis (measured by the I^2 statistic), this made the heterogeneity even higher highlighting the dissimilarity of the studies even within the subgroups.

In addition, for the studies that compared their intervention to standard care, details of what was involved in standard care was generally poorly reported. For the purpose of pooling the data for meta-analysis and meta-regression, the committee made an assumption that standard care in the studies was similar.

Despite the differences in studies and the limited reporting, pooling of these studies, where possible, was considered better than reporting each study separately.

Benefits and harms

Four different types of interventions were considered for this review: interventions which started and finished antenatally, interventions which started antenatally or postnatally but finished postnatally, interventions which involved avoiding foreign objects in the babies mouth (for example dummies) and interventions which involved offering the women financial incentives to breastfeed.

Despite the large quantity of evidence identified for this review, there was no clear direction from the evidence as to the precise nature of breastfeeding intervention that would significantly increase breastfeeding rates. While some interventions were effective, the evidence was not able to indicate which components were effective in either initiating or maintaining breastfeeding. Given the absence of clear conclusions and based on the conclusions of the cost effectiveness analysis, the committee did not recommend any particular breastfeeding intervention in addition to the standard postnatal contacts. However, the committee agreed that based on their knowledge and experience as well as qualitative evidence from evidence review S, breastfeeding should be discussed and information and support on breastfeeding should be provided antenatally so that families are equipped to start breastfeeding and continue postnatally. Furthermore, face-to-face breastfeeding support in the postnatal period should be an integral part of the routine postnatal contacts and should continue throughout the postnatal period until breastfeeding is established and there are no longer problems with breastfeeding. More discussion around the type and content of breastfeeding information and support are provided in evidence reviews Q and S.

There was some evidence that interventions specifically designed to provide information and support to fathers were effective in maintaining breastfeeding. Based on this and qualitative evidence from other reviews, the committee agreed that partners should be given information about breastfeeding and how they can support the woman to breastfeed.

The committee's experience with women postnatally, taken together with the results of the quantitative evidence from this review and qualitative evidence from evidence reviews Q and S led them to conclude that the most valuable approach is likely to be tailored to individuals' needs. Face-to-face support was considered important although this should be supplemented by other types of "remote" support, such as written material or online or telephone support where needed.

There was some evidence that interventions among women from low-income backgrounds were effective in either starting and maintaining breastfeeding. Based on this combined with qualitative evidence from evidence reviews Q and S, the committee agreed that women from a low-income or disadvantaged background as well as younger women may need more support to initiate and subsequently maintain breastfeeding. This is of particular relevance to the interventions that started antenatally and finished postnatally (intervention 1) or the interventions that started and finished postnatally (intervention 2).

The meta-regression analysis showed that interventions that included more than 9 contact sessions and were delivered through a combination of at home and in a healthcare setting were effective in increasing breastfeeding initiation rates, although the increase in breastfeeding rates was relatively modest at around 15%. The committee agreed that while it may well be that 9 contact sessions might have some benefit on breastfeeding rates, such high number of contact sessions would be difficult to implement in practice and would be very costly, particularly if they were to be delivered using both a clinic and at home approach. They therefore agreed not to make a recommendation about this.

The meta-regression analysis also showed that interventions that were delivered in a group were effective at increasing breastfeeding rates. The committee acknowledged that in some areas group sessions do take place as part of the standard antenatal or postnatal care and they may be beneficial. Nevertheless, the evidence for group support came from one small study and the committee agreed that this was too limited to recommend interventions should always be delivered in a group setting.

No recommendations were made about avoiding foreign objectives as there was no evidence to suggest that interventions to avoid foreign objects would be effective.

Evidence showed that providing financial incentives was not effective in increasing the rate of breastfeeding initiation. The committee agreed that it is likely initiation rates would not be affected by financial incentives but whether the woman had a pre-determined plan to initiate breastfeeding would have a greater effect on this outcome. There was some evidence that financial incentives improved the breastfeeding rates later on, however, the committee had concerns about the bias that financial incentives might cause regarding reporting or measurement of the outcome. While there might be a small increase in breastfeeding rates due to financial incentives, they are costly and the committee agreed not to make a recommendation about this.

Furthermore, the committee discussed that the woman's intention to breastfeed would have an impact on breastfeeding rates and potentially on the effectiveness of an intervention. A post-hoc analysis stratifying the studies according to intention to breastfeed was conducted to explore if the intention to breastfeed would impact the effectiveness of the interventions. Most studies did not report whether or not the women intended to breastfeed or they included women with mixed intentions. The results were generally not conclusive and the committee did not make any recommendations based on intention to breastfeed.

Cost-effectiveness and resource use

Existing economic evidence is inconclusive. Most of the published studies found that breastfeeding interventions are more effective than standard care at an additional cost, however, none of the studies used the QALY as the measure of outcome, and therefore it was not possible to conclude whether the interventions are cost-effective within the NICE decision making context. Moreover, all studies had a short time horizon and measured benefits in terms of breastfeeding rates; no study considered the long-term benefits and cost-savings associated with improved breastfeeding rates. Therefore, the committee could not draw any robust conclusions from this evidence.

Evidence from the guideline economic analysis indicated that providing an intervention aimed at promoting breastfeeding, which comprises education, advice or support from a mixture of health professionals and peer volunteers, in addition to standard care, may not be cost-effective compared with standard care alone at the NICE cost-effectiveness threshold of £20,000/QALY. Current standard care in the NHS context is variable and may include provision of written material, antenatal breastfeeding educational programmes, and postnatal breastfeeding support groups run by peers and/or health professionals; in some settings breastfeeding information and support is provided by midwives and/or health visitors as part of routine postnatal care visits.

The economic analysis used information on the clinical effectiveness and intervention resource use from the guideline systematic review and meta-regression; based on this information, the intervention in the guideline economic analysis, added on to standard care, had a modest effect in improving breastfeeding rates at 16-26 weeks after birth over standard care alone (mean RR 1.19); the intervention was assumed to be delivered by a mixture of health professionals (Band 5 NHS salary scale) and volunteer peer supporters, who provided 2 individual contacts and 4 group sessions at a total cost of £84. The guideline economic analysis considered a number of clinical outcomes to women (breast cancer) and their babies (gastrointestinal infection, respiratory tract infection, acute otitis media, mortality due to infectious diseases and SIDS) in the long-term and was characterised by robust methodology

regarding the model structure and data sources. Nevertheless, the committee noted that several other outcomes that are associated with breastfeeding, such as ovarian cancer in women, diabetes in women and babies and obesity in babies were not considered in the analysis. They also noted that the estimated ICER captured only the QALY gains and not any secondary outcomes considered in the analysis. Therefore, they noted that the analysis may have underestimated the cost-effectiveness of the breastfeeding intervention by omitting some important beneficial outcomes of breastfeeding. On the other hand, the committee was aware that, due to lack of more suitable data, the guideline economic analysis overestimated some of the modelled benefits, in particular benefits associated with a reduction in the incidence of breast cancer following provision of the breastfeeding intervention. Moreover, the data on the association between breastfeeding and clinical benefits considered in the guideline model were derived from study designs that were prone to bias; several studies demonstrating clinical benefits associated with breastfeeding had, at best, adjusted for some known, but not all possible, confounders; other studies had made no adjustments for confounding. Consequently, the magnitude of the clinical benefits of breastfeeding may have been overestimated in the literature used to populate the model and, consequently, in the guideline economic analysis. The committee agreed that, on balance, the estimated ICER was reflective of the cost-effectiveness of the breastfeeding intervention, as specified, in terms of effectiveness and resource use, in the published literature, and should be considered as such when making recommendations.

Based on the results of the economic analysis, which suggested that a 6-session intervention that promotes initiation and maintenance of breastfeeding, comprising a mixture of individual and group sessions, is unlikely to be cost-effective when added on to standard care, the committee decided not to recommend a distinct intervention with the resource use characteristics specified in the guideline economic analysis. The committee discussed the results of sensitivity analysis, which suggested that the intervention might become cost-effective if its effectiveness remained the same but its cost was reduced by about 50% (from £84 to around £40-£45 per woman receiving the intervention) or its cost remained the same but its relative effect (RR) versus standard care was improved from 1.19 to 1.35-1.40 (for the outcome of any breastfeeding 16-26 weeks after birth). Based on these results, the committee considered recommending a brief, less costly intervention. However, results of the guideline meta-regression suggested that adding an intervention of up to 3 contacts onto standard care had a very small and uncertain effect. Therefore, the committee decided against recommending a brief intervention.

The committee noted that breastfeeding itself is cost-effective, as it leads to important clinical benefits to women and babies and cost-savings to the health service, parents and the whole society, at no intervention cost. They highlighted the fact that the guideline economic analysis only demonstrated that the breastfeeding intervention, as specified in the economic analysis, was not cost-effective because the clinical benefits and cost-savings resulting from an increase in breastfeeding rates, although important, were not adequate to outweigh the initial intervention costs. This is because the effectiveness of the intervention was relatively small, and the baseline incidence of the clinical conditions assessed in the model is rather low in the general population of women and their babies in the UK; moreover, an important minority of women already breastfeed at 16 weeks (42%) and 26 weeks (34%) after birth, under standard care. Therefore, the additional protective effect of breastfeeding resulting from provision of a breastfeeding intervention has a relatively small impact at a population level.

Following the discussion on the findings, strengths and limitations of the economic analysis and the benefits and cost-savings associated with breastfeeding, the committee decided to make recommendations to ensure that current NHS care is optimised, so as to improve quality and reduce heterogeneity in the provision of breastfeeding advice and support across settings.

Other factors the committee took into account

Overall, the committee discussed that additional 'clinical' interventions provided within the healthcare system seem to have limited impact on breastfeeding rates and perhaps there are larger societal and public health interventions that would affect breastfeeding rates more. For example, banning of marketing of formula milk and parental leave policies have shown to impact breastfeeding rates in many settings. However, the committee recognised these types of interventions are outside the remit of this guideline.

The committee noted during protocol development that certain subgroups of women and health care professionals may require special consideration:

- young women (19 years or under)
- women with physical or cognitive disabilities
- women with severe mental health illness
- women who have difficulty accessing postnatal care services.

A stratified analysis was therefore predefined in the protocol based on these subgroups. Based on the evidence, the committee concluded that women from a low-income or disadvantaged background may need extra support to start and establish breastfeeding. Based on qualitative evidence reported in evidence review S, young women were also considered to potentially benefit from additional support. Otherwise, the committee agreed separate recommendations were not needed as the same recommendations would apply to the other groups.

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Appendices

Appendix A – Review protocol

Review protocol 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 3: Review protocol

Field (based on PRISMA-P)	Content
Review question	What interventions are effective in starting and maintaining breastfeeding (single births)? What interventions are effective in starting and maintaining breastfeeding (twins or triplets)?
Type of review question	Intervention
Objective of the review	This review aims to determine which interventions, implemented antenatally or in the first 8 weeks after birth, are effective in starting and maintaining breastfeeding.
Eligibility criteria – population/disease/condition/issue/domain	Pregnant women and women who have given birth to a healthy baby at term (or to healthy twins or triplets), from the birth of the baby to 8 weeks after birth, and their partners. Women receiving specialist care in relation to breastfeeding will be excluded, for example: • Women with HIV/AIDS • Women abusing substance • Women on toxic medications • Women otherwise contraindicated to breastfeeding Studies of interventions for women with specific conditions will be excluded.

Field (based on PRISMA-P)	Content

Eligibility criteria – intervention(s)	Intervention 1
	• Education, advice or support from peer* or professional provided antenatally, for example:
	  ○ One to one
	  ○ Group classes
	  ○ Professional or peer* breastfeeding support
	  ○ Provision of self-help or educational material, including digital
	
	Intervention 2
	• Education, advice or support from peer* or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth; for example:
	  ○ One to one
	  ○ Group classes
	  ○ Professional or peer* breastfeeding support
	  ○ Provision of self-help or educational material
	*denotes that the person has undergone specific training related to the provision of information and support for breastfeeding.
	
	Intervention 3
	• Avoidance of foreign objects (for example dummies, teats for formula milk) to baby's mouth in first four weeks of life
	
	Intervention 4
	• Financial incentives
	
	Studies will be included if a main aim of the intervention is to start or maintain breastfeeding. If this is not one of the main aims, studies will be excluded.
	
	Early mother-infant contact and "rooming-in" mother and infant will be excluded because the NICE guideline on intrapartum care (CG190) already covers early initiation of breastfeeding. Early skin to skin contact will also be excluded because it is covered by the NICE guideline on caesarean section (CG132).

Field (based on PRISMA-P)	Content
Eligibility criteria – comparator(s)	Comparison 1 • Standard care. • Different kinds of intervention 1 compared against each other Comparison 2 • Standard care • Different kinds of intervention 2 compared against each other Comparison 3. • Using foreign objects (for example dummies, teats for formula milk) to baby's mouth in first four weeks of life Comparison 4. • Standard care • Different kinds of intervention 4 compared against each other Studies will be included if the intervention being evaluated is a combination of any of the above for example 1 and 3 versus nothing. Where data allow, active interventions will also be compared with each other, including those provided antenatally versus. those provided postnatally
Outcomes and prioritisation	Critical • Initiation of breastfeeding (MID: any statistically significant difference) • Breastfeeding (any) up to 6 months* (MID: any statistically significant difference) • Breastfeeding (exclusively) up to 6 months* (MID: any statistically significant difference) Important • Women's satisfaction with breastfeeding interventions (default MIDs)

Field (based on PRISMA-P)	Content
	*Data will be extracted for each follow-up reported in each study. The review team will first create a table showing the interventions and all follow-ups reported in each study. Based on this, the committee will decide what follow-ups to prioritise and what follow-ups can be meta-analysed. **Addendum**: in addition to the outcome 'women's satisfaction', the committee agreed these follow-up groupings for meta-analysis of breastfeeding outcomes: • Proportion of women initiating breastfeeding (any) up to 48 hours following birth) (any statistically significant difference) (if a study provides data on more than one relevant time point belonging to this follow-up grouping, use the latest time point) • Proportion of women breastfeeding at 3-14 days (any and exclusive) (if a study provides data on more than one relevant time point belonging to this follow-up grouping, use the latest time point) • Proportion of women breastfeeding at 6-12 weeks (any and exclusive) (any statistically significant difference) (if a study provides data on more than one relevant time point belonging to this follow-up grouping, use the latest time point; if a study provides data at 3 months, consider this time point as 12 weeks) • Proportion of women breastfeeding at 16 – 26 weeks (any breastfeeding) (any statistically significant difference) (if a study provides data on more than one relevant time point belonging to this follow-up grouping, use the latest time point) Aware of the need to prioritise outcomes the committee chose the follow-up groupings that they believed to most usefully measure initiation or maintenance of breastfeeding. Although there are obvious gaps between the follow-up groups, the committee did not wish to bridge the gaps by extending time points because they believed this would result in pooling data that are too wide apart to be meaningful for the purpose of drafting recommendations.
Eligibility criteria – study design	• Published full text papers only • Systematic reviews • RCTs or cluster RCTs • Quasi-randomised trials and cross-over trials will be excluded • Conference abstracts will not be considered • Exclude papers published before 1995 – when BFI was introduced to the UK.
Other inclusion exclusion criteria	Data from low and middle income countries (according to the World Bank) will be excluded as the configuration of antenatal and postnatal services in these countries might not be representative of that in the UK. In particular,

Field (based on PRISMA-P)	Content
	'standard care' in relation to breastfeeding support is likely to markedly different to the UK and higher income countries. Finally, breastfeeding rates and attitudes toward breastfeeding are different in those countries.
Proposed sensitivity/sub-group analysis, or meta-regression	Groups that will be reviewed and analysed separately: • Fathers (interventions aimed at fathers) In the presence of heterogeneity, the following intervention subgroups will be considered for sensitivity analysis: • How delivered (face-to-face individual, face-to-face group, telephone, self-help) • Where delivered (healthcare setting or home) • Number of contacts (1, 2-3, 4-8, 9+) • Duration of contact (less than 8 weeks, more than 8 weeks) only for the outcome any breastfeeding at 16 to 26 weeks. In the presence of heterogeneity, the following population subgroups will be considered for sensitivity analysis: • Young women (19 years and under) • Single birth v multiple births • Women defined as 'low income' • Obese women Statistical heterogeneity will be assessed by calculating the I2 inconsistency statistic (with an I2 value of more than 50% indicating considerable heterogeneity). An outcome with an I2 value >50% will be downgraded by 1 for inconsistency and >75% will be downgraded by 2.
Selection process – duplicate screening/selection/ analysis	Review questions selected as high priorities for health economic analysis (and those selected as medium priorities and where health economic analysis could influence recommendations) will be subject to dual weeding and study selection; any discrepancies above 10% of the dual weeded resources will be resolved through discussion between the first and second reviewers or by reference to a third person. This review question was prioritised for health economic analysis however no formal dual weeding, study selection (inclusion/exclusion) or data extraction into evidence tables will be undertaken because the technical team was aware of existing Cochrane reviews on the subject and agreed to use these to select the studies up to the latest Cochrane search date. Weeding will be limited to the years from the latest Cochrane search dates or to topics not covered by Cochrane reviews (financial incentives and

Field (based on PRISMA-P)	Content
	breastfeeding support for women who had a caesarean section). (Moreover, internal (NGA) quality assurance processes will include consideration of the outcomes of weeding, study selection and data extraction and the committee will review the results of study selection and data extraction).
Data management (software)	Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5). 'GRADEpro' will be used to assess the quality of evidence for each outcome. Where default MIDs are used to assess the clinical significance of outcomes they will also be used to rate imprecision. For those outcomes for which any statistically significant difference is clinically significant, imprecision will be assessed as follows: • Downgrade once if the confidence interval crosses the line of no effect • Downgrade once if the sample size is below 400 for continuous outcomes and if the total events is below 300 events for dichotomous outcomes.
Information sources – databases and dates	Sources searched: CCRCT, CDSR, DARE, Embase, Emcare, HTA, Medline, Medline in process, NHS EED Limits: Non-English language exclusion Dates: Published from 1995 onwards
Identify if an update	This guideline will update the NICE guideline on postnatal care up to 8 weeks after birth. All reviews are being conducted afresh. However CG37 (2006) includes the following recommendation: All maternity care providers (whether working in hospital or in primary care) should implement an externally evaluated, structured programme that encourages breastfeeding, using the Baby Friendly Initiative as a minimum standard. [2006]
Author contacts	National Guideline Alliance https://www.nice.org.uk/guidance/indevelopment/gid-ng10070
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual
Search strategy – for one database	For details please see appendix B of the guideline

Field (based on PRISMA-P)	Content
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables) of the guideline.
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables) of the guideline.
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual
Methods for analysis – combining studies and exploring (in)consistency	For a full description of methods see Supplement 1.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual.
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual
Rationale/context – Current management	For details please see the introduction to the evidence review guideline.

Field (based on PRISMA-P)	Content
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Dr David Jewell in line with section 3 of Developing NICE guidelines: the manual. Staff from the National Guidelines Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see the methods chapter of the full guideline.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England
PROSPERO registration number	Not registered

BFI: baby friendly initiative; CCRCT: Cochrane central register of controlled trials; CDSR: Cochrane database of systematic reviews; DARE: Database of abstracts of reviews of effects; EED: Economic evaluation database; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health technology appraisal; MID: minimally important difference; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; PRISMA-P: Preferred Reporting Items for Systematic and Meta-analysis Protocols; RCT: randomised controlled trial

Appendix B – Literature search strategies

Literature search strategies 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)?

Clinical search

The search for this topic was last run on 26th April 2019.

Database: Emcare, Embase, Medline, Medline Ahead of Print and In-Process & Other Non-Indexed Citations – OVID [Multifile]

#	Search
1	breast feeding/ or breast feeding education/ or lactation/
2	1 use emczd, emcr
3	exp breast feeding/ or lactation/
4	3 use ppez
5	(breastfeed* or breast feed* or breastfed* or breastfeed* or breast fed or breastmilk or breast milk or expressed milk* or lactat* or (nursing adj (baby or infant* or mother* or neonate* or newborn*))).ti,ab.
6	or/2,4-5
7	exp *cognitive therapy/ or (counseling.sh. and exp *counseling/) or *friend/ or *group processes/ or *group therapy/ or home care/ or *hotline/ or *mindfulness/ or *patient education/ or *peer group/ or *psychotherapy/ or *reality therapy/ or *relaxation training/ or *self help/ or *social adaption/ or *social network/ or *social support/ or *support group/
8	7 use emczd, emcr
9	cognitive behavioral therapy/ or exp counseling/ or education, nonprofessional/ or friends/ or group processes/ or exp home care services/ or hotlines/ or mindfulness/ or patient centered care/ or exp patient education as topic/ or peer group/ or psychotherapy*.sh. or exp psychotherapy, group/ or reality therapy/ or relaxation therapy/ or self-help groups/ or social support/
10	9 use ppez
11	*computer/ or exp *computer assisted therapy/ or *computer network/ or *internet/ or *online system/ or *publication/ or exp *telecommunication/
12	11 use emczd, emcr
13	computers/ or computer assisted instruction/ or computer communication networks/ or exp internet/ or pamphlet*.sh. or therapy, computer assisted/ or exp telecommunications/
14	13 use ppez
15	(((behaviour* or behavior*) adj2 cognitiv*) or cbt or ccbt or cognitive development or ((behavi* or biobehavi* or cognitive*) adj3 (intervention* or manag* or program* or therap* or treat*)) or cognitiv* behav*).ti,ab.
16	counsel*.ti,ab.
17	(((computer or distance based or digital* or dvd or internet or multimedia or online or phone or skill* or technology or telephone or telephealth or telecommunicat* or video* or web) adj based) or ((computer* or distance based or digital or dvd or internet or multimedia or online or technology or telephone or telehealth or telecommunicat* or video* or web) adj3 (coach* or educat* or intervention* or skill* or support* or training*)) or ((education or teaching) adj (intervention or program*

#	Search
	or therap* or psychotherap*)) or elearning or e learning or ((breastfeeding or feeding) adj (diar* or log*)) or booklet* or pamphlet*).ti,ab. or (health education or health promotion).sh.
18	(person centred adj (care or therap*)).ti,ab.
19	(((communit* or social) adj2 support*) or ((home or house) adj2 (call* or visit*)) or skin to skin).ti,ab.
20	(befriend* or be*1 friend* or buddy or buddies or ((community or lay or paid or support) adj (person or worker*))).ti,ab.
21	((peer* or voluntary or volunteer*) adj3 (assist* or advice* or advis* or counsel* or educat* or forum* or help* or mentor* or network* or support* or visit*)).ti,ab.
22	(((peer* or support* or voluntary or volunteer*) adj2 group*) or ((breastfeed* or breast feed* or lactation) adj nurs*)).ti,ab.
23	((breastfeed* or breast feed*) adj2 group*).ti,ab.
24	((peer* or support* or voluntary or volunteer*) adj3 (intervention* or program* or rehab* or th erap* or service* or skill*)).ti,ab.
25	((peer* adj3 (advis* or consultant or educator* or expert* or facilitator* or instructor* or leader* or mentor* or person* or tutor* or worker*)) or expert patient* or mutual aid).ti,ab.
26	(peer* adj3 (assist* or counsel* or educat* or program* or rehab* or service* or supervis*)).ti,ab.
27	((peer*1 or network*) adj2 (discuss* or exchang* or interact* or meeting*)).ti,ab.
28	(((community or family or social) adj (network* or support*)) or group conferencing or ((individualised or individualized) adj support)).ti,ab.
29	((one to one or transition*) adj support*).ti,ab.
30	(lay adj (led or run)).ti,ab.
31	((network* or social or psychosocial) adj (adapt* or reintegrat* or support*)).ti,ab.
32	((well being or wellbeing) adj2 (intervention* or program* or therap* or skill* or strateg* or workshop*)).ti,ab.
33	((support* adj3 (approach* or educat* or forum* or instruct* or interven* or learn* or module* or network* or program* or psychotherap* or strateg* or system* or technique* or therap* or train* or workshop* or work shop*)) or (support* adj (service* or system))).ti,ab.
34	((group adj (prenatal* or antenatal) adj care) or support group*).ti,ab.
35	(helpline or help line or ((phone* or telephone*) adj3 (help* or instruct* or interact* or interven* or mediat* or program* or rehab* or strateg* or support* or teach* or therap* or train* or treat* or workshop*)) or ((phone or telephone*) adj2 (assist* or based or driven or led or mediat*))).ti,ab.
36	(helpseek* or ((search* or seek*) adj3 (care or assistance or counsel* or healthcare or help* or support* or therap* or treat*))).ti,ab.
37	(information adj (needs or provision or support)).ti,ab.
38	(selfhelp or self help or selfmanag* or self manag* or self support or selfsupport).ti,ab.
39	((intervention* or program*) adj3 (continue or continuation or duration or incidence* or initiat*) adj3 (breastfeed* or breastfed* or lactat*)).ti,ab.
40	((intervention* or program*) adj3 increas* adj3 (breastfeed* or breastfed* or lactat*) adj3 (continue or continuation or duration or incidence* or initiat*)).ti,ab.
41	or/8,10,12,14-40
42	intervention 1.ti.

#	Search
43	breast feeding education/ or childbirth education/ or education/ or health education/ or health promotion/ or learning/ or patient education/ or patient education/ or teaching/ or training/
44	43 use emczd, emcr
45	education/ or health education/ or health knowledge, attitudes, practice/ or health promotion/ or mothers/ed or nurse midwives/ed or exp patient education as topic/ or patient education handout/ or prenatal education/ or teaching/
46	45 use ppez
47	((antenatal or father* or mother*) adj2 (eduat* or teach* or train*)).ti,ab.
48	((audiovisual* or education* or print*) adj2 (brochure* or material* or pamphlet*)).ti,ab.
49	(((breastfeed* or breast feed* or breastfed* or lactat*) adj3 (class* or coach* or educat* or intervention* or program* or promotion or session* or support* or taught or teach* or train* or workshop*)) or resourcefulness train* or (skill* adj2 (build* or coach* or educat* or learn* or train))).ti,ab.
50	((antenatal or prenatal or pregnancy) adj2 (class* or coach* or course* or educat* or promotion* or workshop*)).ti,ab.
51	((education* or learning or teaching or training) adj2 (class* or coach* or course* or program* or session* or workshop*)).ti,ab.
52	((education* or learning or teaching or training) adj2 (intervention* or program*)).ti,ab.
53	((computer* or distance based or dvd or internet or multimedia or online or technology or telephone or telephealth or telecommunicat* or video* or web) adj3 educat*).ti,ab.
54	education group*.ti,ab.
55	(best start program* or nursing intervention protocol).ti,ab.
56	((antenatal or prenatal or pregnancy) adj2 visit*).ti,ab.
57	or/42,44,46-56
58	or/41,57
59	"crib (infant equipment)"/ or feeding bottle/ or foreign body/ or pacifier/
60	59 use emczd, emcr
61	foreign bodies/ or exp infant equipment/
62	61 use ppez
63	(binky or dodie* or dummy or dummies or foreign object* or pacifier* or soother* or teat* or teether* or ((plastic* or rubber* or silicon*) adj2 nipple*)).ti,ab.
64	or/60,62-63
65	financial incentive/ or reimbursement/ or (compensation or health promotion or motivation or reward).sh.
66	65 use emczd, emcr
67	(cost* or economics or financ* or funding).sh. use emczd, emcr
68	breast feeding/ec or reimbursement, incentive/ or (compensation* or health promotion or motivation or reward).sh.
69	68 use ppez
70	ec.fs. or (cost* or economics or financ* or funding).sh. use ppez
71	(((cash or financ* or monetary or money) adj3 (incentive* or motivat* or promot* or reward* or token* or transfer*)) or demand side financing or social transfer* or voucher*).ti,ab.
72	(((incentive* or motivat* or reward*) adj3 (breastfeed* or breast fed* or lactation)) or ((incentive* or motivat* or reward*) adj3 (intervention* or strateg*)) or nourishing start for health).ti,ab.

#	Search
73	or/66,67,69-72
74	(adipos* or obes* or (overweight* or over weight*) or (weight adj3 (reduc* or los* or control* or gain*)) or (body mass ind* or bmi or waist hip ratio or skinfold thickness)).ti,ab. or exp obesity/ use emczd, emcr,ppez or overnutrition/ use emczd, emcr or weight reduction/ use emczd, emcr or overweight/ use ppez or weight loss/ use ppez
75	(father* or (male adj2 (partner* or parent*)) or paternal).ti,ab. or father/ use emczd, emcr,ppez
76	or/58,64,73-75
77	clinical trials as topic.sh. or (controlled clinical trial or pragmatic clinical trial or randomized controlled trial).pt. or (placebo or randomi#ed or randomly).ab. or trial.ti.
78	77 use ppez
79	(controlled clinical trial or pragmatic clinical trial or randomized controlled trial).pt. or drug therapy.fs. or (groups or placebo or randomi#ed or randomly or trial).ab.
80	79 use ppez
81	crossover procedure/ or double blind procedure/ or randomized controlled trial/ or single blind procedure/ or (assign* or allocat* or crossover* or cross over* or ((doubl* or singl*) adj blind*) or factorial* or placebo* or random* or volunteer*).ti,ab.
82	81 use emczd, emcr
83	or/78,80,82
84	meta-analysis/
85	meta-analysis as topic/ or systematic reviews as topic/
86	"systematic review"/
87	meta-analysis/
88	(meta analy* or metanaly* or metaanaly*).ti,ab.
89	((systematic or evidence) adj2 (review* or overview*)).ti,ab.
90	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
91	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
92	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
93	(search* adj4 literature).ab.
94	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
95	cochrane.jw.
96	((pool* or combined) adj2 (data or trials or studies or results)).ab.
97	(or/84-85,88,90-95) use ppez
98	(or/86-89,91-96) use emczd, emcr
99	or/97-98
100	or/83,99
101	6 and 76 and 100
102	101
103	limit 102 to english language
104	limit 103 to yr="1995 - 2019"

1 **Database: Database:** CDSR, CCRCT [Wiley]

#	Search
#1	mesh descriptor: [breast feeding] explode all trees
#2	mesh descriptor: [lactation] explode all trees
#3	((breastfeed* or “breast feed*” or breastfed* or breastfeed* or “breast fed” or breastmilk or “breast milk” or “expressed milk* or lactat* or (nursing near/1 (baby or infant* or mother* or neonate* or newborn*))):ti,ab,kw
#4	#1 or #2 or #3
#5	mesh descriptor: [counseling] explode all trees
#6	mesh descriptor: [home care services] explode all trees
#7	mesh descriptor: [mindfulness] this term only
#8	mesh descriptor: [patient-centered care] this term only
#9	(psychotherapy*):kw
#10	mesh descriptor: [psychotherapy, group] explode all trees
#11	mesh descriptor: [reality therapy] this term only
#12	mesh descriptor: [relaxation therapy] this term only
#13	mesh descriptor: [social support] explode all trees
#14	mesh descriptor: [education, nonprofessional] this term only
#15	mesh descriptor: [friends] this term only
#16	mesh descriptor: [group processes] this term only
#17	mesh descriptor: [hotlines] this term only
#18	mesh descriptor: [peer group] this term only
#19	mesh descriptor: [self-help groups] this term only
#20	(pamphlet*):kw
#21	mesh descriptor: [computer-assisted instruction] this term only
#22	mesh descriptor: [computer communication networks] this term only
#23	mesh descriptor: [internet] explode all trees
#24	mesh descriptor: [therapy, computer-assisted] this term only
#25	mesh descriptor: [telecommunications] this term only
#26	((((behaviour* or behavior*) near/2 cognitiv*) or cbt or ccbt or “cognitive development” or ((behavi* or biobehavi* or cognitive*) near/3 (intervention* or manag* or program* or therap* or treat*)) or “cognitiv* behav*”)):ti,ab,kw
#27	(counsel*):ti,ab,kw
#28	((((computer or “distance based” or digital* or dvd or internet or multimedia or online or phone or skill* or technology or telephone or telephealth or telecommunicat* or video* or web) near/1 based) or ((computer* or “distance based” or digital or dvd or internet or multimedia or online or technology or telephone or telehealth or telecommunicat* or video* or web) near/3 (coach* or educat* or intervention* or skill* or support* or training*)) or ((education or teaching) near/1 (intervention or program* or therap* or psychotherap*)) or elearning or “e learning” or ((breastfeeding or feeding) near/1 (diar* or log*)) or booklet* or pamphlet*)):ti,ab,kw
#29	mesh descriptor: [health education] this term only
#30	mesh descriptor: [health promotion] this term only
#31	mesh descriptor: [patient education as topic] explode all trees
#32	mesh descriptor: [consumer health information] explode all trees
#33	((“person centred” near/1 (care or therap*))):ti,ab,kw
#34	((befriend* or “be* friend*” or buddy or buddies or ((community or lay or paid or support) near/1 (person or worker*)))):ti,ab,kw

#	Search
#35	(((peer* or voluntary or volunteer*) near/3 (assist* or advice* or advis* or counsel* or educat* or forum* or help* or mentor* or network* or support* or visit*))):ti,ab,kw
#36	((((peer* or support* or voluntary or volunteer*) near/2 group*) or ((breastfeed* or breast feed* or lactation) near/1 nurs*))):ti,ab,kw
#37	(((breastfeed* or “breast feed*”) near/2 group*)):ti,ab,kw
#38	(((peer* or support* or voluntary or volunteer*) near/3 (intervention* or program* or rehab* or therap* or service* or skill*))):ti,ab,kw
#39	((peer* near/3 (assist* or counsel* or educat* or program* or rehab* or service* or supervis*))):ti,ab,kw
#40	(((peer* near/3 (advis* or consultant or educator* or expert* or facilitator* or instructor* or leader* or mentor* or person* or tutor* or worker*)) or “expert patient*” or “mutual aid”)):ti,ab,kw
#41	(((peer* or network*) near/2 (discuss* or exchang* or interact* or meeting*))):ti,ab,kw
#42	(((“one to one” or transition*) near/1 support*)):ti,ab,kw
#43	((lay near/1 (led or run))):ti,ab,kw
#44	(((network* or social or psychosocial) near/1 (adapt* or reintegrat* or support*))):ti,ab,kw
#45	((((community or family or social) near/1 (network* or support*)) or group conferencing or “individualised support” or “individualized support”)):ti,ab,kw
#46	(((“well being” or wellbeing) near/2 (intervention* or program* or therap* or skill* or strateg* or workshop*))):ti,ab,kw
#47	(((support* near/3 (approach* or educat* or forum* or instruct* or interven* or learn* or module* or network* or program* or psychotherap* or strateg* or system* or technique* or therap* or train* or workshop* or work shop*)) or (support* near/1 (service* or system)))):ti,ab,kw
#48	(((group near/1 (prenatal* or antenatal) near/1 care) or support group*)):ti,ab,kw
#49	((helpline or “help line” or ((phone* or telephone*) near/3 (help* or instruct* or interact* or interven* or mediat* or program* or rehab* or strateg* or support* or teach* or therap* or train* or treat* or workshop*)) or ((phone or telephone*) near/2 (assist* or based or driven or led or mediat*)))):ti,ab,kw
#50	((helpseek* or ((search* or seek*) near/3 (care or assistance or counsel* or healthcare or help* or support* or therap* or treat*)))):ti,ab,kw
#51	((information near/1 (needs or provision or support))):ti,ab,kw
#52	((selfhelp or “self help” or selfmanag* or “self manag*” or “self support” or selfsupport)):ti,ab,kw
#53	(((intervention* or program*) near/3 (continue or continuation or duration or incidence* or initiat*) near/3 (breastfeed* or breastfed* or lactat*))):ti,ab,kw
#54	(((intervention* or program*) near/3 increas* near/3 (breastfeed* or breastfed* or lactat*) near/3 (continue or continuation or duration or incidence* or initiat*))):ti,ab,kw
#55	(intervention*):ti
#56	mesh descriptor: [education] this term only
#57	mesh descriptor: [health education] this term only
#58	mesh descriptor: [health knowledge, attitudes, practice] this term only
#59	mesh descriptor: [patient education handout] this term only
#60	mesh descriptor: [teaching] this term only
#61	mesh descriptor: [mothers] and with qualifier(s): [education - ed]
#62	mesh descriptor: [nurse midwives] and with qualifier(s): [education - ed]
#63	(((antenatal or father* or mother*) near/2 (eduat* or teach* or train*))):ti,ab,kw

#	Search
#64	(((audiovisual* or education* or print*) near/2 (brochure* or material* or pamphlet*))):ti,ab,kw
#65	((((breastfeed* or “breast feed*” or breastfed* or lactat*) near/3 (class* or coach* or educat* or intervention* or program* or promotion or session* or support* or taught or teach* or train* or workshop*)) or “resourcefulness train*” or (skill* near/2 (build* or coach* or educat* or learn* or train)))):ti,ab,kw
#66	(((antenatal or prenatal or pregnancy) near/2 (class* or coach* or course* or educat* or promotion* or workshop*))):ti,ab,kw(((education* or learning or teaching or training) near/2 (class* or coach* or course* or program* or session* or workshop*))):ti,ab,kw
#67	(((education* or learning or teaching or training) near/2 (class* or coach* or course* or program* or session* or workshop*))):ti,ab,kw
#68	(((education* or learning or teaching or training) near/2 (intervention* or program*))):ti,ab,kw
#69	(((computer* or “distance based” or dvd or internet or multimedia or online or technology or telephone or telephealth or telecommunicat* or video* or web) near/3 educat*)):ti,ab,kw
#70	(“education group*”):ti,ab,kw
#71	((“best start program*” or “nursing intervention protocol”)):ti,ab,kw
#72	(((antenatal or prenatal or pregnancy) near/2 visit*)):ti,ab,kw
#73	#5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 or #58 or #59 or #60 or #61 or #62 or #63 or #64 or #65 or #66 or #67 or #68 or #69 or #70 or #71 or #72
#74	mesh descriptor: [foreign bodies] this term only
#75	mesh descriptor: [infant equipment] explode all trees
#76	((binky or dodie* or dummy or dummies or “foreign object*” or pacifier* or soother* or teat* or teether* or ((plastic* or rubber* or silicon*) near/2 nipple*))):ti,ab,kw
#77	#74 or #75 or #76
#78	mesh descriptor: [breast feeding] explode all trees and with qualifier(s): [economics - ec]
#79	mesh descriptor: [reimbursement, incentive] this term only
#80	((compensation* or health promotion or motivation or reward)):kw
#81	((cost* or economics or financ* or funding)):kw
#82	((((cash or financ* or monetary or money) near/3 (incentive* or motivat* or promot* or reward* or token* or transfer*)) or “demand side financing” or “social transfer*” or voucher*)):ti,ab,kw
#83	((((incentive* or motivat* or reward*) near/3 (breastfeed* or breast fed* or lactation)) or ((incentive* or motivat* or reward*) near/3 (intervention* or strateg*)) or “nourishing start for health”)):ti,ab,kw
#84	#78 or #79 or #80 or #81 or #82 or #83
#85	mesh descriptor: [obesity] explode all trees
#86	mesh descriptor: [overweight] this term only
#87	mesh descriptor: [weight loss] this term only
#88	((adipos* or obes* or (overweight* or “over weight*”) or (weight near/3 (reduc* or los* or control* or gain*)) or (“body mass ind*” or bmi or “waist hip ratio” or “skinfold thickness”))):ti,ab,kw
#89	#85 or #86 or #87 or #88
#90	mesh descriptor: [fathers] this term only

#	Search
#91	((father* or (male near/2 (partner* or parent*)) or paternal)):ti,ab,kw
#92	#90 or #91
#93	#73 or #77 or #84 or #89 or #92
#94	#4 and #93
#95	#94 with cochrane library publication date between jan 1995 and apr 2019

1 **Database:** DARE, HTA (global) [CRD Web]

#	Search
1	mesh descriptor postpartum period in dare,hta
2	mesh descriptor peripartum period in dare,hta
3	mesh descriptor postnatal care in dare,hta
4	(nullipara* or peri natal* or perinatal* or postbirth or post birth or postdelivery or post delivery or postnatal* or post natal* or postpartum* or post partum* or primipara* or puerpera* or puerperium* or ((after or follow*) near2 birth*)) in dare, hta
5	#1 or #2 or #3 or #4
6	mesh descriptor breast feeding explode all trees in dare,hta
7	mesh descriptor lactation in dare,hta
8	(breastfeed* or breast feed* or breastfed* or breastfeed* or breast fed or breastmilk or breast milk or expressed milk* or lactat* or (nursing next (baby or infant* or mother* or neonate* or newborn*))) in dare, hta
9	#6 or #7 or #8
10	mesh descriptor bottle feeding in dare,hta
11	mesh descriptor infant formula in dare,hta
12	(((bottle or formula or synthetic) near2 (artificial or fed or feed* or infant* or milk*)) or (artificial next (formula or milk)) or bottlefed or bottlefeed or cup feeding or (milk near2 (substitut* or supplement*)) or ((infant or milk or water or glucose or dextrose or formula) next supplement) or formula supplement* or supplement feed or milk feed or ((baby or babies or infant* or neonate* or newborn*) next (formula* or milk)) or formulafeed or formulated or (milk near2 powder*) or hydrolyzed formula* or (((feeding or baby or infant) next bottle*) or infant feeding or bottle nipple* or milk pump*)) in dare, hta
13	#10 or #11 or #12
14	#5 or #9 or #13

2 **Health economic search**

3 The search for this topic was last run on 5th December 2019.

4 **Database:** Emcare, Embase, Medline, Medline Ahead of Print and In-Process & Other Non-
5 Indexed Citations (global) – OVID [Multifile]

#	Search
1	puerperium/ or perinatal period/ or postnatal care/
2	1 use emczd, emcr
3	postpartum period/ or peripartum period/ or postnatal care/
4	3 use ppez
5	(nullipara* or peri natal* or perinatal* or postbirth or post birth or postdelivery or post delivery or postnatal* or post natal* or postpartum* or post partum* or primipara* or puerpera* or puerperium* or ((after or follow*) adj2 birth*)).ti,ab.

#	Search
6	or/2,4-5
7	breast feeding/ or breast feeding education/ or lactation/
8	7 use emczd, emcr
9	exp breast feeding/ or lactation/
10	9 use ppez
11	(breastfeed* or breast feed* or breastfed* or breastfeed* or breast fed or breastmilk or breast milk or expressed milk* or lactat* or (nursing adj (baby or infant* or mother* or neonate* or newborn*))).ti,ab.
12	or/8,10-11
13	artificial food/ or bottle feeding/ or infant feeding/
14	13 use emczd, emcr
15	bottle feeding/ or infant formula/
16	15 use ppez
17	(((bottle or formula or synthetic) adj2 (artificial or fed or feed* or infant* or milk*)) or (artificial adj (formula or milk)) or bottlefed or bottlefeed or cup feeding or (milk adj2 (substitut* or supplement*)) or ((infant or milk or water or glucose or dextrose or formula) adj supplement) or formula supplement* or supplement feed or milk feed or ((baby or babies or infant* or neonate* or newborn*) adj (formula* or milk)) or formulafeed or formulated or (milk adj2 powder*) or hydrolyzed formula* or (((feeding or baby or infant) adj bottle*) or infant feeding or bottle nipple* or milk pump*)).ti,ab.
18	or/14,16-17
19	or/6,12,18
20	budget/ or exp economic evaluation/ or exp fee/ or funding/ or exp health care cost/ or health economics/
21	20 use emczd, emcr
22	exp budgets/ or exp "costs and cost analysis"/ or economics/ or exp economics, hospital/ or exp economics, medical/ or economics, nursing/ or economics, pharmaceutical/ or exp "fees and charges"/ or value of life/
23	22 use ppez
24	budget*.ti,ab. or cost*.ti. or (economic* or pharmaco?economic*).ti. or (price* or pricing*).ti,ab. or (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab. or (financ* or fee or fees).ti,ab. or (value adj2 (money or monetary)).ti,ab.
25	or/21,23-24
26	economic model/ or quality adjusted life year/ or "quality of life index"/
27	(cost-benefit analysis.sh. and (cost-effectiveness ratio* and (perspective* or life expectanc*)).tw.)
28	((quality of life or qol).tw. and cost benefit analysis.sh.)
29	or/26-28 use emczd, emcr
30	models, economic/ or quality-adjusted life years/
31	(cost-benefit analysis.sh. and (cost-effectiveness ratio* and (perspective* or life expectanc*)).tw.)
32	((quality of life or qol).tw. and cost-benefit analysis.sh.)
33	or/30-32 use ppez
34	(eq-5d* or eq5d* or eq-5* or eq5* or euroqual* or euro qual* or euroqual 5d* or euro qual 5d* or euro qol* or euroqol*or euro quol* or euroquol* or euro quol5d* or euroquol5d* or eur qol* or eurqol* or eur qol5d* or eurqol5d* or eur?qul* or eur?qul5d* or euro* quality of life or european qol).tw.

#	Search
35	(euro* adj3 (5 d* or 5d* or 5 dimension* or 5dimension* or 5 domain* or 5domain*)).tw.
36	(hui or hui2 or hui3).tw.
37	(illness state* or health state*).tw.
38	(multiattibute* or multi attribute*).tw.
39	(qaly* or qal or qald* or qale* or qtime* or qwb* or daly).tw.
40	(quality adjusted or quality adjusted life year*).tw.
41	(sf36 or sf 36 or sf thirty six or sf thirtysix).tw.
42	sickness impact profile.sh.
43	(time trade off*1 or time tradeoff*1 or tto or timetradeoff*1).tw.
44	(utilit* adj3 (score*1 or valu* or health* or cost* or measur* or disease* or mean or gain or gains or index*)).tw.
45	utilities.tw.
46	((qol or hrqol or quality of life).tw. or *quality of life/) and ((qol or hrqol* or quality of life) adj2 (change*1 or declin* or decreas* or deteriorat* or effect or effects or high* or impact*1 or impacted or improve* or increas* or low* or reduc* or score or scores or worse)).ab.
47	quality of life.sh. and ((health-related quality of life or (health adj3 status) or ((quality of life or qol) adj3 (chang* or improv*)) or ((quality of life or qol) adj (measure*1 or score*1))).tw. or (quality of life or qol).ti. or ec.fs.)
48	or/29,33-47
49	or/25,48
50	19 and 50
51	limit 50 to english language
52	(animals/ not humans/) or exp animals, laboratory/ or exp animal experimentation/ or exp models, animal/ or exp rodentia/
53	52 use ppez
54	(animal/ not human/) or nonhuman/ or exp animal experiment/ or exp experimental animal/ or animal model/ or exp rodent/
55	54 use emczd, emcr
56	(rat or rats or mouse or mice).ti.
57	or/53,55-56
58	51 not 57

1 **Database:** HTA, NHS EED (global) [CRD Web]

#	Search
1	mesh descriptor postpartum period in hta, nhs eed
2	mesh descriptor peripartum period in hta, nhs eed
3	mesh descriptor postnatal care hta, nhs eed
4	(nullipara* or peri natal* or perinatal* or postbirth or post birth or postdelivery or post delivery or postnatal* or post natal* or postpartum* or post partum* or primipara* or puerpera* or puerperium* or ((after or follow*) near2 birth*)) hta, nhs eed
5	#1 or #2 or #3 or #4
6	mesh descriptor breast feeding explode all trees hta, nhs eed
7	mesh descriptor lactation hta, nhs eed
8	(breastfeed* or breast feed* or breastfed* or breastfeed* or breast fed or breastmilk or breast milk or expressed milk* or lactat* or (nursing next (baby or infant* or mother* or neonate* or newborn*))) hta, nhs eed
9	#6 or #7 or #8
10	mesh descriptor bottle feeding hta, nhs eed

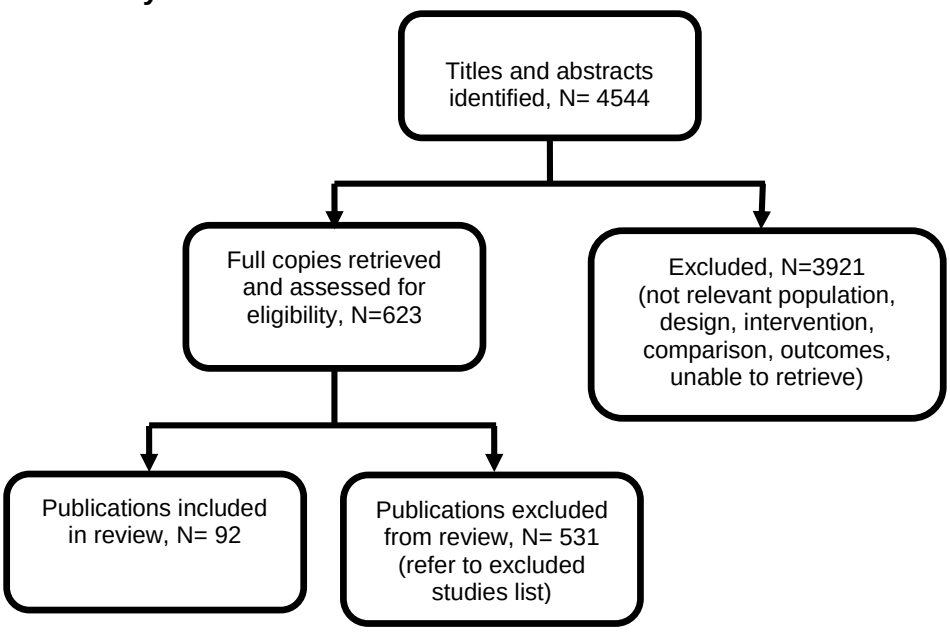
#	Search
11	mesh descriptor infant formula hta, nhs eed
12	(((bottle or formula or synthetic) near2 (artificial or fed or feed* or infant* or milk*)) or (artificial next (formula or milk)) or bottlefed or bottlefeed or cup feeding or (milk near2 (substitut* or supplement*)) or ((infant or milk or water or glucose or dextrose or formula) next supplement) or formula supplement* or supplement feed or milk feed or ((baby or babies or infant* or neonate* or newborn*) next (formula* or milk)) or formulafeed or formulated or (milk near2 powder*) or hydrolyzed formula* or (((feeding or baby or infant) next bottle*) or infant feeding or bottle nipple* or milk pump*)) hta, nhs eed
13	#10 or #11 or #12
14	#5 or #9 or #13

1

Appendix C – Clinical evidence study selection

Clinical study selection 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)?

Figure 1: Study selection flow chart



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)?

See separate document 'Evidence review P: Breastfeeding interventions [appendix D Clinical evidence tables]'.

Appendix E – Forest plots

Forest plots 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)?

Education, advice or support from peer or professional provided antentally (Intervention 1)

Comparison 1.1. Education, advice or support from peer or professional provided antentally (Intervention 1) versus standard care

Figure 2: Initiation of breastfeeding

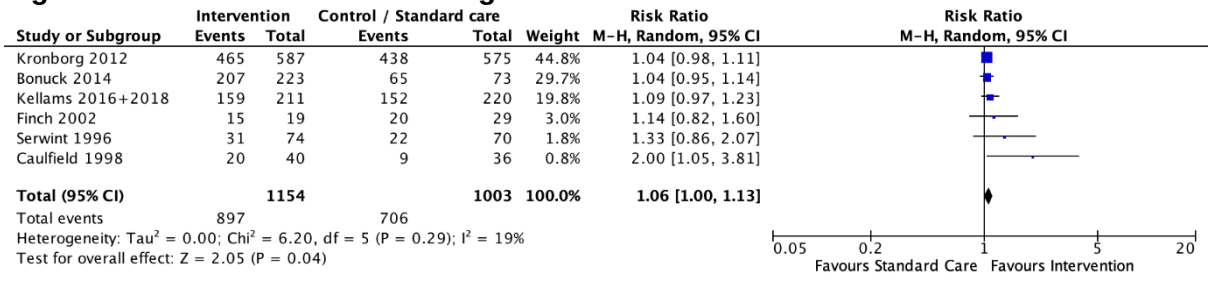


Figure 3: Initiation of breastfeeding, subgroup analysis based on the womans intention to breastfeed

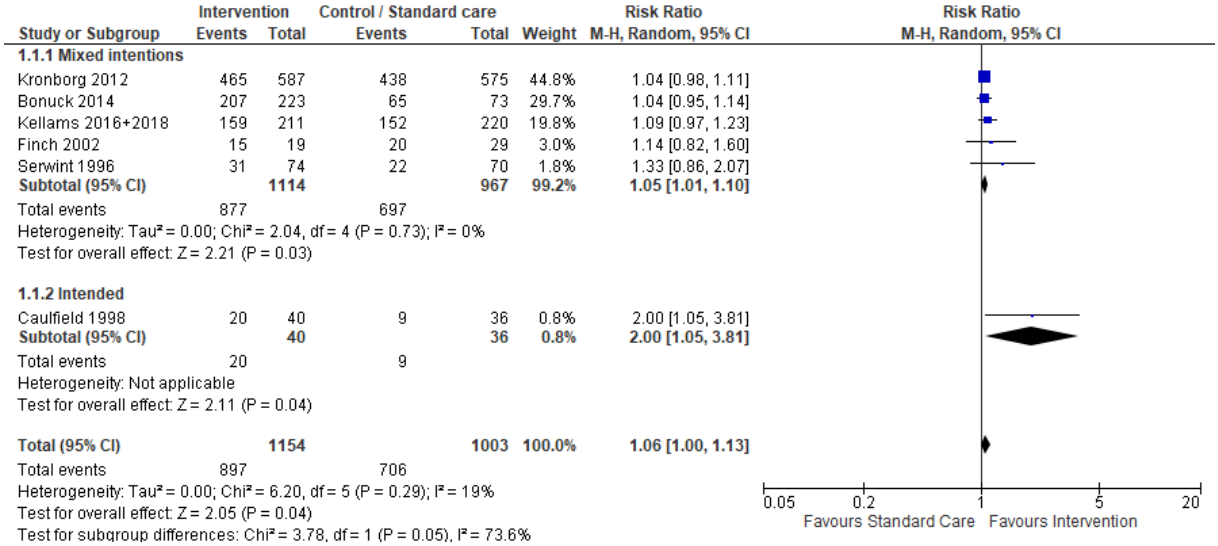
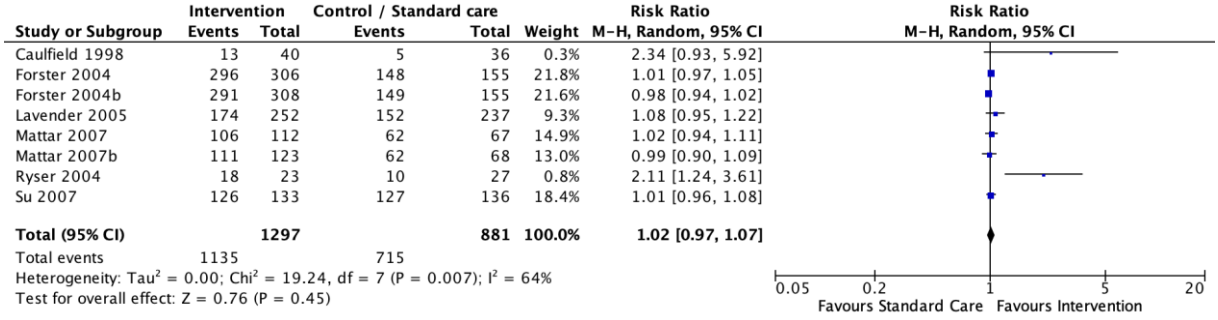
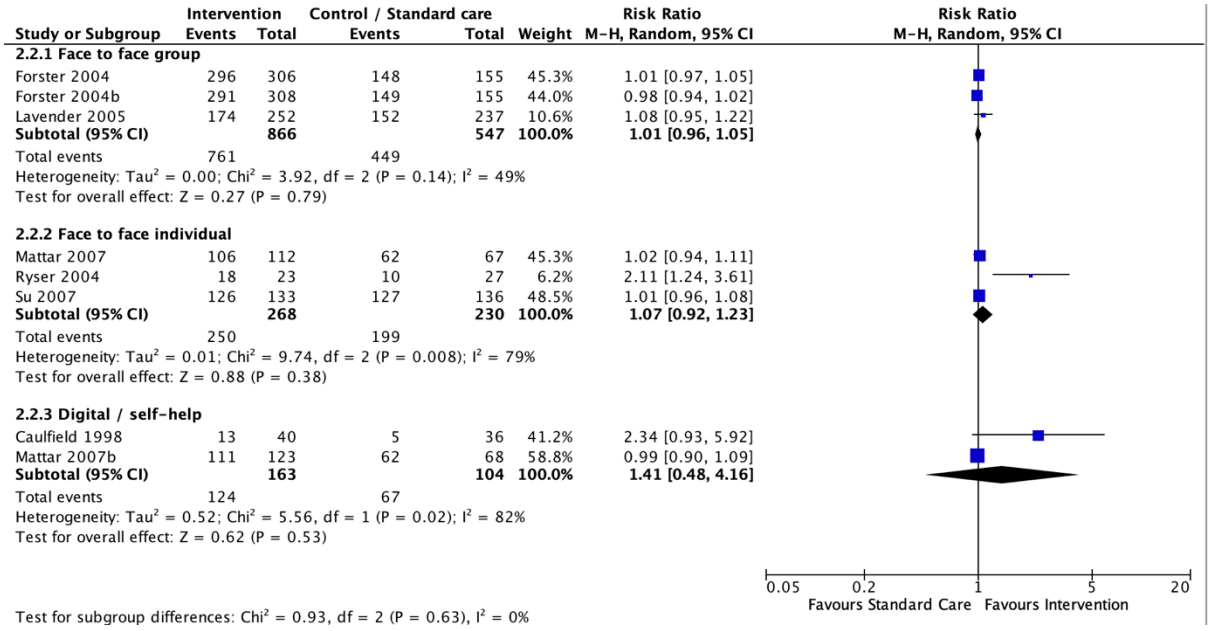


Figure 4: Any breastfeeding between 3 and 14 days, all studies



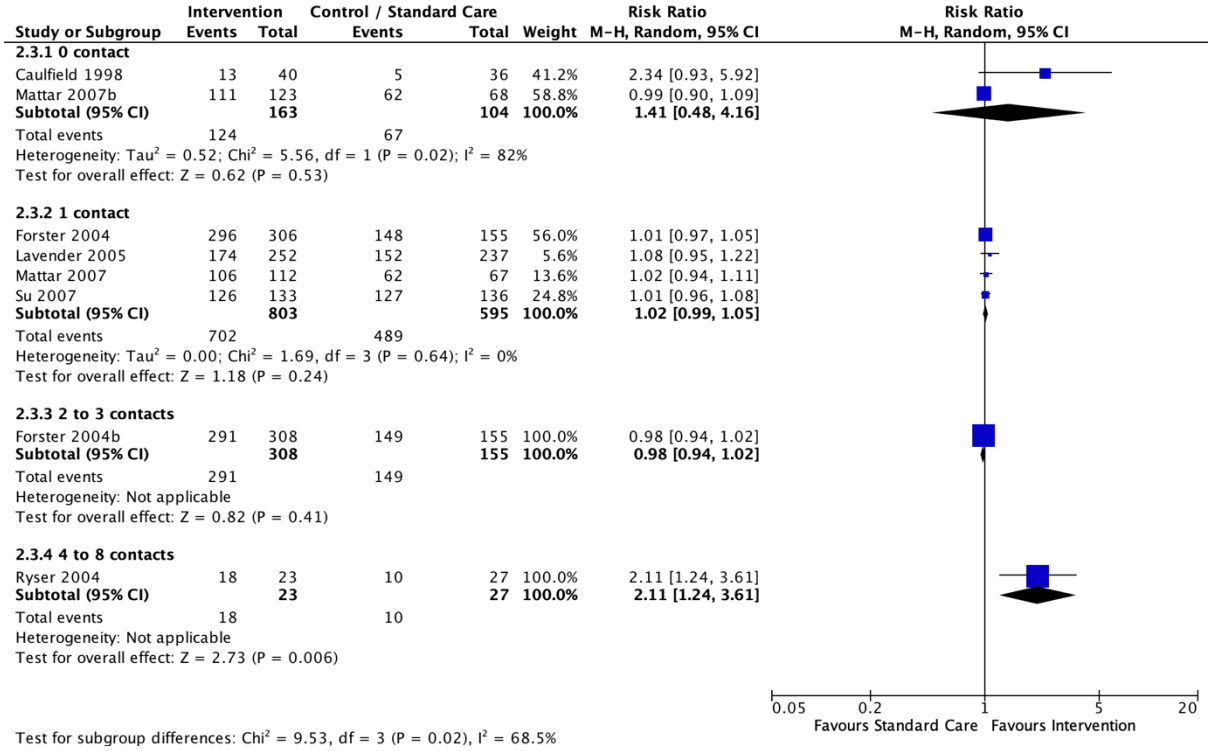
1

Figure 5: Any breastfeeding between 3 and 14 days, subgroup analysis based on how the intervention was delivered



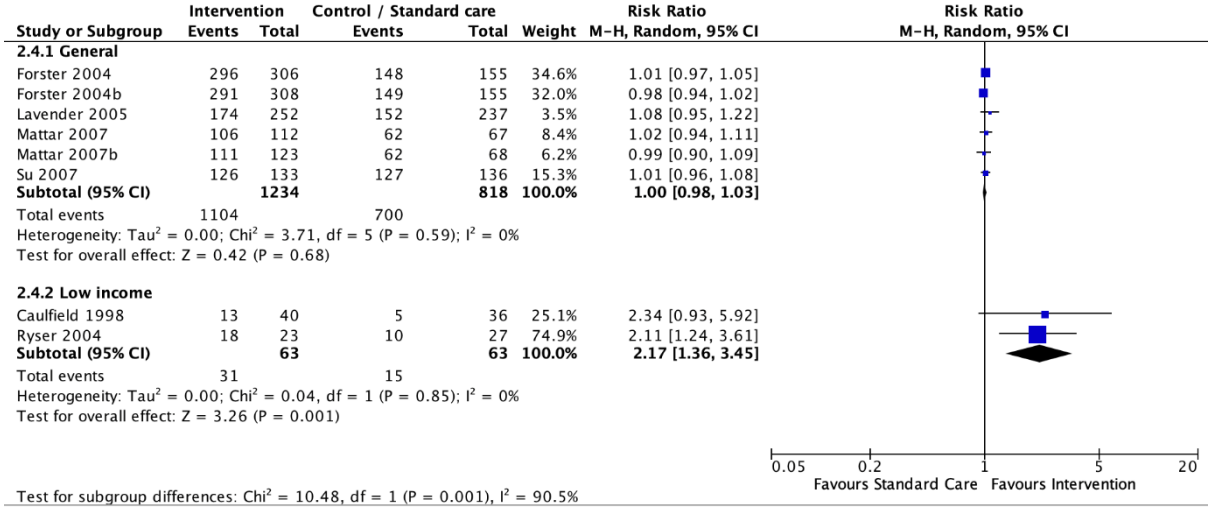
2

Figure 6: Any breastfeeding at 3 to 14 days, subgroup analysis based on number of contacts



1

Figure 7: Any breastfeeding at 3 to 14 days, subgroup analysis based on population



2

Figure 8: Any breastfeeding 3 to 14 days, subgroup analysis based on the womans intention to breastfeed

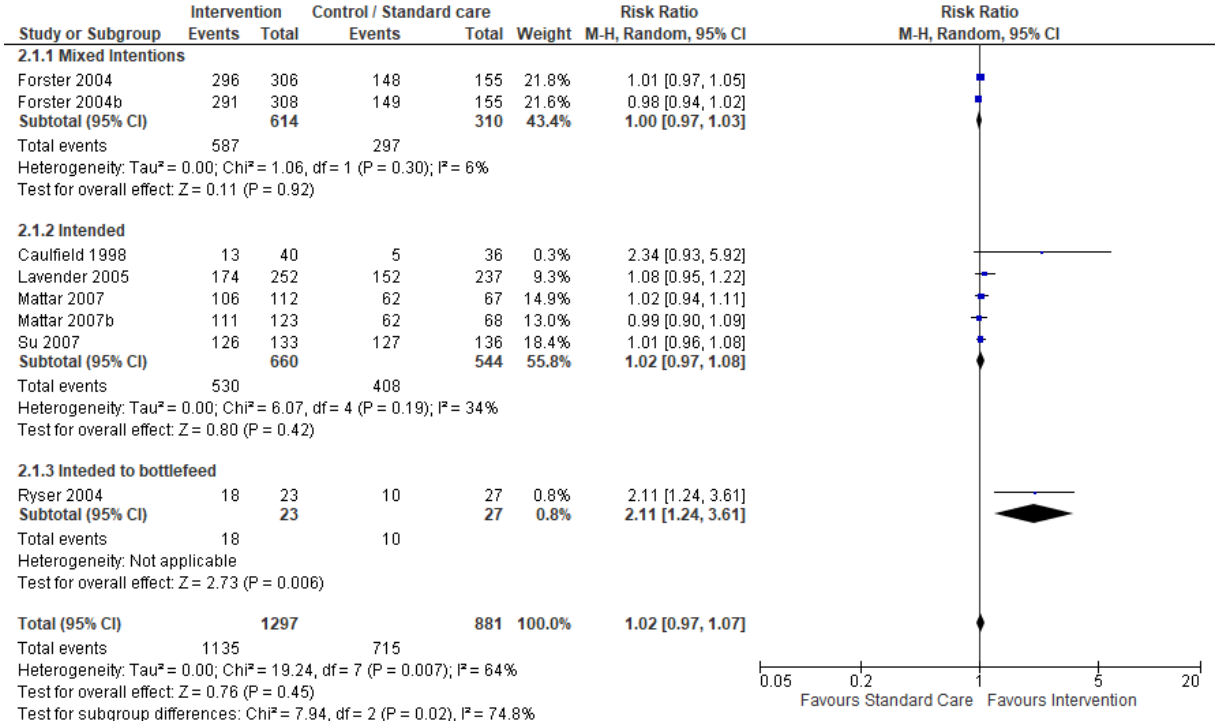


Figure 9: Exclusive breastfeeding at 3 to 14 days, all studies

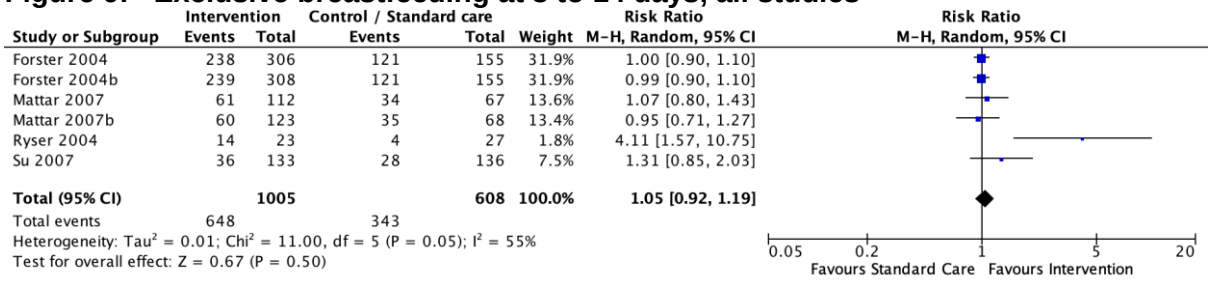
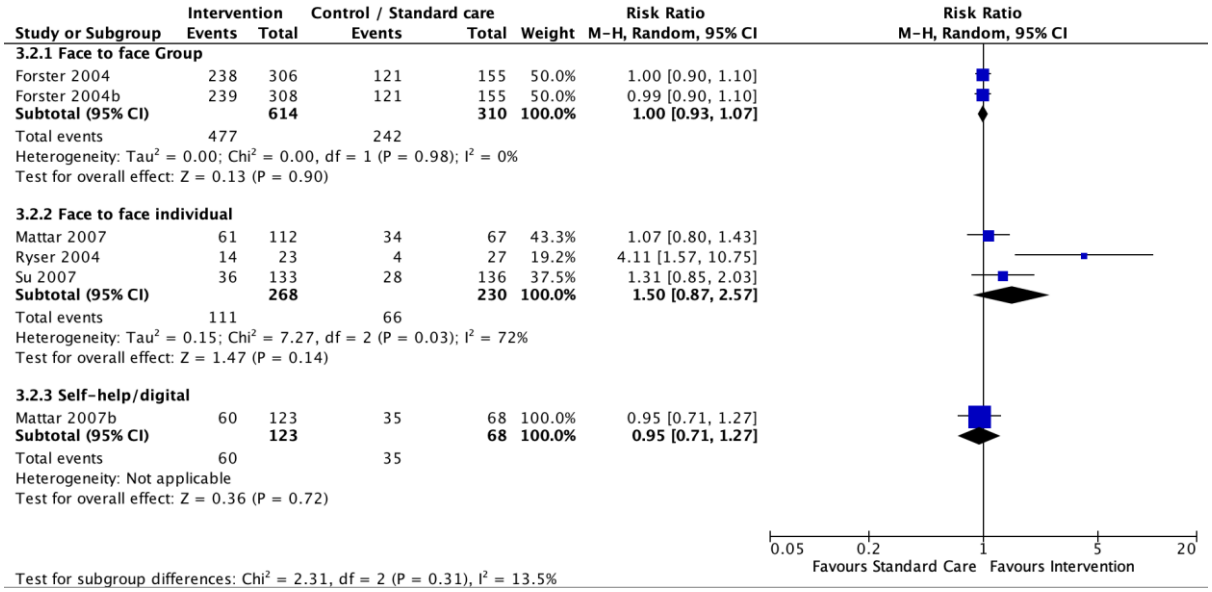
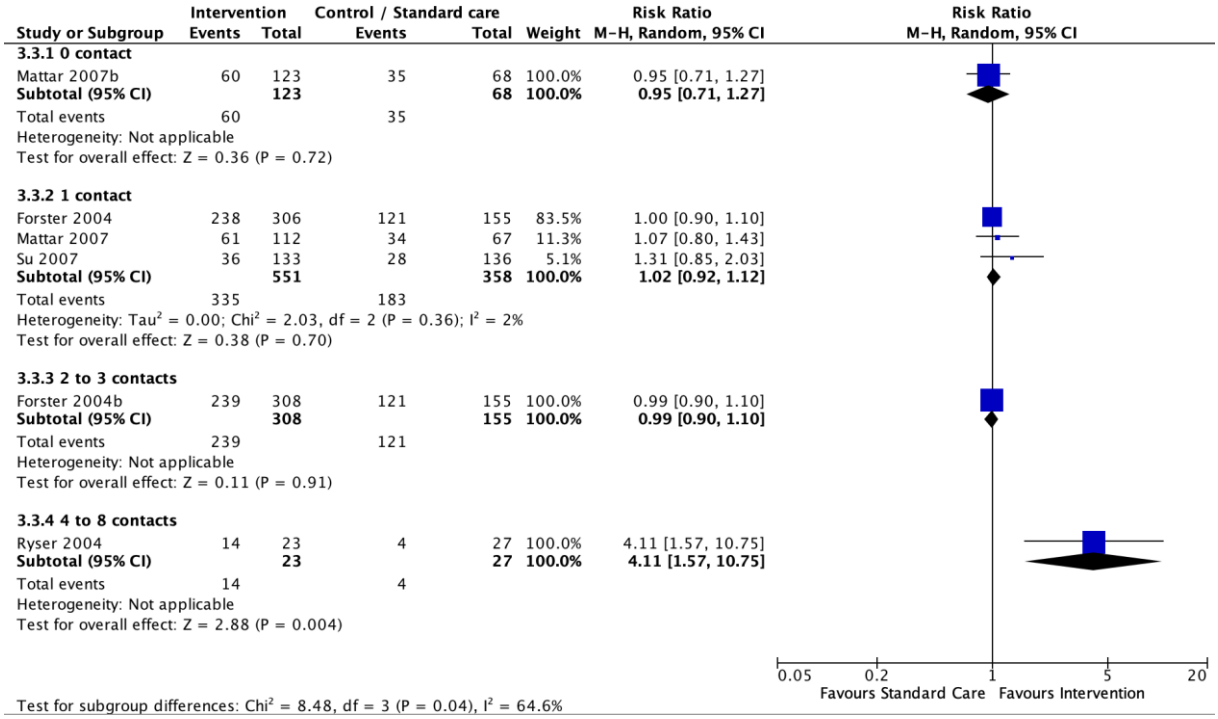


Figure 10: Exclusive breastfeeding at 3 to 14 days, subgroup analysis based on how the intervention was delivered



1

Figure 11: Exclusive breastfeeding at 3 to 14 days, subgroup analysis based on number of contacts



2

Figure 12: Exclusive breastfeeding at 3 to 14 days, subgroup analysis based on population

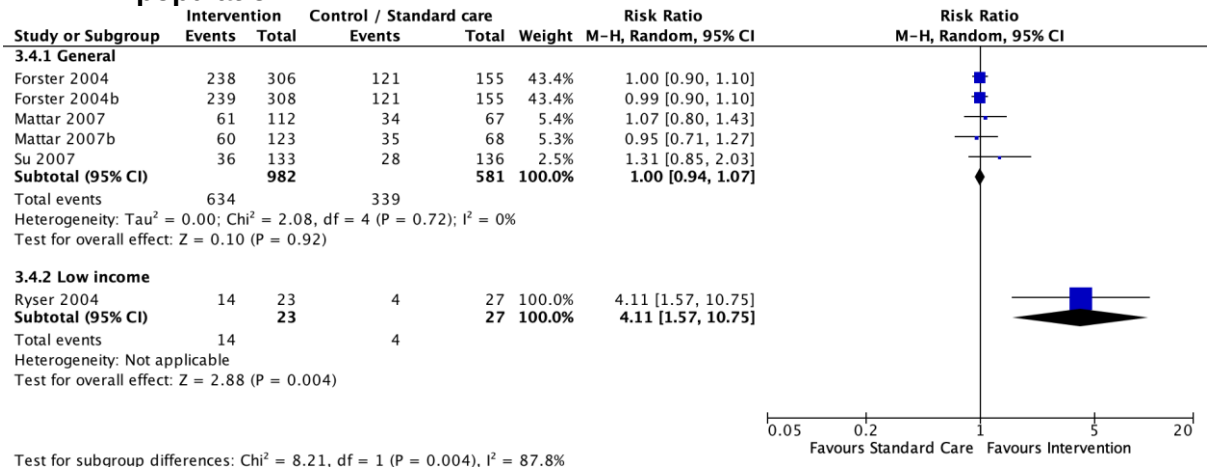


Figure 13: Exclusive breastfeeding 3 to 14 days, subgroup analysis based on the womans intention to breastfeed

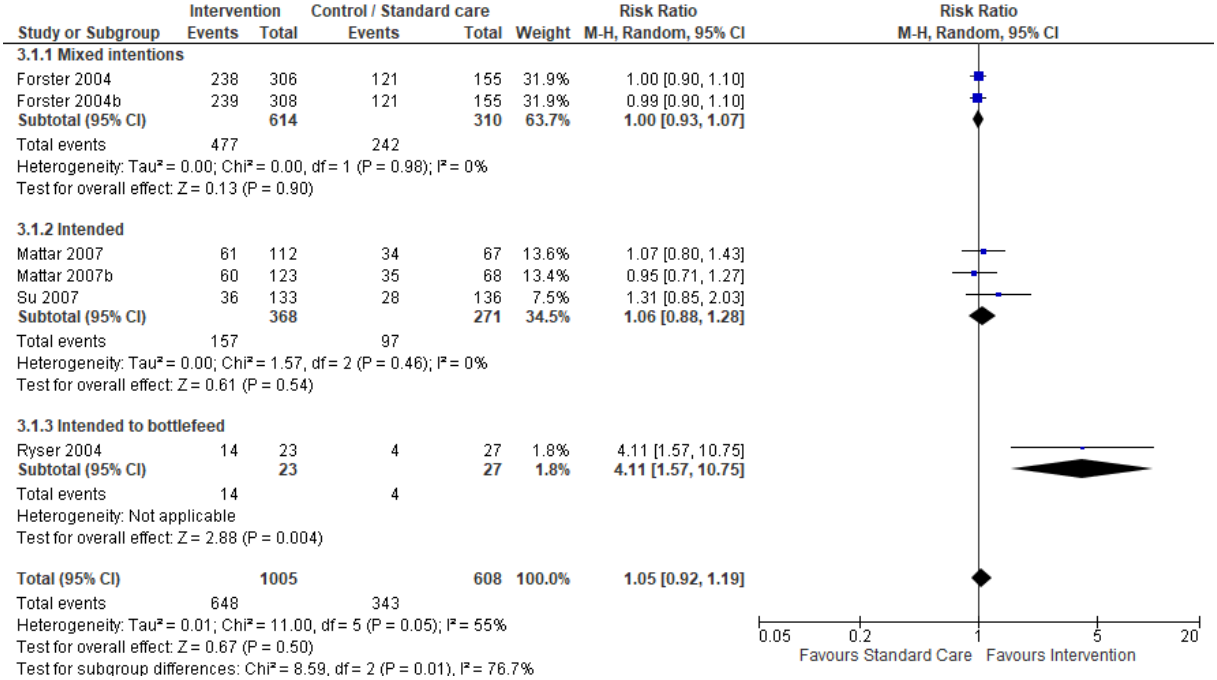
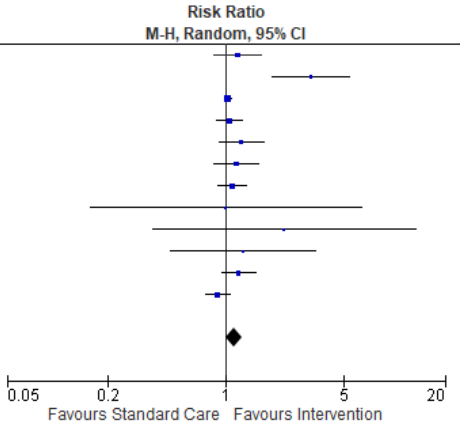


Figure 14: Any breastfeeding at 6 to 12 weeks, all studies

Study or Subgroup	Intervention Events	Intervention Total	Control / Standard care Events	Control / Standard care Total	Weight	Risk Ratio M-H, Random, 95% CI
Bonuck 2014	102	229	28	74	7.4%	1.18 [0.85, 1.63]
Duffy 1997	32	35	10	35	3.6%	3.20 [1.88, 5.46]
Kronborg 2012	503	587	478	575	19.9%	1.03 [0.98, 1.08]
Lavender 2005	130	252	116	237	13.6%	1.05 [0.88, 1.26]
Mattar 2007	64	112	30	65	8.0%	1.24 [0.91, 1.68]
Mattar 2007b	66	120	31	65	8.2%	1.15 [0.85, 1.56]
Noel-Weiss 2006	40	47	35	45	12.6%	1.09 [0.90, 1.33]
Schlickau 2005	3	9	1	3	0.4%	1.00 [0.16, 6.35]
Schlickau 2005b	5	9	1	4	0.4%	2.22 [0.37, 13.38]
Serwint 1996	8	54	6	51	1.2%	1.26 [0.47, 3.38]
Su 2007	73	127	65	134	11.0%	1.18 [0.94, 1.49]
Wong 2014	116	233	131	236	13.8%	0.90 [0.75, 1.07]
Total (95% CI)		**1814**		**1524**	**100.0%**	**1.12 [1.01, 1.26]**
Total events	1142		932			

Heterogeneity: Tau² = 0.02; Chi² = 25.70, df = 11 (P = 0.007); I² = 57%
Test for overall effect: Z = 2.05 (P = 0.04)

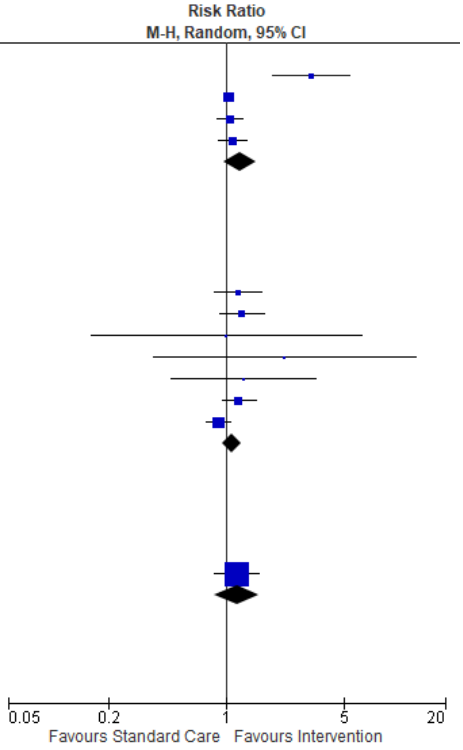


1

Figure 15: Any breastfeeding at 6 to 12 weeks, subgroup analysis based on how the intervention was delivered

Study or Subgroup	Intervention Events	Intervention Total	Control / Standard care Events	Control / Standard care Total	Weight	Risk Ratio M-H, Random, 95% CI
4.2.1 Face to Face group						
Duffy 1997	32	35	10	35	11.3%	3.20 [1.88, 5.46]
Kronborg 2012	503	587	478	575	33.7%	1.03 [0.98, 1.08]
Lavender 2005	130	252	116	237	28.1%	1.05 [0.88, 1.26]
Noel-Weiss 2006	40	47	35	45	26.9%	1.09 [0.90, 1.33]
Subtotal (95% CI)		**921**		**892**	**100.0%**	**1.20 [0.96, 1.49]**
Total events	705		639			
Heterogeneity: Tau² = 0.04; Chi² = 18.63, df = 3 (P = 0.0003); I² = 84%						
Test for overall effect: Z = 1.62 (P = 0.11)						
4.2.2 Face to Face individual						
Bonuck 2014	102	229	28	74	14.5%	1.18 [0.85, 1.63]
Mattar 2007	64	112	30	65	16.1%	1.24 [0.91, 1.68]
Schlickau 2005	3	9	1	3	0.5%	1.00 [0.16, 6.35]
Schlickau 2005b	5	9	1	4	0.5%	2.22 [0.37, 13.38]
Serwint 1996	8	54	6	51	1.8%	1.26 [0.47, 3.38]
Su 2007	73	127	65	134	26.2%	1.18 [0.94, 1.49]
Wong 2014	116	233	131	236	40.4%	0.90 [0.75, 1.07]
Subtotal (95% CI)		**773**		**567**	**100.0%**	**1.07 [0.94, 1.22]**
Total events	371		262			
Heterogeneity: Tau² = 0.00; Chi² = 6.69, df = 6 (P = 0.35); I² = 10%						
Test for overall effect: Z = 1.00 (P = 0.32)						
4.2.3 Digital / Self Help						
Mattar 2007b	66	120	31	65	100.0%	1.15 [0.85, 1.56]
Subtotal (95% CI)		**120**		**65**	**100.0%**	**1.15 [0.85, 1.56]**
Total events	66		31			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.93 (P = 0.35)						

Test for subgroup differences: Chi² = 0.84, df = 2 (P = 0.66), I² = 0%



2

Figure 16: Any breastfeeding at 6 to 12 weeks, subgroup analysis based on number of contacts

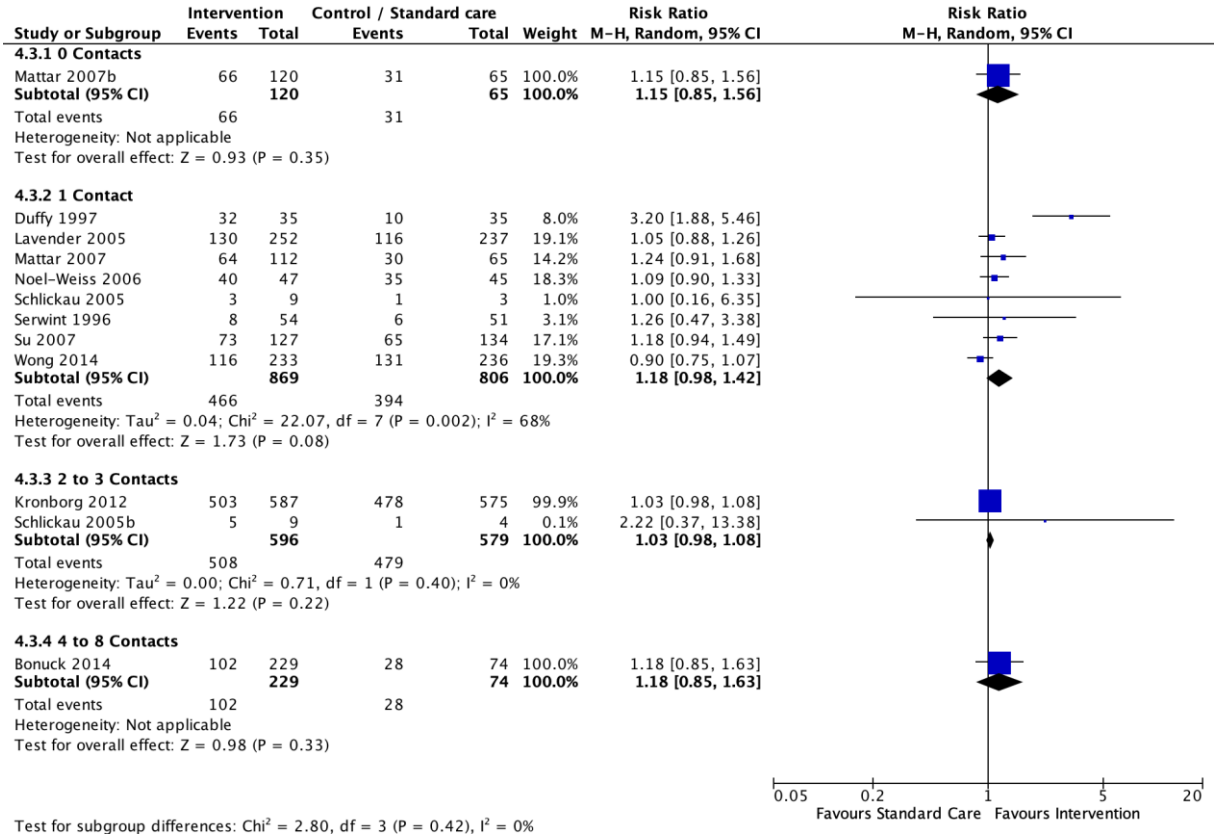
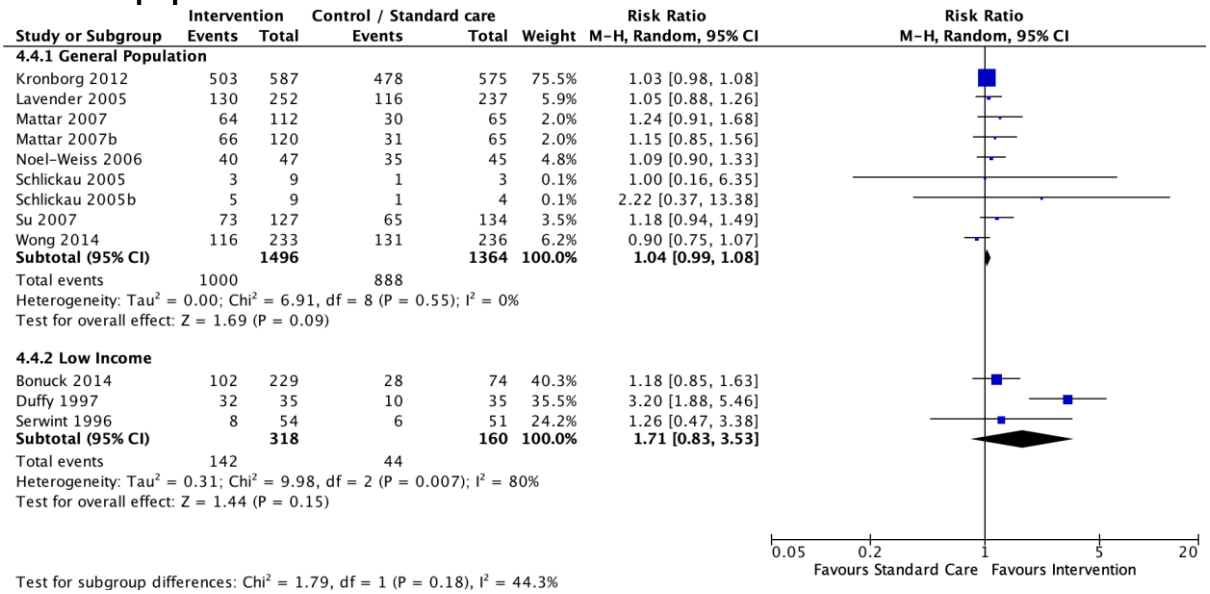


Figure 17: Any breastfeeding at 6 to 12 weeks, subgroup analysis based on population



1

Figure 18: Any breastfeeding at 6 to 12 weeks, subgroup analysis based on the womans intention to breastfeed

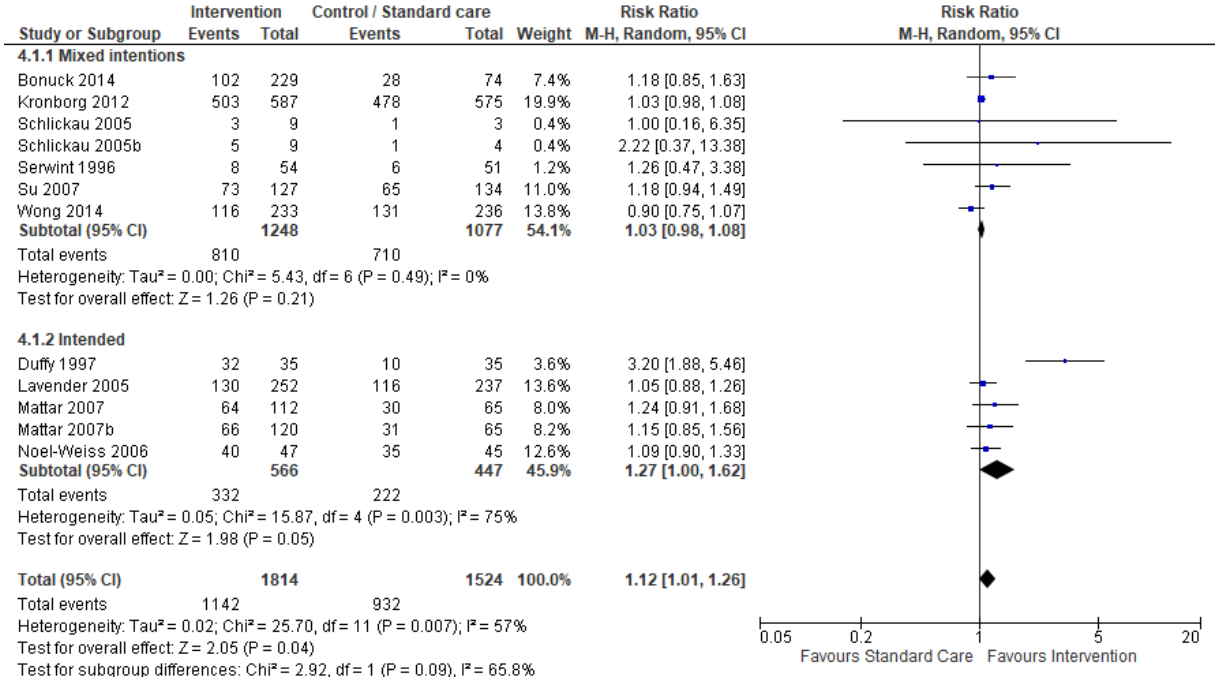


Figure 19: Exclusive breastfeeding at 6 to 12 weeks, all studies

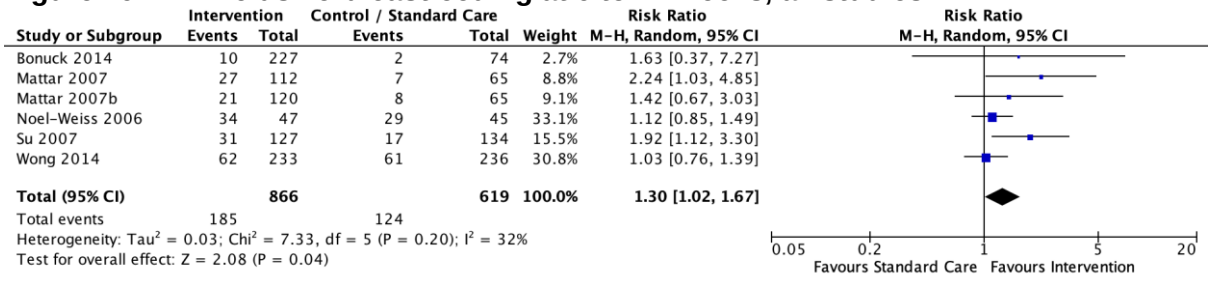


Figure 20: Exclusive breastfeeding at 6 to 12 weeks, subgroup analysis based on the womans intention to breastfeed

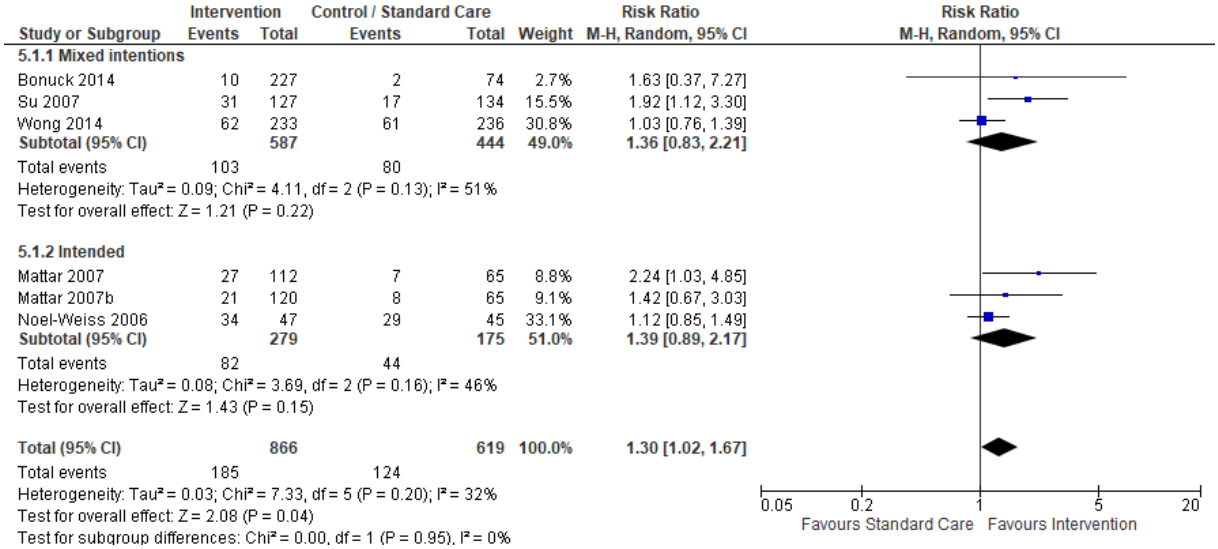


Figure 21: Any breastfeeding at 16 to 26 weeks, all studies

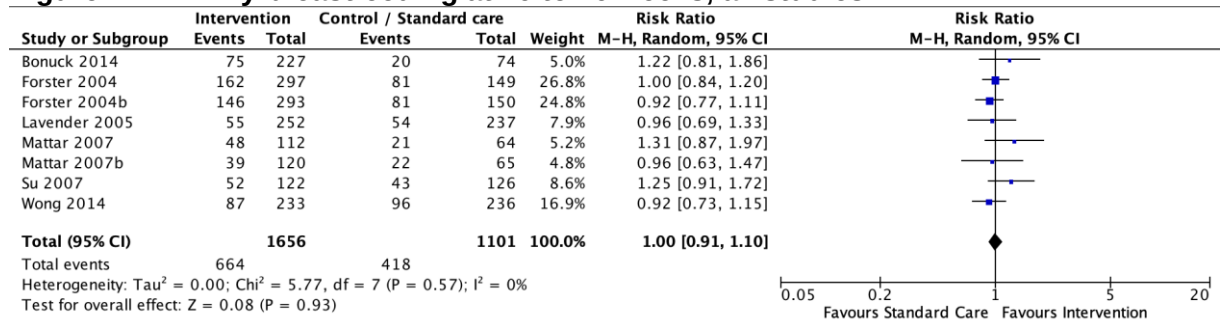
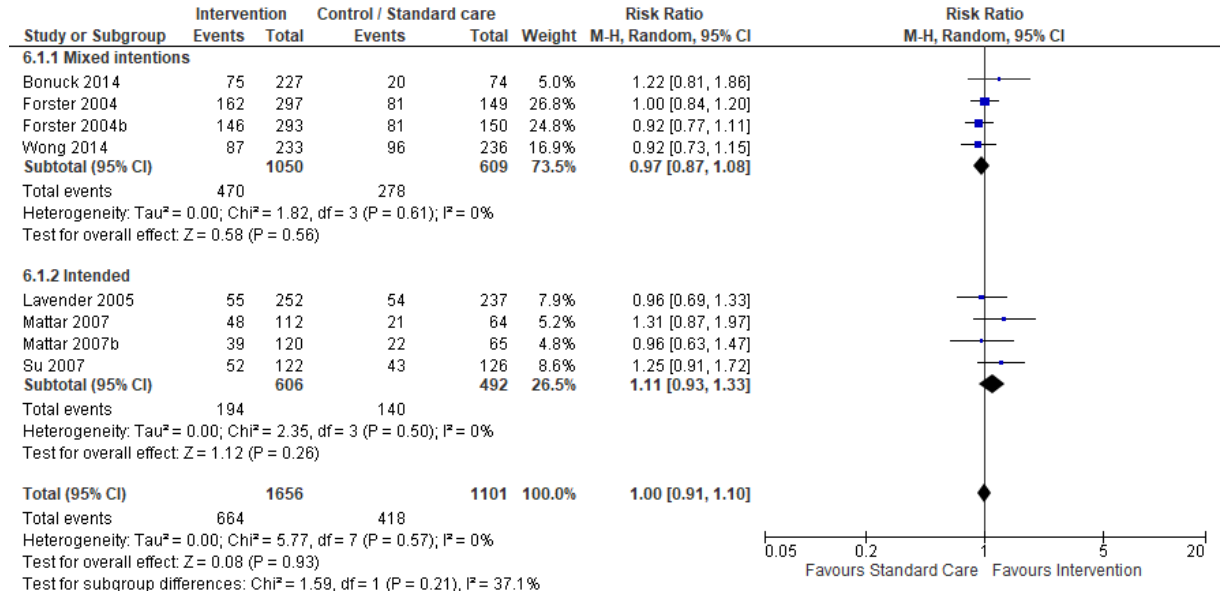


Figure 22: Any breastfeeding at 16 to 26 weeks, subgroup analysis based on the womans intention to breastfeed



Comparison 1.2. One-contact antenatal intervention focusing on practical skills without partners versus two-contact antenatal intervention focusing on attitudes and involving partners

No meta-analysis was conducted for this comparison so there are no forest plots.

Comparison 1.3. Antenatal provision of booklet plus video plus one contact versus antenatal provision of booklet and video only

No meta-analysis was conducted for this comparison so there are no forest plots.

Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) Comparison 2.1.

Comparison 2.1. Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus standard care

Figure 23: Initiation of breastfeeding, all studies

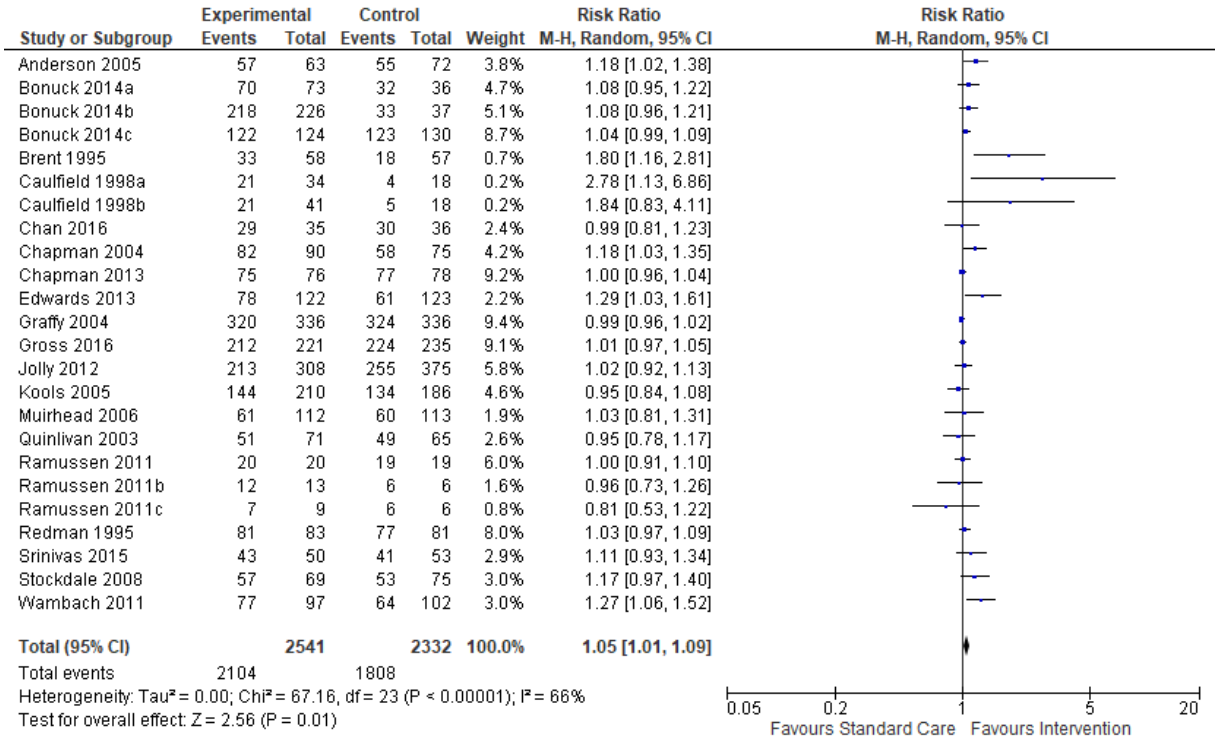


Figure 24: Subgroup analysis for initiation of breastfeeding

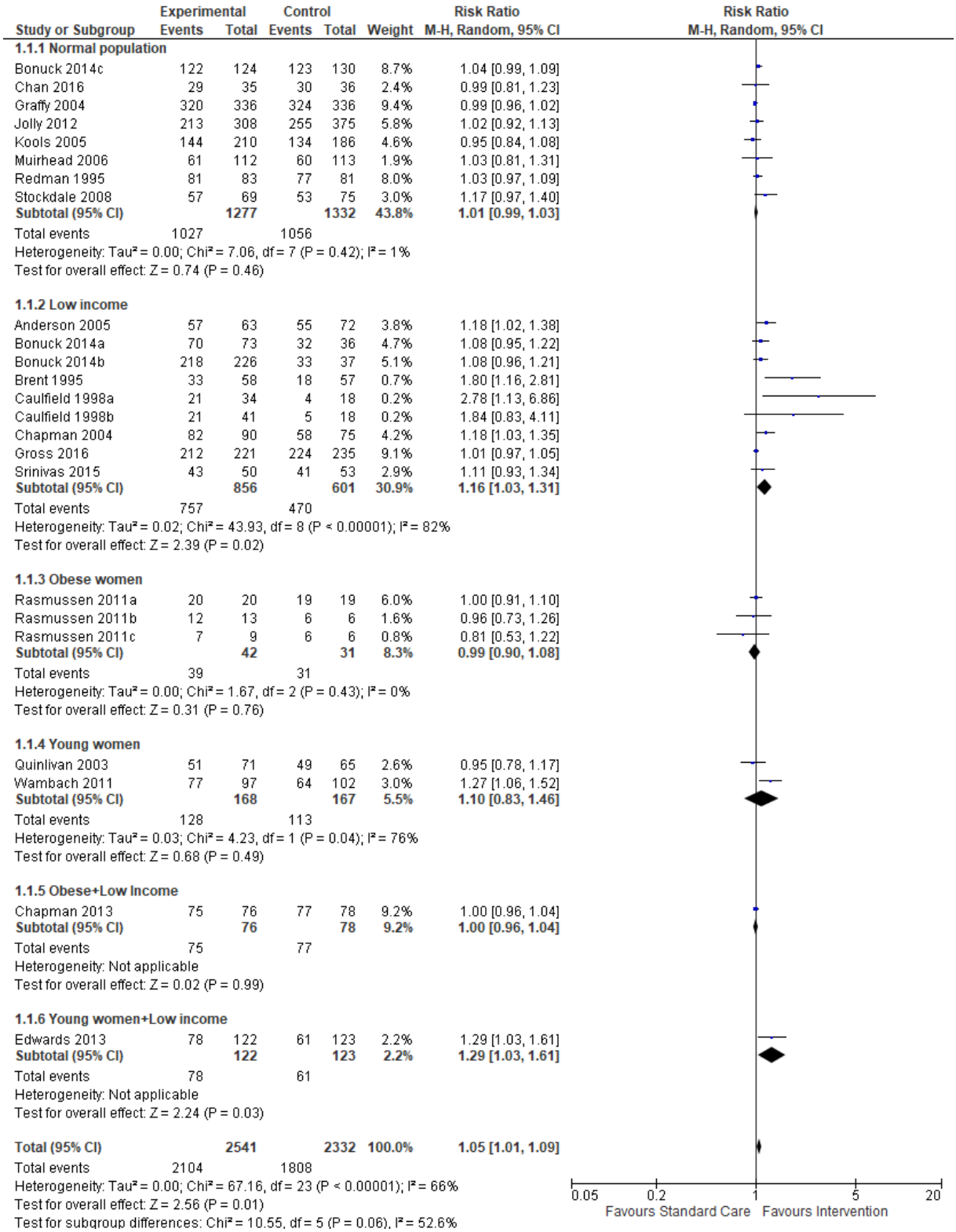


Figure 25: Subgroup analysis for initiation of breastfeeding based on breastfeeding intentions

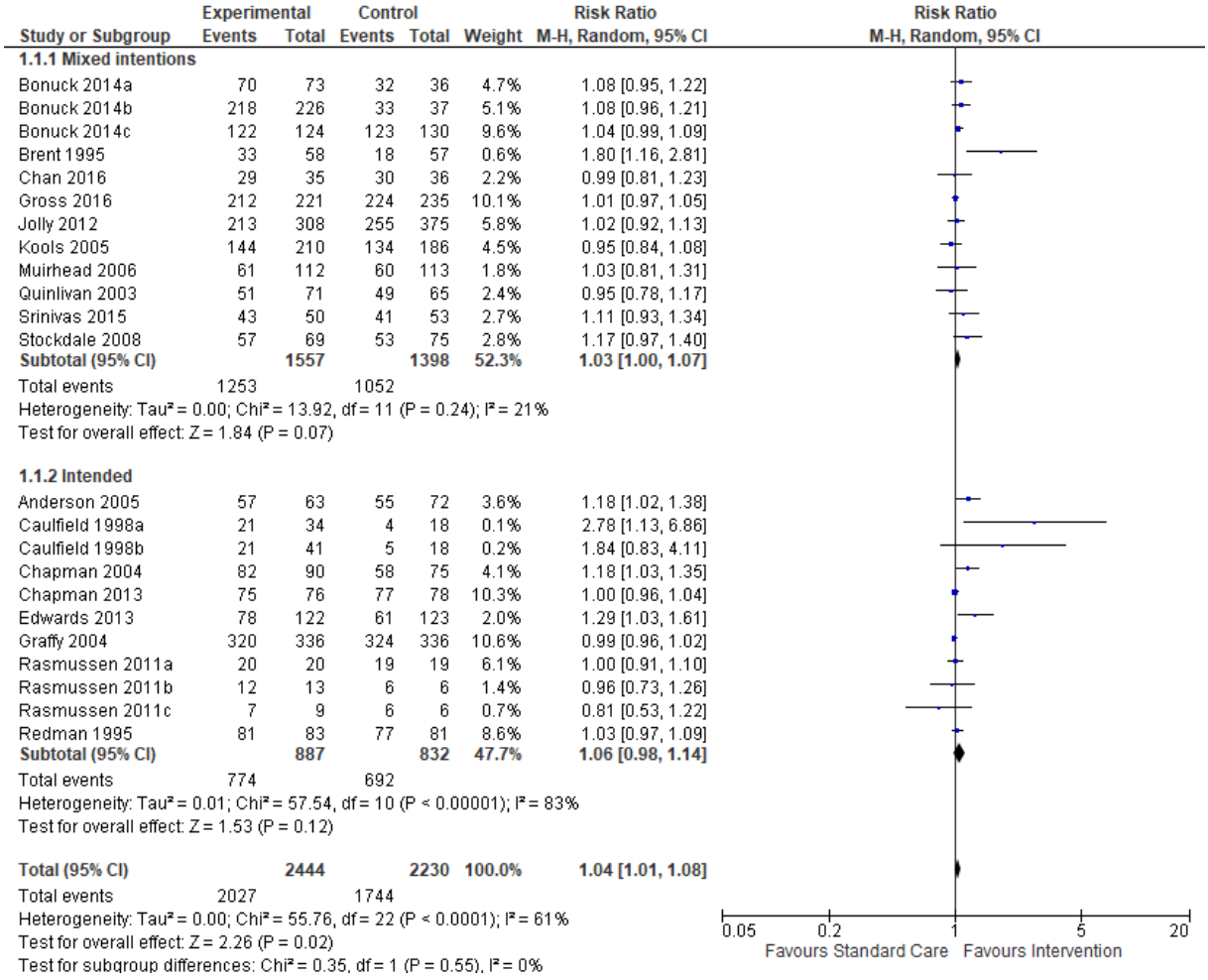


Figure 26: Any breastfeeding at 3 to 14 days, all studies

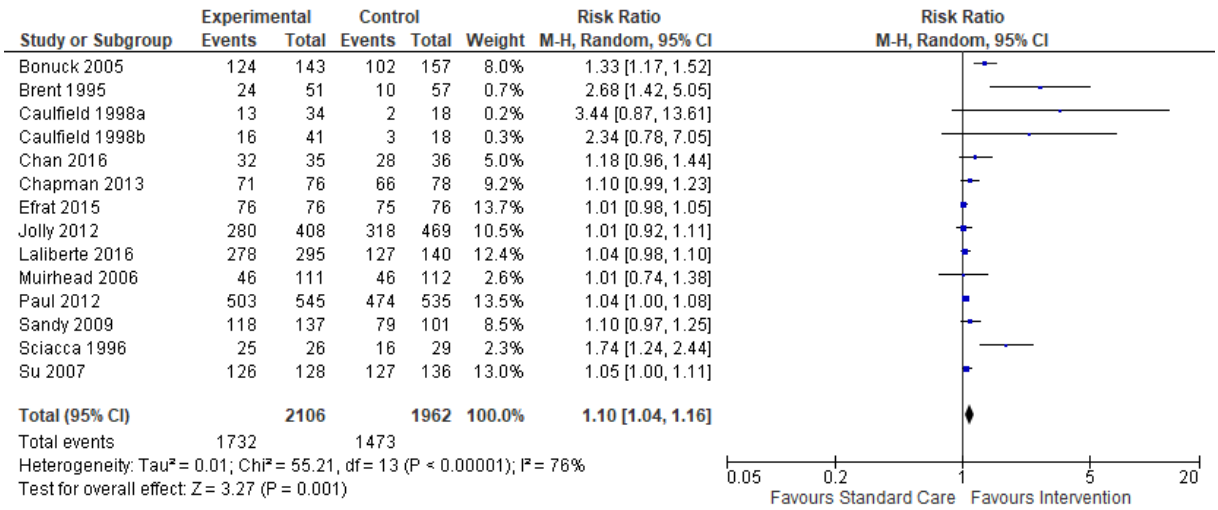


Figure 27: Subgroup analysis for any breastfeeding 3 to 14 days

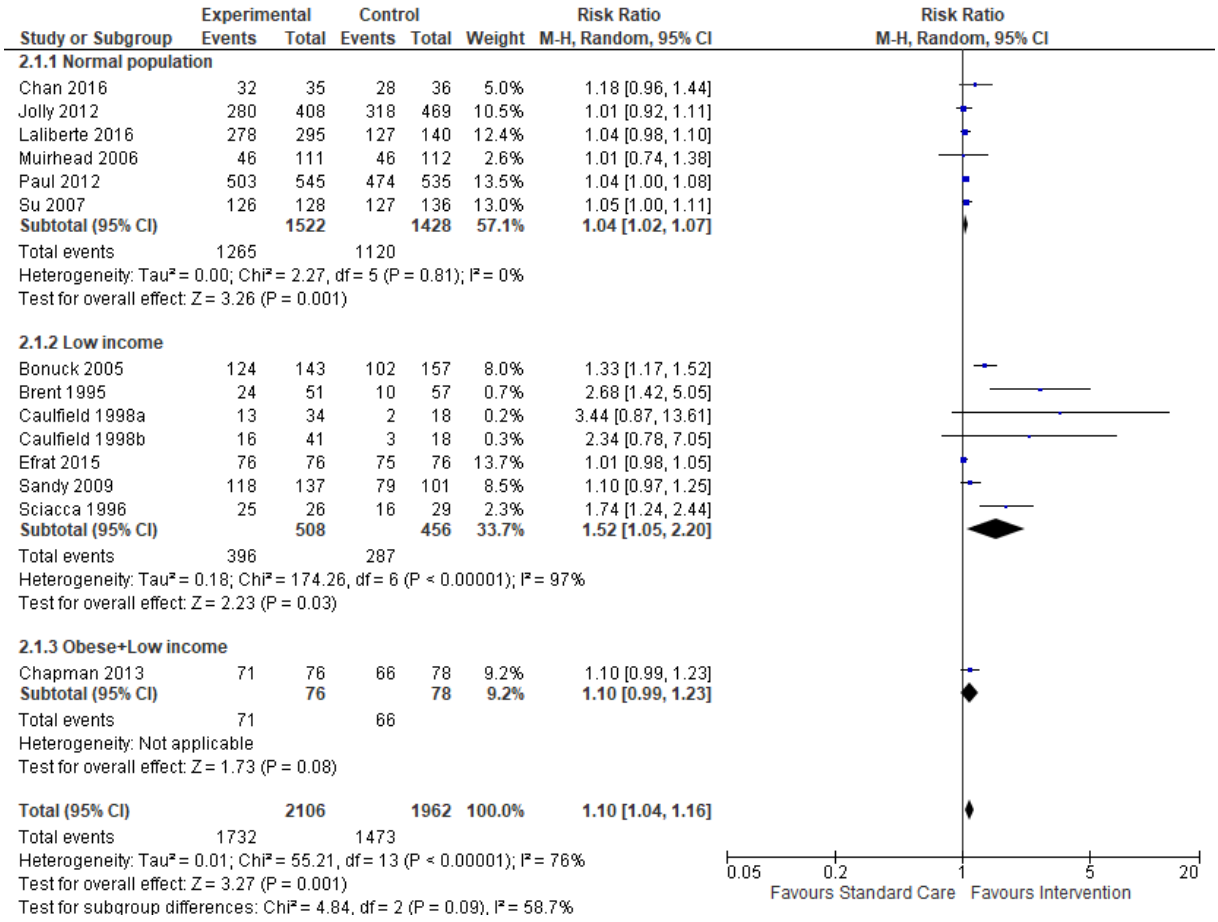


Figure 28: Subgroup analysis for any breastfeeding 3 to 14 days based on breastfeeding intentions

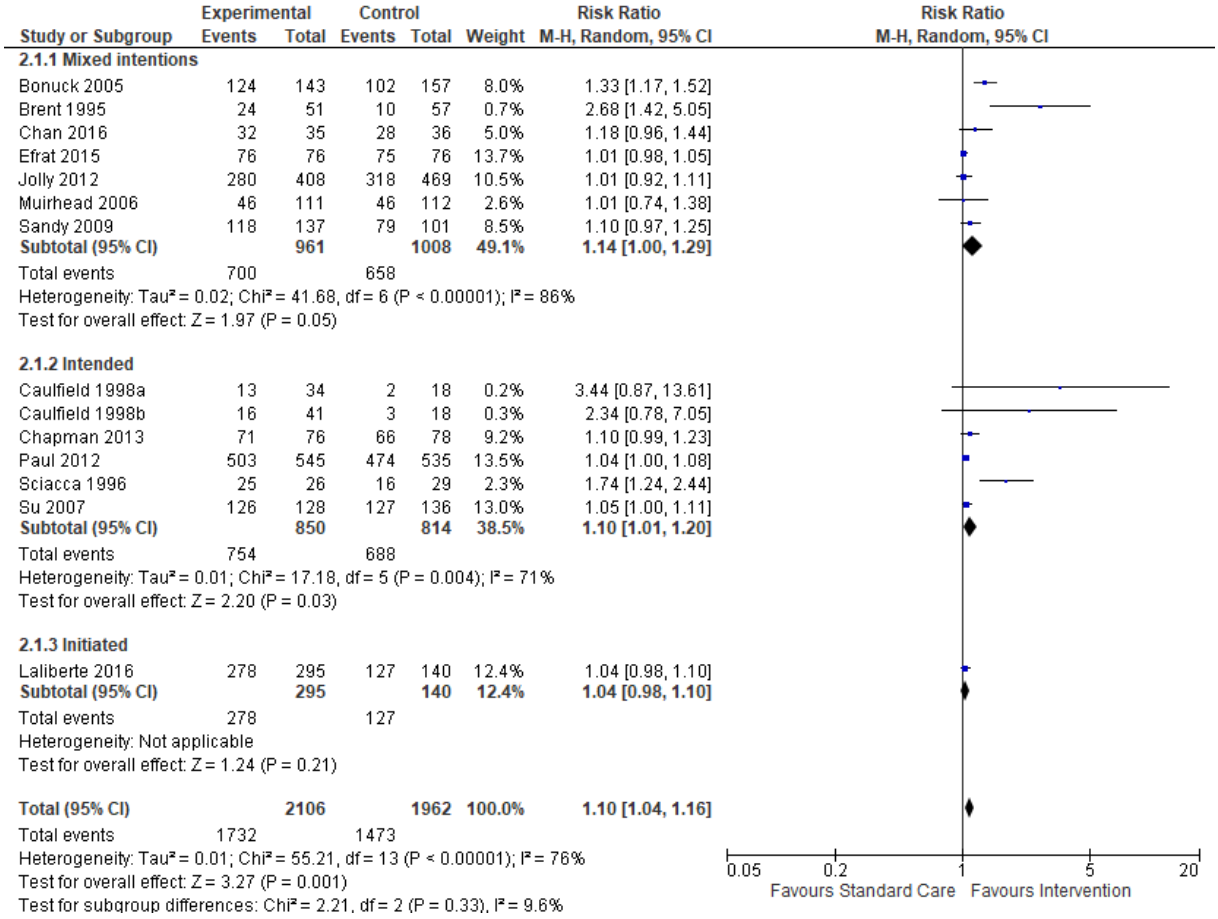


Figure 29: Exclusive breastfeeding at 3 to 14 days, all studies

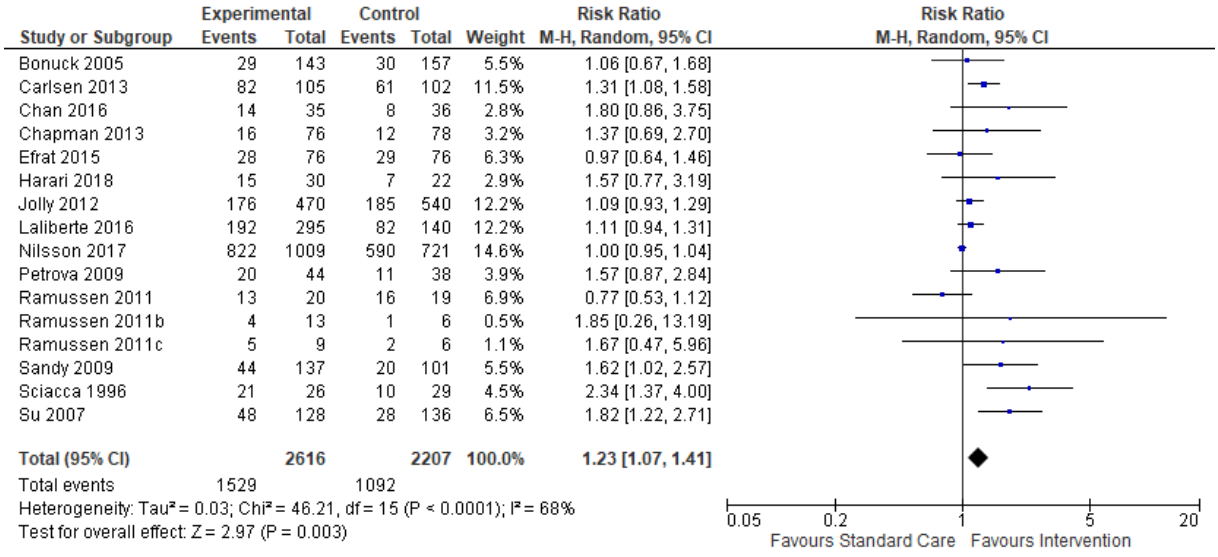


Figure 30: Subgroup analysis for exclusive breastfeeding 3 to 14 days

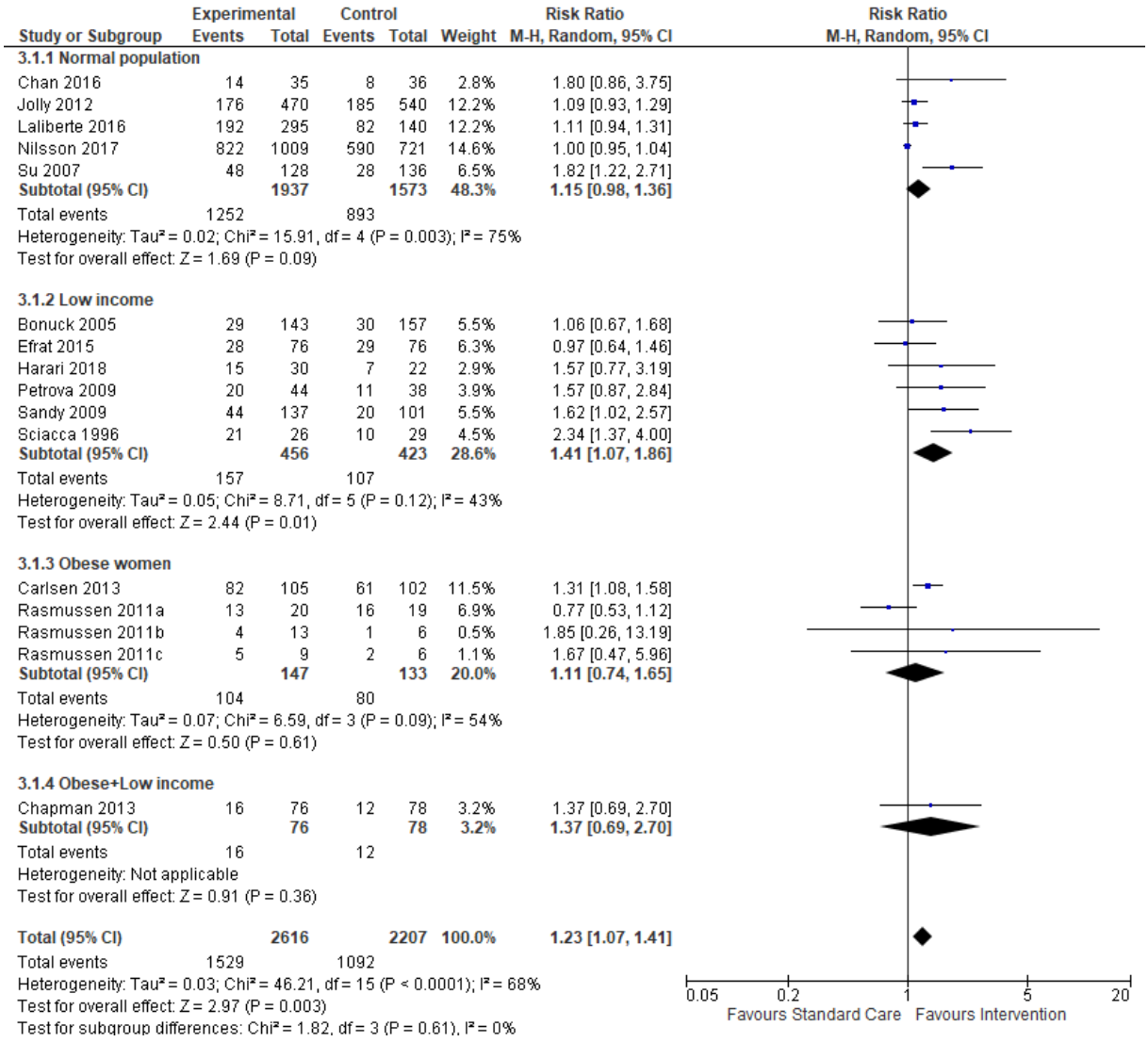


Figure 31: Subgroup analysis for exclusive breastfeeding 3 to 14 days based on breastfeeding intentions

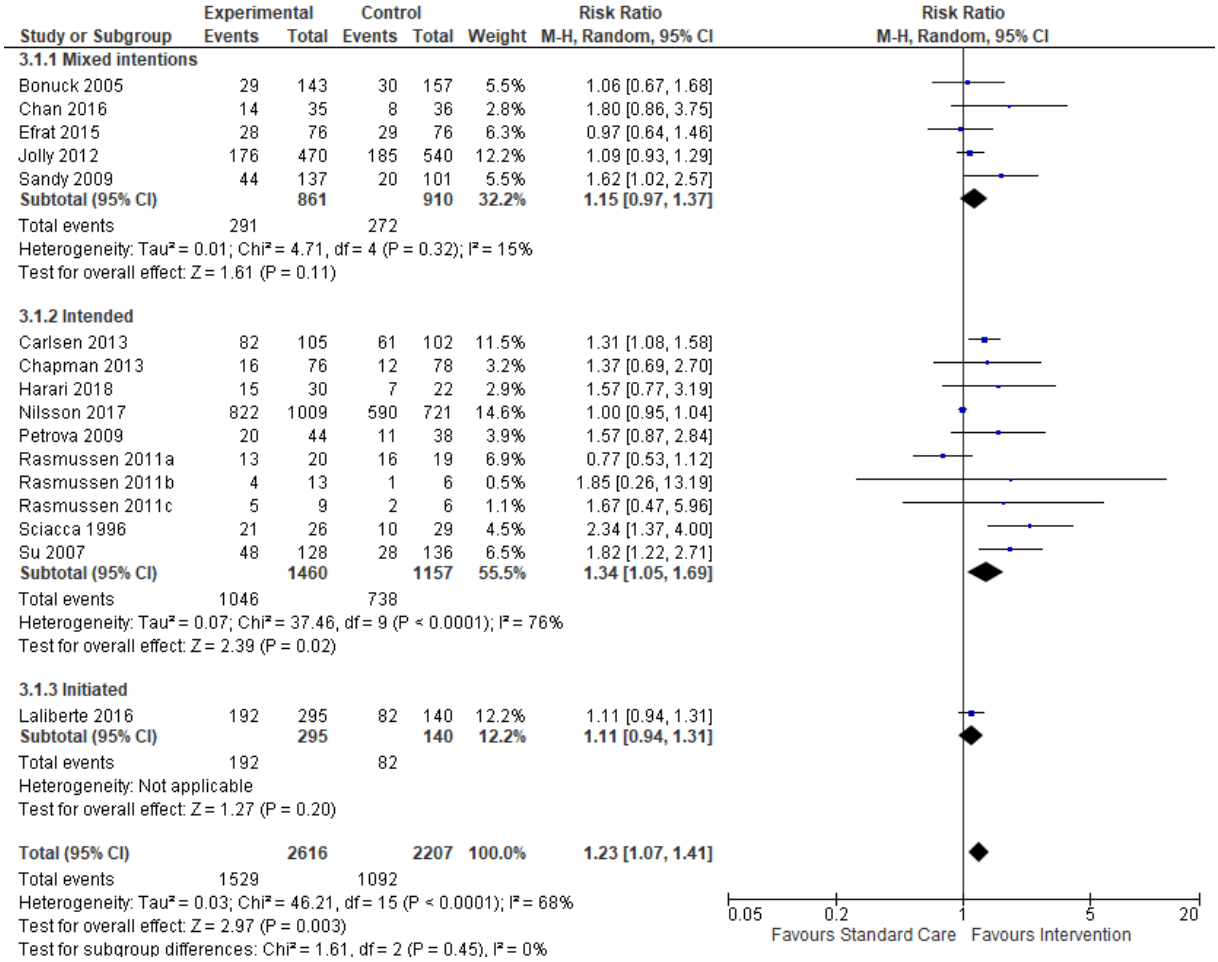


Figure 32: Any breastfeeding at 6 to 12 weeks, all studies

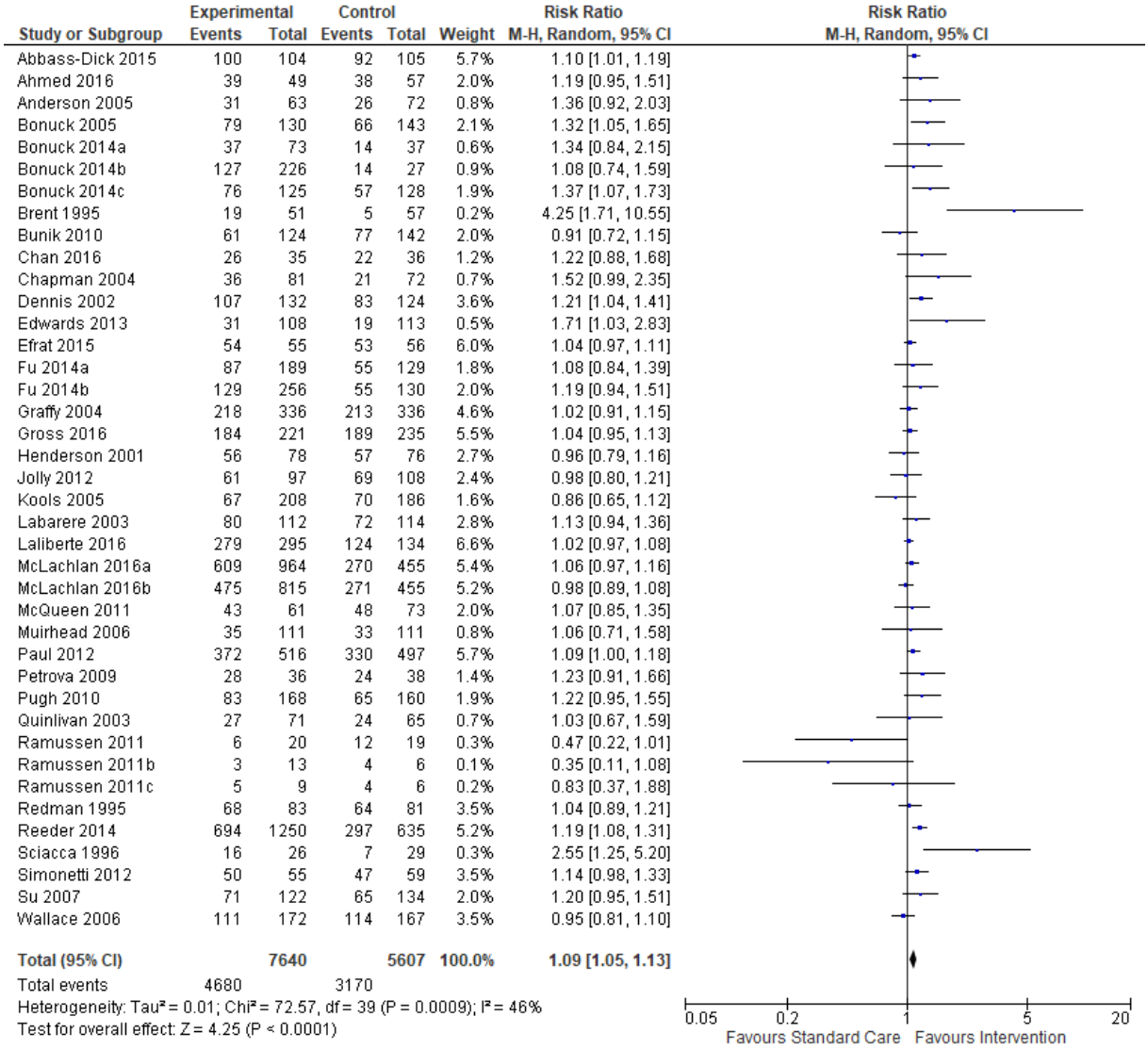


Figure 33: Subgroup analysis for any breastfeeding 6 to 12 weeks based on breastfeeding intentions

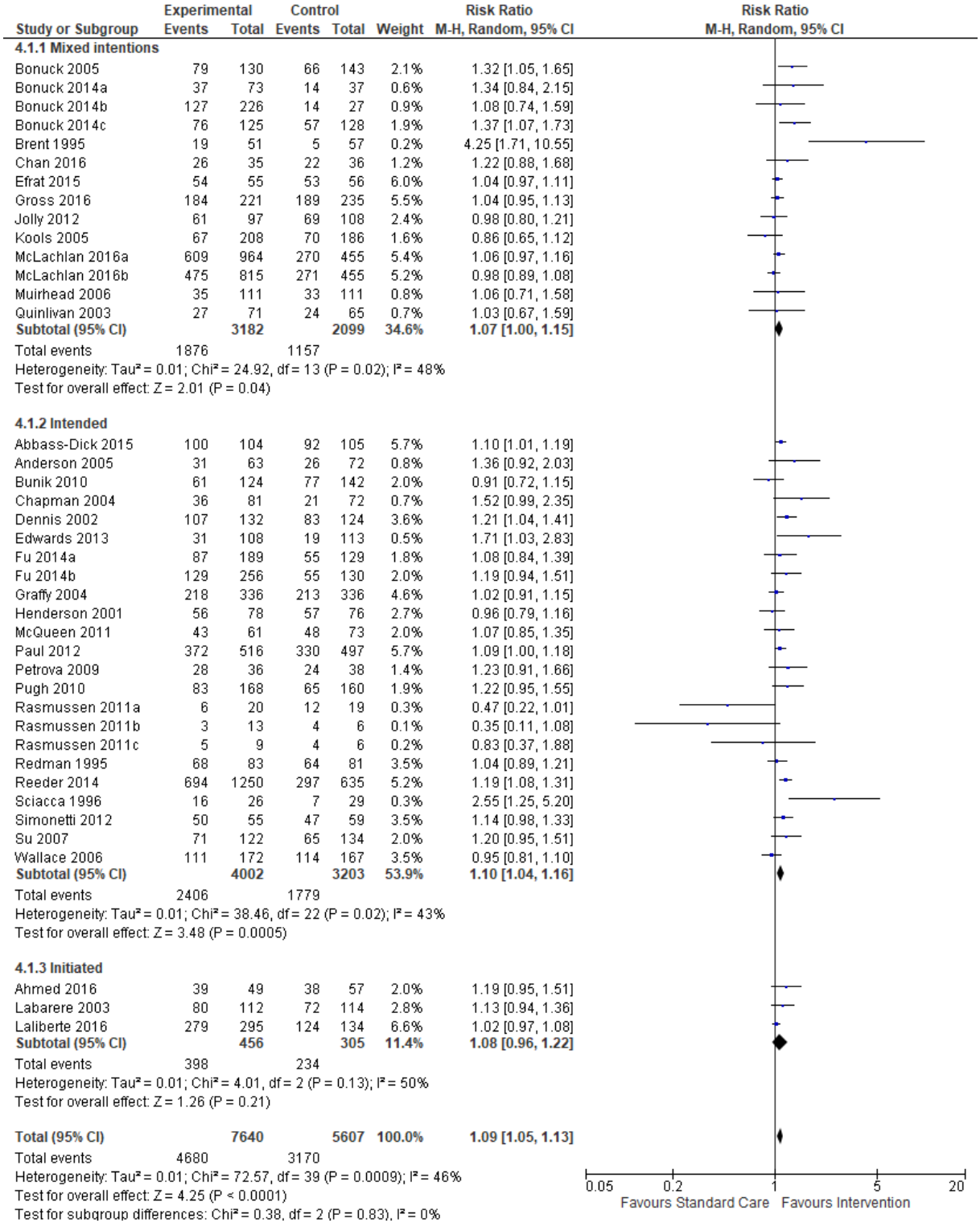


Figure 34: Exclusive breastfeeding at 6 to 12 weeks, all studies

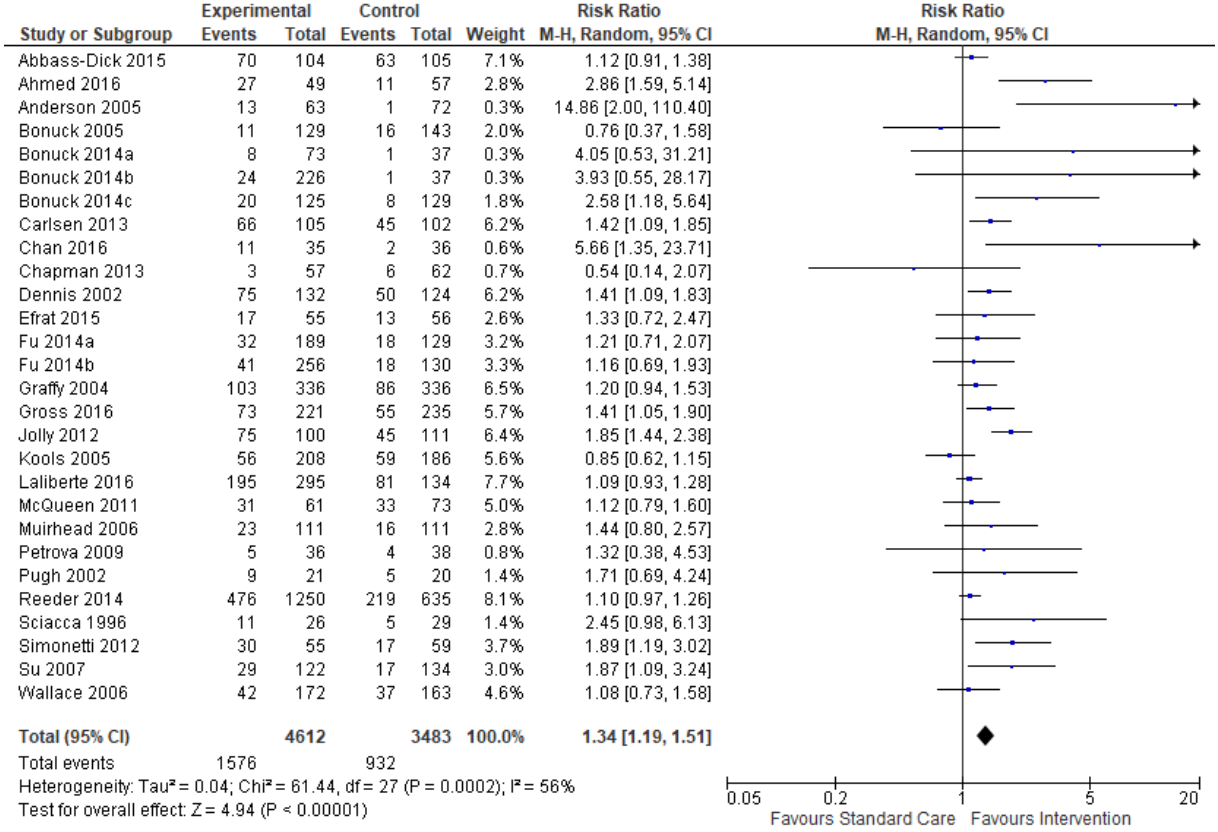


Figure 35: Subgroup analysis for exclusive breastfeeding 6 to 12 weeks

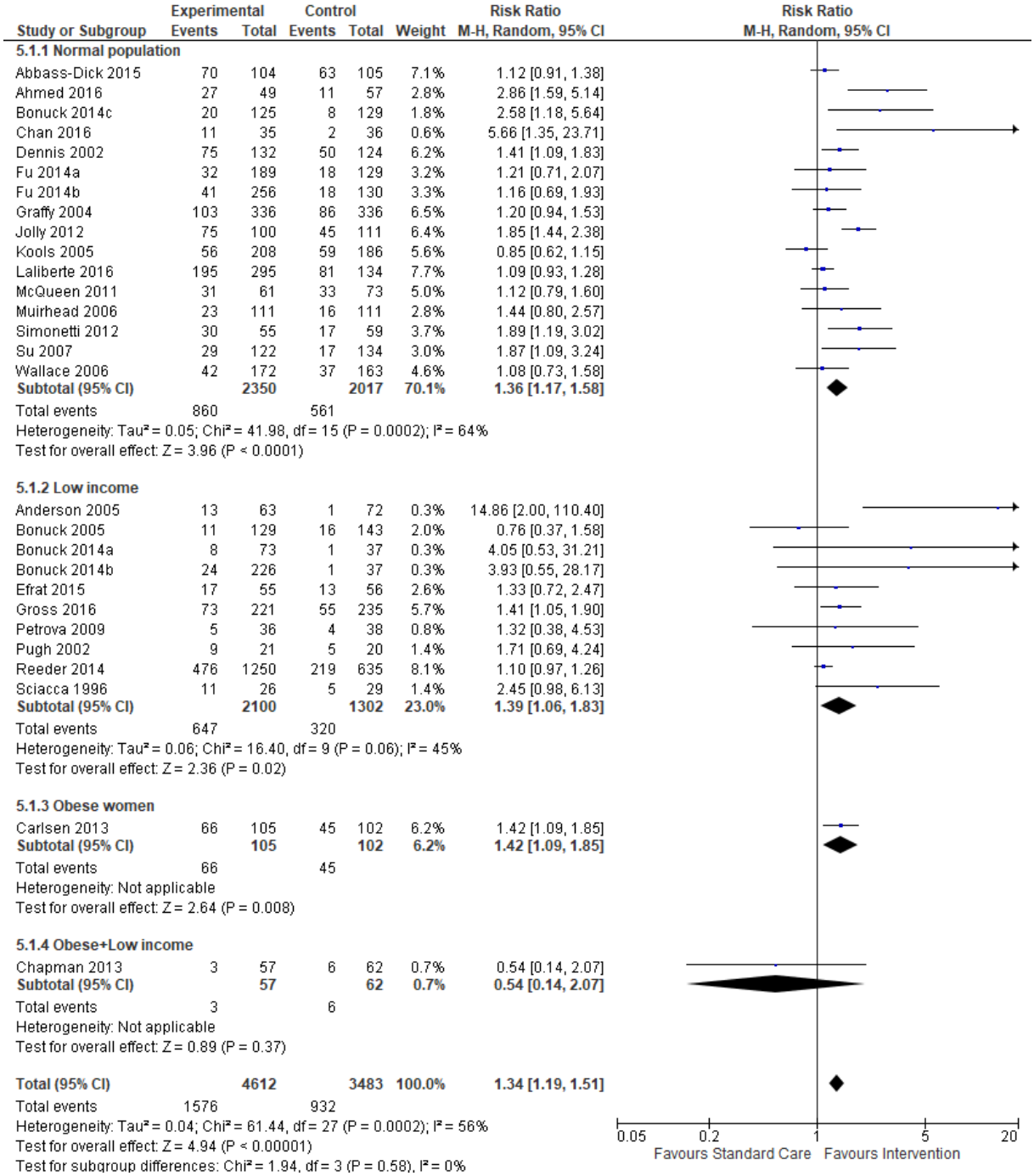


Figure 36: Subgroup analysis for exclusive breastfeeding 6 to 12 weeks based on breastfeeding intentions

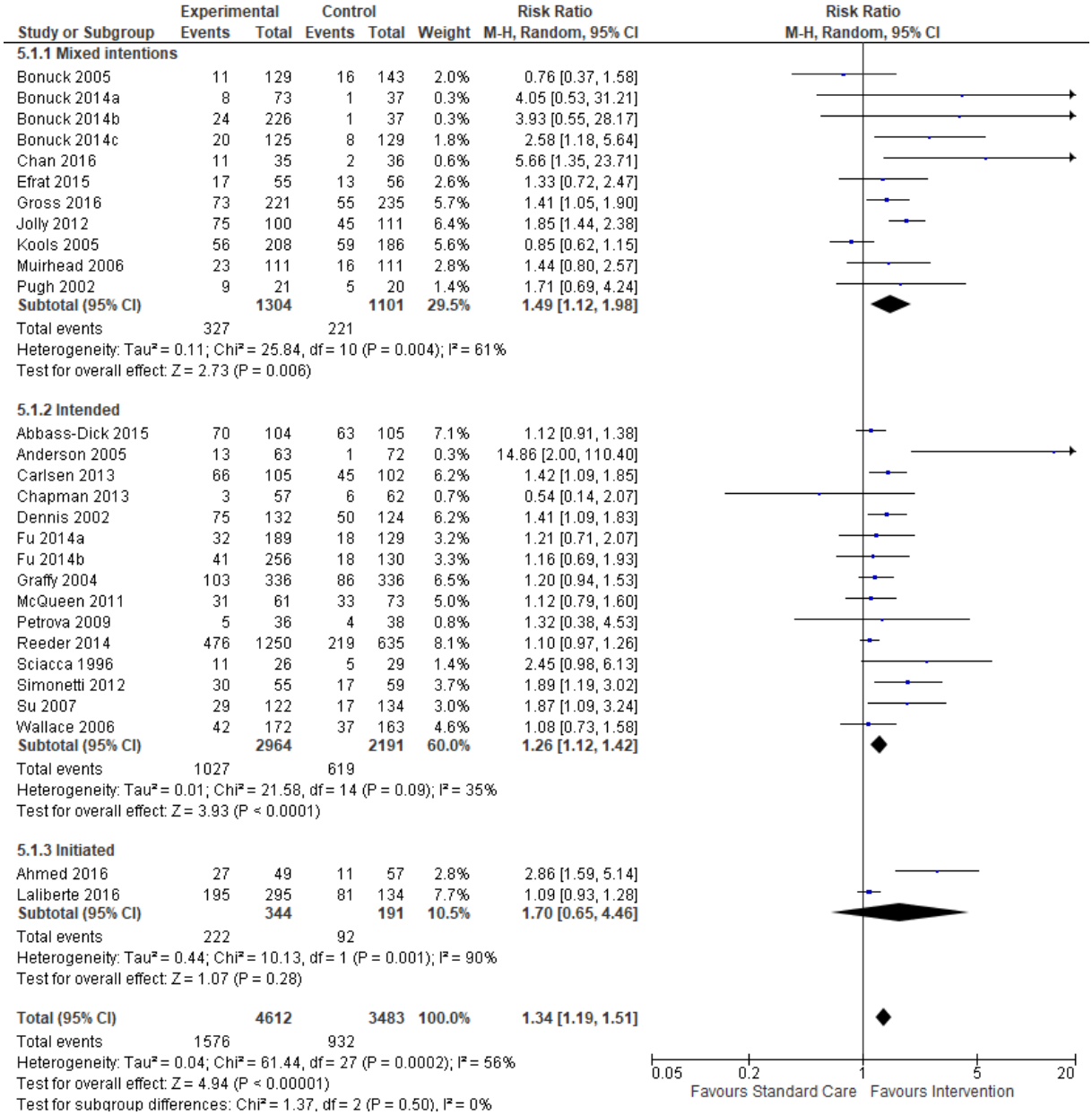


Figure 37: Any breastfeeding at 16 to 26 weeks, all studies

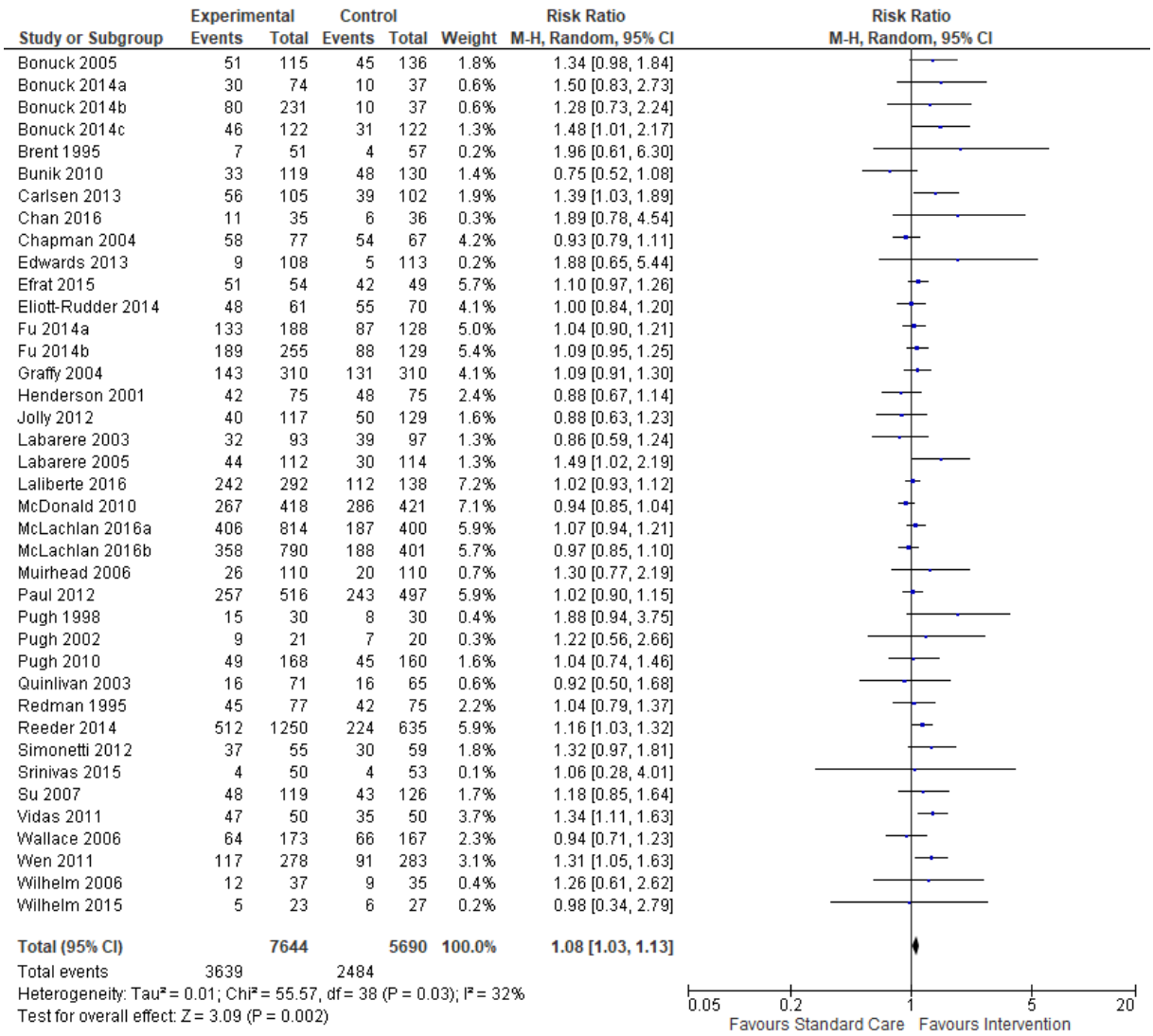
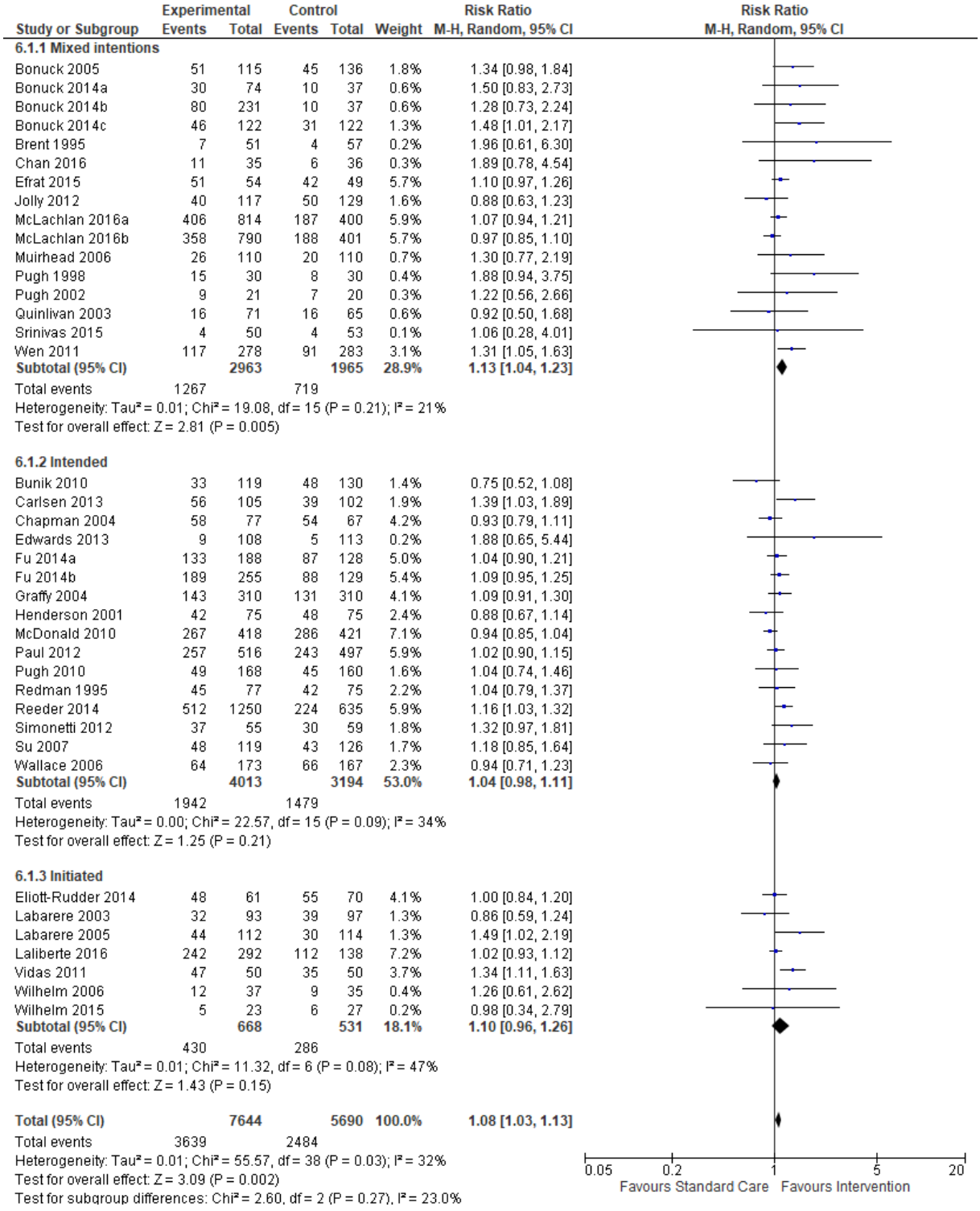


Figure 38: Subgroup analysis for any breastfeeding 16 to 26 weeks based on breastfeeding intentions



Comparison 2.2. Education, advice or support from peer or professional provided antentally (Intervention 1) versus Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2)

Figure 39: Initiation of breastfeeding, all studies

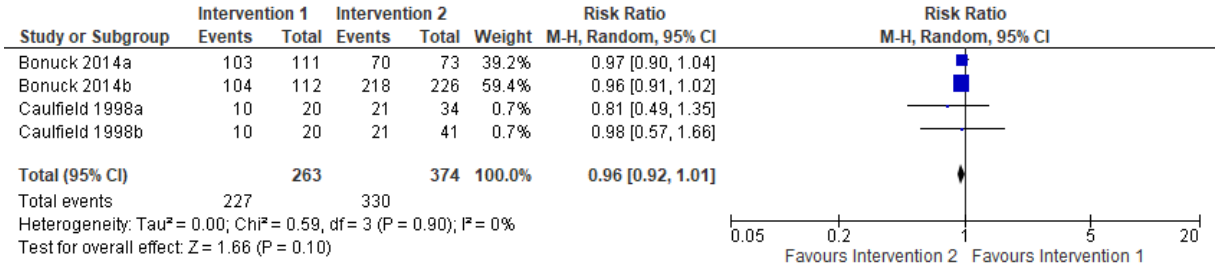


Figure 40: Any breastfeeding 3 to 14 days, all studies

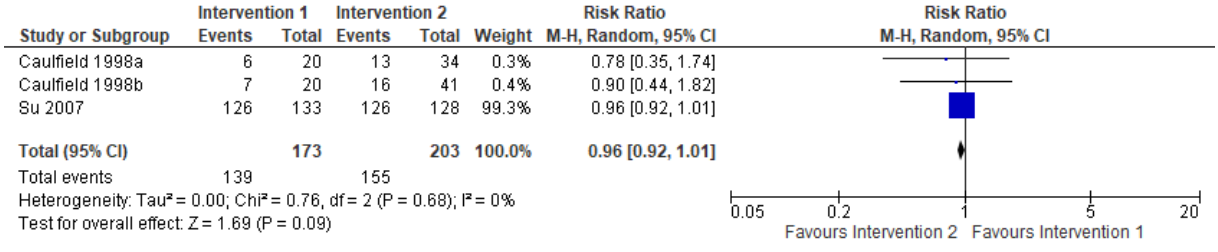


Figure 41: Subgroup analysis for any breastfeeding at 3 to 14 days

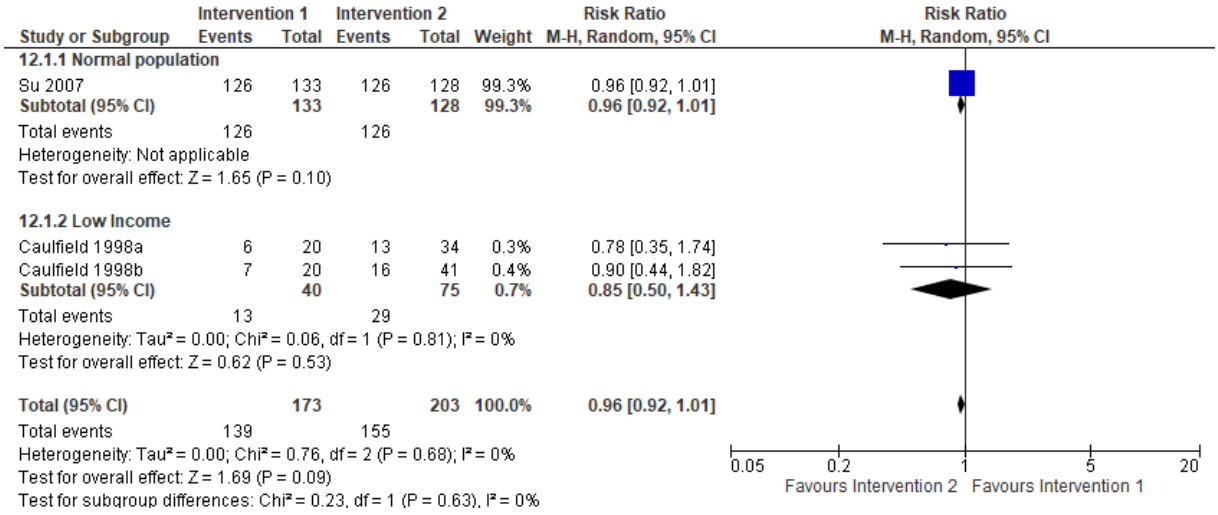


Figure 42: Any breastfeeding at 6 to 12 weeks, all studies

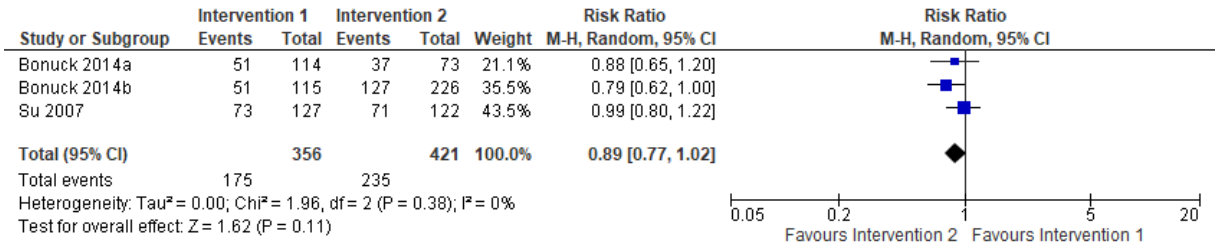


Figure 43: Subgroup analysis for any breastfeeding 6 to 12 weeks

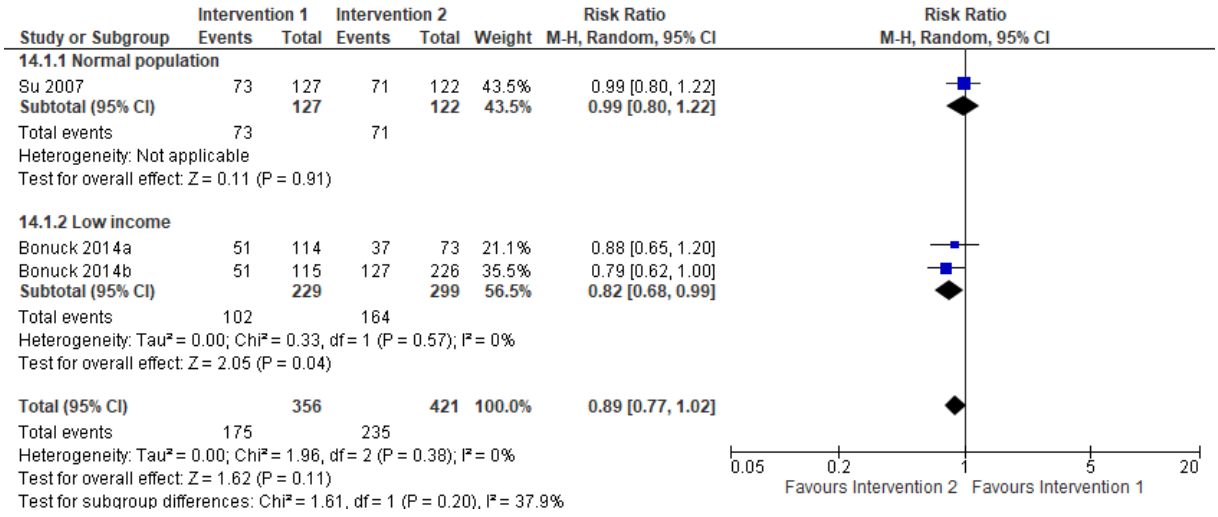


Figure 44: Exclusive breastfeeding at 6 to 12 weeks, all studies

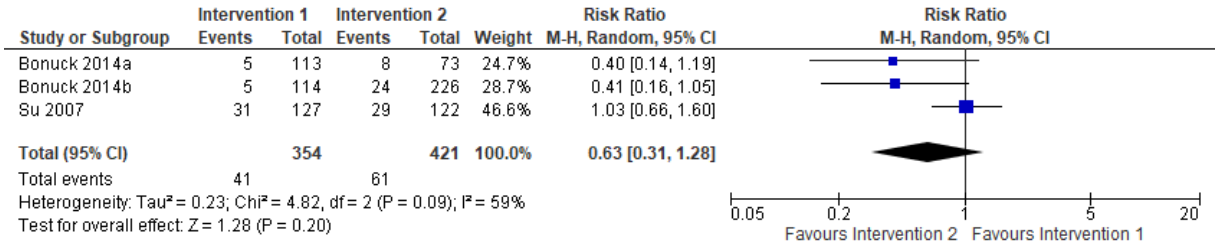


Figure 45: Subgroup analysis for exclusive breastfeeding 6 to 12 weeks

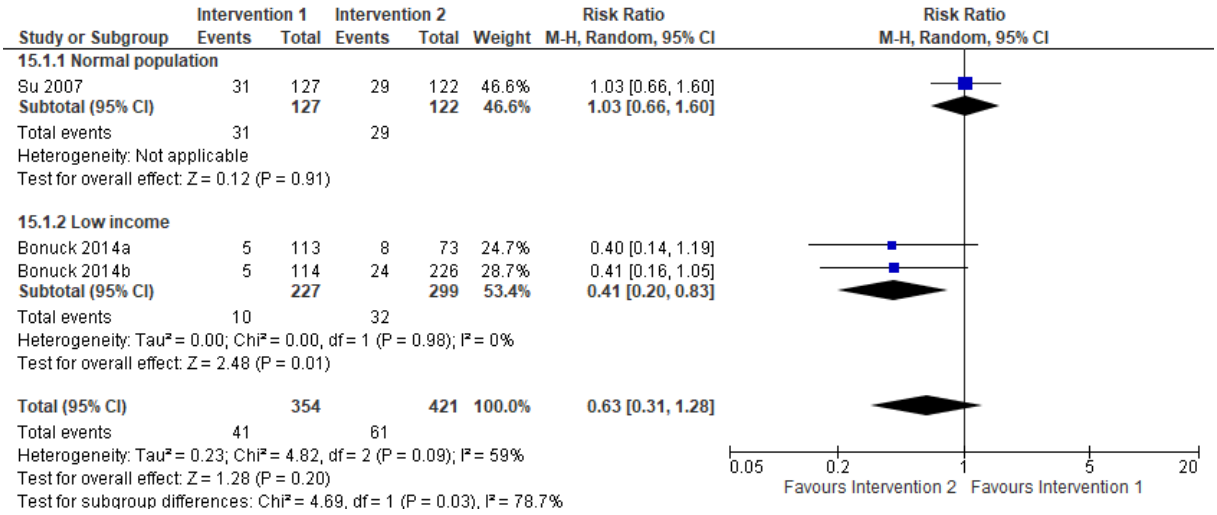


Figure 46: Any breastfeeding at 16 to 26 weeks, all studies

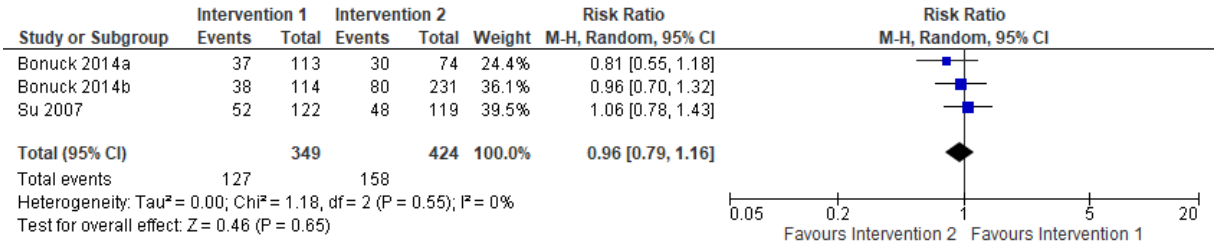
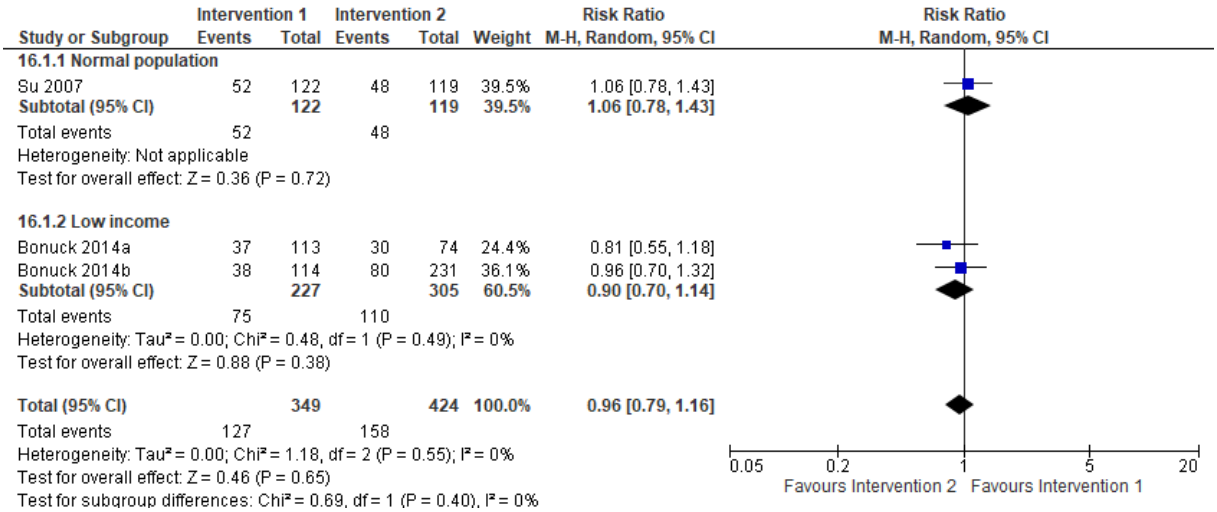


Figure 47: Subgroup analysis for any breastfeeding 16 to 26 weeks



Comparison 2.3. Counselling session + booklet versus counselling session

No meta-analysis was conducted for this comparison so there are no forest plots.

Comparison 2.4. Video + keeping a log book versus video

No meta-analysis was conducted for this comparison so there are no forest plots.

Comparison 2.5. Two home visits versus a telephone call on day of discharge

No meta-analysis was conducted for this comparison so there are no forest plots.

Comparison 2.6. Regular home visits versus printed educational materials

No meta-analysis was conducted for this comparison so there are no forest plots.

Comparison 2.7. Home contact versus clinic contact

No meta-analysis was conducted for this comparison so there are no forest plots.

Comparison 2.8. Proactive phonecalls versus reactive phonecalls

No meta-analysis was conducted for this comparison so there are no forest plots.

Avoidance of foreign objects (Intervention 3)

Figure 48: Any breastfeeding at 6 to 12 weeks

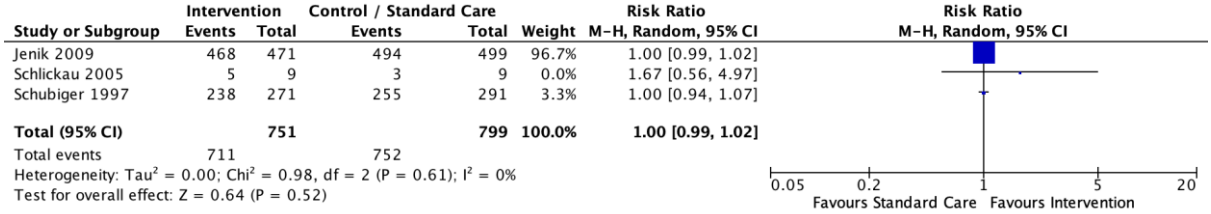


Figure 49: Exclusive breastfeeding at 6 to 12 weeks

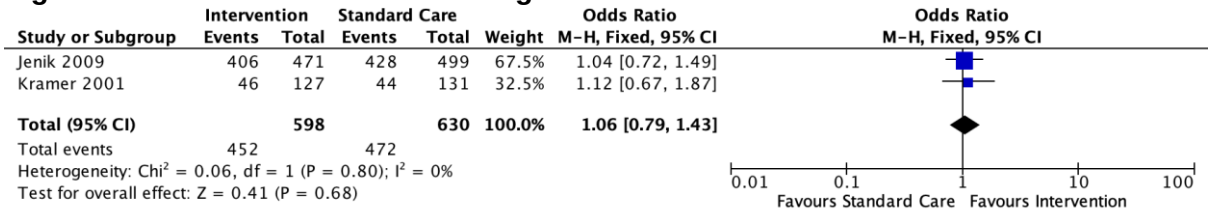


Figure 50: Any breastfeeding at 16 to 26 weeks, all studies

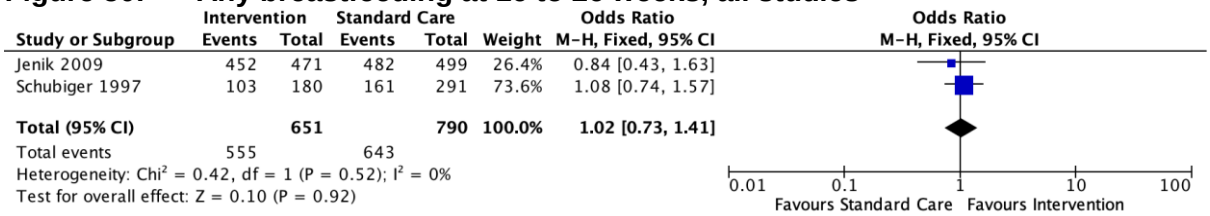
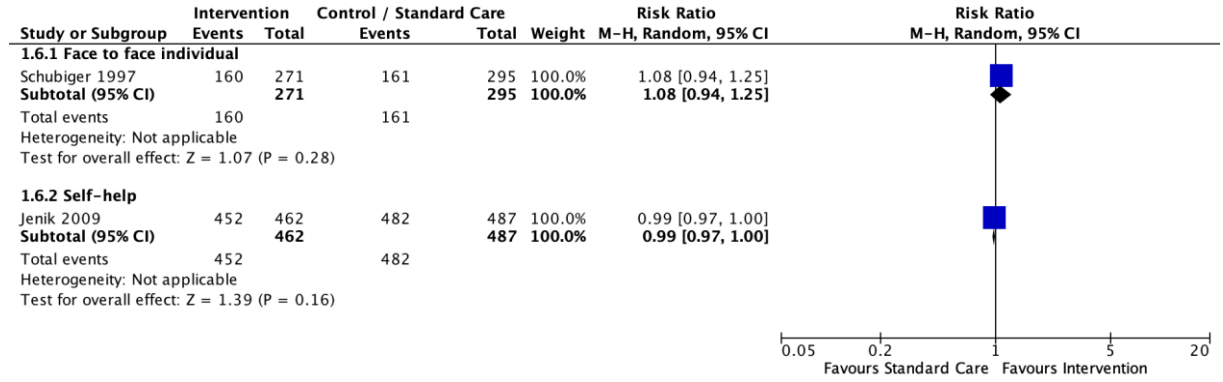


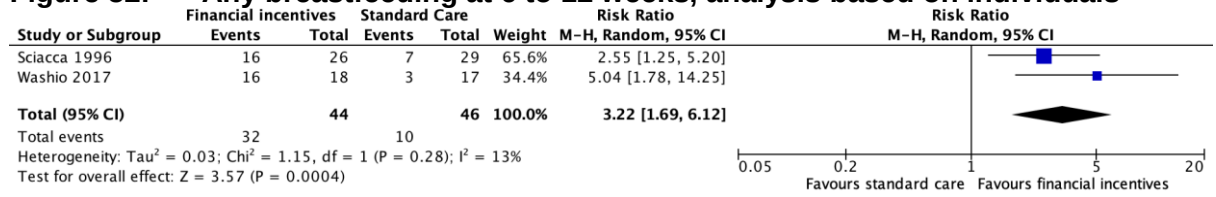
Figure 51: Any breastfeeding at 16 to 26 weeks, subgroup analysis based on how the intervention was delivered



1

2 ***Intervention 4: Financial incentives***

Figure 52: Any breastfeeding at 6 to 12 weeks, analysis based on individuals



3

Appendix F – GRADE tables

GRADE 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)?

Comparision 1.1. Education, advice or support from peer or professional provided antentally (Intervention 1) versus standard care

Table 4: Clinical evidence profile for education, advice or support from peer of professional provided antenatally versus standard care

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Standard care**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Full analysis, initiation of breastfeeding												
6[1]	randomised trials	serious	no serious inconsistency	no serious indirectness	serious[2]	none	897/1154 (77.7%)	706/1003 (70.4%)	RR 1.06 (1.00 to 1.13)	42 more per 1000 (from 0 more to 92 more)	LOW	CRITICAL
Fathers, initiation of breastfeeding												
1 (Wolfberg 2004)	randomised trials	serious [3]	no serious inconsistency	no serious indirectness	serious[4]	none	20/27 (74.1%)	13/32 (40.6%)	RR 1.82 (1.13 to 2.93)	333 more per 1000 (from 53 more to 784 more)	LOW	CRITICAL
Full Analysis, any breastfeeding at 3 to 14 days												
6[1]	randomised trials	serious [5]	very serious[6]	no serious indirectness	serious[2]	none	1135/1297 (87.5%)	715/881 (81.2%)	RR 1.02 (0.97 to 1.07)	16 more per 1000 (from 24 fewer to 57 more)	VERY LOW	CRITICAL
How delivered - Face-to-face group, any breastfeeding at 3 to 14 days												
2[1]	randomised trials	serious	no serious inconsistency	no serious indirectness	serious[2]	none	761/866 (87.9%)	449/547 (82.1%)	RR 1.01 (0.96 to 1.05)	8 more per 1000 (from 33	LOW	CRITICAL

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute	Quality	Importance
										fewer to 41 more)		
How delivered - Face-to-face individual, any breastfeeding at 3 to 14 days												
3[1]	randomised trials	serious [5]	very serious[6]	no serious indirectness	serious[2]	none	250/268 (93.3%)	199/230 (86.5%)	RR 1.07 (0.92 to 1.23)	61 more per 1000 (from 69 fewer to 199 more)	VERY LOW	CRITICAL
How delivered - Digital / self-help, any breastfeeding at 3 to 14 days												
2[1]	randomised trials	serious [5]	very serious[6]	no serious indirectness	very serious[2,4]	none	124/163 (76.1%)	67/104 (64.4%)	RR 1.41 (0.48 to 4.16)	264 more per 1000 (from 335 fewer to 1000 more)	VERY LOW	CRITICAL
Number of contacts - 0 contact, any breastfeeding at 3 to 14 days												
2[1]	randomised trials	serious [5]	very serious[6]	no serious indirectness	very serious[2,4]	none	124/163 (76.1%)	67/104 (64.4%)	RR 1.41 (0.48 to 4.16)	264 more per 1000 (from 335 fewer to 1000 more)	VERY LOW	CRITICAL
Number of contacts - 1 contact, any breastfeeding at 3 to 14 days												
4[1]	randomised trials	serious [7]	no serious inconsistency	no serious indirectness	serious[2]	none	702/803 (87.4%)	489/595 (82.2%)	RR 1.02 (0.99 to 1.05)	16 more per 1000 (from 8 fewer to 41 more)	LOW	CRITICAL
Number of contacts - 2 to 3 contacts, any breastfeeding at 3 to 14 days												
1 (Forster 2004)	randomised trials	serious [7]	no serious inconsistency	no serious indirectness	serious[2]	none	291/308 (94.5%)	149/155 (96.1%)	RR 0.98 (0.94 to 1.02)	19 fewer per 1000 (from 58	LOW	CRITICAL

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute	Quality	Importance
										fewer to 19 more)		
Number of contacts - 4 to 8 contacts, any breastfeeding at 3 to 14 days												
1 (Ryser 2004)	randomised trials	serious [8]	no serious inconsistency	no serious indirectness	serious[4]	none	18/23 (78.3%)	10/27 (37%)	RR 2.11 (1.24 to 3.61)	411 more per 1000 (from 89 more to 967 more)	LOW	CRITICAL
Population – General, any breastfeeding at 3 to 14 days												
4[1]	randomised trials	serious [7]	no serious inconsistency	no serious indirectness	serious[2]	none	1104/1234 (89.5%)	700/818 (85.6%)	RR 1 (0.98 to 1.03)	0 fewer per 1000 (from 17 fewer to 26 more)	LOW	CRITICAL
Population - Low income, any breastfeeding at 3 to 14 days												
2[1]	randomised trials	serious [9]	no serious inconsistency	no serious indirectness	serious[2]	none	31/63 (49.2%)	15/63 (23.8%)	RR 2.17 (1.36 to 3.45)	279 more per 1000 (from 86 more to 583 more)	LOW	CRITICAL
Full Analysis, exclusive breastfeeding at 3 to 14 days												
4[1]	randomised trials	serious [5]	serious[10]	no serious indirectness	serious[2]	none	648/1005 (64.5%)	343/608 (56.4%)	RR 1.05 (0.92 to 1.19)	28 more per 1000 (from 45 fewer to 107 more)	VERY LOW	CRITICAL
How delivered - Face-to-face Group, exclusive breastfeeding at 3 to 14 days												
1 (Forster 2004)	randomised trials	serious [7]	no serious inconsistency	no serious indirectness	serious[2]	none	477/614 (77.7%)	242/310 (78.1%)	RR 1 (0.93 to 1.07)	0 fewer per 1000 (from 55 fewer to 55 more)	LOW	CRITICAL
How delivered - Face-to-face individual, exclusive breastfeeding at 3 to 14 days												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute		
3[1]	randomised trials	serious [5]	serious[10]	no serious indirectness	very serious[2,4]	none	111/268 (41.4%)	66/230 (28.7%)	RR 1.5 (0.87 to 2.57)	143 more per 1000 (from 37 fewer to 451 more)	VERY LOW	CRITICAL
How delivered - Self-help/digital, exclusive breastfeeding at 3 to 14 days												
1 (Mattar 2007)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2,4]	none	60/123 (48.8%)	35/68 (51.5%)	RR 0.95 (0.71 to 1.27)	26 fewer per 1000 (from 149 fewer to 139 more)	LOW	CRITICAL
Number of contacts - 0 contact, exclusive breastfeeding at 3 to 14 days												
1 (Mattar 2007)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2,4]	none	60/123 (48.8%)	35/68 (51.5%)	RR 0.95 (0.71 to 1.27)	26 fewer per 1000 (from 149 fewer to 139 more)	LOW	CRITICAL
Number of contacts - 1 contact, exclusive breastfeeding at 3 to 14 days												
3[1]	randomised trials	serious [5]	no serious inconsistency	no serious indirectness	serious [2]	none	335/551 (60.8%)	183/358 (51.1%)	RR 1.02 (0.92 to 1.12)	10 more per 1000 (from 41 fewer to 61 more)	LOW	CRITICAL
Number of contacts - 2 to 3 contacts, exclusive breastfeeding at 3 to 14 days												
1 (Forster 2005)	randomised trials	serious [7]	no serious inconsistency	no serious indirectness	serious [2]	none	239/308 (77.6%)	121/155 (78.1%)	RR 0.99 (0.9 to 1.1)	8 fewer per 1000 (from 78 fewer to 78 more)	LOW	CRITICAL
Number of contacts - 4 to 8 contacts, exclusive breastfeeding at 3 to 14 days												
1 (Ryser 2004)	randomised trials	serious [9]	no serious inconsistency	no serious indirectness	serious[4]	none	14/23 (60.9%)	4/27 (14.8%)	RR 4.11 (1.57 to 10.75)	461 more per 1000 (from 84 more to 1000 more)	LOW	CRITICAL
Population – General, exclusive breastfeeding at 3 to 14 days												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Standard care**	**Relative (95% CI)**	**Absolute**		
3[1]	randomised trials	serious [5]	no serious inconsistency	no serious indirectness	serious[2]	none	634/982 (64.6%)	339/581 (58.3%)	RR 1 (0.94 to 1.07)	0 fewer per 1000 (from 35 fewer to 41 more)	LOW	CRITICAL
Population - Low income, exclusive breastfeeding at 3 to 14 days												
1 (Ryser 2004)	randomised trials	serious [9]	no serious inconsistency	no serious indirectness	serious[4]	none	14/23 (60.9%)	4/27 (14.8%)	RR 4.11 (1.57 to 10.75)	461 more per 1000 (from 84 more to 1000 more)	LOW	CRITICAL
Full Analysis, any breastfeeding at 6 to 12 weeks												
12[1]	randomised trials	serious [11]	serious[10]	no serious indirectness	no serious imprecision	none	1142/1814 (63%)	932/1524 (61.2%)	RR 1.12 (1.01 to 1.26)	73 more per 1000 (from 6 more to 159 more)	LOW	CRITICAL
How Delivered - Face-to-face group, any breastfeeding at 6 to 12 weeks												
4[1]	randomised trials	serious [12]	very serious[6]	no serious indirectness	serious[2]	none	705/921 (76.5%)	639/892 (71.6%)	RR 1.2 (0.96 to 1.49)	143 more per 1000 (from 29 fewer to 351 more)	VERY LOW	CRITICAL
How Delivered - Face-to-face individual, any breastfeeding at 6 to 12 weeks												
6[1]	randomised trials	serious [11]	no serious inconsistency	no serious indirectness	serious[2]	none	371/773 (48%)	262/567 (46.2%)	RR 1.07 (0.94 to 1.22)	32 more per 1000 (from 28 fewer to 102 more)	LOW	CRITICAL
How Delivered - Digital / Self Help, any breastfeeding at 6 to 12 weeks												
1 (Mattar 2007)	randomised trials	no serious	no serious inconsistency	no serious indirectness	very serious[2,4]	none	66/120 (55%)	31/65 (47.7%)	RR 1.15 (0.85 to 1.56)	72 more per 1000 (from 72	LOW	CRITICAL

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute	Quality	Importance
		risk of bias								fewer to 267 more)		
Number of Contacts - 0 Contacts, any breastfeeding at 6 to 12 weeks												
1 (Mattar 2007)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2,4]	none	66/120 (55%)	31/65 (47.7%)	RR 1.15 (0.85 to 1.56)	72 more per 1000 (from 72 fewer to 267 more)	LOW	CRITICAL
Number of Contacts - 1 Contact, any breastfeeding at 6 to 12 weeks												
8[1]	randomised trials	serious[11]	serious[10]	no serious indirectness	serious[2]	none	466/869 (53.6%)	394/806 (48.9%)	RR 1.18 (0.98 to 1.42)	88 more per 1000 (from 10 fewer to 205 more)	VERY LOW	CRITICAL
Number of Contacts - 2 to 3 Contacts, any breastfeeding at 6 to 12 weeks												
2[1]	randomised trials	serious[12]	no serious inconsistency	no serious indirectness	serious[2]	none	508/596 (85.2%)	479/579 (82.7%)	RR 1.03 (0.98 to 1.08)	25 more per 1000 (from 17 fewer to 66 more)	LOW	CRITICAL
Number of Contacts - 4 to 8 Contacts, any breastfeeding at 6 to 12 weeks												
1 (Bonuck 2014)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	very serious[2,4]	none	102/229 (44.5%)	28/74 (37.8%)	RR 1.18 (0.85 to 1.63)	68 more per 1000 (from 57 fewer to 238 more)	VERY LOW	CRITICAL
Population - General Population, any breastfeeding at 6 to 12 weeks												
7[1]	randomised trials	serious[11]	no serious inconsistency	no serious indirectness	serious[2]	none	1000/1496 (66.8%)	888/1364 (65.1%)	RR 1.04 (0.99 to 1.08)	26 more per 1000 (from 7 fewer to 52 more)	LOW	CRITICAL
Population - Low Income, any breastfeeding at 6 to 12 weeks												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute		
3[1]	randomised trials	serious [11]	very serious[6]	no serious indirectness	very serious[2,4]	none	142/318 (44.7%)	44/160 (27.5%)	RR 1.71 (0.83 to 3.53)	195 more per 1000 (from 47 fewer to 696 more)	VERY LOW	CRITICAL
Fathers, any breastfeeding at 6 to 12 weeks												
1 (Wolfberg 2004)	randomised trials	serious [3]	no serious inconsistency	no serious indirectness	serious[4]	none	9/26 (34.6%)	6/31 (19.4%)	RR 1.79 (0.73 to 4.36)	153 more per 1000 (from 52 fewer to 650 more)	LOW	CRITICAL
Full Analysis, exclusive breastfeeding at 6 to 12 weeks												
5[1]	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	no serious imprecision	none	185/866 (21.4%)	124/619 (20%)	RR 1.3 (1.02 to 1.67)	60 more per 1000 (from 4 more to 134 more)	MODERATE	CRITICAL
Full Analysis, any breastfeeding at 16 to 26 weeks												
6[1]	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	serious[2]	none	664/1656 (40.1%)	418/1101 (38%)	RR 1 (0.91 to 1.1)	0 fewer per 1000 (from 34 fewer to 38 more)	LOW	CRITICAL

1 See forest plots for study references
2 Evidence downgraded by 1 level due to serious imprecision, confidence interval crosses the line of no effect
3 Serious risk of bias due to concerns with blinding, randomisation and selective reporting.
4 Evidence downgraded by 1 level due to risk of serious imprescision as total events is below 300 events for dichotomous outcome
5 Serious risk of bias due to concerns with blinding and missing data
6 Evidence downgraded by 2 levels due to very serious risk of inconsistency, I squared >75%
7 Serious risk of bias due to concerns with blinding and adherence
8 Serious risk of bias due to concerns with blinding, randomisation, outcome measures and selective reporting
9 Serious risk of bias due to concerns with blinding, randomisation, missing data, outcome measures and selective reporting
10 Evidence downgraded by 1 level due to serious risk of inconsistency, I squared >50%

11 Serious risk of bias due to concerns with around blinding, missing data and selective reporting
12 Serious risk of bias due to concerns with blinding and selective reporting
NB General population in this case means any study that was relevant to this outcome but not classified within another subgroup

Comparison 1.2. One-contact antenatal intervention focusing on practical skills without partners versus two-contact antenatal intervention focusing on attitudes and involving partners

Table 5: Clinical evidence profile for comparison 1.2 - One-contact antenatal intervention focusing on practical skills without partners versus two-contact antenatal intervention focusing on attitudes and involving partners

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**1 contact practical skills without partners**	**2 contacts attitudes with partners**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Any breastfeeding at 3 to 14 days												
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	296/306 (96.7%)	291/308 (94.5%)	RR 1.02 (0.99 to 1.06)	19 more per 1000 (from 9 fewer to 57 more)	LOW	CRITICAL
Exclusive breastfeeding at 3 to 14 days												
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	238/306 (77.8%)	239/308 (77.6%)	RR 1 (0.92 to 1.09)	0 fewer per 1000 (from 62 fewer to 70 more)	LOW	CRITICAL
Any breastfeeding at 16 to 26 weeks												
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	162/297 (54.5%)	146/293 (49.8%)	RR 1.09 (0.94 to 1.28)	45 more per 1000 (from 30 fewer to 140 more)	LOW	CRITICAL
Class was enjoyable, median on Likert scale (Better indicated by higher values)												
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	197	225	-	Median score in both groups: 4	MODERATE	IMPORTANT
Useful for decision making on feeding method, median on Likert scale (Better indicated by higher values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**1 contact practical skills without partners**	**2 contacts attitudes with partners**	**Relative (95% CI)**	**Absolute**		
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	197	225	-	Median score in practical skills group: 5; median score in attitudes group: 4	MODERATE	IMPORTANT
Did not learn anything new, median on Likert scale (Better indicated by lower values)												
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	197	225	-	Median score in both groups: 1	MODERATE	IMPORTANT
Sufficient opportunities to ask questions, median on Likert scale (Better indicated by higher values)												
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	197	225	-	Median score in both groups: 5	MODERATE	IMPORTANT
Class leader was able to answer question, median on Likert scale (Better indicated by higher values)												
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	197	225	-	Median score in both groups: 5	MODERATE	IMPORTANT
Felt uncomfortable participating in the classes, median on Likert scale (Better indicated by lower values)												
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	197	225	-	Median score in both groups: 1	MODERATE	IMPORTANT
Time and place of class was convenient, median on Likert scale (Better indicated by higher values)												
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	197	225	-	Median score in both groups: 4	MODERATE	IMPORTANT
I would recommend to other women, median on Likert scale (Better indicated by higher values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	1 contact practical skills without partners	2 contacts attitudes with partners	Relative (95% CI)	Absolute		
1 (Forster 2004)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	197	225	-	Median score in both groups: 5	MODERATE	IMPORTANT

1 Serious risk of bias due to concerns with blinding and adherence
2 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses the line of no effect

Comparison 1.3. Antenatal provision of booklet plus video plus one contact versus antenatal provision of booklet and video only

Table 6: Clinical evidence profile for comparison 1.3 - Antenatal provision of booklet plus video plus one contact versus antenatal provision of booklet and video only

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Booklet+video+1 contact	Booklet and video only	Relative (95% CI)	Absolute		
Any breastfeeding at 3 to 14 days												
1 (Mattar 2007)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1,2]	none	106/112 (94.6%)	111/123 (90.2%)	RR 1.05 (0.97 to 1.13)	45 more per 1000 (from 27 fewer to 117 more)	LOW	CRITICAL
Exclusive breastfeeding at 3 to 14 days												
1 (Mattar 2007)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1,2]	none	61/112 (54.5%)	60/123 (48.8%)	RR 1.12 (0.87 to 1.43)	59 more per 1000 (from 63 fewer to 210 more)	LOW	CRITICAL
Any breastfeeding at 6 to 12 weeks												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Booklet+video+1 contact**	**Booklet and video only**	**Relative (95% CI)**	**Absolute**		
1 (Mattar 2007)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1,2]	none	64/112 (57.1%)	66/120 (55%)	RR 1.04 (0.83 to 1.3)	22 more per 1000 (from 94 fewer to 165 more)	LOW	CRITICAL
Exclusive breastfeeding at 6 to 12 weeks												
1 (Mattar 2007)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1,2]	none	27/112 (24.1%)	21/120 (17.5%)	RR 1.38 (0.83 to 2.29)	67 more per 1000 (from 30 fewer to 226 more)	LOW	CRITICAL
Any breastfeeding at 16 to 26 weeks												
1 (Mattar 2007)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1,2]	none	48/112 (42.9%)	39/120 (32.5%)	RR 1.32 (0.94 to 1.84)	104 more per 1000 (from 20 fewer to 273 more)	LOW	CRITICAL

1 *1 Evidence downgraded by 1 level due to risk of serious imprescision as confidence interval crosses the line of no effect*
2 *2 Evidence downgraded by 1 level due to risk of serious imprescision as total events is below 300 events for dichotomous outcome*
3

Comparison 2.1. Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus standard care

Table 7: Clinical evidence profile for intervention 2 versus standard care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute		
Full analysis, initiation of breastfeeding												
24[1]	randomised trials	serious[2]	serious[3]	serious[4]	no serious imprecision	none	2104/2541 (82.8%)	1808/2332 (77.5%)	RR 1.05 (1.01 to 1.09)	39 more per 1000 (from 8 more to 70 more)	VERY LOW	CRITICAL
Subgroup analysis - General population, initiation of breastfeeding												
8[1]	randomised trials	serious[5]	no serious inconsistency	serious[6]	serious[7]	none	1027/1277 (80.4%)	1056/1332 (79.3%)	RR 1.01 (0.99 to 1.03)	8 more per 1000 (from 8 fewer to 24 more)	VERY LOW	CRITICAL
Subgroup analysis - Low income, initiation of breastfeeding												
9[1]	randomised trials	serious[2]	very serious[8]	serious[9]	no serious imprecision	none	757/856 (88.4%)	470/601 (78.2%)	RR 1.16 (1.03 to 1.31)	125 more per 1000 (from 23 more to 242 more)	VERY LOW	CRITICAL
Subgroup analysis - Obese women, initiation of breastfeeding												
3[1]	randomised trials	very serious[10]	no serious inconsistency	serious[11]	very serious[7, 12]	none	39/42 (92.9%)	31/31 (100%)	RR 0.99 (0.9 to 1.08)	10 fewer per 1000 (from 100 fewer to 80 more)	VERY LOW	CRITICAL
Subgroup analysis - Young women, initiation of breastfeeding												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute		
2[1]	randomised trials	serious[2]	very serious[8]	no serious indirectness	very serious[7,12]	none	128/168 (76.2%)	113/167 (67.7%)	RR 1.1 (0.83 to 1.46)	68 more per 1000 (from 115 fewer to 311 more)	VERY LOW	CRITICAL
Subgroup analysis - Obese+Low Income, initiation of breastfeeding												
1 (Chapman 2013)	randomised trials	serious[13]	no serious inconsistency	no serious indirectness	very serious[7,12]	none	75/76 (98.7%)	77/78 (98.7%)	RR 1 (0.96 to 1.04)	0 fewer per 1000 (from 39 fewer to 39 more)	VERY LOW	CRITICAL
Subgroup analysis - Young women+Low income, initiation of breastfeeding												
1 (Edwards 2013)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	serious[7]	none	78/122 (63.9%)	61/123 (49.6%)	RR 1.29 (1.03 to 1.61)	144 more per 1000 (from 15 more to 303 more)	LOW	CRITICAL
Full analysis, any breastfeeding for 3 to 14 days												
14[1]	randomised trials	serious[14]	very serious[8]	serious[15]	no serious imprecision	none	1732/2106 (82.2%)	1473/1962 (75.1%)	RR 1.1 (1.04 to 1.16)	75 more per 1000 (from 30 more to 120 more)	VERY LOW	CRITICAL
Subgroup analysis - General population, any breastfeeding for 3 to 14 days												
6[1]	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	no serious imprecision	none	1265/1522 (83.1%)	1120/1428 (78.4%) 83.2%	RR 1.04 (1.02 to 1.07)	31 more per 1000 (from 16 more to 55 more)	MODERATE	CRITICAL
Subgroup analysis - Low income, any breastfeeding for 3 to 14 days												
7[1]	randomised trials	very serious[16]	very serious[8]	serious[15]	no serious imprecision	none	396/508 (78%)	287/456 (62.9%)	RR 1.52 (1.05 to 2.2)	327 more per 1000 (from 31 more to 755 more)	VERY LOW	CRITICAL
Subgroup analysis - Obese+Low income, any breastfeeding for 3 to 14 days												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute		
1 (Chapman 2013)	randomised trials	serious[13]	no serious inconsistency	no serious indirectness	very serious[7,12]	none	71/76 (93.4%)	66/78 (84.6%)	RR 1.1 (0.99 to 1.23)	85 more per 1000 (from 8 fewer to 195 more)	VERY LOW	CRITICAL
Full analysis, exclusive breastfeeding 3 to 14 days												
16[1]	randomised trials	serious[14]	serious[3]	serious[4]	no serious imprecision	none	1529/2616 (58.4%)	1092/2207 (49.5%)	RR 1.23 (1.07 to 1.41)	114 more per 1000 (from 35 more to 203 more)	VERY LOW	CRITICAL
Subgroup analysis - General population, exclusive breastfeeding 3 to 14 days												
5[1]	randomised trials	serious[17]	serious[3]	no serious indirectness	serious[7]	none	1252/1937 (64.6%)	893/1573 (56.8%)	RR 1.15 (0.98 to 1.36)	85 more per 1000 (from 11 fewer to 204 more)	VERY LOW	CRITICAL
Subgroup analysis - Low income, exclusive breastfeeding 3 to 14 days												
6[1]	randomised trials	very serious[16]	no serious inconsistency	very serious[18]	no serious imprecision	none	157/456 (34.4%)	107/423 (25.3%)	RR 1.41 (1.07 to 1.86)	104 more per 1000 (from 18 more to 218 more)	VERY LOW	CRITICAL
Subgroup analysis - Obese women, exclusive breastfeeding 3 to 14 days												
4[1]	randomised trials	very serious[10]	serious[3]	serious[11]	very serious[7,12]	none	104/147 (70.7%)	80/133 (60.2%)	RR 1.11 (0.74 to 1.65)	66 more per 1000 (from 156 fewer to 391 more)	VERY LOW	CRITICAL
Subgroup analysis - Obese+Low income, exclusive breastfeeding 3 to 14 days												
1 (Chapman 2013)	randomised trials	serious[13]	no serious inconsistency	no serious indirectness	very serious[7,12]	none	16/76 (21.1%)	12/78 (15.4%)	RR 1.37 (0.69 to 2.7)	57 more per 1000 (from 48 fewer to 262 more)	VERY LOW	CRITICAL
Full analysis, any breastfeeding 6 to 12 weeks												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute		
40[1]	randomised trials	serious[5]	no serious inconsistency	serious[19]	no serious imprecision	none	4680/7640 (61.3%)	3170/5607 (56.5%)	RR 1.09 (1.05 to 1.13)	51 more per 1000 (from 28 more to 73 more)	LOW	CRITICAL
Fathers, any breastfeeding 6 to 12 weeks												
1 (Maycock 2013)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	no serious imprecision	none	288/295 (97.6%)	224/298 (75.2%)	RR 1.3 (1.21 to 1.39)	226 more per 1000 (from 158 more to 293 more)	MODERATE	CRITICAL
Full analysis, exclusive breastfeeding 6 to 12 weeks												
28[1]	randomised trials	serious[2]	serious[3]	serious[4]	no serious imprecision	none	1576/4612 (34.2%)	932/3483 (26.8%)	RR 1.34 (1.19 to 1.51)	91 more per 1000 (from 51 more to 136 more)	VERY LOW	CRITICAL
Subgroup analysis - General population, exclusive breastfeeding 6 to 12 weeks												
16[1]	randomised trials	serious[5]	serious[3]	serious[6]	no serious imprecision	none	860/2350 (36.6%)	561/2017 (27.8%)	RR 1.36 (1.17 to 1.58)	100 more per 1000 (from 47 more to 161 more)	VERY LOW	CRITICAL
Subgroup analysis - Low income, exclusive breastfeeding 6 to 12 weeks												
10[1]	randomised trials	serious[14]	no serious inconsistency	serious[4]	no serious imprecision	none	647/2100 (30.8%)	320/1302 (24.6%)	RR 1.39 (1.06 to 1.83)	96 more per 1000 (from 15 more to 204 more)	LOW	CRITICAL
Subgroup analysis - Obese women, exclusive breastfeeding 6 to 12 weeks												
1 (Carlsen 2013)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	serious[12]	none	66/105 (62.9%)	45/102 (44.1%)	RR 1.42 (1.09 to 1.85)	185 more per 1000 (from 40 more to 375 more)	LOW	CRITICAL
Subgroup analysis - Obese+Low income, exclusive breastfeeding 6 to 12 weeks												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute		
1 (Chapman 2013)	randomised trials	serious[13]	no serious inconsistency	no serious indirectness	very serious[7,12]	none	3/57 (5.3%)	6/62 (9.7%)	RR 0.54 (0.14 to 2.07)	45 fewer per 1000 (from 83 fewer to 104 more)	VERY LOW	CRITICAL
Fathers, exclusive breastfeeding 6 to 12 weeks												
1 (Maycock 2013)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	no serious imprecision	none	164/295 (55.6%)	133/298 (44.6%)	RR 1.25 (1.06 to 1.47)	112 more per 1000 (from 27 more to 210 more)	MODERATE	CRITICAL
Full analysis, any breastfeeding 16 to 26 weeks												
39[1]	randomised trials	serious[2]	no serious inconsistency	serious[20]	no serious imprecision	none	3639/7644 (47.6%)	2484/5690 (43.7%)	RR 1.08 (1.03 to 1.13)	35 more per 1000 (from 13 more to 57 more)	LOW	CRITICAL
Fathers, any breastfeeding 16 to 26 weeks												
1 (Pisacane 2005)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	very serious[7,12]	none	31/59 (52.5%)	26/59 (44.1%)	RR 1.19 (0.82 to 1.74)	84 more per 1000 (from 79 fewer to 326 more)	VERY LOW	CRITICAL

1 See forest plots for study references
2 Serious risk of bias due to concerns with blinding, randomisation and selective reporting
3 Evidence downgraded by 1 level due to serious risk of inconsistency, I squared >50%
4 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with three studies that provided breast pumps to their participants as part of the intervention (Bonuck 2014, Chapman 2004 and Ramussen 2011)
5 Serious risk of bias due to concerns with blinding and selective reporting
6 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with one study that provided a breast pump to their participants as part of the intervention (Bonuck 2014)
7 Evidence downgraded by 1 level due to risk of serious imprescision as confidence interval crosses the line of no effect
8 Evidence downgraded by 2 levels due to very serious risk of inconsistency, I squared >75%
9 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with two studies that provided breast pumps to their participants as part of the intervention (Bonuck 2014 and Chapman 2004)
10 Very serious risk of bias due to concerns with blinding, randomisation, adherence, missing data, and selective reporting
11 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with one study that provided breast pumps to their participants as part of the intervention (Ramussen 2011)
12 Evidence downgraded by 1 level due to risk of serious imprescision as total events is below 300 events for dichotomous outcome
13 Serious risk of bias due to concerns with blinding, randomisation and missing data
14 Serious risk of bias due to concerns with blinding, randomisation, missing data and selective reporting

15 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with two studies that provided breast pumps to their participants as part of the intervention (Bonuck 2005 and Efrat 2015) and one study provided gift incentives as part of the intervention (Sciacca1996)
16 Very serious risk of bias due to concerns with blinding, missing data, randomisation, outcome measurement and selective reporting
17 Serious risk of bias due to concerns with blinding and randomisation
18 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with two studies that provided breast pumps to their participants as part of the intervention (Bonuck 2014 and Efrat 2015), one study that provided gift incentives as part of the intervention (Sciacca 1996) and one that study provided a £25 gift for completing the study
19 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with four studies that provided breast pumps to their participants as part of the intervention (Bonuck 2005, Bonuck 2014, Efrat 2015 and Ramussen 2011) and one study that provided gift incentives as part of the intervention (Sciacca 1996)
20 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with four studies provided breast pumps to their participants as part of the intervention (Bonuck 2014, Bonuck 2005, Chapman 2004 and Efrat 2015), two studies that recruited women at 8 weeks postpartum and who had already established breastfeeding (Eliott-Rudder 2014 and Vidas 2011)
NB General population in this case means any study that was relevant to this outcome but not classified within another subgroup

Table 8: Clinical evidence profile for intervention 2 versus standard care: maternal satisfaction

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Standard care	Relative (95% CI)	Absolute		
Received less advice and help from health service than wanted												
1 (Jolly 2012)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	73/271 (26.9%)	91/301 (30.2%)	RR 0.89 (0.69 to 1.16)	33 fewer per 1000 (from 94 fewer to 48 more)	LOW	IMPORTANT
Are you satisfied with feeding advice by hospital nurse (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	187	155	-	MD 0.18 higher (0.05 lower to 0.41 higher)	MODERATE	IMPORTANT
Are you satisfied with feeding advice by general practitioner (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	139	105	-	MD 0 higher (0.22 lower to 0.22 higher)	MODERATE	IMPORTANT
Are you satisfied with feeding advice by paediatrician (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	127	99	-	MD 0.05 higher (0.19 lower to 0.29 higher)	MODERATE	IMPORTANT
Are you satisfied with feeding advice by child healthcare nurse (1=not at all, 5=very much) (Better indicated by lower values)												

1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	300	268	-	MD 0.07 lower (0.19 lower to 0.05 higher)	MODERATE	IMPORTANT
Are you satisfied with feeding advice by child healthcare physician (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	297	269	-	MD 0.09 lower (0.22 lower to 0.04 higher)	MODERATE	IMPORTANT
Are you satisfied with feeding advice by lactation consultant (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[4]	none	73	28	-	MD 0.11 lower (0.53 lower to 0.31 higher)	LOW	IMPORTANT
Did the hospital nurse reckon with your opinion (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	262	222	-	MD 0.01 lower (0.19 lower to 0.17 higher)	MODERATE	IMPORTANT
Did the general practitioner reckon with your opinion (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	260	227	-	MD 0.02 higher (0.15 lower to 0.19 higher)	MODERATE	IMPORTANT
Did the paediatrician reckon with your opinion (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	244	218	-	MD 0.04 lower (0.21 lower to 0.13 higher)	MODERATE	IMPORTANT
Did the child healthcare nurse reckon with your opinion (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	312	279	-	MD 0.05 higher (0.11 lower to 0.21 higher)	MODERATE	IMPORTANT
Did the child healthcare physician reckon with your opinion (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	317	280	-	MD 0.09 higher (0.07 lower to 0.25 higher)	MODERATE	IMPORTANT
Did the lactation consultant reckon with your opinion (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	211	184	-	MD 0.13 higher (0.06 lower to 0.32 higher)	MODERATE	IMPORTANT
Satisfaction with the reach of caregivers (1=not at all, 5=very much) (Better indicated by lower values)												

1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	327	283	-	MD 0.02 higher (0.12 lower to 0.16 higher)	MODERATE	IMPORTANT
Did you receive contradictory feeding advice (1=not at all, 5=very much) (Better indicated by lower values)												
1 (Kools 2005)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	329	287	-	MD 0.08 lower (0.15 to 0.01 lower)	MODERATE	IMPORTANT
Mother's reported INFORMATION support according to average value per health visitor (Better indicated by lower values)												
1 (Kronborg 2008)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	serious[4]	none	52	57	-	MD 0.63 higher (0.38 to 0.88 higher)	LOW	IMPORTANT
Mother's reported INSTRUMENTAL support according to average value per health visitor (Better indicated by lower values)												
1 (Kronborg 2008)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	serious[4]	none	52	57	-	MD 0.28 higher (0.23 to 0.33 higher)	LOW	IMPORTANT
Mother's reported COMPREHENSIBLE support according to average value per health visitor (Better indicated by lower values)												
1 (Kronborg 2008)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	serious[4]	none	52	57	-	MD 0.16 higher (0.05 to 0.27 higher)	LOW	IMPORTANT
Satisfied with amount of information given by HCP (n=very satisfied or satisfied)												
1 (Laliberte 2016)	randomised trials	serious[6]	no serious inconsistency	no serious indirectness	no serious imprecision	none	252/295 (85.4%)	108/134 (80.6%)	RR 1.06 (0.96 to 1.17)	48 more per 1000 (from 32 fewer to 137 more)	MODERATE	IMPORTANT
Satisfied with breastfeeding support received (n=very satisfied or satisfied)												
1 (Laliberte 2016)	randomised trials	serious[6]	no serious inconsistency	no serious indirectness	serious[2]	none	258/295 (87.5%)	86/134 (64.2%)	RR 1.36 (1.19 to 1.56)	231 more per 1000 (from 122 more to 359 more)	LOW	IMPORTANT
Satisfied with support received transitioning from hospital to home (n=very satisfied or satisfied)												
1 (Laliberte 2016)	randomised trials	serious[6]	no serious inconsistency	no serious indirectness	serious[2]	none	249/295 (84.4%)	97/134 (72.4%)	RR 1.17 (1.04 to 1.31)	123 more per 1000 (from 29 more to 224 more)	LOW	IMPORTANT
Total general satisfaction score (Better indicated by lower values)												
1 (Laliberte 2016)	randomised trials	serious[6]	no serious inconsistency	no serious indirectness	serious[4]	none	295	135	-	MD 5.2 higher (3.58 to 6.82 higher)	LOW	IMPORTANT

Women felt breastfeeding support was respectful												
1 (Srinivas 2005)	randomised trials	serious[6]	no serious inconsistency	no serious indirectness	serious[2]	none	30/41 (73.2%)	11/46 (23.9%)	RR 3.06 (1.77 to 5.29)	493 more per 1000 (from 184 more to 1000 more)	LOW	IMPORTANT
Women felt that standard care was sufficient												
1 (Srinivas 2005)	randomised trials	serious[6]	no serious inconsistency	no serious indirectness	serious[2]	none	7/41 (17.1%)	28/46 (60.9%)	RR 0.28 (0.14 to 0.57)	438 fewer per 1000 (from 262 fewer to 523 fewer)	LOW	IMPORTANT
Satisfaction with maternal and newborn care (Better indicated by lower values)												
1 (Paul 2012)	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[7]	none	0	-	-	MD 0.25 higher (0.61 lower to 1.11 higher)	VERY LOW	IMPORTANT

1 Serious risk of bias due to concerns with blinding, randomisation, deviations from intended interventions and missing data.
2 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses one default MID
3 Serious risk of bias due to concerns with blinding and selective reporting
4 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses one calculated MID (calculated from SD of control arm)
5 Serious risk of bias due to concerns with blinding, missing data and selective reporting
6 Serious risk of bias due to concerns with blinding, randomisation, outcome measurements and selective reporting
7 Evidence downgraded by 2 levels due to risk of very serious imprecision as confidence interval crosses two MID boundaries

Table 9: Clinical evidence profile for intervention 2 versus standard care: Any breastfeeding 3 to 14 days (Areas)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Standard care**	**Relative (95% CI)**	**Absolute**		
Any breastfeeding 3 to 14 days (Better indicated by lower values)												
1 (Hoddinott 2009)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	0	-	-	MD 0 higher (0.03 lower to 0.03 higher)	LOW	CRITICAL
Any breastfeeding 6 to 12 weeks (areas) (Better indicated by lower values)												
1 (Hoddinott 2009)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	0	-	-	MD 0.02 lower (0.04 lower to 0 higher)	LOW	CRITICAL

Duke-UNC functional social support scale (Better indicated by lower values)												
1 (Hoddinott 2009)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	822	517	-	MD 0 higher (0.03 lower to 0.03 higher)	MODERATE	IMPORTANT

1 Serious risk of bias due to concerns with blinding and missing data
2 Confidence interval crosses the line of no effect

Table 10: Clinical evidence profile for intervention 2 versus standard care: intervention delivered to healthcare professionals

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention to healthcare professionals**	**Standard care**	**Relative (95% CI)**	**Absolute**		
Initiation of Breastfeeding												
1 (Ekstrom 2006+2012)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1,2]	none	63/63 (100%)	57/59 (96.6%)	RR 1.04 (0.98 to 1.1)	39 more per 1000 (from 19 fewer to 97 more)	LOW	IMPORTANT
Satisfied with knowing 'where to ask if any problems with baby or breastfeeding' (Better indicated by lower values)												
1 (Ekstrom 2006+2012)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[3]	none	116	76	-	MD 0.57 higher (0.06 to 1.08 higher)	MODERATE	IMPORTANT
Satisfied with 'breastfeeding information' (Better indicated by lower values)												
1 (Ekstrom 2006+2012)	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[3]	none	116	76	-	MD 0.77 higher (0.24 to 1.3 higher)	MODERATE	IMPORTANT

1 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses the line of no effect
2 Evidence downgraded by 1 level due to risk of serious imprecision as total events is below 300 events for dichotomous outcome
3 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses one calculated MID (Calculated from SD of control arm)

Comparison 2.2. Education, advice or support from peer or professional provided antentally (Intervention 1) versus Education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2)

Table 11: Clinical evidence profile for intervention 1 versus intervention 2

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention 1	Intervention 2	Relative (95% CI)	Absolute		
Initiation of breastfeeding												
4[1]	randomised trials	serious[2]	no serious inconsistency	serious[3]	serious[4]	none	227/263 (86.3%)	330/374 (88.2%)	RR 0.96 (0.92 to 1.01)	35 fewer per 1000 (from 71 fewer to 9 more)	VERY LOW	CRITICAL
Any breastfeeding 3 to 14 days												
2[1]	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	very serious[4,6]	none	139/173 (80.3%)	155/203 (76.4%)	RR 0.96 (0.92 to 1.01)	31 fewer per 1000 (from 61 fewer to 8 more)	VERY LOW	CRITICAL
General population, any breastfeeding 3 to 14 days												
1 (Su 2007)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	very serious[4,6]	none	126/133 (94.7%)	126/128 (98.4%)	RR 0.96 (0.92 to 1.01)	39 fewer per 1000 (from 79 fewer to 10 more)	VERY LOW	CRITICAL
Low Income, any breastfeeding 3 to 14 days												
1 (Caulfield 1998)	randomised trials	serious[7]	no serious inconsistency	no serious indirectness	very serious[4,6]	none	13/40 (32.5%)	29/75 (38.7%)	RR 0.85 (0.5 to 1.43)	58 fewer per 1000 (from 193 fewer to 166 more)	VERY LOW	CRITICAL
Exclusive breastfeeding 3 to 14 days												
1 (Su 2007)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[4,6]	none	36/133 (27.1%)	48/128 (37.5%)	RR 0.72 (0.5 to 1.03)	105 fewer per 1000 (from 188 fewer to 11 more)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention 1	Intervention 2	Relative (95% CI)	Absolute		
Any breastfeeding 6 to 12 weeks												
2[1]	randomised trials	serious[8]	no serious inconsistency	no serious indirectness	serious[4]	none	175/356 (49.2%)	235/421 (55.8%)	RR 0.89 (0.77 to 1.02)	61 fewer per 1000 (from 128 fewer to 11 more)	LOW	CRITICAL
General population, any breastfeeding 6 to 12 weeks												
1 (Su 2007)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	very serious[4,6]	none	73/127 (57.5%)	71/122 (58.2%)	RR 0.99 (0.8 to 1.22)	6 fewer per 1000 (from 116 fewer to 128 more)	VERY LOW	CRITICAL
Low income, any breastfeeding 6 to 12 weeks												
1 (Bonuck 2014)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[6]	none	102/229 (44.5%)	164/299 (54.8%)	RR 0.82 (0.68 to 0.99)	99 fewer per 1000 (from 5 fewer to 176 fewer)	LOW	CRITICAL
Exclusive breastfeeding 6 to 12 weeks												
2[1]	randomised trials	serious[8]	serious[9]	no serious indirectness	serious[4]	none	41/354 (11.6%)	61/421 (14.5%)	RR 0.63 (0.31 to 1.28)	54 fewer per 1000 (from 100 fewer to 41 more)	VERY LOW	CRITICAL
General population, exclusive breastfeeding 6 to 12 weeks												
1 (Su 2007)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	very serious[4,6]	none	31/127 (24.4%)	29/122 (23.8%)	RR 1.03 (0.66 to 1.6)	7 more per 1000 (from 81 fewer to 143 more)	VERY LOW	CRITICAL
Low income, exclusive breastfeeding 6 to 12 weeks												
1 (Bonuck 2014)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[6]	none	10/227 (4.4%)	32/299 (10.7%)	RR 0.41 (0.2 to 0.83)	63 fewer per 1000 (from 18 fewer to 86 fewer)	LOW	CRITICAL
Any breastfeeding 16 to 26 weeks												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention 1	Intervention 2	Relative (95% CI)	Absolute		
2[1]	randomised trials	serious[9]	no serious inconsistency	no serious indirectness	very serious[4,6]	none	127/349 (36.4%)	158/424 (37.3%)	RR 0.96 (0.79 to 1.16)	15 fewer per 1000 (from 78 fewer to 60 more)	VERY LOW	CRITICAL
General population, any breastfeeding 16 to 26 weeks												
1 (Su 2007)	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	very serious[4,6]	none	52/122 (42.6%	48/119 (40.3%)	RR 1.06 (0.78 to 1.43)	24 more per 1000 (from 89 fewer to 173 more)	VERY LOW	CRITICAL
Low income, any breastfeeding 16 to 26 weeks												
1 (Bonuck 2014)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	very serious[4,6]	none	75/227 (33%)	110/305 (36.1%)	RR 0.9 (0.7 to 1.14)	36 fewer per 1000 (from 108 fewer to 50 more)	VERY LOW	CRITICAL

1 See forest plots for study references
2 Serious risk of bias due to concerns with blinding, outcome measures and selective reporting
3 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with one study that provided breast pumps as part of the intervention (Bonuck 2014)
4 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses the line of no effect
5 Serious risk of bias due to concerns with blinding and missing data
6 Evidence downgraded by 1 level due to risk of serious imprecision as total events is below 300 events for dichotomous outcomes
7 Serious risk of bias due to concerns with blinding, missing data and randomisation
9 Serious risk of bias due to concerns with randomisation, missing data, outcome measurement and selective reporting
NB General population in this case means any study that was relevant to this outcome but not classified within another subgroup

Comparison 2.3. Counselling session + booklet versus counselling session

Table 12: Clinical evidence profile for counselling session + booklet versus counselling session only

Quality assessment	No of patients	Effect	Quality	Importance

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Counselling session + booklet	Counselling session only	Relative (95% CI)	Absolute		
Any breastfeeding 16 to 26 weeks												
1[1]	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	very serious[3,4]	none	61/103 (59.2%)	50/97 (51.5%)	RR 1.15 (0.89 to 1.48)	77 more per 1000 (from 57 fewer to 247 more)	VERY LOW	CRITICAL

1 Curro 2007
2 Serious risk of bias due to concerns with blinding, randomisation, selective reporting
3 Evidence downgraded by 1 level due to risk of serious imprecision as total events is below 300 events for dichotomous outcome
4 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses the line of no effect

Comparison 2.4. Video + keeping a log book versus video

Table 13: Clinical evidence profile for video and feeding log versus video

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Video + feeding log	Video	Relative (95% CI)	Absolute		
Any breastfeeding at 6 to 12 weeks												
1 (Pollard 2010)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	23/41 (56.1%)	18/43 (41.9%)	RR 1.34 (0.86 to 2.09)	142 more per 1000 (from 59 fewer to 456 more)	VERY LOW	CRITICAL
Any breastfeeding 16 to 26 weeks												
1 (Pollard 2010)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	15/41 (36.6%)	14/43 (32.6%)	RR 1.12 (0.62 to 2.03)	39 more per 1000 (from 124 fewer to 335 more)	VERY LOW	CRITICAL

1 Serious risk of bias due to concerns with blinding, randomisation, selective reporting
2 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses the line of no effect
3 Evidence downgraded by 1 level due to risk of serious imprecision as total events is below 300 events for dichotomous outcome

Comparison 2.5. Two home visit versus a telephone call on day of discharge

Table 14: Clinical evidence profile for home visit versus telephone call

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Home visit	Telephone call	Relative (95% CI)	Absolute		
Any breastfeeding 3 to 14 days												
1 (Steel O'Connor 2003)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	271/339 (79.9%)	292/370 (78.9%)	RR 1.01 (0.94 to 1.09)	8 more per 1000 (from 47 fewer to 71 more)	VERY LOW	CRITICAL
Any breastfeeding 16 to 26 weeks												
1 (Steel O'Connor 2003)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	146/248 (58.9%)	149/262 (56.9%)	RR 1.04 (0.89 to 1.2)	23 more per 1000 (from 63 fewer to 114 more)	VERY LOW	CRITICAL

1 Serious risk of bias due to concerns with blinding and selective reporting
2 Evidence downgraded by 1 level due to risk of serious imprecision as total events is below 300 events for dichotomous outcome
3 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses the line of no effect

Comparison 2.6. Regular home visits versus printed educational materials

Table 15: Clinical evidence profile for regular home visits versus printed educational materials

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Regular home visits	Printed educational materials	Relative (95% CI)	Absolute		
Initiation of breastfeeding												

1 (Lutenbacher 2018)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	78/91 (85.7%)	71/86 (82.6%)	RR 1.04 (0.91 to 1.18)	33 more per 1000 (from 74 fewer to 149 more)	VERY LOW	CRITICAL
Any breastfeeding 3 to 14 days												
1 (Lutenbacher 2018)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	75/90 (83.3%)	68/85 (80%)	RR 1.04 (0.9 to 1.2)	32 more per 1000 (from 80 fewer to 160 more)	VERY LOW	CRITICAL
Exclusive breastfeeding 3 to 14 days												
1 (Lutenbacher 2018)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	19/90 (21.1%)	8/86 (9.3%)	RR 2.27 (1.05 to 4.91)	118 more per 1000 (from 5 more to 364 more)	LOW	CRITICAL
Any breastfeeding 6 to 12 weeks												
1 (Lutenbacher 2018)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	61/90 (67.8%)	60/85 (70.6%)	RR 0.96 (0.79 to 1.17)	28 fewer per 1000 (from 148 fewer to 120 more)	VERY LOW	CRITICAL
Exclusive breastfeeding 6 to 12 weeks												
1 (Lutenbacher 2018)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	2/90 (2.2%)	1/86 (1.2%)	RR 1.91 (0.18 to 20.69)	11 more per 1000 (from 10 fewer to 229 more)	VERY LOW	CRITICAL
Any breastfeeding 16 to 26 weeks												
1 (Lutenbacher 2018)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	45/90 (50%)	42/85 (49.4%)	RR 1.01 (0.75 to 1.36)	5 more per 1000 (from 124 fewer to 178 more)	VERY LOW	CRITICAL

1 *1 Serious risk of bias due to concerns with blinding, randomisation and selective reporting*
2 *2 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses the line of no effect*
3 *3 Evidence downgraded by 1 level due to risk of serious imprecision as total events is below 300 events for dichotomous outcome*

4 ***Comparison 2.7. Home contact versus clinic contact***

5 **Table 16: Clinical evidence profile for home contact versus clinic contact**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Home contact	Clinic contact	Relative (95% CI)	Absolute		
Any breastfeeding 3 to 14 days												
1 (Gagnon 2002)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	247/259 (95.4%)	243/254 (95.7%)	RR 1 (0.96 to 1.03)	0 fewer per 1000 (from 38 fewer to 29 more)	LOW	CRITICAL
Exclusive breastfeeding 3 to 14 days												
1 (Gagnon 2002)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	183/259 (70.7%)	171/254 (67.3%)	RR 1.05 (0.93 to 1.18)	34 more per 1000 (from 47 fewer to 121 more)	LOW	CRITICAL
Client satisfaction questionnaire (CSQ-8) (Better indicated by lower values)												
1 (Gagnon 2002)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	259	253	-	MD 0.3 higher (1.08 lower to 1.68 higher)	MODERATE	IMPORTANT

1 *1 Serious risk of bias due to concerns with blinding and selective reporting*
2 *2 Evidence downgraded by 1 level due to risk of serious imprescision as confidence interval crosses the line of no effect*

3 ***Comparison 2.8. Proactive phone calls versus reactive phone calls***

4 **Table 17: Clinical evidence profile for proactive phone calls versus reactive phone calls**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Proactive phone calls	Reactive phonecalls	Relative (95% CI)	Absolute		
Any breastfeeding at 6 to 12 weeks												
1 (Hoddinott 2012)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	22/32 (68.8%)	17/32 (53.1%)	RR 1.29 (0.87 to 1.93)	154 more per 1000 (from 69 fewer to 494 more)	VERY LOW	CRITICAL

Exclusive breastfeeding 6 to 12 weeks												
1 (Hoddinott 2012)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2,3]	none	17/32 (53.1%)	8/26 (30.8%)	RR 1.73 (0.89 to 3.35)	225 more per 1000 (from 34 fewer to 723 more)	VERY LOW	CRITICAL
Satisfaction with help at home (Better indicated by lower values)												
1 (Hoddinott 2012)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	32	26	-	MD 0.6 higher (0.31 lower to 1.51 higher)	LOW	IMPORTANT

1 Serious risk of bias due to concerns with blinding, missing data and selective reporting
2 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses one calculated MID (calculated from SD of control arm)
3 Evidence downgraded by 2 levels due to risk of very serious imprecision as confidence interval crosses two calculated MID (calculated from SD of control arm)

Intervention 2. Meta-regression results

Table 18: Clinical evidence profile for meta-regression results

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Intervention**	**Control**	**Relative (95% CI)**	**Absolute**		
Initiation of breastfeeding												
20[1]	randomised trials	serious[2]	no serious inconsistency	serious[3]	serious[4]	none	See Meta Regression results in Appendix M				VERY LOW	CRITICAL
Any breastfeeding at 3 to 14 days												
16[1]	randomised trials	serious[5]	serious[6]	serious[7]	serious[4]	none	See Meta Regression results in Appendix M				VERY LOW	CRITICAL
Exclusive breastfeeding at 3 to 14 days												
16[1]	randomised trials	serious[5]	serious[6]	serious[8]	very serious[9]	none	See Meta Regression results in Appendix M				VERY LOW	CRITICAL

Any breastfeeding at 6 to 12 weeks									
37[1]	randomised trials	serious[10]	serious[6]	serious[11]	serious[4]	none	See Meta Regression results in Appendix M	VERY LOW	CRITICAL
Exclusive breastfeeding at 6 to 12 weeks									
27[1]	randomised trials	serious[2]	very serious[12]	serious[13]	serious[4]	none	See Meta Regression results in Appendix M	VERY LOW	CRITICAL
Any breastfeeding at 16 to 26 weeks									
39[1]	randomised trials	serious[2]	very serious[12]	serious[14]	serious[4]	none	See Meta Regression results in Appendix M	VERY LOW	CRITICAL

1 See forest plots for study references (combination of Intervention 2 versus standard care and Intervention 2 versus Intervention 2)
2 Serious risk of bias due to concerns with blinding, randomisation and selective reporting
3 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with three studies that provided breast pumps to their participants as part of the intervention (Bonuck 2014, Chapman 2004 and Ramussen 2011)
4 Evidence downgraded by 1 level due to serious risk of imprecision as beween 25-50% of all meta-regression results are significant
5 Serious risk of bias due to concerns with blinding, randomisation, missing data and selective reporting
6 Evidence downgraded by 1 level due to serious risk of inconsistency as concerns DIC for overall meta-regression model is not lower than all individual models
7 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with two studies that provided breast pumps to their participants as part of the intervention (Bonuck 2005 and Efrat 2015) and one study provided gift incentives as part of the intervention (Sciacca1996)
8 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with three studies that provided breast pumps to their participants as part of the intervention (Bonuck 2014, Efrat 2015 and Ramussen 2011), one study provided gift incentives as part of the intervention (Sciacca 1996) and one study provided a £25 gift for completing the study
9 Evidence downgraded by 2 levels due to very serious risk of imprecision as <25% of all meta-regression results are significant
10 Serious risk of bias due to concerns with blinding and selective reporting
11 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with four studies that provided breast pumps to their participants as part of the intervention (Bonuck 2005, Bonuck 2014, Efrat 2015 and Ramussen 2011) and one study provided gift incentives as part of the intervention (Sciacca 1996)
12 Evidence downgraded by 1 level due to serious risk of inconsistency as concerns DIC for overall meta-regression model is higher that all individual models
13 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with three studies that provided breast pumps to their participants as part of the intervention (Bonuck 2005, Bonuck 2014 and Efrat 2015), one study that provided gift incentives as part of the intervention (Sciacca 1996)
14 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with four studies that provided breast pumps to their participants as part of the intervention (Bonuck 2014, Bonuck 2005, Chapman 2004 and Efrat 2015), two studies that recruited women at 8 weeks postpartum and who had already established breastfeeding (Eliott-Rudder 2014 and Vidas 2011)

Intervention 3. Avoidance of foreign objects

Table 19: Clinical evidence profile for advice against pacifiers versus no advice

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Advice against pacifiers**	**No advice**	**Relative (95% CI)**	**Absolute**		
Any breastfeeding 6-12 weeks												
3[1]	randomised trials	serious[2]	no serious inconsistency	serious[3,4,5]	serious[6]	none	711/751 (94.7%)	752/799 (94.1%)	RR 1 (0.99 to 1.02)	0 fewer per 1000 (from 9 fewer to 19 more)	VERY LOW	CRITICAL
Exclusive breastfeeding 6-12 weeks												
2[1]	randomised trials	serious[2]	no serious inconsistency	serious[3]	no serious imprecision	none	452/598 (75.6%)	472/630 (74.9%)	RR 1.01 (0.96 to 1.06)	7 more per 1000 (from 30 fewer to 45 more)	LOW	CRITICAL
Any breastfeeding 16-26 weeks												
2[1]	randomised trials	serious[2]	very serious[7]	serious[3,5]	serious[6]	none	612/733 (83.5%)	643/782 (82.2%)	RR 1.03 (0.83 to 1.27)	25 more per 1000 (from 140 fewer to 222 more)	VERY LOW	CRITICAL
Subgroup analysis, any breastfeeding 16-26 weeks - Face-to-face individual												
1 (Schuubiger 1997)	randomised trials	serious[8]	no serious inconsistency	serious[5]	very serious[6,9]	none	160/271 (59%)	161/295 (54.6%)	RR 1.08 (0.94 to 1.25)	44 more per 1000 (from 33 fewer to 136 more)	VERY LOW	CRITICAL
Subgroup analysis, any breastfeeding 16-26 weeks - Self-help												
1 (Jenik 2009)	randomised trials	serious[10]	no serious inconsistency	serious[3]	serious[3]	none	452/462 (97.8%)	482/487 (99%)	RR 0.99 (0.97 to 1)	10 fewer per 1000 (from 30 fewer to 0 more)	VERY LOW	CRITICAL

1 See forest plots for study references
2 Serious risk of bias due to concerns with participants and personnel not blinded, along with concerns over adherence and selective reporting
3 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with the evidence from Jenik 2009 where pacifiers were avoided by all for the first two weeks, after which the control arm were given pacifiers and a booklet on how to use them whilst the intervention arm were given a booklet on how to comfort the baby without a pacifier.
4 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with the evidence from Schlickau 2005 as the intervention also includes encouragement of breastfeeding commitment which may confound the results.
5 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with the evidence from Schubiger 1997 as the control group also receives supplements by bottle or breastfeeding which may confound the results.
6 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses the line of no effect

7 Evidence downgraded by 2 levels due to very serious risk of inconsistency, I squared >75%
8 Serious risk of bias due to concerns with blinding of participants and personnel, unknown adherence and unable to assess selective reporting
9 Evidence downgraded by 1 level due to risk of serious imprecision as total events is below 300 events for dichotomous outcome
10 Serious risk of bias due to concerns with adherence and blinding of participants and personnel

Intervention 4. Financial incentives

Table 20: Clinical evidence profile for financial incentives versus standard care

Quality assessment							No of patients		Effect			
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Financial incentives for breastfeeding behaviour**	**Standard care**	**Relative (95% CI)**	**Absolute**	**Quality**	**Importance**
Initiation of breastfeeding, areas (better indicated by higher values)												
1 (Relton 2018)	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	46 areas (4973 people)	46 areas (4234 people)	-	MD 2.9 higher (0.4 lower to 6.2 higher)[3]	LOW	CRITICAL
Any breastfeeding 3-14 days												
1 (Sciacca 1998)	randomised trials	very serious[4]	no serious inconsistency	serious[5]	serious[6]	none	25/26 (96.2%)	16/29 (55.2%)	RR 1.74 (1.24 to 2.44)	408 more per 1000 (from 132 more to 794 more)	VERY LOW	CRITICAL
Exclusive breastfeeding 3-14 days												
1 (Sciacca 1998)	randomised trials	very serious[4]	no serious inconsistency	serious[5]	serious[6]	none	21/26 (80.8%)	10/29 (34.5%)	RR 2.34 (1.37 to 4)	462 more per 1000 (from 128 more to 1000 more)	VERY LOW	CRITICAL
Any breastfeeding 6-12 weeks												
2[7]	randomised trials	very serious [8]	no serious inconsistency	serious[5]	serious[6]	none	32/44 (72.7%)	10/46 (21.7%)	RR 3.22 (1.69 to 6.12)	483 more per 1000 (from 150 more to 1000 more)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Financial incentives for breastfeeding behaviour	Standard care	Relative (95% CI)	Absolute	Quality	Importance
Any breastfeeding 6-12 weeks, areas (better indicated by higher values)												
1 (Relton 2018)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	no serious imprecision	none	46 areas (4973 people)	46 areas (4234 people)	-	MD 4.5 higher (1.5 to 7.5 higher)[9]	MODERATE	CRITICAL
Exclusive breastfeeding 6-12 weeks												
1 (Sciacca 1998)	randomised trials	very serious[6]	no serious inconsistency	serious[5]	very serious[10]	none	11/26 (42.3%)	5/29 (17.2%)	RR 2.45 (0.98 to 6.13)	250 more per 1000 (from 3 fewer to 884 more)	VERY LOW	CRITICAL
Exclusive breastfeeding 6-12 weeks, areas (better indicated by higher values)												
1 (Relton 2018)	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	serious[3]	none	46 areas (4973 people)	46 areas (4234 people)	-	MD 2.3 higher (0.2 lower to 4.8 higher)[11]	LOW	CRITICAL
Any breastfeeding 16-26 weeks												
1 (Washio 2017)	randomised trials	very serious[12]	no serious inconsistency	no serious indirectness	serious[8]	none	13/18 (72.2%)	0/17 (0%)	RR 25.58 (1.64 to 399.35)	-	VERY LOW	CRITICAL

1 Serious risk of bias due to concerns with participants and personnel not blinded, along with outcome measures and selective reporting
2 Evidence downgraded by 1 level due to risk of serious imprecision as confidence interval crosses the line of no effect
3 Calculated by study authors after weighting and adjusting for local government areas and baseline 6- to 8 week breastfeeding prevalence (as a proxy for the unknown baseline breastfeeding initiation prevalence)
4 Very serious risk of bias due to concerns with randomisation, blinding, missing data and selective reporting
5 Evidence downgraded by 1 level due to serious risk of indirectness as concerns with Sciacca 1995, as the intervention group received an additional 2-hr antenatal breastfeeding class for expectant couples as well as financial incentives
6 Evidence downgraded by 1 level due to risk of serious imprecision as total events is below 300 events for dichotomous outcome
7 See forest plot for study details
8 Very serious risk of bias due to concerns with randomisation, blinding, missing data, outcome measurements and selective reporting
9 Calculated by study authors after weighting to reflect unequal electoral ward area-level variances and adjusting for local government area, baseline 6- to 8 week breastfeeding prevalence, Index of Multiple Deprivation, the proportion of women aged 16-44 years in 2011, the proportion of the population who identified as non-white in the 2011 UK census, and the count of births in 2015

10 Evidence downgraded by 1 level due to risk of serious imprescision as total events is below 300 for dichotomous outcome and downgraded by 1 level due to risk of serious imprecision as the confidence interval crosses the line of no effect

11 Calculated by study authors after weighting and adjusting for local government area and baseline 6- to 8 week breastfeeding prevalence (as a proxy for the unknown baseline exclusive breastfeeding prevalence)

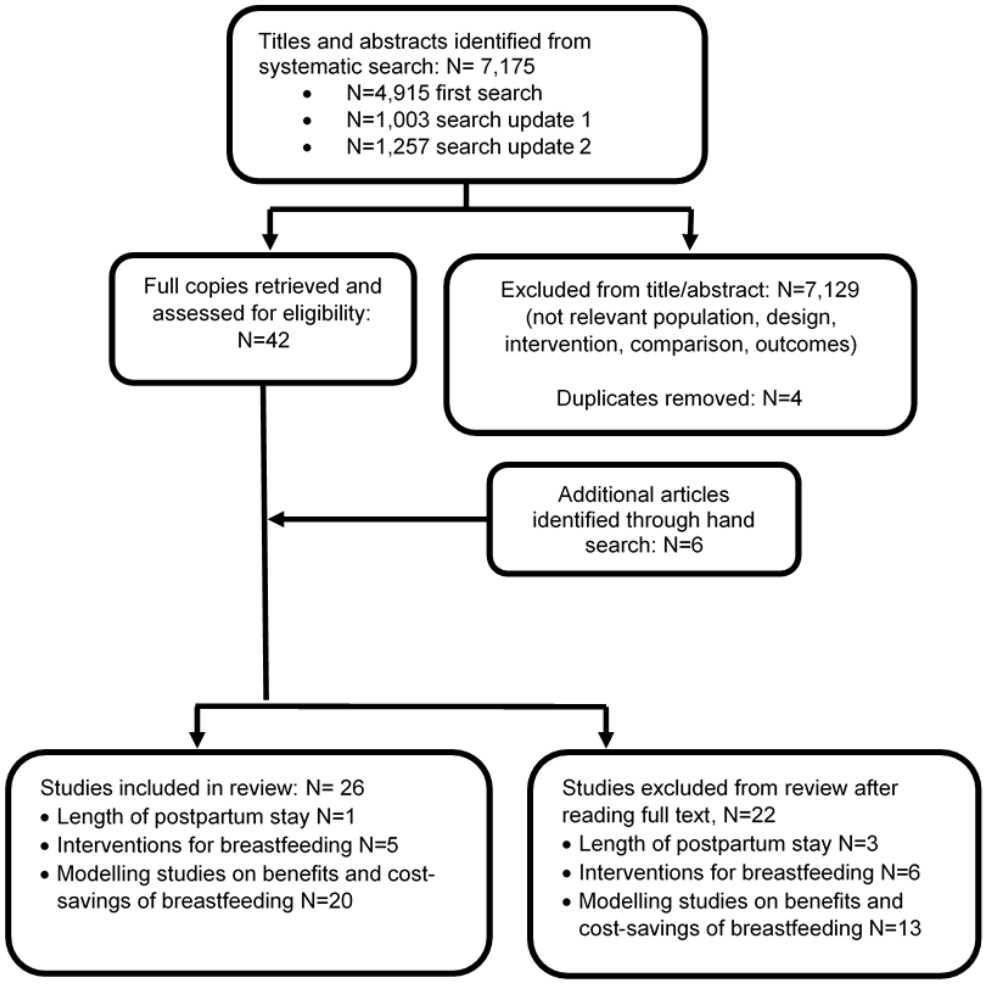
12 Very serious risk of bias due to concerns with blinding, missing data, outcome measurements and selective reporting

Appendix G – Economic evidence study selection

Economic evidence study selection 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)?

A global health economics search was undertaken for all areas covered in the guideline. Figure 53 shows the flow diagram of the selection process for economic evaluations of postnatal care interventions, including modelling studies on the benefits and cost-savings of breastfeeding.

Figure 53: Flow diagram of selection process for economic evaluations of postnatal care interventions and modelling studies on the benefits and cost-savings of breastfeeding



Appendix H – Economic evidence tables

Economic 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 21: Economic evidence tables for interventions aiming at initiating and maintaining breastfeeding

Study Country Study type	Intervention details	Study population Study design Data sources	Costs and outcomes: description and values	Results: Cost-effectiveness	Comments
Anokye 2020 England Cost-effectiveness analysis	Interventions: Financial incentive (over 6 months) on breastfeeding to women living in areas with low breastfeeding prevalence (<40% at 6–8 weeks). Up to five vouchers (£40 each) were offered to women if their baby was receiving breastmilk at the following ages: 2 days, 10 days, 6 weeks, 3 months and 6 months. Treatment as usual (TAU), in which no financial incentives on breastfeeding were given	Women who gave birth and lived in areas with low breastfeeding prevalence (<40% at 6–8 weeks) and their babies Cluster RCT (Relton 2018) [N= 5398 mother-infant dyads in intervention arm and 4612 mother-infant dyads in the control arm] Source of efficacy and resource use data: RCT Source of unit costs: national sources & administrative records for the vouchers	Costs: intervention including set up (website development, design and planning, booklet production, procurement, initial local engagement and staff induction) and delivery costs (vouchers, processing of claims) Mean intervention cost: £9,989 (5538) per ward; £91.45 per mother-infant dyad Primary outcome measure: proportion of any breastfeeding at 6-8 weeks Proportion of any breastfeeding at 6-8 weeks (pre / post trial): Intervention: 0.29 / 0.38 Control: 0.27 / 0.32 Difference 0.057 (p<0.001), adjusted for pre-trial rate	ICER of intervention versus control £974 per additional baby breastfed at 6-8 weeks Probability of intervention being cost-effective 0.54 at WTP of £1000 per additional baby breastfed at 6-8 weeks; 0.94 at WTP £1500; 0.99 at WTP £2000	Perspective: NHS (intervention cost only) Currency: GBP£ Cost year: 2016 Time horizon: for outcomes 6-8 weeks; for costs 6 months Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

1

Study Country Study type	Intervention details	Study population Study design Data sources	Costs and outcomes: description and values	Results: Cost-effectiveness	Comments
Frick 2012 US Cost-effectiveness analysis	Interventions: Intervention aiming at maintaining breastfeeding, which included postpartum hospital visits by a breastfeeding support team, home visits, telephone support and 24 hour pager access Treatment as usual (TAU), comprising access to an inpatient visit by a lactation consultant (LC) for breastfeeding mothers, a hospital-based LC available via a telephone "warm-line" (an answering machine checked at least every 24 hours) post-discharge, and access to a post-discharge office visit with the LC upon request.	Low-income breastfeeding mothers of full-term infants (eligible for the Special Supplemental Nutrition Program for Women, Infants, and Children) RCT (Pugh 2010) (N=328; completers at 6 weeks postpartum=280; at 24 weeks postpartum=243) Source of efficacy and resource use data: RCT Source of unit costs: national sources	Costs: intervention (staff time and travel/mileage) Mean intervention cost: $296.45 (range $274.12 to $320.97) Primary outcome measure: proportion of breastfeeding at 6, 12, and 24 weeks postpartum. Proportion of breastfeeding: 6 weeks postpartum Intervention 0.67; TAU 0.57 OR 1.71 (95% CI 1.07 to 2.76); p=0.05 12 weeks postpartum Intervention 0.49; TAU 0.41 p=0.07 24 weeks postpartum Intervention 0.29; TAU 0.28; p=0.46	ICER per additional woman breastfeeding: $3,025 at 6 weeks postpartum $3,369 at 12 weeks postpartum $26,950 at 24 weeks postpartum	Perspective: healthcare (intervention cost only, relating to staff time and travel) Currency: US$ Cost year: 2009 Time horizon: 24 weeks Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

2

Study Country Study type	Intervention details	Study population Study design Data sources	Costs and outcomes: description and values	Results: Cost-effectiveness	Comments
Hoddinott 2009 Scotland Cost-effectiveness analysis	Interventions: Implementation of a policy to set up new breastfeeding groups to provide population coverage; weekly group meetings were facilitated by a health professional and aimed at promoting initiation and maintenance of breastfeeding; a woman-centred approach was adopted and at least 50% of the group meeting time was social and interactive Treatment as usual (TAU), in which group breastfeeding activity was not changed	Pregnant women, breastfeeding mothers and babies registered with general practices in relatively deprived areas of Scotland that routinely collect breastfeeding outcome data Cluster RCT (Hoddinott 2009 & 2010) [N=18,603 in 14 clusters; 1310 women attended the groups in total, of whom 74 attended from nonparticipating general practices, and 138 attended from control locality general practices] Source of efficacy and resource use data: RCT Source of unit costs: not reported, possibly national sources	Costs: intervention (staff time, including travel time) Mean intervention cost: £13,400 per locality annually; £143 per woman attending the group intervention Primary outcome measure: proportion of any breastfeeding at 6-8 weeks Proportion of any breastfeeding at 6-8 weeks (pre / post trial): Intervention: 0.27 / 0.26 Control: 0.29 / 0.30 Difference -0.017 (p=0.08), adjusted for pre-trial rate	Intervention dominated by TAU [higher cost and no difference in effect]	Perspective: NHS (intervention cost only, relating to staff time, including travel time) Currency: GBP£ Cost year: 2005/06 Time horizon: median group attendance 4 weeks; outcomes collected 2 years before policy and 2 years after policy was implemented Discounting: NA Applicability: directly applicable Quality: potentially serious limitations

1
2

1

Study Country Study type	Intervention details	Study population Study design Data sources	Costs and outcomes: description and values	Results: Cost-effectiveness	Comments
Hoddinott 2012 Scotland Cost-effectiveness analysis	Interventions: Proactive and reactive telephone support at home for up to 14 days after hospital discharge Reactive only telephone support at home for up to 14 days after hospital discharge	Women living in disadvantaged areas who breastfed at hospital discharge Exclusion criteria: women aged <16 years, with serious medical or psychiatric problems or with insufficient spoken English to communicate by telephone RCT (Hoddinott 2012) (N=69; 59 completers) Source of efficacy and resource use data: RCT Source of unit costs: not reported, possibly national sources	Costs: intervention (staff time relating to telephone ward contact and case note /discussion time) Mean intervention cost: Intervention: £41.25 Control: £21.13 Difference: £20.12 Primary outcome measure: any breastfeeding rate at 6-8 weeks Any breastfeeding rate at 6-8 weeks (completers' analysis): Intervention: 0.69 Control: 0.46 RR 1.49 (95%CI 0.92 to 2.40)	ICER: £87 per additional woman breastfeeding Costs sensitive to service organisation	Perspective: NHS (intervention cost only, relating to staff time) Currency: GBP£ Cost year: not reported, likely 2010 Time horizon: 14 days for costs; 6-8 weeks for outcomes Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

2
3

Study Country Study type	Intervention details	Study population Study design Data sources	Costs and outcomes: description and values	Results: Cost-effectiveness	Comments
Stevens 2006 Canada Cost-effectiveness analysis	Interventions: Early hospital discharge (at 24-36 hours postpartum) and home-based support (2-3 visits) from certified nurse lactation consultants Standard hospital discharge (at 48-60 hours postpartum) and hospital-based support by nurse lactation consultants	Mother-infant dyads, with infants being term (>37 weeks gestational age) or near term (35–37 weeks gestational age) RCT (McKeever 2002) (N=138, 101 term and 37 near term babies; n=102 completers, 75 term and 27 near term babies) Source of efficacy and resource use data: RCT Source of unit costs: national sources	Costs: healthcare (hospital, ambulatory & home-based appointments with healthcare professionals, medication, laboratory tests, equipment and supplies provided by the hospital, emergency visits, telephone calls to the 24-hour help line, visits & telephone calls to the breastfeeding clinic or to community practitioners; costs to the family reported separately Mean cost Term babies Hospitalisation for giving birth Intervention $2529, control $2630; p=0.22 Post-discharge Intervention: $179, control: $61; p<0.0001 Near term babies Hospitalisation for giving birth Intervention $2692, control $2686; p=0.73 Post-discharge Intervention: $223, control: $538; p=0.57 Primary outcome measure: proportion of exclusive breastfeeding at follow-up (5-12 days postpartum) Proportion of exclusive breastfeeding at follow-up Term babies Intervention: 0.95, control: 0.74; p=0.02 Near term babies Intervention: 0.73, control: 0.68; p=1.00	ICER: $81 per additional term baby exclusively breastfeeding Intervention dominant for near term babies (less costly and more effective); results characterised by high uncertainty (n=24 for costs, cost results non-significant)	Perspective: healthcare plus costs to the family (out-of-pocket and time costs of unpaid caregivers), which were reported separately Currency: Canadian $ Cost year: 2000 Time horizon: from birth and up to the 7th day postpartum [costs]; 5-12 days postpartum [outcome] Discounting: NA Applicability: partially applicable Quality: potentially serious limitations

Appendix I – Economic evidence profiles

Economic evidence profiles 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 22: Economic evidence profile. Provision of breastfeeding groups for population coverage versus treatment as usual (which included some breastfeeding groups) for pregnant women and breastfeeding mothers and babies

Economic evidence profile: Provision of breastfeeding groups for population coverage versus treatment as usual (which included some breastfeeding groups) for pregnant women and breastfeeding mothers and babies							
Study and country	**Limitations**	**Applicability**	**Other comments**	**Incremental cost (£)[1]**	**Incremental effect**	**ICER (£/effect)[1]**	**Uncertainty[1]**
Anokye 2020 England	Potentially serious limitations[2]	Partially applicable[3]	Outcome: proportion of women breastfeeding at 6-8 weeks postpartum	93	0.06	996	Probability of intervention being cost-effective 0.54 at WTP of £1022 per additional baby breastfeeding at 6-8 weeks; 0.94 at WTP £1533; 0.99 at WTP £2044
1. Costs converted and uplifted to 2018 UK pounds using purchasing power parity (PPP) exchange rates and the UK hospital and community health services index (Curtis & Burns, Unit costs of Health and Social Care 2018. Canterbury: Personal Social Services Research Unit, The University of Kent 2018). 2. Time horizon 6 months for costs; 6-8 weeks for benefits); analysis based on cluster pragmatic RCT (N=10,010 in 92 wards); national unit costs; consideration of intervention costs only 3. English study; NHS perspective; no QALYs estimated							

Table 23: Economic evidence profile. Intervention aiming at maintaining breastfeeding, which included postpartum hospital visits by a breastfeeding support team, home visits, telephone support and 24 hour pager access versus treatment as usual (TAU)

Economic evidence profile: Intervention aiming at maintaining breastfeeding, which included postpartum hospital visits by a breastfeeding support team, home visits, telephone support and 24 hour pager access versus treatment as usual (TAU)							
Study and country	**Limitations**	**Applicability**	**Other comments**	**Incremental cost (£)[1]**	**Incremental effect**	**ICER (£/effect)[1]**	**Uncertainty[1]**
Frick 2012 US	Potentially serious limitations[2]	Partially applicable[3]	TAU comprised access to an inpatient visit by a lactation consultant (LC) for breastfeeding mothers, a hospital-based LC available via a telephone "warm-line" (an answering machine checked at least every 24 hours) post-discharge, and access to a post-discharge office visit with the LC upon request. Outcome: proportion of women breastfeeding at 6, 12 and 24 weeks postpartum	238	0.10 at 6 weeks postpartum 0.08 at 12 weeks postpartum 0.01 at 24 weeks postpartum	2,429/extra woman breastfeeding at 6 weeks postpartum 2,705/extra woman breastfeeding at 12 weeks postpartum 21,637/extra woman breastfeeding at 24 weeks postpartum	Difference in outcome between groups statistically significant (p<0.05) at 6 weeks; not statistically significant at 12 or 24 weeks
1. Costs converted and uplifted to 2018 UK pounds using purchasing power parity (PPP) exchange rates and the hospital and community health services index (Curtis & Burns, Unit costs of Health and Social Care 2018. Canterbury: Personal Social Services Research Unit, The University of Kent 2018). 2. Time horizon 24 weeks; analysis based on RCT (N=328; completers at 6 weeks postpartum=280; at 24 weeks postpartum=243); national unit costs used; sensitivity analysis around variation in time conducted; consideration of intervention costs (staff time and mileage) only; study not powered to detect healthcare cost differences 3. US study; healthcare perspective; no QALYs							

Table 24: Economic evidence profile. Provision of breastfeeding groups for population coverage versus treatment as usual (which included some breastfeeding groups) for pregnant women and breastfeeding mothers and babies

Economic evidence profile: Provision of breastfeeding groups for population coverage versus treatment as usual (which included some breastfeeding groups) for pregnant women and breastfeeding mothers and babies							
Study and country	**Limitations**	**Applicability**	**Other comments**	**Incremental cost (£)[1]**	**Incremental effect**	**ICER (£/effect)[1]**	**Uncertainty[1]**
Hoddinott 2009 Scotland	Potentially serious limitations[2]	Directly applicable[3]	Outcome: proportion of women breastfeeding at 6-8 weeks postpartum	179	-0.017	Intervention dominated by control	Difference in outcome between groups not statistically significant

1. Costs converted and uplifted to 2018 UK pounds using purchasing power parity (PPP) exchange rates and the UK hospital and community health services index (Curtis & Burns, Unit costs of Health and Social Care 2018. Canterbury: Personal Social Services Research Unit, The University of Kent 2018).

2. Time horizon equalled the duration of intervention for estimation of costs [median 4 weeks] and 6-8 weeks postpartum for estimation of benefits (total costs were measured over a period of 2 years of implementation; benefits were measured 2 years before and 2 years after implementation); analysis based on cluster pragmatic RCT (N=18,603 in 14 clusters; 1310 women attended the groups in total); source of unit costs not reported, possibly national unit costs used; uncertainty not reported for costs; no sensitivity analysis conducted around costs; consideration of intervention costs (staff time, including travel time) only; control group implemented the intervention partly, which may have contaminated the results.

3. Scottish study; NHS perspective; no QALYs estimated but groups had very similar effects

Table 25: Economic evidence profile. Proactive and reactive versus reactive telephone support at home for up to 14 days after hospital discharge for women living in disadvantaged areas who breastfed at hospital discharge

Economic evidence profile: Proactive and reactive versus reactive telephone support at home for up to 14 days after hospital discharge for women living in disadvantaged areas who breastfed at hospital discharge							
Study and country	**Limitations**	**Applicability**	**Other comments**	**Incremental cost (£)[1]**	**Incremental effect**	**ICER (£/effect)[1]**	**Uncertainty[1]**
Hoddinott 2012 Scotland	Potentially serious limitations[2]	Partially applicable[3]	Outcome: proportion of women breastfeeding at 6-8 weeks postpartum	23	0.23	98	Costs sensitive to service organisation

1. Costs converted and uplifted to 2018 UK pounds using purchasing power parity (PPP) exchange rates and the UK hospital and community health services index (Curtis & Burns, Unit costs of Health and Social Care 2018. Canterbury: Personal Social Services Research Unit, The University of Kent 2018).

2. Time horizon 14 days of intervention; outcome measured at 6-8 weeks postpartum; analysis based on RCT (N=69); source of unit costs not reported, possibly national unit costs used; uncertainty not reported; very limited sensitivity analysis conducted; consideration of intervention costs (staff time) only; not all women provided complete data; the proportion that provided complete data was not equal across groups

3. Scottish study; NHS perspective; no QALYs estimated

Table 26: Economic evidence profile. Early hospital discharge (at 24-36 hours postpartum) and home-based support (2-3 visits) from certified nurse lactation consultants versus standard hospital discharge (at 48-60 hours postpartum) and hospital-based support by nurse lactation consultants for mothers and their infants

Economic evidence profile: Early hospital discharge (at 24-36 hours postpartum) and home-based support (2-3 visits) from certified nurse lactation consultants versus standard hospital discharge (at 48-60 hours postpartum) and hospital-based support by nurse lactation consultants for mothers and their infants							
Study and country	**Limitations**	**Applicability**	**Other comments**	**Incremental cost (£)[1]**	**Incremental effect**	**ICER (£/effect)[1]**	**Uncertainty[1]**
Stevens 2006 Canada	Potentially serious limitations[2]	Partially applicable[3]	Outcome: proportion of babies exclusively breastfed at 5-12 days postpartum Term and near terms babies analysed separately	Term 16 Near term -284	Term 0.21 Near term 0.05	81 per additional term baby exclusively breastfeeding Intervention dominant for near term babies (less costly and more effective)	Only post discharge cost differences statistically significant for term babies; total cost difference not statistical significant

1. Costs converted and uplifted to 2018 UK pounds using purchasing power parity (PPP) exchange rates and the UK hospital and community health services index (Curtis & Burns, Unit costs of Health and Social Care 2018. Canterbury: Personal Social Services Research Unit, The University of Kent 2018).

2. Time horizon from birth and up to 7th day postpartum [costs]; 5-12 days postpartum [outcome]; analysis based on RCT (N=130); national unit costs used; no synthesis of costs and outcomes undertaken, so no uncertainty around the ICER was reported; lack of statistical power for near-term baby sub-group

3. Canadian study; healthcare and family (out-of-pocket and unpaid time) perspective, but healthcare costs reported separately; no QALYs estimated

Table 27: Economic evidence profile. Provision of an intervention aimed at promoting initiation and maintenance of breastfeeding added on standard care versus standard care alone for pregnant women and breastfeeding mothers and babies

Economic evidence profile: Provision of an intervention aimed at promoting initiation and maintenance of breastfeeding added on standard care versus standard care alone for pregnant women and breastfeeding mothers and babies							
Study and country	**Limitations**	**Applicability**	**Other comments**	**Incremental cost (£)[1]**	**Incremental effect (QALY)**	**ICER (£/effect)[1]**	**Uncertainty[1]**
Guideline economic analysis	Potentially serious limitations[2]	Directly applicable[3]	Outcome: QALY Clinical conditions assessed: In babies: • gastrointestinal infections • respiratory tract infections • acute otitis media • mortality due to infectious diseases • mortality due to SIDS In mothers • Breast cancer	65.2	0.00121	54,051	Intervention becomes cost-effective (ICER £20,000/QALY) if base-case RR rises from 1.19 to 1.35-1.40 and if intervention cost falls from £84 to £40-45.
1. Cost year 2018 2. Time horizon ranging from 1 year to lifetime, varying by clinical condition examined; effectiveness of intervention based on guideline meta-regression; outcomes of breastfeeding based on published systematic reviews and meta-analyses, but primary studies were prone to bias, as some studies adjusted for known counfounders but others did not, meaning that the magnitude of the clinical benefits of breastfeeding may have been overestimated; epidemiological, utility and cost data obtained from national sources and other published literature; a selection of clinical conditions examined, due to complexity of modelling or unavailability of suitable data for some clinical conditions 3. English study; NHS/personal social services perspective; QALY was the primary outcome (based mostly on EQ-5D ratings)							

Appendix J – Economic analysis

Economic analysis 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)?

Introduction – objective of economic modelling

The assessment of the cost-effectiveness of interventions aiming at starting and maintaining breastfeeding was identified by the committee as an area with potentially major resource implications. Existing economic evidence in this area is rather limited and has not considered the long-term benefits to women and their babies and related cost-savings associated with breastfeeding. An economic model was therefore developed to assess the long-term cost-effectiveness of an intervention for women, initiated antenatally or in the first 8 weeks after birth, that is effective in starting and/or maintaining breastfeeding in the UK.

Economic modelling methods

Population

The study population of the economic model comprised women who are pregnant or gave birth to healthy babies at term, and their babies. The age of women at the start of the model was 30 years, as this is the mean age of women who give birth in England and Wales (Office for National Statistics 2019a). The starting age of the cohort was needed in order to model benefits to women associated with breastfeeding over women's lifetime. Women could have single or multiple births. In accordance with national epidemiological data, the mean number of babies per live birth was 1.016 (Office for National Statistics 2019b).

Intervention

The characteristics of the intervention assessed in the guideline economic analysis, in terms of effectiveness and resource use (number of sessions, format, people delivering the intervention, etc.), were determined by the findings of the guideline systematic review and meta-regression undertaken to inform the review questions, supplemented by the committee's expert opinion.

The focus of the economic analysis was on an intervention that comprised education, advice or support from a peer or professional, that was provided postnatally and was initiated either antenatally or within the first eight weeks after birth, because the majority of clinical evidence was available for this type of intervention. In accordance with available evidence, the intervention was assumed to be provided in addition to standard care; the comparator of the analysis was standard care alone. The definition of standard care varied widely across the RCTs included in the guideline systematic review and meta-regression that informed the economic analysis. Standard care in the RCTs ranged from no intervention, through written materials and peer breastfeeding support, to availability of breastfeeding educational programmes of variable intensity in-hospital or in the community. In the UK NHS, standard care is also variable and may include provision of written material, antenatal breastfeeding

educational programmes, and postnatal breastfeeding support groups run by peers and/or health professionals; in some settings breastfeeding information and support is provided by midwives and/or health visitors as part of routine postnatal care visits.

In order to identify effective components of an intervention promoting breastfeeding and specify the intervention for consideration in the economic analysis, effectiveness data on 'any breastfeeding between 16 and 26 weeks after birth', obtained from the guideline systematic review and meta-regression (described in appendix M), were inspected (Table 28). This outcome was amongst critical outcomes for this review, as determined by the committee. Data on 'any breastfeeding' were selected because most of the outcome data on the clinical conditions associated with breastfeeding that informed the economic model were relevant to 'any' rather than 'exclusive' breastfeeding, as it will be discussed later for individual clinical conditions modelled; moreover, the period between 16 and 26 weeks after birth was chosen to ensure that breastfeeding was established and therefore could have an impact on longer-term mother and baby outcomes, and over this period no data on exclusive breastfeeding were available. The components of the intervention considered for the economic analysis were specified by looking at the intervention characteristics that demonstrated a statistically significant effect (risk ratio, RR) versus standard care.

Table 28: Effectiveness of interventions for starting and maintaining breastfeeding – results of guideline meta-analysis and meta-regression for 'any breastfeeding 16 to 26 weeks after birth'

Comparisons	Risk Ratio	Lower 95% CI	Upper 95% CI
Intervention vs standard care	**1.08**	**1.03**	**1.13**
How			
Face-to-face individual vs standard care	**1.07**	**1.01**	**1.14**
Face-to-face group vs standard care	**1.95**	**1.45**	**2.27**
Remote vs standard care	**1.15**	**1.05**	**1.26**
Self-help vs standard care	1.06	0.74	1.40
Number of Contacts			
0 vs standard care	1.18	0.96	1.39
1 vs standard care	1.05	0.95	1.14
2-3 vs standard care	1.07	0.97	1.17
4-8 vs standard care	**1.19**	**1.10**	**1.30**
9 vs standard care	**1.13**	**1.00**	**1.26**
Duration of Intervention			
Less than 8 weeks vs standard care	1.04	0.97	1.10
More than 8 weeks vs standard care	**1.20**	**1.11**	**1.29**
Where delivered			
Home vs standard care	**1.12**	**1.05**	**1.19**
Healthcare setting vs standard care	1.06	0.96	1.17
Mixed vs standard care	**1.16**	**1.03**	**1.30**
Meta regression model results			
Contact 1 vs Contact 0	1.09	0.87	1.36
Contact 2 to 3 vs Contact 0	1.13	0.89	1.40
Contact 4 to 8 vs Contact 0	1.19	0.99	1.41

Contact 9+ vs Contact 0	1.10	0.93	1.35
Individual vs standard care	0.97	0.81	1.10
Group vs standard care	**1.91**	**1.27**	**2.25**
Self-help vs standard care	1.05	0.73	1.46
Healthcare setting vs mixed	0.97	0.79	1.13
Home vs mixed	1.01	0.84	1.16

Comparisons with statistically significant effects have been highlighted in bold.

From the above table, it can be seen that face-to-face interventions, delivered either individually or in group format, and also interventions delivered remotely appear to be effective compared with standard care (it needs to be noted that the effect for group intervention was based on a single small study and therefore results should be interpreted with caution). Interventions comprising 4-8 contacts appear to have the greatest effect. Interventions seem to be effective if they are delivered at home or in a mixed home and healthcare setting.

Effectiveness of the intervention

The economic analysis utilised the effect on any breastfeeding at 16-26 weeks after birth for "4-8 contacts vs standard care" [mean RR 1.19, 95% CI 1.10 to 1.30]. It is noted that this figure is closer to the mean effect reported for the individual, rather than the group, format of the intervention; it is also similar to the effect estimated for interventions delivered remotely, those delivered at home and in mixed home and healthcare settings.

Sensitivity analysis explored the impact of changes in the mean effect (range of RR from 1.05 to 2.00 tested) on the cost-effectiveness of the intervention.

Intervention cost

The intervention cost was estimated assuming that the intervention consisted of 6 contacts, which is the average of 4-8 contacts corresponding to the effectiveness estimate used in the economic analysis. Based on the committee's advice on patterns of routine practice regarding postnatal care in the UK, four contacts comprised individual face-to-face sessions lasting 30 minutes each, and two contacts comprised group face-to-face sessions delivered to groups of 6 women, lasting 45 minutes each.

The first two individual sessions were assumed to be provided by a health professional in NHS England Agenda for Change (AfC) Band 5. The mean annual basic pay per full time equivalent (FTE) for nursing, midwifery and health visiting staff by AfC Band 5, NHS England is £26,231 and the cost per patient-related hour has been estimated at £59, including salary, salary on-costs and overheads, having taken into account actual working time and the ratio of direct time (i.e. time on direct care) to indirect time (i.e. time on care planning, assessment and co-ordination, travelling, administrative tasks and other duties) (Curtis and Burns, 2018). Health professionals' travel expenses relating to home visits are small compared with their unit cost per hour and were not included in the total intervention cost estimate as relevant data are not available. Indirect time for travel was considered when estimating the unit cost per patient-related hour.

The remaining two individual and two group sessions were assumed to be provided by a volunteer trained peer supporter. The unit cost per patient-related hour was assumed to be

£20, based on expert advice, including the costs of training, supervision, co-ordination and travel. This cost can be higher if it includes additional costs, for example childcare.

The total estimated intervention cost using the above assumptions was £84. Details on the estimation of the intervention cost are provided in Table 29. The intervention was assumed to be offered in addition to standard care, and therefore the description and cost of standard care was omitted from both arms of the model. If the intervention is expected to be provided as an alternative (and not in addition) to standard care, then its net cost is lower than the estimate used in the model.

Table 29. Cost of intervention for starting and maintaining breastfeeding

Cost element	Unit cost	Cost per woman
2 individual face-to-face sessions lasting 30 minutes each (total 60 minutes), provided by a health professional in NHS England Agenda for Change (AfC) Band 5 (nursing, midwifery and health visiting staff).	£59 per patient-related hour[1]	**£59**
2 individual face-to-face sessions lasting 30 minutes each (total 60 minutes), delivered by a volunteer trained peer supporter	£20 per patient-related hour[2]	**£20**
2 group face-to-face sessions delivered to groups of 6 women, lasting 45 minutes each (total 90 minutes / 6 women = 15 minutes per woman), delivered by a volunteer trained peer supporter	£20 per patient-related hour[2]	**£5**
TOTAL COST PER WOMAN		**£84**

1 Curtis and Burns, 2018. Unit cost includes salary, salary on-costs and overheads; actual working time and the ratio of direct time (direct care) to indirect time (care planning, assessment and co-ordination, travelling, administrative tasks and other duties) taken into account. Travel expenses not included.
2 Expert advice. Unit cost includes training, supervision, co-ordination and travel.

Sensitivity analysis explored the impact of changes in the intervention cost (range in cost from £20 to £100 tested) on the cost-effectiveness of the intervention.

Overview of costs and outcomes considered in the analysis

The economic analysis adopted the perspective of the NHS and personal social services (PSS), as recommended by NICE (NICE 2014). Costs consisted of the intervention cost (healthcare professional time) and costs associated with breastfeeding outcomes that are incurred in community, primary or secondary health care or personal social service settings. Costs to parents relating to formula feeding (milk powder, bottles, sterilising equipment) were not considered. The cost year was 2018.

The primary measure of outcome was the QALY. Other secondary measures of outcome were determined by the clinical conditions considered in the economic analysis and are described later, for each clinical condition.

Selection of clinical conditions for mothers and babies associated with breastfeeding for consideration in the economic model

An important objective of the economic analysis was to estimate the clinical benefits to mothers and babies resulting from increased rates of breastfeeding following provision of the intervention. The guideline systematic review of the clinical effectiveness of interventions for starting and maintaining breastfeeding captured only the increase in breastfeeding rates,

following provision of the intervention, as a measure of outcome; the RCTs included in the review did not report longer-term clinical outcomes to mothers and babies associated with such an increase. The evaluation and quantification of the clinical benefits of breastfeeding was beyond the scope of this guideline. Therefore, this part of the economic analysis (that is, linking the increase in breastfeeding rates to the clinical benefits to mothers and babies) was informed by evidence identified via separate, additional literature searches.

A systematic review of studies that modelled long-term clinical benefits to mother and babies (and/or related cost-savings to health and personal social services) associated with breastfeeding was undertaken in order to identify data on long-term clinical outcomes associated with breastfeeding, as well as relevant epidemiological and resource use data that could be adopted or adapted to inform the guideline economic analysis. The search of modelling studies was part of a global health economics search that was undertaken for all areas covered in the guideline. The search strategy is provided in appendix B. Other information on the process followed for the review, including inclusion and exclusion criteria for this review is provided in Supplement 1: Methods. The information of interest sought from modelling studies that met inclusion criteria is shown in Table 30.

Table 30: Information sought from modelling studies that estimated long-term benefits to mothers and babies and related cost-savings associated with breastfeeding

Information sought from modelling studies
Country.
Clinical conditions modelled and model structure for each, including time horizon.
Data on the association of breastfeeding with clinical outcomes; data that were specifically relevant to developing countries were not considered.
Whether data on the association of breastfeeding with clinical outcomes had been adjusted for potential confounders, and, if so, for which.
Incidence of the clinical conditions in the general population and other relevant epidemiological data, if a UK study.
Healthcare resource use and cost data related to modelled clinical conditions, if a UK study; productivity losses were not of interest as these are beyond the remit of NICE evaluations. For the same reason, individual expenses were also not considered.

The review of modelling studies of outcomes and costs associated with breastfeeding included 20 publications; 13 publications were reviewed full-text and subsequently excluded from the review. Full references of included studies and an overview of their characteristics as well as excluded studies with reasons for exclusions are provided in appendix N.

The review identified two studies that were considered to be of high quality and directly relevant to the objective of this study, that is, the modelling of long-term outcomes and cost-savings associated with the breastfeeding.

Renfrew (2012) developed an economic model to estimate long-term benefits to mothers and babies and cost-savings to the healthcare system in the UK associated with breastfeeding. The study, which was commissioned by UNICEF UK, was informed by high quality systematic reviews regarding the benefits of breastfeeding to mothers and babies.

Victora (2016) examined the association between breastfeeding and clinical outcomes to mothers and babies based on the results of 28 systematic reviews and meta-analyses, 22 of which were commissioned by the World Health Organization (WHO).

Regarding the other modelling studies included in the review, with the exception of one study (Unar-Munguía 2017a) that utilised data on the association between breastfeeding and breast cancer from a meta-analysis published in 2017 (Unar-Munguía 2017b), all other studies that assessed long-term outcomes and cost-savings associated with breastfeeding were either considered by Renfrew (2012), or they used Renfrew (2012) and/or Victora (2016) as data sources to quantify the association between breastfeeding and maternal and baby outcomes, or they used alternative data sources to quantify this association, but these sources were also considered by Renfrew (2012) and/or Victora (2016).

Based on the findings of the review, it was decided to use the economic analysis undertaken by Renfrew (2012) as the starting point for selecting and modelling the clinical benefits (and related NHS/PSS cost-savings) associated with breastfeeding in the guideline economic analysis, after updating the data on the association between breastfeeding and clinical outcomes using, where available, more up-to-date evidence reported in Victora (2016). The analysis by Renfrew (2012) was selected as the starting point for our model because it was informed by high quality systematic reviews regarding the association of breastfeeding with outcomes for mothers and babies; moreover, the epidemiological and resource use data utilised in the analysis were directly relevant to the UK. This study was used as the basis in terms of the guideline economic model structure, the clinical conditions modelled, the evidence on the association of breastfeeding with clinical outcomes, epidemiological and healthcare resource use data considered, and further modelling assumptions. However, all clinical, epidemiological and resource use data were updated, where more recent data of good quality were identified. Furthermore, we reviewed the evidence reported in Victora (2016) and explored the feasibility and appropriateness of including in our economic analysis additional clinical conditions that had not been considered in Renfrew (2012).

Table 31 shows clinical outcomes potentially related to breastfeeding that were either considered by Renfrew (2012) as candidates for economic modelling and/or assessed for their association with breastfeeding in Victora (2016). The committee considered this evidence and selected the outcomes to include in the guideline economic analysis, also taking into account feasibility issues and the expected magnitude of clinical benefits and cost-savings per person associated with a change in breastfeeding rates. The committee's decisions together with the justification for each outcome are provided in Table 32. In making these decisions, the committee agreed that available evidence suggests that breastfeeding results in clinical benefits to women and their babies. However, these findings were derived from study designs that were prone to bias; several studies demonstrating clinical benefits associated with breastfeeding had, at best, adjusted for some known, but not all possible, confounders; other studies had made no adjustments for confounding. Consequently, the magnitude of the clinical benefits of breastfeeding may have been overestimated in this literature. Therefore, it is likely that, by using the available data, the economic analysis has overestimated the benefits and associated cost-savings related to breastfeeding.

Table 31. Clinical outcomes to mothers and babies that are potentially associated with breastfeeding, as considered by Renfrew (2012) and/or Victora (2016)

Clinical condition	Modelled in Renfrew (2012)?	Evidence reported in Victora (2016)		
		Conclusion on association with breastfeeding	No studies	Data (mean effect [95% CI])
Breast cancer – mother	Yes, full	Consistent protective effect	76 47	Highest vs lowest duration of breastfeeding: OR 0.81 [0.77 to 0.86] Some evidence of publication bias Thoroughly adjusted pooled analysis: Ever vs. never breastfeeding: OR 0.96 for every 12 months of breastfeeding
Gastrointestinal infection – baby [Diarrhoea]	Yes, full	Strong evidence of major protection	23 11 15 9	More versus less breastfeeding: Incidence: RR 0.37 [0.27 to 0.50] age <6 months Incidence: RR 0.46 [0.28 to 0.78] age 6 months to 5years Incidence: RR 0.69 [0.58 to 0.82] age <5 years Hospitalisation: RR 0.28 [0.16 to 0.50] age <5 years Most studies from low and medium income countries, where effects would be likely underestimated due to confounding Confounder-adjusted studies showed similar effects
Respiratory tract infection – baby [RTI]	Yes, full	Strong evidence of protection	16 17	More versus less breastfeeding: Incidence or prevalence - lower RTI: RR 0.68 [0.60 to 0.77] age <2 years Hospitalisation - any RTI: RR 0.43 [0.33 to 0.55] age <2 years Most studies from low and medium income countries, where effects would be likely underestimated due to confounding Confounder-adjusted studies showed similar effects No evidence of publication bias

Acute otitis media – baby	Yes, full	Consistent evidence of protection during first 2 years of age; no evidence of protection after 2 years of age	11 5	<u>More versus less breastfeeding:</u> OR 0.67 [0.62 to 0.72] age ≤2 years OR 1.21 [0.60 to 2.45] age >2 years Weak evidence of publication bias
Necrotising enterocolitis – baby [neonatal units]	Yes, full	Evidence of protection	4	<u>Ever vs. never breastfeeding:</u> 58% reduction [4% to 82%] No quality assessment by Victora (2016); evidence already considered by Renfrew (2012)
SIDS – baby	Only narrative assessment due to uncertainty around the scale of the effect	Evidence of protection	6	<u>Ever vs. never breastfeeding:</u> 36% reduction [19% to 49%] No quality assessment by Victora (2016) ; evidence already considered by Renfrew (2012)
Cognitive outcomes – baby [Intelligence]	Only narrative assessment due to uncertainty around the scale of the effect	Consistent evidence of effect	16 9	<u>Ever vs never or longer vs shorter duration of breastfeeding:</u> IQ increase: 3.44 [2.30 to 4.58] childhood through adulthood After adjusting for mother's IQ: IQ increase: 2.62 [1.25 to 3.98] childhood through adulthood
Obesity – baby	Only narrative assessment due to uncertainty around the scale of the effect	Suggestive evidence of protection	113	<u>Ever vs never or longer vs shorter duration of breastfeeding:</u> OR 0.74 [0.70 to 0.78] childhood through adulthood Some evidence of publication bias
Ovarian cancer – mother	No, important outcome but inadequate evidence for modelling	Suggestive evidence of protection	41 NR	<u>Highest vs lowest duration of breastfeeding:</u> OR 0.70 [0.64 to 0.75] Some evidence of publication bias After adjustment for parity and exclusion of nulliparous women: OR 0.82 [0.75 to 0.89]

Type 2 diabetes – mother	No, limited evidence from a single study	Restricted evidence of protection	6	Highest vs lowest duration of breastfeeding: OR 0.68 [0.57 to 0.82] Adjusted for several confounding factors
Asthma or wheezing – baby	No, inadequate exposure and outcome measures; environmental genetic, and dietary factors interact	Inconclusive evidence of association	29 16	More versus less breastfeeding: OR 0.91 [0.85 to 0.98] age 5-18 years After thorough control for confounders: OR 0.95 [0.85 to 1.06]
Diabetes – baby	No, inadequate evidence for modelling	Restricted evidence of protection	11	Ever vs never or longer vs shorter duration of breastfeeding: OR 0.65 [0.49 to 0.86] childhood through adulthood No evidence of publication bias
Leukaemia – baby	No, inadequate evidence for modelling	Some evidence of protection	18	Any breastfeeding for ≥ 6 months vs no/shorter breastfeeding: 19% reduction [11% to 27%] in childhood incidence No quality assessment by Victora (2016) Evidence derived from Amitay and Keinan-Bokeret (2015), but quality of the meta-analysis questioned by Ojha and Asdahl (2015)
Coeliac disease – baby	No, inadequate evidence for modelling	Not assessed		
Cardiovascular disease – baby	No, evidence based mainly on bio-markers rather than disease; inadequate for modelling	Not assessed		

Sepsis – baby [neonatal units]	No, inadequate exposure measures	Not assessed		
Mortality due to infectious diseases – baby	Not considered for modelling	Consistent evidence of major protection	3 3 2 9	<u>Exclusive vs predominant breastfeeding:</u> OR 0.59 [0.41 to 0.85] age <6 months <u>Exclusive vs partial breastfeeding:</u> OR 0.22 [0.14 to 0.34] age <6 months <u>Exclusive breastfeeding vs none:</u> OR 0.12 [0.04 to 0.31] age <6 months <u>Any breastfeeding vs none:</u> OR 0.48 [0.38 to 0.60] age 6-23 months All studies from low and medium income countries, where effects would be likely underestimated due to confounding Confounder-adjusted studies showed similar effects
Eczema – baby	Not considered for modelling	No evidence of association	17 20	<u>More vs less breastfeeding:</u> OR 0.95 [0.85 to 1.07] age ≤2 years OR 1.09 [0.99 to 1.20] age >2 years Some evidence of publication bias
Food allergies – baby	Not considered for modelling	No evidence of association	10 4	<u>More vs less breastfeeding:</u> OR 1.07 [0.90 to 1.26] age ≤5 years OR 1.08 [0.73 to 1.26] age >5 years High heterogeneity across studies for age ≤5 years
Allergic rhinitis – baby	Not considered for modelling	Possible protection up to 5 years of age; no evidence of association after 5 years of age	5 9	<u>More vs less breastfeeding:</u> OR 0.79 [0.63 to 0.98] age ≤5 years OR 1.05 [0.99 to 1.12] age >5 years High heterogeneity across studies for age ≤5 years
Systolic blood pressure – baby Diastolic blood pressure – baby	Not considered for modelling	No evidence of association	43	<u>Ever vs never or longer vs shorter duration of breastfeeding:</u> -0.80 mm Hg [-1.17 to -0.43] childhood through adulthood

			38	-0.24 mm Hg [-0.50 to 0.02] childhood through adulthood Evidence of publication bias No evidence of association on systolic blood pressure observed among larger studies
Total cholesterol – baby	Not considered for modelling	No evidence of association	46	<u>Ever vs never or longer vs shorter duration of breastfeeding:</u> -0.01 mmol/L [-0.05 to 0.02] No evidence of heterogeneity across studies
Osteoporosis – mother	Not considered for modelling	Insufficient evidence	 4 4	<u>Highest vs lowest duration of breastfeeding:</u> Distal radius: SMD -0.132 [-0.260 to -0.003] Femoral neck: SMD -0.142 [-0.426 to 0.142]
Dental carries – baby	Not considered for modelling	Consistent evidence on detrimental effect if breastfeeding lasts >12 months	4	Breastfeeding >12 months vs ≤ months OR 2.69 [1.28 to 5.64] age <6 years Publication bias likely

More versus less breastfeeding: exclusive vs non-exclusive; predominant vs partial; partial vs none; any breastfeeding vs no breastfeeding
BMI: body mass index; CI: confidence intervals; OR: odds ratio; RR: risk ratio; SIDS: sudden infant death syndrome; SMD: standardised mean difference

Table 32. Decision on clinical conditions in mothers and babies for inclusion in the guideline economic analysis

Clinical condition	Decision for inclusion in guideline economic analysis – justification
Breast cancer – mother	Yes – modelled in Renfrew (2012), clinical data updated in Victora (2016) and further, more recent data of good quality were available; data on other parameters required for modelling were available
Gastrointestinal infection – baby	Yes – modelled in Renfrew (2012), clinical data updated in Victora (2016), data on other parameters required for modelling were available
Respiratory tract infection – baby	Yes – modelled in Renfrew (2012), clinical data updated in Victora (2016), data on other parameters required for modelling were available
Acute otitis media – baby	Yes – modelled in Renfrew (2012), clinical data updated in Victora (2016), data on other parameters required for modelling were available
Necrotising enterocolitis – baby [neonatal units]	No – modelled in Renfrew (2012) but population outside the guideline scope (babies in neonatal units)
SIDS – baby	Yes – only narrative assessment in Renfrew (2012) but possible to model; it is noted that Victora (2016) did not report up-to-date evidence on the association with breastfeeding but reported data reviewed by Renfrew (2012)
Cognitive outcomes – baby	No – economic consequences (productivity) beyond NICE scope
Obesity – baby	No – only narrative assessment in Renfrew (2012). Victora (2016) show suggestive evidence of association with breastfeeding. However, obesity is affected by multiple factors which may have an effect during different time periods over a person's life and modelling obesity related exclusively to non-breastfeeding would be particularly complex.
Ovarian cancer – mother	No – suggestive evidence of effect in Victora (2016) but not modelled in Renfrew (2012), so modelling would require identification and collection of several model parameters; moreover, low incidence of ovarian cancer meant that clinical and economic benefits per person owing to breastfeeding are likely to be small compared with other clinical conditions
Type 2 diabetes – mother	No – not modelled in Renfrew (2012), restricted evidence of protection in Victora (2016) and complex modelling required
Asthma or wheezing – baby	No – inconclusive evidence of association with breastfeeding in Victora (2016)
Diabetes – baby	No – not modelled in Renfrew (2012), restricted evidence of protection in Victora (2016) and complex modelling required
Leukaemia – baby	No – not modelled in Renfrew (2012), some evidence of protection in Victora (2016) but quality of the evidence has been question (Ojha and Asdahl, 2015). Moreover, relatively complex modelling required
Coeliac disease – baby	No – not modelled in Renfrew (2012) due to inadequate evidence and no evidence update in Victora (2016)
Cardiovascular disease – baby	No – not modelled in Renfrew (2012) due to evidence being based mainly on bio-markers rather than disease, no evidence update in Victora (2016), and complex modelling required

Sepsis – baby [neonatal units]	No – population outside the guideline scope (babies in neonatal units)
Mortality due to infectious diseases – baby	Yes – not considered for modelling by Renfrew (2012) but consistent evidence of major protection in Victora (2016) and modelling feasible; it is noted that evidence came from low and medium income countries, so findings may not be directly relevant to the UK
Eczema – baby	No – not considered for modelling by Renfrew (2012) and no evidence of association found in Victora (2016)
Food allergies – baby	No – not considered for modelling by Renfrew (2012) and no evidence of association found in Victora (2016)
Allergic rhinitis – baby	No – not considered for modelling by Renfrew (2012); only possible protection up to 5 years of age according to Victora (2016) and clinical benefits and cost-savings per person resulting from breastfeeding relatively small compared with other clinical conditions
Systolic blood pressure – baby Diastolic blood pressure – baby	No – not considered for modelling by Renfrew (2012) and no evidence of association in Victora (2016)
Total cholesterol – baby	No – not considered for modelling by Renfrew (2012) and no evidence of association in Victora (2016)
Osteoporosis – mother	No – not considered for modelling by Renfrew (2012) and insufficient evidence of association in Victora (2016)
Dental carries – baby	No – not considered for modelling by Renfrew (2012) and period of breastfeeding required to lead to dental carries is beyond the timeframe over which outcomes (breastfeeding rates) were measured in the guideline systematic review of breastfeeding interventions

The clinical conditions that were considered in the guideline economic analysis are summarised in Table 33.

Table 33. Clinical conditions considered in the guideline economic analysis of cost-effectiveness of interventions for starting and maintaining breastfeeding

Clinical conditions in babies	Clinical conditions in mothers
• Gastrointestinal infection • Respiratory tract infection • Acute otitis media • Mortality due to infectious diseases • Mortality due to sudden infant death syndrome (SIDS)	Breast cancer

Model structure

A hybrid decision-analytic model was constructed using Microsoft Office Excel 2013. The model estimated the total costs and benefits to mothers and babies associated with the provision of a breastfeeding intervention to women who are pregnant or have given birth to healthy babies at term. The structure of the model, which aimed to simulate the course of a number of clinical conditions whose incidence is associated with breastfeeding, was driven by patterns of clinical practice in the UK and the availability of relevant clinical data.

According to the model structure, hypothetical cohorts of women who are pregnant or have given birth to healthy babies at term were either initiated on a breastfeeding intervention in

addition to standard care, or received standard care only. Following care received, women either breastfed or they did not breastfeed their babies at 16-26 weeks after birth. Women and their babies were subsequently followed for a period of time that ranged from one year after birth to lifetime, depending on the clinical condition assessed, to estimate their outcomes and associated costs resulting from the mothers' and babies' breastfeeding status at 16-26 weeks after birth. The clinical conditions assessed are those listed in Table 33.

The first part of the guideline economic model, which assessed the impact of the breastfeeding intervention on breastfeeding rates at 16-26 weeks after birth, took the form of a decision-tree. This part of the model, which was informed by the results of the guideline systematic review and meta-regression, was followed by separate models on each of the clinical conditions considered for mothers and babies, which took the form of either a decision-tree or a Markov model, as appropriate for the condition examined.

The models on gastrointestinal infection, respiratory tract infection and acute otitis media in babies took the form of a simple decision tree, where babies either developed one of the infections or not. Those who developed an infection were treated by GPs, with a sub-group of those developing gastrointestinal infection and respiratory tract infection being hospitalised for further treatment. The time horizon of those models was one year.

One model was developed for mortality due to SIDS or infectious diseases in babies. Babies who did not die because of SIDS or infectious diseases over their first year of life entered a very simple, two-state Markov model, with a one-year cycle, that considered the states of 'alive' and 'dead' over the babies' lifetimes.

One three-state Markov model was developed to assess costs and outcomes for women at risk for breast cancer over their lifetime. Women entered the model at 30 years of age, which is the mean age of women who give birth in England and Wales. The model considered the states of 'no breast cancer', 'breast cancer' and death; the model cycle was one year and a half-cycle correction was applied. Breast cancer in women who survived was assumed to last 10 years, after which women who survived re-entered the 'no breast cancer' state and were at risk of developing a new breast cancer. The state of 'breast cancer' consisted of 10 tunnel states, one for each year of breast cancer, so that the time women spent with breast cancer could be estimated and a breast cancer's duration-dependent mortality, as well as time-dependent costs and utilities associated with breast cancer, could be applied.

The overall structure of the economic model assessing the cost-effectiveness of an intervention for starting and maintaining breastfeeding is shown in Figure 54. Figure 55 shows the economic model component on mothers' breast cancer.

Figure 54. Schematic structure of the economic model assessing the cost-effectiveness of an intervention for women aiming at starting and maintaining breastfeeding

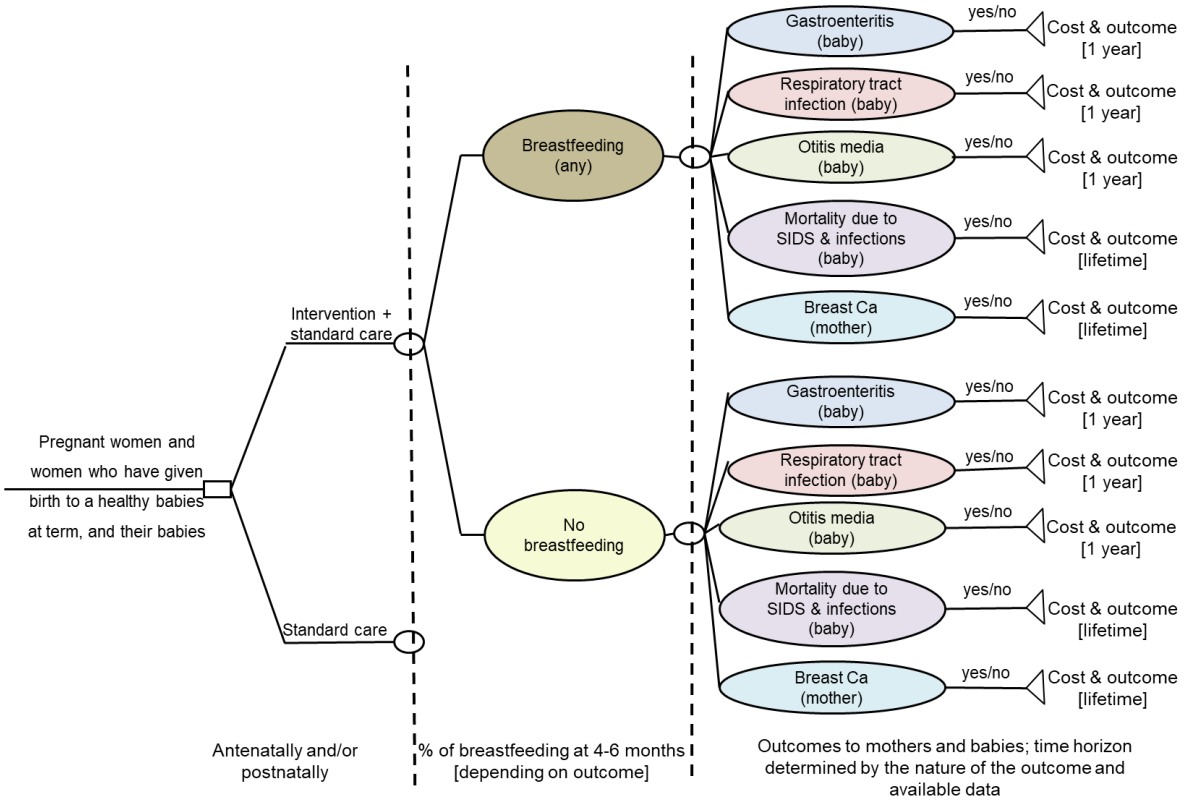
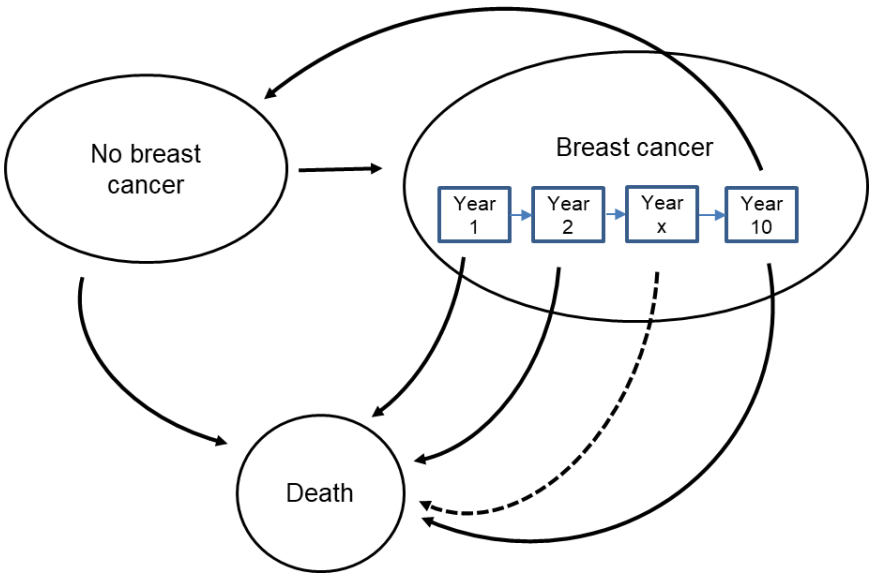


Figure 55. Schematic structure of the economic model component on mothers' breast cancer



Clinical and cost data associated with each of the clinical conditions that were considered in the economic analysis and related outcomes measured

Gastrointestinal infection in babies

Details of model structure, assumptions and clinical data utilised in the model

The guideline economic analysis utilised the model structure developed by Renfrew (2012) for gastrointestinal infection in babies. The analysis considered the protective effect of breastfeeding on the risk of gastrointestinal infection in babies up to their first year of age, with each infection assumed to correspond to one GP contact, as well as on the rate of hospitalisations in babies aged up to one year due to gastrointestinal infection.

According to the model, provision of a breastfeeding intervention is expected to increase breastfeeding rates; the protective effect of increased breastfeeding rates was subsequently applied onto the current (baseline) incidence of gastrointestinal infection and related numbers of hospitalisations in babies aged up to one year, to estimate the reduction in the incidence of gastrointestinal infection and in the related number of hospitalisations in babies aged 0-1 years following provision of the intervention. The model took into account the fact that the current (baseline) incidence of gastrointestinal infection and related hospitalisations reflect the current mix of babies who are breastfed and those who are not (i.e. all healthy babies born at term under standard care).

Updated data on the protective effect of breastfeeding on i) the incidence of gastrointestinal infection and ii) the risk of hospitalisation due to gastrointestinal infection in babies were obtained from Victora (2016). It is noted that Renfrew (2012) reported that the protective effect of breastfeeding on gastrointestinal infection wears off soon after breastfeeding stops, based on available evidence at the time. In contrast, Victora (2016) presented evidence that demonstrates a protective effect of breastfeeding on gastrointestinal infection in babies over the first 5 years of their life, although this effect appears to be stronger in younger ages. Nevertheless, the guideline economic analysis estimated costs and outcomes associated with gastrointestinal infection in babies over their first year of life, to retain consistency with the analysis undertaken by Renfrew (2012) and also because relevant epidemiological data required for this model component were available for babies up to one year old.

The data from Victora (2016) utilised in the guideline economic analysis were i) the risk ratio (RR) of more versus less breastfeeding on the incidence of diarrhoea in babies and children between 6 months and 5 years of age (0.46, 95% CI 0.28 to 0.78) and ii) the RR of more versus less breastfeeding on hospitalisation due to diarrhoea in babies and children up to 5 years of age (0.28, 95% CI 0.16 to 0.50). It is noted that for the RR relating to the incidence of diarrhoea there were data available on 3 age groups of babies and children: up to 6 months old; between 6 months and 5 years of age; and up to 5 years old. The RR value relating to the age group between 6 months and 5 years old was used in the economic analysis as it was between the other two values and seemed relevant for the age of babies at the end of the time horizon of the analysis (one year of age); moreover, it had the largest evidence base as it was informed by 23 studies.

The baseline incidence of gastrointestinal infection in babies up to one year of age in England was assumed to equal the number of GP consultations on babies up to one year of age for the clinical diagnoses of diarrhoea, intestinal infectious diseases, non-infective enteritis, and colitis (4,682 per 100,000). This figure was based on data reported in Renfrew (2012), derived from the Royal College of General Practitioners (RCGP) database, due to lack of more recent available data. The baseline rate of hospital admissions due to gastrointestinal infection over the first year of life (15.3/1000 live births) was estimated using data on admissions for babies aged 0-1 years of age for infectious intestinal diseases in

England (NHS Digital, 2018), divided by the population aged 0-1 years in England (Office for National Statistics, 2018c).

In order to estimate the incidence of gastrointestinal infection and hospitalisation due to gastrointestinal infection under current standard practice in babies aged up to 1 years that were breastfed (BF) and those that were not breastfed (nonBF) the following formulae were used, taken from Renfrew (2012) who, in turn, adopted them from Bartick and Reinhold (2010):

$$Incidence\ in\ nonBF = \frac{Overall\ incidence}{Current\ BF\ rate\ x\ RR + 1 - current\ BF\ rate}$$

and

$$Incidence\ in\ BF = Incidence\ in\ nonBF\ x\ RR$$

where 'overall incidence' is the incidence of the clinical condition (in this case gastrointestinal infection; and also hospitalisation due to gastrointestinal infection) in the overall population of babies aged up to 1 years old, and RR the risk ratio expressing the protective effect of breastfeeding on the clinical condition examined.

Resource use and cost data

The unit cost of a GP visit (£37) was obtained from national data (Curtis and Burns, 2018). The cost of hospitalisation for gastrointestinal infection (£756 per admitted child) was estimated using NHS reference costs for the year 2018 (NHS Improvement, 2018).

Outcome measures

The outcomes measured in this model were the number of cases of gastrointestinal infection and the number of hospitalisations due to gastrointestinal infection in babies aged up to one year. These were secondary outcomes in the guideline economic analysis.

Respiratory tract infection in babies

Details of model structure, assumptions and clinical data utilised in the model

The guideline economic analysis utilised the model structure developed by Renfrew (2012) for respiratory tract infection (RTI) in babies. The analysis considered the protective effect of breastfeeding on the risk of lower RTI in babies up to their first year of age, with each infection assumed to correspond to one GP contact, as well as on the rate of hospitalisations in babies aged up to one year due to any (lower and upper, according to available evidence) RTI.

According to the model, provision of a breastfeeding intervention is expected to increase breastfeeding rates; the protective effect of increased breastfeeding rates was subsequently applied onto the current (baseline) incidence of lower RTI and the numbers of hospitalisations due to (any) RTI in babies aged up to one year to estimate the reduction in the incidence of lower RTI and in the number of hospitalisations due to RTI in babies aged 0-1 years following provision of the intervention. The model took into account the fact that the current (baseline) incidence of lower RTI and hospitalisations due to RTI reflect the current mix of babies who are breastfed and those who are not (i.e. all healthy babies born at term under standard care).

Updated data on the protective effect of breastfeeding on i) the incidence of lower RTI and ii) the risk of hospitalisation due to RTI in babies were obtained from Victora (2016). It is noted

that Renfrew (2012) reported that the protective effect of breastfeeding on lower RTI wears off soon after breastfeeding stops, based on available evidence at the time. In contrast, Victora (2016) presented evidence that demonstrates a protective effect of breastfeeding on lower RTI and on hospitalisations due to RTI in babies over the first 2 years of their lives. Nevertheless, the guideline economic analysis estimated costs and outcomes associated with RTI in babies over their first year of life, to retain consistency with the analysis undertaken by Renfrew (2012) and also because relevant epidemiological data required for this model component were available for babies aged up to one year.

The data from Victora (2016) utilised in the guideline economic analysis were i) the RR of more versus less breastfeeding on the incidence or prevalence of lower RTI in babies and children below two years of age (0.68, 95% CI 0.60 to 0.77) and ii) the RR of more versus less breastfeeding on hospitalisation due to RTI in babies and children below two years of age (0.43, 95% CI 0.33 to 0.55).

The baseline incidence of lower RTI in babies up to one year of age in England was assumed to equal the number of GP consultations on babies up to one year of age for the clinical diagnosis of lower RTI (23,433 per 100,000). This figure was based on data reported in Renfrew (2012), derived from the RCGP database, due to lack of more recent available data. The baseline rate of hospital admissions due to RTI over the first year of life (115.4/1000 live births) was estimated using data on admissions for babies aged 0-1 years of age for RTI in England (NHS Digital, 2018), divided by the population aged 0-1 years in England (Office for National Statistics, 2018c).

In order to estimate the incidence of lower RTI and hospitalisation due to RTI under current standard practice in babies aged up to 1 years that were breastfed and those that were not breastfed, the same formulae described earlier were used, taken from Renfrew (2012) who adopted them from Bartick and Reinhold (2010).

Resource use and cost data

The unit cost of a GP visit (£37) was obtained from national data (Curtis and Burns, 2018). The cost of hospitalisation for RTI (£1,094 per admitted child) was estimated using NHS reference costs for the year 2018 (NHS Improvement, 2018).

Outcome measures

The outcomes measured in this model were the number of cases of lower RTI and the number of hospitalisations due to RTI in babies aged up to one year. These were secondary outcomes in the guideline economic analysis.

Acute otitis media in babies

Details of model structure, assumptions and clinical data utilised in the model

The guideline economic analysis also utilised the model structure developed by Renfrew (2012) for acute otitis media in babies. The analysis considered the protective effect of breastfeeding on the risk of acute otitis media in babies up to their first year of age, with each infection assumed to correspond to one GP contact.

According to the model, provision of a breastfeeding intervention is expected to increase breastfeeding rates; the protective effect of increased breastfeeding rates was subsequently applied onto the current (baseline) incidence of acute otitis media in babies aged up to one year to estimate the reduction in the incidence of acute otitis media in babies aged 0-1 years following provision of the intervention. The model took into account the fact that the current

(baseline) incidence of acute otitis media reflects the current mix of babies who are breastfed and those who are not (i.e. all healthy babies born at term under standard care).

Updated data on the protective effect of breastfeeding on the incidence of acute otitis media in babies were obtained from Victora (2016). It is noted that Renfrew (2012) reported that the protective effect of breastfeeding on acute otitis media wears off soon after breastfeeding stops, based on available evidence at the time. In contrast, Victora (2016) presented evidence that demonstrates a protective effect of breastfeeding on acute otitis media in babies over their first 2 years of life. Nevertheless, the guideline economic analysis estimated costs and outcomes associated with acute otitis media in babies over their first year of life, to retain consistency with the analysis undertaken by Renfrew (2012) and also because relevant epidemiological data required for this model component were available for babies up to one year old.

The data from Victora (2016) utilised in the guideline economic analysis comprise the odds ratio (OR) of more versus less breastfeeding on the incidence of acute otitis media in babies and children below two years of age (0.67, 95% CI 0.62 to 0.72).

The baseline incidence of acute otitis media in babies up to one year of age in England was assumed to equal the number of GP consultations on babies up to one year of age for the clinical diagnosis of acute otitis media (13,556/100,000). This figure was based on data reported in Renfrew (2012), derived from the RCGP database, due to lack of more recent available data.

In order to estimate the incidence of acute otitis media under current standard practice in babies aged up to 1 years that were breastfed and those that were not breastfed, the same formulae described earlier were used, taken from Renfrew (2012) who adopted them from Bartick and Reinhold (2010). It is noted that these formulae utilise RR rather than OR. However, when the incidence of an event at baseline is rare (<10%), then OR approximates RR and the formulae can produce accurate results using OR instead of RR (Zhang and Yu, 1998).

Resource use and cost data

The unit cost of a GP visit (£37) was obtained from national data (Curtis and Burns, 2018).

Outcome measure

The outcome measured in this model was the number of cases of acute otitis media in babies aged up to one year. This was a secondary outcome in the guideline economic analysis.

Mortality due to infectious diseases and sudden infant death syndrome (SIDS) in babies

Details of model structure, assumptions and clinical data

Renfrew (2012) did not consider mortality due to infectious diseases in economic modelling, and assessed costs and outcomes associated with SIDS in a narrative economic analysis. The guideline economic analysis considered the protective effect of breastfeeding on mortality due to infectious diseases and SIDS in babies up to their first year of age, and modelled the reduced mortality and associated benefits in babies whose life was saved over their lifetime.

According to the model, provision of a breastfeeding intervention is expected to increase breastfeeding rates; the protective effect of increased breastfeeding rates was subsequently applied onto the current (baseline) incidence of mortality due to infectious diseases and SIDS

in babies aged up to one year to estimate the reduction in mortality due to infectious diseases and SIDS in babies aged 0-1 years following provision of the intervention. The model took into account the fact that the current (baseline) mortality due to infectious diseases and SIDS reflects the current mix of babies who are breastfed and those who are not (i.e. all healthy babies under standard care).

Data on the protective effect of breastfeeding on mortality due to infectious diseases were obtained from Victora (2016). The data utilised in the guideline economic analysis comprised the OR of any versus no breastfeeding on mortality due to infectious diseases in babies and children aged 6-23 months (0.48, 95% CI 0.38 to 0.60). It is noted that these data came from studies from low and medium income countries, and therefore are not directly relevant to the UK context.

Victora (2016) did not update data on the protective effect of breastfeeding on mortality due to SIDS, but reported the same data as those considered by Renfrew (2012). These data were also adopted in the guideline economic analysis and comprised the OR of any versus no breastfeeding on mortality due to SIDS in babies and children aged ≥2 months (0.38, 95% CI 0.27 to 0.54).

It needs to be noted that both outcomes (ORs) used in the guideline economic analysis reflected the difference in mortality between babies that have been breastfed and those that have never been breastfed. The difference in mortality between babies that were breastfed for longer versus shorter periods of time is likely to be lower, as a shorter duration of breastfeeding has also a protective effect on mortality due to infectious diseases and SIDS in babies. The effect (RR) of the breastfeeding intervention obtained from the guideline meta-analysis was applied onto the baseline rate of any breastfeeding at 4 months in order to estimate the increase in the number of babies that were breastfed at 4 months following provision of the intervention. However, babies in the economic model that were not breastfed at 4 months may have been breastfed until some earlier point and are not necessarily babies that were never breastfed, so they may have already received some protection on mortality due to infectious diseases and SIDS from a shorter duration of breastfeeding. Therefore, the guideline economic analysis has likely overestimated the benefits and cost-savings of the breastfeeding intervention to babies regarding the reduction in mortality due to infectious diseases and SIDS.

The baseline mortality due to infectious diseases (12 per 100,000) and SIDS (25 per 100,000) in babies aged 0-1 years was estimated by dividing the number of deaths due to infectious diseases and SIDS in babies aged 0-1 years with the number of live births, using infant mortality data in England and Wales (Office for National Statistics, 2019c).

In order to estimate the mortality due to infectious diseases and SIDS under current standard practice in babies aged up to 1 years that were breastfed and those that were not breastfed, the same formulae described earlier were used, taken from Renfrew (2012) who adopted them from Bartick and Reinhold (2010). These formulae utilise RR rather than OR, however, because mortality due to infectious diseases and SIDS in babies aged 0-1 years is a rare event, OR approximates RR and the formulae can produce accurate results using OR instead of RR (Zhang and Yu, 1998).

Babies whose life was saved as a result of breastfeeding (i.e. they did not die from infectious diseases or SIDS as a result of the protective effect of breastfeeding) were followed up over lifetime. Two types of data were needed in order to estimate their mortality in each cycle of the model:

- The proportion of males among babies whose life was saved. This was estimated using the number of males and females aged one year in England (Office for National Statistics, 2018c) due to lack of more relevant data (i.e. data on the proportion of males versus

females whose life was saved as a result of the protective effect of breastfeeding on mortality due to infectious diseases and SIDS).

- Age- and gender-specific overall mortality over lifetime (Office for National Statistics, 2018b)

Resource use and cost data

The cost of death due to an infectious disease or SIDS per baby (£204) was derived from NHS reference costs for the year 2018 for code VB99Z 'Emergency medicine, patient dead on arrival' (NHS Improvement, 2018). This was the only cost considered for this clinical condition (mortality in babies). It is acknowledged that babies dying from an infectious disease are likely to have incurred further healthcare costs due to infection, however, some of these may have already been considered under other clinical conditions in babies associated with breastfeeding and were therefore not considered in this part of the model. In any case, the intention of this model component was to attach a cost specifically to death due to an infectious disease, rather than to consider the costs of the full pathway of infection that led to babies' death. On the other hand, there are considerable intangible emotional costs to parents following the death of a baby, which were not possible to include in the analysis.

Outcome measures and utility data

The outcomes measured in this model were the number of QALYs gained over saved babies' lifetime (primary outcome of the guideline economic analysis) and the number of deaths due to infectious diseases and SIDS in babies aged up to one year (secondary outcome).

To estimate total QALYs over lifetime, age- and gender-specific EQ-5D-derived utility values for the UK population were used (Kind 1999), shown in Table 34.

Table 34. Utility values of the general UK population - EQ-5D ratings (Kind 1999)

Age (years)	Utility mean (SE)	
	Males	Females
Under 25	0.94 (0.01)	0.94 (0.01)
25 to 34	0.93 (0.01)	0.93 (0.01)
35 to 44	0.91 (0.01)	0.91 (0.01)
45 to 54	0.84 (0.02)	0.85 (0.01)
55 to 64	0.78 (0.02)	0.81 (0.02)
65 to 74	0.78 (0.02)	0.78 (0.02)
75+	0.75 (0.03)	0.71 (0.02)

Breast cancer in mothers

Details of model structure, assumptions and clinical data

The guideline economic analysis used the same overall model structure for breast cancer in mothers with the model developed by Renfrew (2012), in terms of the 3 health states of 'no breast cancer', 'breast cancer' and 'death'. However, the guideline economic analysis used a different approach and considered more parameters associated with the risk of breast cancer in parous women, employed different assumptions to model the course of disease (in particular mortality), and utilised different epidemiological, utility and cost data on breast cancer. The analysis considered the protective effect of breastfeeding on the risk of breast cancer in women over their lifetime. The age of women at the start of the model was 30

years, as this is the mean age of women who give birth in England and Wales (Office for National Statistics, 2019a).

According to the model, provision of a breastfeeding intervention is expected to increase breastfeeding rates; the protective effect of increased breastfeeding rates was subsequently applied onto the current (baseline) incidence of breast cancer in parous women over lifetime to estimate the reduction in the incidence of breast cancer in parous women following provision of the intervention. The model took into account the fact that the current (baseline) incidence of breast cancer in parous women reflects the current mix of parous women who have breastfed and those who have not (i.e. all parous women that have received standard care in the postnatal period).

Data on the protective effect of breastfeeding on the incidence of breast cancer were obtained from a published meta-analysis (Unar-Munguía 2017b) which pooled data from 25 studies on parous women and adjusted for several confounders such as age, parity, age at first pregnancy and family history of breast cancer. The standardised RR for breast cancer in parous women for any versus no breastfeeding for 6 months was used (0.86, 95% CI 0.82 to 0.91). This study, which was judged to be of high quality, had not been considered by Victora (2016) as it was published at a later time. The evidence on the protective effect of breastfeeding on the incidence of breast cancer reported in Victora (2016) was subject to publication bias; therefore the authors reported the results of an older, high-quality meta-analysis (Collaborative Group on Hormonal Factors in Breast Cancer, 2002), which analysed data from 47 epidemiological studies in 30 countries and was also the study that had informed the economic analysis of Renfrew (2012). According to these older, also high-quality data, the impact of any versus no breastfeeding for up to 6 months on breast cancer is very small and non-significant (OR 0.98, 95% CI 0.95 to 1.01), while the impact of any versus no breastfeeding for a duration of 7-18 months is statistically significant but still small (OR 0.94, 95% CI 0.91 to 0.97).

The meta-analysis by Unar-Munguía (2017b) was used to inform the economic model because it was considered to be of high-quality and it was more recent that the meta-analysis conducted by the Collaborative Group on Hormonal Factors in Breast Cancer (2002). The two meta-analyses included studies conducted over different years, so there was no overlap in included evidence between them. Results are contradictory and do not allow robust conclusions on whether breastfeeding for a duration of up to 6 months can reduce the incidence of breast cancer, but it is acknowledged that informing the economic model using data by Unar-Munguía (2017b) may have favoured the breastfeeding intervention.

It is noted that the protective effect of breastfeeding on the incidence of breast cancer reported in Unar-Munguía (2017b) as well as the data reported in Renfrew (2012) reflect the difference in incidence between women that have breastfed over at least 6 months and those that have never breastfed. The difference in the incidence of breast cancer between women that have breastfed for longer versus shorter periods of time may be lower, as there seems to be a dose-response association between breastfeeding and breast cancer, so that a shorter duration of breastfeeding may also have a protective effect on breast cancer in women. The effect (RR) of the breastfeeding intervention obtained from the guideline meta-analysis was applied onto the baseline rate of any breastfeeding at 6 months in order to estimate the increase in the number of women that breastfed at 6 months following provision of the intervention. However, women in the economic model who did not breastfeed at 6 months may have done so until some earlier point and are not necessarily women who have never breastfed, so they may have already received some protection on breast cancer from a shorter duration of breastfeeding. Therefore, the guideline economic analysis has likely overestimated the benefits and cost-savings of the breastfeeding intervention to women regarding the reduction in the incidence of breast cancer.

The baseline incidence of breast cancer in parous women was estimated using the following data:

- The age-specific incidence of breast cancer in women in the general population, i.e. a mixture of parous and nulliparous women (Cancer research UK, 2019a). These data are shown in Table 35.
- The percentage of nulliparous women in the population of women aged 30 years and over. This was 48% at 30 years of age; 27% at 35 years of age; 19% at 40 years of age; and 18% at 45 years of age and above (Office for National Statistics, 2018a).
- The mean number of children per parous woman aged 30 years and over (including previous births), which was approximately 2, starting from 1.90 at 30 years of age and reaching 2.23 at 45 years of age (Office for National Statistics, 2018a). This information was needed in order to estimate the incidence of breast cancer in parous women, as parity reduces the incidence of breast cancer and the reduction depends on the number of children per woman.
- The protective effect of parity on breast cancer, expressed as an OR of incidence of breast cancer in parous women with 2 live births versus non-parous women (0.84, 95% CI 0.80 to 0.89) (Lambe, 1996). Parous women with 2 live births were selected as the relevant sub-population of parous women, as the mean number of children of parous women aged 30 years and over (which is the study population) is 2, as reported above.

For every year in the model, starting at 30 years of age, the incidence of breast cancer in parous women and in nulliparous women was estimated using the formulae reported in Bartick and Reinhold (2010) as described earlier, using the overall age-specific incidence of breast cancer in women in the general population, the percentage of nulliparous women amongst women in the general population, and the protective effect of parity on breast cancer. Subsequently, the same formulae were used to estimate the incidence of breast cancer under current standard practice in women aged 30 years and over who breastfed and those who did not, amongst parous women. These formulae utilise RR rather than OR, however, because breast cancer in women is a rare event (<10%), OR approximates RR and the formulae can produce accurate results using OR instead of RR (Zhang and Yu, 1998).

Table 35. Incidence (new cases) and mortality of breast cancer in women in the general population

Age	Incidence – new breast cancer cases per 100,000 women (Cancer Research UK, 2019a)	Mortality due to breast cancer per 100,000 women (Cancer Research UK, 2019b)
15 to 19	0.1	0
20 to 24	1.5	0.1
25 to 29	10.7	0.9
30 to 34	30.4	3.1
35 to 39	65.1	7.7
40 to 44	123.9	13.8
45 to 49	217.1	23.4
50 to 54	282.0	35.2
55 to 59	278.9	41.8
60 to 64	344.6	49.3
65 to 69	419.2	63.3
70 to 74	370.9	80.8
75 to 79	407.1	112.9
80 to 84	445.0	160.1

85 to 89	466.6	220.5
90+	459.4	317.1

Women in the model were followed up over their lifetime to estimate the costs and benefits (QALYs) associated with the development of breast cancer. Mortality in women without breast cancer was derived from age-specific mortality data for women in the general population (Office for National Statistics, 2018b). It is acknowledged that women in the general population include women with breast cancer, who have higher mortality than women without breast cancer, and therefore the mortality of women without breast cancer in the model has been overestimated. However, because women with breast cancer are only a very small proportion of women in the general population, the overestimation of mortality in women without breast cancer in the economic model was probably negligible.

For women with breast cancer, mortality was estimated using age-specific data on mortality in the general population (Office for National Statistics, 2018b), age-specific data on mortality due to breast cancer in women in the general population as shown in Table 35 (Cancer Research UK 2019b) and the following assumptions:

- The general population comprises women with breast cancer and women without breast cancer
- Women with breast cancer may die from breast cancer or from other causes
- Women without breast cancer may die from other causes only (i.e. any cause except breast cancer)
- Mortality due to other causes (any cause except breast cancer) is overall the same for women with breast cancer and those without; it is acknowledged that there is uncertainty around this assumption and that women with breast cancer may have higher or lower mortality due to other causes compared with women without breast cancer, but no relevant data were available to allow different assumptions and, on balance, the assumption appeared to be reasonable according to committee's expert opinion.

Based on the above assumptions it was possible to estimate the overall age-specific mortality in women with breast cancer in every model cycle.

Mortality in women with breast cancer depends on their age but also on the number of years lived with breast cancer (that is, the duration of breast cancer). A RR of mortality in women with breast cancer between 1-10 years after diagnosis versus women with breast cancer in the first year after diagnosis was estimated, using age-adjusted net survival data for women with breast cancer over 1-10 years after diagnosis (Cancer Research UK, 2019c). Survival data and the estimated RRs are shown in Table 36. From these data, and using (i) the estimated age-specific mortality in women with breast cancer in every model cycle and (ii) the number of women with breast cancer for 1, 2, 3 and up to 10 years after diagnosis in every cycle, it was possible to estimate the age- and breast cancer's duration-specific mortality in women with breast cancer, depending on the number of years after diagnosis (that is, number of years lived with breast cancer).

Table 36. Age-adjusted survival from breast cancer in women over 1-10 years from development and estimated mortality

Year	Age-adjusted % net survival up to 10 years after diagnosis*	Estimated mortality in those alive at the start of each year	Estimated RR of mortality in year x versus year 1
1	0.960	0.040	1.00
2	0.933	0.028	0.70
3	0.908	0.027	0.67
4	0.886	0.024	0.61

5	0.866	0.023	0.56
6	0.848	0.021	0.52
7	0.830	0.021	0.53
8	0.814	0.019	0.48
9	0.798	0.020	0.49
10	0.784	0.018	0.44

**Cancer Research UK (2019c)*
RR: risk ratio

Women with breast cancer surviving after 10 years with breast cancer were assumed to return to the mortality of the women in the general population (rather than retaining an increased mortality associated with breast cancer for the rest of their lives), but were at risk of developing a new breast cancer (in which case their mortality was again increased). This assumption was necessary as no relevant UK survival data for women with breast cancer beyond 10 years after diagnosis were available in the literature and it was considered reasonable because mortality of women with breast cancer after 10 years from diagnosis is not expected to differ considerably from that of women of the same age in the general population, unless women experience a recurrence of breast cancer. Given that women were at risk of developing a new breast cancer after 10 years from initial breast cancer diagnosis, the impact of this assumption on the results is expected to be minimal.

Resource use and cost data

Healthcare costs incurred by women with breast cancer and those without were obtained from a study that estimated total healthcare costs using data from national databases (National Cancer Data Repository, Hospital Episode Statistics, and the National Schedules of Reference Costs) on 359,771 women with breast cancer in England (Laudicella 2016). The study reported annual healthcare costs for each year of breast cancer between 1-9 years after diagnosis; it also reported annual healthcare costs incurred between 1-3 years before diagnosis of breast cancer. Costs were reported separately for women aged 18-64 years, and those ≥ 65 years. Based on the available data, the following costs were estimated and used in the guideline economic analysis:

- For women with breast cancer one year after diagnosis in the model, the cost figure for one year after diagnosis reported in Laudicella (2016) was combined with the excess cost reported in the same study for one year before breast cancer diagnosis (the healthcare cost one year before diagnosis of breast cancer was notably higher than the cost incurred over 2 and 3 years before diagnosis).
- For women with breast cancer 2-9 years after diagnosis in the model, the respective cost figures for 2-9 years after diagnosis reported in Laudicella (2016) were used.
- For women with breast cancer 10 years after diagnosis in the model, the healthcare cost reported for 9 years after diagnosis reported in Laudicella (2016) was used, due to lack of cost data specific to 10 years after diagnosis.
- After 10 years from breast cancer diagnosis, it was assumed that women incurred the same costs as women without breast cancer, unless they developed a new breast cancer.
- For women without breast cancer, averaged costs for 3 and 2 years before diagnosis of breast cancer reported in Laudicella (2016) were used.

Depending on the women's age in the model, relevant data for women aged 18-64 years or ≥ 65 years were used.

Cost data reported by Laudicella (2016) were updated to 2018 prices using the hospital and community health services index up to year 2014, and then the new health services index using the consumer prices index for health for years between 2014 and 2018 (Curtis and

Burns, 2018). Annual healthcare costs for women with breast cancer and those without breast cancer that were utilised in the guideline economic analysis are shown in Table 37.

Table 37. Annual healthcare costs (2018 prices) for women with breast cancer and women without breast cancer utilised in the guideline economic model

Health state	Cost in women aged 18-64 years	Cost in women aged ≥ 65 years
No breast cancer	£196	£470
Breast cancer – year 1	£12,836	£9,549
Breast cancer – year 2	£4,132	£3,007
Breast cancer – year 3	£2,446	£2,552
Breast cancer – year 4	£2,003	£2,566
Breast cancer – year 5	£1,920	£2,457
Breast cancer – year 6	£1,850	£2,498
Breast cancer – year 7	£1,640	£2,384
Breast cancer – year 8	£1,610	£2,410
Breast cancer – year 9	£1,479	£2,559
Breast cancer – year 10	£1,479	£2,559
All costs estimated based on data reported in Laudicella, 2016		

Outcome measures and utility data

The outcomes measured in this model were the number of QALYs (primary outcome of the guideline economic analysis) and the number of new cases of breast cancer over lifetime (secondary outcome).

To estimate QALYs for women without breast cancer, age-specific EQ-5D-derived utility values for women in the UK population were used (Kind 1999), shown in Table 34.

Utility values for women with breast cancer were estimated based on data reported in a systematic review and meta-analysis of utility values for breast cancer (Peasgood 2010). The study reported a mean utility value for early breast cancer between 0.648 and 0.725; and for metastatic breast cancer between 0.614 and 0.640. In order to estimate the proportion of women with metastatic breast cancer among women with breast cancer, the following data were utilised: among prevalent cases of women with metastatic breast cancer, 28% have de novo stage IV (metastatic) disease and 72% have progressed from initially stage I-III (non-metastatic) breast cancer (Mariotto 2017). Between 6% and 7% of women with breast cancer have metastases at diagnosis (Cancer Research UK, 2014). By combining these data and ignoring mortality over time, the proportion of women with metastatic breast cancer among women with breast cancer was estimated at approximately 23%. Given that mortality of metastatic breast cancer is expected to be higher than non-metastatic breast cancer, the proportion of breast cancer cases that are metastatic at any time was assumed to reach 20%. Using this estimate and averaging between the lowest and highest utility for early breast cancer and for metastatic breast cancer, the mean utility value for breast cancer was estimated to be 0.67. This value was used for years 1-5 following diagnosis of breast cancer. For years 6-10 after breast cancer diagnosis, it was assumed that the mean utility value of women with breast cancer was the average between the utility of breast cancer (0.67) and the age-specific utility of women without breast cancer. After 10 years with breast cancer, women were assumed to return to the utility value of women without breast cancer (i.e. the age-specific utility of women in the general population), unless they developed a new breast cancer.

Baseline probability of breastfeeding

Current breastfeeding rates under standard care for the period of 16 weeks (4 months) to 26 weeks (6 months) after birth were obtained from national statistics. The period between 16 and 26 weeks after birth was chosen to ensure that breastfeeding was established and therefore could have an impact on longer-term mother and baby outcomes. Over this period, only data on the effectiveness of intervention on any breastfeeding were available from the guideline systematic review and meta-regression. Moreover, the protective effect of breastfeeding on most clinical conditions considered in the guideline economic analysis referred to any breastfeeding (more versus less, longer versus shorter duration, any versus none, etc.) rather than exclusive breastfeeding.

For baby outcomes, baseline rates of any breastfeeding at 4 months after birth were used, as breastfeeding is established and benefits from breastfeeding can be enjoyed by this time point, and evidence suggests that the protective effect of breastfeeding is retained even after breastfeeding stops.

For breast cancer in mothers, baseline rates of any breastfeeding at 6 months after birth were used, as evidence suggests that the effect of breastfeeding on the incidence of breast cancer is significant from 6 months of breastfeeding onwards.

The most recent rates of any breastfeeding at 4 and 6 months after birth in England were available for the year 2010 from the Infant Feeding Survey conducted in the UK (NHS Digital, 2012). The most recent (2019) data on any breastfeeding were available only for 6-8 weeks after birth (Public Health England, 2019). However, it was possible to estimate the rates of any breastfeeding at 4 and 6 months after birth for 2019, using the 2019 figure for the prevalence of any breastfeeding at 6-8 weeks and the instant rate of reduction in any breastfeeding between 6 weeks and 4 months (16 weeks) and between 4 months and 6 months (26 weeks) as calculated from the available 2010 data, assuming exponential decrease of breastfeeding over time. The actual and estimated rates of any breastfeeding at different time points following birth for the years 2010 and 2019 are shown in Table 38.

Table 38: Prevalence of any breastfeeding at different points after birth

Time point	Prevalence of any breastfeeding	
	2010 (NHS Digital, 2012)	2018 (Public Health England, 2019)
Birth	83%	
6-8 weeks after birth	57% [6 weeks]	49% [6-8 weeks]*
4 months after birth	44%	42% [estimated][1]
6 months after birth	36%	34% [estimated][1]

** known cases only*
1. estimated using the 2018 figure for the prevalence of any breastfeeding at 6-8 weeks and the instant rate of reduction in any breastfeeding between 6 weeks and 4 months, and between 4 months and 6 months, as calculated from 2010 data (assuming exponential decrease).

Discounting

Where costs and/or outcomes were measured over a period longer than one year (i.e. estimation of QALYs gained over lifetime associated with mortality due to infectious diseases and SIDS in babies; and estimation of costs and QALYs associated with breast cancer in mothers over their lifetime), costs and benefits were discounted at an annual rate of 3.5% as recommended by NICE (2014).

Handling uncertainty

Model input parameters were synthesised in a probabilistic analysis. This means that the input parameters were assigned probabilistic distributions (rather than being expressed as point estimates); this approach allowed more comprehensive consideration of the uncertainty characterising the input parameters and captured the non-linearity characterising the economic model structure. Subsequently, 10,000 iterations were performed, each drawing random values out of the distributions fitted onto the model input parameters. Results (mean costs and QALYs for each intervention) were averaged across the 10,000 iterations. This exercise provides more accurate estimates than those derived from a deterministic analysis (which utilises the mean value of each input parameter ignoring any uncertainty around the mean), by capturing the non-linearity characterising the economic model structure (Briggs, 2006).

ORs and RRs expressing (i) the effectiveness of the breastfeeding intervention, (ii) the impact of breastfeeding on the incidence of the clinical conditions considered in the economic model, and (iii) the impact of parity on the incidence of breast cancer were assigned a log-normal distribution.

A beta distribution was assigned to the following parameters: the baseline probability of breastfeeding at 4 and 6 months; the proportion of breast cancer cases that are metastatic at any time; the baseline incidence of all clinical conditions examined in the economic analysis, (with the exception of hospitalisations due to gastrointestinal infection and RTI in babies aged 0-1 years as these were derived from national data that were not subject to uncertainty); and all the utility values utilised in the economic model (i.e. age- and gender-specific utilities in the general population and utilities in women with breast cancer), after applying the method of moments on utility data reported in the relevant literature.

NHS/PSS costs associated with the ‘breast cancer’ and ‘no breast cancer’ health states, the unit costs of hospitalisations due to gastrointestinal infection and RTI in babies aged 0-1 years and the unit cost associated with death in babies were assigned a gamma distribution. The cost of the breastfeeding intervention and the unit cost of a GP visit were assigned a normal distribution.

The following parameters were not assigned a probability distribution as they were estimated based on nationally collected data and therefore were not subject to uncertainty: the age-specific mortality in the general population; the age-specific incidence of breast cancer and mortality due to breast cancer in women of the general population; the mortality due to infectious diseases and SIDS in babies aged 0-1 years; the age-adjusted net survival in women with breast cancer; the percentage of nulliparous women among women of different age groups; the proportion of males among babies who did not die due to infectious diseases or SIDS following breastfeeding intervention; and the incidence of hospitalisations due to gastrointestinal infection and RTI in babies aged up to one year.

Table 39 reports the mean values of all input parameters utilised in the guideline economic model and provides details on the types of distributions assigned to each input parameter and the methods employed to define their range.

A two-way sensitivity analysis was undertaken, by changing concurrently the mean effect (RR) and cost of the intervention, to explore the impact of changes on the cost-effectiveness results. The ranges tested were from 1.05 to 2.00 for the intervention effect; and from £20 to £100 for the intervention cost.

Table 39. Input parameters (deterministic values and probability distributions) that informed the guideline economic model of an intervention for women aiming at starting and maintaining breastfeeding

Input parameter	Mean deterministic value	Probability distribution	Source of data – comments
Mean number of babies per live birth	1.016	None	Office for National Statistics 2019b; total number of liveborn babies born to single and multiple maternities were divided by number of maternities that resulted in at least one liveborn
Intervention specification			
Effect	1.19	Log-normal: 95% CI 1.01 to 1.30	Guideline meta-regression that considered the number of contacts as a variable; effect for 4-8 contacts (in addition to standard care) vs standard care on 'any breastfeeding between 16 and 26 weeks after birth'
Cost	£84	Normal: SE = 0.10 of the mean	See Table 29 Distribution based on assumption
Baseline probability of 'any breastfeeding'			
At 4 months	0.42	Beta distribution: α=418; β=582	Estimated using the 2019 figure for the prevalence of any breastfeeding at 6-8 weeks (Public Health England, 2019) and the instant rate of reduction in any breastfeeding between 6 weeks and 4 months, and between 4 months and 6 months, as calculated from 2010 data (NHS Digital, 2012), assuming exponential decrease in breastfeeding. Distribution based on assumption
At 6 months	0.34	Beta distribution: α=342; β=658	
Gastrointestinal infection [GI] in babies			
Breastfeeding effect (RR) on the incidence of GI	0.46	Log-normal: 95% CI 0.28 to 0.78	Victora 2016; pooled figures for 'more versus less breastfeeding', from a mixture of studies with different definitions of the 'risk factor' (e.g. exclusive vs non-exclusive; predominant vs partial; partial vs none; any vs none) Effect on incidence of GI from studies in babies and children aged 6 months to 5 years
Breastfeeding effect (RR) on the incidence of hospitalisation due to GI	0.28	Log-normal: 95%'# CI 0.16 to 0.50	

Input parameter	Mean deterministic value	Probability distribution	Source of data – comments
			Effect on incidence of hospitalisation due to GI from studies in babies and children aged < 5 years
Number of GP consultations for GI in babies aged 0-1 years – current (baseline)	0.047	Beta distribution: α=47; β=953	Renfrew 2012; 4,682 GP consultations per 100,000 babies aged <1 year based on the RCGP database, for the clinical diagnoses of diarrhoea, intestinal infectious diseases, non-infective enteritis, and colitis Distribution based on assumption
Hospital admissions for GI in babies aged 0-1 years – current (baseline)	0.015	None	Admissions for babies aged 0-1 years of age for infectious intestinal diseases (ICD10 A00-A09) in England (NHS Digital, 2018), divided by the population aged 0-1 years in England (Office for National Statistics, 2018c).
Unit cost of GP visit	£37	Normal: SE = 0.10 of the mean	Curtis and Burns, 2018; cost per consultation lasting 9.22 minutes, including direct care staff and qualification costs. Distribution based on assumption
Cost per hospital admission for GI	£756	Gamma: SE = 0.10 of the mean	NHS Improvement, 2018; weighted unit costs for HRG codes PF21A & PF21B, i.e. 'Paediatric, Infectious or Non-Infectious Gastroenteritis', with CC Score 1+ and CC Score 0, respectively. Distribution based on assumption
Respiratory tract infection [RTI] in babies			
Breastfeeding effect (RR) on the incidence of lower RTI	0.68	Log-normal: 95% CI 0.60 to 0.77	Victora 2016; pooled figures for 'more versus less breastfeeding', from a mixture of studies with different definitions of the 'risk factor' (e.g. exclusive vs non-exclusive; predominant vs partial; partial vs none; any vs none). Effects derived from studies in babies and children aged < 2 years
Breastfeeding effect (RR) on the incidence of hospitalisation due to RTI	0.43	Log-normal: 95% CI 0.33 to 0.55	
Number of GP consultations for lower RTI in babies aged 0-1 years – current (baseline)	0.234	Beta distribution: α=234; β=766	Renfrew 2012; 23,433 GP consultations per 100,000 babies aged <1 year based on the RCGP database, for the clinical diagnosis of lower RTI Distribution based on assumption

Input parameter	Mean deterministic value	Probability distribution	Source of data – comments
Hospital admissions for RTI in babies aged 0-1 years – current (baseline)	0.115	None	Admissions for babies aged 0-1 years of age for respiratory infectious diseases (ICD10 J00-J22) in England (NHS Digital, 2018), divided by the population aged 0-1 years in England (Office for National Statistics, 2018c).
Unit cost of GP visit	£37	Normal: SE = 0.10 of the mean	Curtis and Burns, 2018; cost per consultation lasting 9.22 minutes, including direct care staff and qualification costs. Distribution based on assumption
Cost per hospital admission for RTI	£1,094	Gamma: SE = 0.10 of the mean	NHS Improvement, 2018; weighted unit costs for HRG codes PD11, Paediatric, Acute Upper Respiratory Tract Infection or Common Cold, with CC Score 0 to 4+, PD14, Paediatric Lower Respiratory Tract Disorders without Acute Bronchiolitis, with CC Score 0 to 11+, PD15, Paediatric Acute Bronchiolitis with CC Score 0 to 5+, PD65, Paediatric Upper Respiratory Tract Disorders with CC Score 0 to 5+, and PD12, Paediatric, Asthma or Wheezing, with CC Score 0 to 4+ Distribution based on assumption
Acute otitis media in babies			
Breastfeeding effect (OR) on the incidence of acute otitis media	0.67	Log-normal: 95% CI 0.62 to 0.72	Victora 2016; pooled figures for 'more versus less breastfeeding', from a mixture of studies with different definitions of the 'risk factor' (e.g. exclusive vs non-exclusive; predominant vs partial; partial vs none; any vs none). Effect derived from studies in babies and children aged ≤ 2 years
Number of GP consultations for acute otitis media in babies aged 0-1 years – current (baseline)	0.136	Beta distribution: α=136; β=864	Renfrew 2012; 13,556 GP consultations per 100,000 babies aged <1 year based on the RCGP database, for the clinical diagnosis of acute otitis media Distribution based on assumption
Unit cost of GP visit	£37	Normal: SE = 0.10 of the mean	Curtis and Burns, 2018; cost per consultation lasting 9.22 minutes, including direct care staff and qualification costs.

Input parameter	Mean deterministic value	Probability distribution	Source of data – comments
Mortality due to infectious diseases and SIDS in babies			
Breastfeeding effect (OR) on mortality due to infectious diseases	0.48	Log-normal: 95% CI 0.30 to 0.60	Victora 2016; pooled figure for 'any versus never breastfeeding' Effect derived from studies in babies and children aged 6-23 months
Breastfeeding effect (RR) on mortality due to SIDS	0.38	Log-normal: 95% CI 0.27 to 0.54	Renfrew 2012; pooled figure for 'any versus never breastfeeding'. Effect derived from studies in babies and children aged ≥2 months.
Mortality due to infectious diseases in babies aged 0-1 years – current (baseline)	0.00012	None	Number of deaths due to infectious diseases and SIDS in babies aged 0-1 years divided by the number of live births, according to infant mortality data for England and Wales (Office for National Statistics, 2019c).
Mortality due to SIDS in babies aged 0-1 years – current (baseline)	0.00025	None	
Unit cost of death	£204	Gamma: SE = 0.10 of the mean	NHS Improvement, 2018; unit cost for HRG code VB99Z 'Emergency medicine, patient dead on arrival' Distribution based on assumption
Proportion of males among babies whose life was saved.	0.513	None	Estimated using the number of males and females aged one year in England (Office for National Statistics, 2018c)
Age- and gender-specific mortality in the general population	(multiple data – not shown)	None	Office for National Statistics, 2018b
Age- and gender-specific utility in the general population	See Table 34	Normal – for SE see Table 34	Kind 1999
Breast cancer in women			
Starting age of women (years)	30	None	Office for National Statistics, 2019a
Proportion of nulliparous women - At 30 years of age - At 35 years of age - At 40 years of age	 0.48 0.27 0.19	None	Office for National Statistics, 2018a

Input parameter	Mean deterministic value	Probability distribution	Source of data – comments
- At 45+ years of age	0.18		
Mean total number of children per parous woman (including previous births)	2	None	Office for National Statistics, 2018a [1.90 at 30 years of age, reaching 2.23 at 45 years of age]
Effect of parity (OR) on breast cancer - parous women with 2 live births (including previous births) vs non-parous women	0.84	Log-normal: 95% CI 0.80 to 0.89	Lambe 1996. The effect has been applied onto age-specific incidence of breast cancer in the general population (comprising parous and nulliparous women), to get the incidence of breast cancer in parous women
Breastfeeding effect (OR) on the incidence of breast cancer	0.86	Log-normal: 95% CI 0.82 to 0.91	Unar-Munguria 2017b; pooled figure for 'any breastfeeding over 6 months versus never breastfeeding' adjusted for age, parity, age at first pregnancy, and family history of breast cancer
Incidence of breast cancer – women in the general population	See Table 35	None	Cancer Research UK, 2019a
Mortality from breast cancer – women in the general population	See Table 35	None	Cancer Research UK, 2019b
Age-specific mortality – women in the general population	(multiple data – not shown)	None	Office for National Statistics, 2018b
Age-adjusted survival from breast cancer in women over 1-10 years from development	See Table 36	None	Cancer Research UK, 2019c. After 10 years with breast cancer, women were assumed to return to the mortality of the women in the general population, unless they re-developed breast cancer.
Utility in women with breast cancer (years 1-5)	0.67	Beta distribution: $\alpha=67.46$; $\beta=32.54$	Estimated based on data reported by Peasgood (2010) according to which the mean utility value for early breast cancer is between 0.648 and 0.725 and for metastatic breast cancer is between 0.614 and 0.640 and assuming that the proportion of breast Ca cases that are metastatic at any time is 20%, based on the information that between 6% and 7% of people have metastases at diagnosis (stage IV) (Cancer Research UK, 2014) and that among prevalent cases of

Input parameter	Mean deterministic value	Probability distribution	Source of data – comments
			women with metastatic breast cancer, 28% have de novo stage IV (metastatic) disease and 72% have progressed from initially stage I-III (non-metastatic) breast cancer (Mariotto 2017). For years 6-10 in breast cancer, 50% of women were assumed to have the utility of breast cancer and 50% of women were assumed to have the age-specific utility of the women in the general population. After 10 years, women were assumed to return to the utility of the women in the general population, unless they re-develop breast cancer; distribution based on assumption
Age-specific utility in women of the general population	See Table 34	Normal – for SE see Table 34	Kind 1999
Healthcare cost in women with breast cancer and those without breast cancer	See Table 37	Gamma: SE = 0.10 of the mean	Laudicella 2016; data on 359,771 women with breast cancer. For breast cancer in year 1, the excess cost of one year before breast cancer diagnosis was added. For breast cancer in year 10, same cost as for year 9 was assumed, due to lack of relevant cost data. After 10 years, it is assumed that women incur the same costs as women without breast cancer, unless they re-develop breast cancer. Costs for women without breast cancer assumed to equal averaged data 3 and 2 years before diagnosis of breast cancer. Distribution based on assumption
Annual discount rate	0.035	None	Applied to both costs and outcomes. NICE, 2014

CI: confidence intervals; GI: gastrointestinal infection; GP: general practitioner; HRG: hospital related group; OR: odds ratio; RCGP: Royal College of General Practitioners; RR: risk ratio; RTI: respiratory tract infection; SE: standard error; SIDS: sudden infant death syndrome

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Presentation of the results

Mean total costs, QALYs and other outcomes are presented for each option (intervention added on standard care and standard care alone. The ICER was calculated using the following formula:

$$ICER = \Delta C / \Delta E$$

where ΔC is the difference in total costs between two treatment options considered and ΔE the difference in their effectiveness (QALYs). The ICER expresses the extra cost per extra unit of benefit (QALY) associated with one treatment option relative to its comparator. If an option has an ICER of up to £20,000-£30,000/QALY relative to its comparator (NICE lower and upper cost-effectiveness threshold, respectively) then the intervention is considered to be cost-effective (NICE, 2013).

Validation of the economic model

The economic model (including the conceptual model and the identification and selection of clinical outcomes and input parameters) was developed by the health economist in collaboration with a health economics sub-group formed by members of the committee, using as a basis a previous economic model (Renfrew 2012). As part of the model validation, all inputs and model formulae were systematically checked; the model was tested for logical consistency by setting input parameters to null and extreme values and examining whether results changed in the expected direction. The base-case results and results of sensitivity analyses were discussed with the committee to confirm their plausibility. Moreover, where modelling structure components were identical to those of Renfrew (2012), for example the modelling components on babies' infections, input data from that study were used to confirm that its results could be replicated using the guideline model.

Economic modelling results

The results of the base-case economic analysis are provided in Table 40. The table provides the total intervention cost as well as total costs and outcomes (QALYs and secondary outcomes, as relevant) associated with every clinical condition considered in the economic analysis, for 1000 women and their babies. The intervention had better outcomes and resulted in cost-savings across all conditions examined, when added on standard care compared with standard care alone. However, it was costlier overall than its comparator as the cost-savings resulting from provision of the intervention were not adequate to offset the intervention costs. The ICER of the intervention added on standard care compared with standard care alone was £51,946/QALY, which is well above the NICE upper cost-effectiveness threshold of £30,000/QALY, suggesting that the intervention is not cost-effective.

Results of deterministic and probabilistic sensitivity analysis were very similar; the table shows the results of the deterministic analysis as these are directly comparable to the results of the two-way sensitivity analysis. The ICER of the probabilistic analysis was £51,639/QALY.

The results of two-way sensitivity analysis are shown in Table 41, for different combinations of intervention effect and intervention cost. Green cells show combinations for which the intervention is cost-effective, with an ICER below the NICE lower cost-effectiveness threshold of £20,000/QALY. Yellow cells show combinations for which the intervention is not cost-effective, with an ICER above the NICE upper cost-effectiveness threshold of £30,000/QALY. Blue cells show combinations where the ICER is between £20,000-£30,000/QALY. The orange cells show the intervention cost and effect values used in base-case analysis and the base-case ICER.

It can be seen that, as expected, the cost-effectiveness of the intervention improved as its effectiveness increased and its intervention cost decreased. At the base-case relative effect (RR) of 1.19 (for any breastfeeding at 16-26 weeks after birth), the intervention was cost-effective (<£20,000/QALY) if its cost per woman receiving the intervention was approximately £40-£45. On the other hand, at the base-case cost of £84, the intervention was cost-effective if its effectiveness (in terms of breastfeeding rates), when added on standard care, was at least 35%-40% higher than the effectiveness of standard care alone (i.e. if the RR reached 1.35-1.40).

Table 40. Base-case results of the guideline economic analysis: intervention for starting and maintaining breastfeeding (results for 1000 women and their babies)

Parameter		Intervention + SC	SC alone	Difference
Intervention cost		£84,000	£0	£84,000
Gastrointestinal infection in babies	Infections	44.91	47.56	-2.65
	Hospitalisations	14.27	15.55	-1.28
	Costs	£12,469	£13,535	-£1,066
(lower) RTI in babies	Infections	231.01	238.04	-7.02
	Hospitalisations	110.26	117.27	-7.01
	Costs	£129,272	£137,204	-£7,932
Acute otitis media in babies	Infections	133.49	137.70	-4.21
	Costs	£4,993	£5,150	-£157
Mortality in babies	Deaths due to infections	0.11	0.12	-0.01
	Deaths due to SIDS	0.24	0.25	-0.02
	Costs of deaths prevented	-£1		-£1
	QALYs gained	0.16		0.16
Breast cancer in women	New cases	138.35	139.65	-1.29
	QALYs	20,945.72	20,944.63	1.09
	Costs	£7,033,056	£7,043,111	-£10,056
Total difference in QALYs				1.25
Total difference in costs				£64,787
ICER		**£51,946/QALY**		

ICER: incremental cost-effectiveness ratio; RTI: respiratory tract infection; SC: standard care

Table 41. Guideline economic analysis, results of two-way sensitivity analysis: intervention for starting and maintaining breastfeeding

Intervention effect	Intervention cost																
	£20	£25	£30	£35	£40	£45	£50	£55	£60	£65	£70	£75	£80	£84	£90	£95	£100
1.05	£45,852	£61,166	£76,480	£91,795	£107,109	£122,423	£137,737	£153,052	£168,366	£183,680	£198,994	£214,309	£229,623	£241,874	£260,251	£275,566	£290,880
1.10	£15,224	£22,881	£30,538	£38,195	£45,852	£53,509	£61,166	£68,823	£76,480	£84,138	£91,795	£99,452	£107,109	£113,235	£122,423	£130,080	£137,737
1.15	£5,014	£10,119	£15,224	£20,328	£25,433	£30,538	£35,642	£40,747	£45,852	£50,957	£56,061	£61,166	£66,271	£70,355	£76,480	£81,585	£86,690
1.19	£631	£4,640	£8,649	£12,658	£16,667	£20,676	£24,685	£28,694	£32,703	£36,712	£40,721	£44,729	£48,738	£51,946	£56,756	£60,765	£64,774
1.25	dominant	dominant	£2,972	£6,035	£9,098	£12,161	£15,224	£18,286	£21,349	£24,412	£27,475	£30,538	£33,601	£36,051	£39,726	£42,789	£45,852
1.30	dominant	dominant	dominant	£2,462	£5,014	£7,566	£10,119	£12,671	£15,224	£17,776	£20,328	£22,881	£25,433	£27,475	£30,538	£33,090	£35,642
1.35	dominant	dominant	dominant	dominant	£2,097	£4,285	£6,473	£8,660	£10,848	£13,036	£15,224	£17,411	£19,599	£21,349	£23,974	£26,162	£28,350
1.40	dominant	dominant	dominant	dominant	dominant	£1,824	£3,738	£5,652	£7,566	£9,481	£11,395	£13,309	£15,224	£16,755	£19,052	£20,966	£22,881
1.45	dominant	dominant	dominant	dominant	dominant	dominant	£1,611	£3,312	£5,014	£6,716	£8,417	£10,119	£11,820	£13,182	£15,224	£16,925	£18,627
1.50	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£1,441	£2,972	£4,504	£6,035	£7,566	£9,098	£10,323	£12,161	£13,692	£15,224
1.55	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£1,301	£2,694	£4,086	£5,478	£6,870	£7,984	£9,655	£11,047	£12,439
1.60	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£1,185	£2,462	£3,738	£5,014	£6,035	£7,566	£8,843	£10,119
1.65	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£1,087	£2,265	£3,443	£4,386	£5,799	£6,977	£8,155
1.70	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£1,003	£2,097	£2,972	£4,285	£5,379	£6,473
1.75	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£930	£1,747	£2,972	£3,993	£5,014
1.80	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£675	£1,824	£2,781	£3,738
1.85	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£810	£1,711	£2,612
1.90	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£760	£1,611
1.95	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	£715
2.00	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant	dominant

White cells – tested values (x axis – intervention cost; y axis: intervention effect)
Orange cells: intervention cost and effect values used in base-case analysis; results of base-case analysis
Yellow cells: results where ICER > £30,000/QALY;
Blue cells: results where ICER is between £20,000-£30,000/QALY
Green cells: results where ICER < £20,000/QALY; dominant = intervention + standard care is less costly and more effective than standard care alone

Discussion – conclusions, strengths and limitations of economic analysis

The guideline economic analysis assessed the cost-effectiveness of an intervention initiated antenatally or in the first 8 weeks after birth aiming at starting and maintaining breastfeeding. The results of the analysis suggest that adding the intervention on to standard care is not cost-effective, as its ICER when added on to standard care versus standard care alone was £51,946/QALY, which is well above the NICE upper cost-effectiveness threshold of £30,000/QALY. Results of sensitivity analysis suggest that the intervention may become cost-effective if its effectiveness remains the same but its cost is reduced by about 50% (from £84 to around £40-£45 per woman receiving the intervention) or its cost remains the same but its relative effect (RR) versus standard care is improved from 1.19 to 1.35-1.40 (for the outcome of any breastfeeding 16-26 weeks after birth).

It is noted that even a less resource intensive intervention comprising two individual 30-minute sessions provided by a health professional in NHS England AfC Band 5 has a cost of £59, which is higher than the cost of £40-45 that would be required for the intervention to be cost-effective; moreover, according to the guideline meta-regression, such an intervention would have a small and non-significant effect (RR 1.07, 95% CI 0.98 to 1.17, for 2-3 contacts versus standard care). On the other hand, a cost of £40 could be achieved by 4 individual 30-minute sessions provided by a peer supporter, assuming a unit cost of £20 per hour. However, it is not certain whether an intervention delivered exclusively by peer supporters would reach the effectiveness of an intervention led, or at least initiated, by health professionals. Moreover, it is possible that the unit cost of a peer supporter is higher, if childcare costs are taken into account, meaning that an intervention cost as low as £40 may not be achievable even by provision of the intervention by a peer supporter offering 4 individual 30-minute sessions.

In addition, it is noted that the RR of 1.35-1.40 that would be required for the intervention to be cost-effective is above the upper 95% CI of the relative effect used in the base-case analysis (mean RR 1.19, 95% CI 1.10 to 1.30). Therefore, it appears that the intervention needs to be both more effective and less costly than its specification in the economic analysis, for it to be cost-effective within the NICE decision-making context.

The effectiveness of the intervention in improving breastfeeding rates was determined by the guideline systematic review and meta-regression of RCTs and its cost was estimated based on intervention characteristics that were found to improve effectiveness according to the guideline meta-regression (e.g. in terms of format, number of contacts, setting) supplemented with the committee's expert advice on patterns of routine practice regarding postnatal care in the UK. The baseline breastfeeding rates were estimated using national statistical data.

The economic analysis considered a number of long-term benefits and associated cost-savings resulting from improved breastfeeding rates, including a reduction in gastrointestinal infections, respiratory tract infections and acute otitis media in babies aged up to one year, a reduction in babies' mortality due to infectious diseases or SIDS during their first year of life, and a reduction in the incidence of breast cancer in women over lifetime. The economic analysis utilised best quality information: the structure of the economic model was based, for the majority of the assessed outcomes, on a UK modelling study that estimated long-term benefits and cost-savings associated with breastfeeding that was commissioned by UNICEF UK (Renfrew 2012). Effectiveness data on the protective effect of breastfeeding in mothers and babies were mostly derived from a study reporting the results of 28 systematic reviews and meta-analyses that had adjusted for confounders, 22 of which were commissioned by WHO (Victora 2016), which was identified following a systematic review of studies that modelled the long-term benefits and cost-savings associated with breastfeeding, conducted specifically to inform the guideline economic analysis.

Epidemiological data utilised in the model were derived from national statistics and large administrative databases (RCGP database), although it is acknowledged that date derived from the latter were relatively old (2012) due to lack of availability of more recent data. Utility data were estimated based on national UK norms (Kind 1999) and a systematic review and meta-analysis of utility data in women with breast cancer (Peasgood 2010). Cost data were taken from national sources and a large study on 359,771 women with breast cancer in England, which utilised information from national databases (Laudicella 2016). The time horizon of the analysis varied across the clinical conditions modelled, but reached lifetime in conditions where mortality of babies (due to infectious diseases and SIDS) and mothers (breast cancer) and future HRQoL of mothers (breast cancer) were affected.

The analysis considered a range of clinical outcomes in mothers and babies associated with breastfeeding. However, breastfeeding has been found to be associated with several other outcomes that were not possible to consider in the economic model, either due to lack of suitable and/or good quality epidemiological and cost data that would allow robust modelling to be conducted, or due to the complexity or uncertainty of modelling owing to the multifactorial nature of some diseases. For example, breastfeeding has been associated with a reduced risk of diabetes both in mothers and babies and a reduced risk of obesity in babies over their lifetime. It has also been associated with improved cognitive outcomes in babies and reduced incidence of ovarian cancer in mothers (Victora 2016). Furthermore, there is indication that breastfeeding has a protective effect on the development of triple negative breast cancer (John 2018; Ma 2017), which is considered to be more aggressive and have a poorer prognosis compared with other types of breast cancer. These clinical benefits associated with breastfeeding were not captured in the guideline economic analysis, which means that clinical benefits and cost-savings resulting from provision of the breastfeeding intervention may have been underestimated in the analysis.

Moreover, the estimated ICER has only captured benefits expressed in the form of QALYs. Other clinical benefits, including the reduction in the incidence of gastrointestinal infections, respiratory tract infections and acute otitis media in babies were not considered in the estimation of the ICER. On the other hand, the impact of these outcomes on the health-related quality of life of the babies is important but is usually very brief and therefore the QALY gains resulting from a reduction in the incidence of these infections are expected to be negligible. The ICER has also not captured the intangible benefits to parents associated with improved outcomes in babies, in particular the psychological burden avoided by a reduction in mortality due to infectious diseases and SIDS.

The intervention was assumed to be offered in addition to standard care, and therefore the description and cost of standard care was omitted from both arms of the model. If the intervention is expected to be provided as an alternative (and not in addition) to standard care, then its net cost is lower than the figure utilised in the model, and its cost-effectiveness is higher. Furthermore, the intervention is expected to lead to additional cost-savings to the parents, as breastfeeding reduces parents' personal expenses associated with formula feeding, including costs of bottles, formula milk powder or sterilising equipment; these costs were beyond the NHS/PSS perspective of the analysis and therefore were not included in the estimation of total costs.

On the other hand, various clinical data utilised in the model may have overestimated the magnitude of the modelled benefits and associated cost-savings of the breastfeeding intervention:

- The clinical data on the protective effect of breastfeeding on mortality due to infectious diseases and SIDS in babies that were utilised in the model expressed the difference in mortality between babies that were breastfed and those that were never breastfed. However, both the effectiveness of the breastfeeding intervention and the baseline breastfeeding rates that were utilised in the guideline analysis referred to a single time point and reflected the proportions of babies that were or were not breastfed at 4 months;

some of the babies who were not breastfed at 4 months may have been breastfed for shorter time periods (i.e. they are not necessarily babies that have never been breastfed between birth and 4 months), and therefore they may have received the protective effects of breastfeeding on mortality due to infectious diseases and SIDS. This means that the guideline economic analysis has likely overestimated the benefits to babies and associated cost-savings of breastfeeding (and, consequently, of the breastfeeding intervention) regarding the reduction in babies' mortality due to infectious diseases and SIDS. However, as infant mortality from both infectious diseases and SIDS is rare, benefits and cost-savings due to a reduction in mortality resulting from an increase in breastfeeding are very small and thus their overestimation is expected to have been negligible and highly unlikely to have impacted on the results and conclusions of the analysis. One further point to note is that evidence on the association between breastfeeding and mortality from infectious diseases were derived exclusively from low and medium income countries, so findings may not be directly relevant to the population in the UK.

- Similarly, the clinical data on the protective effect of breastfeeding on the incidence of breast cancer utilised in the model expressed the difference in the incidence of breast cancer between parous women that were breastfeeding at 6 months after birth and those who had never breastfed. However, both the effectiveness of the breastfeeding intervention and the baseline breastfeeding rates that were utilised in the guideline analysis referred to a single time point and reflected the proportions of women that were or were not breastfeeding at 6 months; some of the mothers who were not breastfeeding at 6 months may have breastfed for shorter time periods (i.e. they are not necessarily mothers that have never breastfed between birth and 6 months), and therefore they may have received the protective effects of breastfeeding on the incidence of breast cancer. This means that the guideline economic analysis has likely overestimated the benefits and cost-savings of breastfeeding (and, consequently, of the breastfeeding intervention) to mothers regarding the reduction in the incidence of breast cancer. This overestimation is likely significant, given that the clinical benefits (QALYs) and cost-savings from the reduction in the incidence of breast cancer contributed considerably to the estimation of the ICER (QALYs gained due to a reduction in the incidence of breast cancer accounted for 95% of total QALYs gained following provision of the breastfeeding intervention; cost-savings due to a reduction in the incidence of breast cancer accounted for 51% of the total cost-savings following provision of the breastfeeding intervention).
- Further to the above, according to alternative, older high-quality data (Collaborative Group on Hormonal Factors in Breast Cancer, 2002), the impact of any versus no breastfeeding for up to 6 months on breast cancer is very small and non-significant (OR 0.98, 95% CI 0.95 to 1.01), while the impact of any versus no breastfeeding for a duration of 7-18 months is statistically significant but still small (OR 0.94, 95% CI 0.91 to 0.97), and smaller that the estimate reported by Unar-Munguía (2017b) that informed the guideline economic analysis. These data suggest that the guideline economic model may have further overestimated the clinical benefits and associated cost-savings of the breastfeeding intervention, in relation to the reduction in the incidence of breast cancer.

Overall, the data on the protective effect of breastfeeding were derived from study designs that were prone to bias; several studies demonstrating clinical benefits associated with breastfeeding which were included in the evidence reported by Victora (2016) had adjusted for some known confounders; however, it is possible that there are other unknown confounders impacting on the relation between breastfeeding and clinical benefits, which the studies did not adjust for. Moreover, other studies had made no adjustments for confounding. This means that the magnitude of the clinical benefits of breastfeeding may have been overestimated in this literature. Therefore, it is likely that, by using the available data, the economic analysis has overestimated the benefits and associated cost-savings related to breastfeeding.

In conclusion, after taking into account the strengths and the weaknesses of the economic analysis, adding to standard care an intervention for women aiming at starting and/or maintaining breastfeeding, which is initiated antenatally or in the first 8 weeks after birth, does not appear to be cost-effective in the UK.

It needs to be clarified that, as other literature suggests, worldwide, breastfeeding itself is cost-effective as it leads to important clinical benefits to mothers and babies and cost-savings to the health service, parents and the whole society, at no intervention cost (Bartick 2017; Büchner 2007; Colchero 2015; Ma 2013; Rollins 2016; Renfrew 2019; Rollins 2016; Unar-Munguía 2017a; Walters 2019). The guideline economic analysis only demonstrated that the breastfeeding intervention, as specified in the economic analysis, was not cost-effective because the clinical benefits and cost-savings resulting from an increase in breastfeeding rates, although important, were not adequate to outweigh the initial intervention costs. This is because the effectiveness of the intervention in improving breastfeeding rates at 16-26 weeks was relatively small (the mean RR of the intervention added onto standard care versus standard care alone was 1.19), and the baseline incidence of the clinical conditions assessed in the model is rather low in the general population of women and their babies in the UK. Therefore, the additional protective effect of breastfeeding resulting from provision of a breastfeeding intervention has a relatively small impact at a population level: practically, the intervention has an effect only on women (and their babies) who would not be breastfeeding at 4-6 months without the intervention but who would breastfeed, at these time points, following provision of the intervention – using the model input parameters these women were estimated to amount to 8% (4 months) and 6.5% (6 months) of women receiving the intervention, as currently 42% and 34% of women are estimated to be breastfeeding at 4 and 6 months, respectively, anyway, under standard care alone (i.e. without provision of the intervention). This suggests that the cost-effectiveness of the intervention might be improved if it was targeted exclusively to women who do not intend to breastfeed following birth.

Overall conclusion from the guideline economic analysis

The guideline economic analysis suggests that adding to standard care an intervention for women aiming at starting and/or maintaining breastfeeding, which is initiated antenatally or in the first 8 weeks after birth, is unlikely to be cost-effective in the UK.

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Appendix K – Excluded studies

Excluded studies 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)?

Clinical studies

Table 42 Excluded studies and reasons for their exclusion

Study	Reason for exclusion
NCT00222118. Kansas University Teen Mothers Project. clinicaltrials.gov/show/NCT00222118 Date first received: 13 September 2005.	Trial registration
ISRCTN47056748. Successful breastfeeding promotion: a motivational instructional model applied and tested. isrctn.com/ISRCTN47056748 Date first received: 16 July 2007.	Trial registration
NCT00397150. PROMISE EBF: safety and efficacy of exclusive breastfeeding promotion in the era of HIV in sub- Saharan Africa. clinicaltrials.gov/show/NCT00397150 Date first received: 7 November 2006.	Trial registration
ISRCTN37327292. A randomised controlled trial of the effectiveness of support from breastfeeding counsellors for women who want to breastfeed. isrctn.com/ ISRCTN37327292 (date first received 23 January 2014).	Trial registration
NCT01623128. Prenatal education video study (PEVS). clinicaltrials.gov/ct2/show/NCT01623128 Date first received: 15 June 2012	Trial registration
NCT01022788. Improving newborn surviv a l in rural southern Tanzania: a study to evaluate the impact and cost of a scaleable package of interventions at community level with health system strengthening. clinicaltrials.gov/show/ record/NCT01022788 (date first received 29 November 2009).	Trial registration
ISRCTN27207603. Proactive telephone support for breastfeeding women in disadvantaged areas provided by a postnatal ward feeding support team. isrctn.com/ ISRCTN27207603 (date first received June 2010). DOI 10.1186/ISRCTN27207603], 2010	Trial registration
NCT01648114. A randomized controlled trial of an antenatal intervention to increase exclusive breastfeeding (ABFS). clinicaltrials.gov/ct2/show/NCT01648114 Date first received: 18 July 2012.	Trial registration
NCT00619632. Boosting breastfeeding in low-income, multi-ethnic women: a primary care based RCT (BINGO). clinicaltrials.gov/show/NCT00619632 Date first received: 1 February 2008.	Trial registration
Abolyan,L.V., The breastfeeding support and promotion in Baby-Friendly Maternity Hospitals and Not-as-Yet Baby-Friendly Hospitals in Russia, Breastfeeding Medicine: The Official Journal of the Academy of Breastfeeding Medicine, 1, 71-78, 2006	Study conducted in Russia

Study	Reason for exclusion
Aidam BA, Perez-Escamilla R, Lartey A. , Lactation counseling increases exclusive breastfeeding rates in Ghana., Journal of Nutrition 2005;135(7):1691â□“5., 2005	Study conducted in Ghana
Akram, D. S., Agboatwalla, M., Shamshad, S., Effect of intervention on promotion of exclusive breast feeding, JPMA - Journal of the Pakistan Medical Association, 47, 46-8, 1997	Study conducted in India
Aksu H, Kucuk M, Duzgun G. , The effect of postnatal breastfeeding education/support offered at home 3 days after delivery on breastfeeding duration and knowledge: a randomized trial., Journal of Maternal-Fetal and Neonatal Medicine , 24, 354â□“61, 2011	Study conducted in Turkey
Albernaz E, Victora C. , Impact of face-to-face counselling on duration of exclusive breastfeeding: a review. , Pan American Journal of Public Health 2003;14(1):17â□“24., 2003	Study conducted in Brazil
Albernaz E, Victora CG, Haisma H, Wright A, Coward WA. , Lactation counseling increases breast-feeding duration but not breast milk intake as measured by isotopic methods. , Journal of Nutrition 2003;133(1):205â□“10., 2003	Study conducted in Brazil
Anonymous,, Obesity and breastfeeding--a review of the evidence, The practising midwife, 13, 36-38, 2010	Literature review
Arlotti, J. P., Cottrell, B. H., Lee, S. H., Curtin, J. J., Breastfeeding among low-income women with and without peer support, Journal of Community Health Nursing, 15, 163-178, 1998	Not an RCT
Ashman, A. M., Brown, L. J., Collins, C. E., Rollo, M. E., Rae, K. M., Factors Associated with Effective Nutrition Interventions for Pregnant Indigenous Women: A Systematic Review, Journal of the Academy of Nutrition and Dietetics, 117, 1222-1253, 2017	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included
Baerug, A., Langsrud, O., Loland, B. F., Tufte, E., Tylleskar, T., Fretheim, A., Effectiveness of Baby-friendly community health services on exclusive breastfeeding and maternal satisfaction: a pragmatic trial, Maternal and Child Nutrition, 12, 428-439, 2016	Not an RCT
Balogun, O. O, O'Sullivan, E. J, McFadden, A, Ota, E, Gavine, A, Garner, C. D, Renfrew, M. J, MacGillivray, S., Interventions for promoting the initiation of breastfeeding, Cochrane Database of Systematic Reviews, 2016	Cochrane systematic review - used to identify studies for this review
Balogun, O. O., Dagvadorj, A., Yourkavitch, J., da Silva Lopes, K., Suto, M., Takemoto, Y., Mori, R., Rayco-Solon, P., Ota, E., Health Facility Staff Training for Improving Breastfeeding Outcome: A Systematic Review for Step 2 of the Baby-Friendly Hospital Initiative, Breastfeeding Medicine: The Official Journal of the Academy of Breastfeeding Medicine, 12, 537-546, 2017	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Barlow,A., Mullany,B., Neault,N., Compton,S., Carter,A., Hastings,R., Billy,T., Coho-Mescal,V., Lorenzo,S., Walkup,J.T., Effect of a paraprofessional home-visiting intervention on American Indian teen woman and infants' behavioral risks: a randomized controlled trial, American Journal of Psychiatry, 170, 83-93, 2013	Not relevant intervention
Barros FC, Halpern R, Victora CG, Teixera AM, Beria J., A randomised intervention study to increase breastfeeding prevalence in southern Brazil., Revista de Saud e Publica , 28, 277-83, 1994	Study conducted in Brazil
Bashour HN, Kharouf MH, Abdulsalam AA , El Asmar K, Tabbaa MA, Cheikha SA., Effect of postnatal home visits on maternal/infant	Study conducted in Syria

Study	Reason for exclusion
outcomes in Syria: a randomized controlled trial., Public Health Nursing 2008;25(2):115âå,¬25., 2008	
Beake, S., Bick, D., Narracott, C., Chang, Y. S., Interventions for women who have a caesarean birth to increase uptake and duration of breastfeeding: A systematic review, Maternal and Child Nutrition, 13 (4) (no pagination), 2017	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Bechara Coutinho S, Cabral de L ira P, de Carvalho Lima M, Ashworth A., Comparison of the effects of two systems for the promotion of exclusive breastfeeding., Lancet 2005; 366:1094âå,¬100., 2005	Study conducted in Brazil
Beiler JS, Schaefer EW, Alleman N, Paul IM., Newborn anticipatory guidance delivered at office-based vs. home nurse visits., Pediatric Academic Societies and Asian Society for Pediatric Research Joint Meeting; 2011 April 30-May 3; Denver, Colorado, USA. 2011., 2011	Conference abstract
Benitez I, de la Cruz J, Suplido A, Oblepias V, Kennedy K, Visness C. , Extending lactational amenorrhoea in Manila: a successful breast-feeding education programme. , Journal of Biosocial Science, 24(2):211â□“31., 1992	Study conducted in the Philippines
Berlepsch-Schreiner, H., Jeitziner, M. M., Jähnke, A., Bischofberger, I., A micro-education programme for breastfeeding women: a pilot study to investigate the educations' effect on injured and painful nipples, Pflege, 25, 343â€• 351, 2012	Language - study not written in English.
Bhandari N, Bahl R, Mazumdar S, Martines J, Black RE , Bhan MK, et al., Effect of community-based promotion of exclusive breastfeeding on diarrhoeal illness and growth: a cluster randomised controlled trial, Lancet 2003;361: 1418â□“23., 2003	Study conducted in India
Bhandari, N., Bahl, R., Mazumdar, S., Martines, J., Black, R. E., Bhan, M. K., Effect of community-based promotion of exclusive breastfeeding on diarrhoeal illness and growth: A cluster randomised controlled trial, Lancet, 361, 1418-1423, 2003	Study conducted in India
Bliss, M. C., Wilkie, J., Acredolo, C., Berman, S., Tebb, K. P., The effect of discharge pack formula and breast pumps on breastfeeding duration and choice of infant feeding method, BirthBirth (Berkeley, Calif.), 24, 90-7, 1997	No relevant intervention
Bolam A, Manandhar DS, Shrestha P, Ellis M, Costello AM. , The effects of postnatal health education for mothers on infant care and family planning practices in Nepal: a randomised controlled trial. , BMJ, 316(7134):805â□“11., 1998	Study conducted in Nepal
Bonuck K, Stuebe A, Barnett J, Fletcher J, Bernstein P. , Routine, primary-care based interventions to increase breastfeeding: results of two randomized controlled trials. , Breastfeeding Medicine 2013;8(Suppl 1):Sâ□“19., 2013	Conference abstract
Bortolini GA, Vitolo MR. , The impact of systematic dietary counseling during the first year of life on prevalence rates of anemia and iron deficiency at 12-16 months., Jornal de Pediatria 2012;88(1):33â□“9., 2012	Study conducted in Brazil
Boulvain,M., Perneger,T.V., Othenin-Girard,V., Petrou,S., Berner,M., Irion,O., Home-based versus hospital-based postnatal care: A randomised trial, BJOG: An International Journal of Obstetrics and Gynaecology, 111, 807-813, 2004	Included in the review on length of postpartum stay

Study	Reason for exclusion
Britton,C., McCormick,F.M., Renfrew,M.J., Wade,A., King,S.E., Support for breastfeeding mothers, Cochrane Database of Systematic Reviews, 2007. Article Number, -, 2007	Cochrane review that has since been updated
Brockway, M., Benzies, K., Hayden, K. A., Interventions to Improve Breastfeeding Self-Efficacy and Resultant Breastfeeding Rates: A Systematic Review and Meta-Analysis, Journal of Human Lactation, 33, 486-499, 2017	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Buccini, G. D. S., Perez-Escamilla, R., Paulino, L. M., Araujo, C. L., Venancio, S. I., Pacifier use and interruption of exclusive breastfeeding: Systematic review and meta-analysis, Maternal and Child Nutrition, 13 (3) (no pagination), 2017	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Bunik M , Beaty B, Dickinson M, Shobe P, Kempe A, Oâå,¬â„¢Connor ME., Early formula supplementation in breastfeeding mothers: how much is too much for BF duration success?, Breastfeeding Medicine , 2, 184, 2007	Conference abstract
Bunik M, Shobe P, Crane L, Kempe A., Low-income Latina woman perspectives on breastfeeding issues and participation in a telephone based support intervention., Breastfeeding Medicine, 2, 184, 2007	Conference abstract
Bunik M, Shobe P, O'Connor ME, Beaty B, Langendoerfer S, Crane L, et al., Telephone support intervention for breastfeeding in low-income Latina mothers, Pediatric Academic Societies Annual Meeting; 2007 May 5-8; Toronto, Canada. 2007, 2007	Conference abstract
Bunik M, Shobe P, O'Connor ME, Beaty B, Langendoerfer S, Crane L, et al., Randomized controlled trial to evaluate a telephone support intervention for breastfeeding in low-income Latina mothers., Breastfeeding Medicine , 2, 183, 2007	Conference abstract
Bunik,, Telephone Support Intervention for Breastfeeding in Low-Income Latina Mothers, Pediatric academic society, http://www.abstracts2view.com/pas/, 2007	Conference abstract
Bunik, M., Clark, L., Zimmer, L. M., Jimenez, L. M., O'Connor, M. E., Crane, L. A., Kempe, A., Early infant feeding decisions in low-income Latinas, Breastfeeding medicine : the official journal of the Academy of Breastfeeding Medicine, 1, 225-235, 2006	Study design - qualitative
Bunik, M., Shobe, P., Crane, L., Kempe, A., Low-income Latina woman perspectives on breastfeeding issues and participation in a telephone based support intervention, Breastfeeding Medicine, 2, 184, 2007	Conference abstract
Bunik, M., Shobe, P., O'Connor, M. E., Beaty, B., Langendoerfer, S., Crane, L., Randomized controlled trial to evaluate a telephone support intervention for breastfeeding in low-income Latina mothers, Breastfeeding Medicine, 2, 183, 2007	Conference abstract
Caldeira AP, Fagundes GC, de Aguiar GN., Educational intervention on breastfeeding promotion to the Family Health Program team [Intervencao educacional em equipes de Programa de Saude de Familia para promocao da amamentacao]., Revista de Saud e Publica , 42, 1027-33, 2008	Study conducted in Brazil
Cameron S L, Heath AM, Gray AR, Churcher B, Davies RS, Newlands A, et al. , Lactation consultant support from late pregnancy with an educational intervention at 4 months of age delays the introduction of complementary foods in a randomized controlled trial., 2015	No relevant outcomes

Study	Reason for exclusion
Cameron SL, Taylor RW, Gray AR, Taylor BJ, Heath AL. , Exclusive breastfeeding to six months: Results from a randomised controlled trial including lactation consultant support. , FASEB Journal, 27, [Abstract no: lb345]., 2013	Conference abstract
Cattaneo A, Buzzetti R. Effect on rates of breast feeding, Effect on rates of breast feeding of training for the Baby Friendly Hospital Initiative. , BMJ, 323(7325):1358â□“62. , 2001	Not an RCT
Centuori, S., Burmaz, T., Ronfani, L., Fragiacomo, M., Quintero, S., Pavan, C., Davanzo, R., Cattaneo, A., Nipple care, sore nipples, and breastfeeding: a randomized trial, Journal of human lactation : official journal of International Lactation Consultant Association, 15, 125-130, 1999	No relevant intervention
Chapman D, Damio G, Young S, Perez-Escamilla R. , Association of degree and timing of exposure to breastfeeding peer counseling services with breastfeeding duration. , Advances in Experimental Medicine and Biology , 554, 306-6, 2004	Not an RCT
Chapman DJ, Bermudez-Millan A, Wetzel K, Damio G, Kyer N, Young S, et al. , Breastfeeding education and support trial for obese women. , FASEB 2008;22:1080.4, 2008	Conference abstract
Chapman DJ, Perez-Escamilla R. , Acculturative type is associated with breastfeeding duration among low-income Latinas. , Maternal and Child Nutrition 2013;9(2):188â□“98., 2013	No relevant comparison
Chapman, D. J., Morel, K., Bermudez-Millan, A., Young, S., Damio, G., Kyer, N., Breastfeeding education and support trial for obese women: effects of a specialized peer counseling intervention on breastfeeding and health outcomes, Journal of Human Lactation, 27, 75â€• 76, 2011	Conference abstract
Chapman, D. J., Young, S., Ferris, A. M., Perez-Escamilla, R., Impact of breast pumping on lactogenesis stage II after cesarean delivery: a randomized clinical trial, Pediatrics, 107, E94, 2001	No relevant intervention
Chapman,D.J., Perez-Escamilla,R., Breastfeeding among minority women: moving from risk factors to interventions, Advances in Nutrition, 3, 95-104, 2012	Literature review
Chertok,I.R., Breast-feeding initiation among post-Caesarean women of the Negev, Israel, British Journal of Nursing, 15, 205-208, 2006	Not an RCT
Chola L, Fadnes LT, Engebretsen IM, Nkonki L, Nankabirwa V, Sommerfelt H, et al. , Cost-effectiveness of peer counselling for the promotion of exclusive breastfeeding in Uganda., PLOS One 2015;10(11):e0142718., 2015	Study conducted in Uganda
Chola L, Fadnes LT, Engebretsen IM, Tumwine JK, Tylleskar T, Robberstad B, et al., Infant feeding survival and Markov transition probabilities among children under age 6 months in Uganda. , American Journal of Epidemiology, 177, 453â□“62, 2013	Study conducted in Uganda
Christie J, Bunting B., The effect of health visitors' postpartum home visit frequency on first-time mothers: cluster randomised trial., 48, 689-702, 2011	No relevant intervention
Cleveland, L., Hill, C. M., Pulse, W. S., DiCioccio, H. C., Field, T., White-Traut, R., Systematic Review of Skin-to-Skin Care for Full-Term, Healthy Newborns, Journal of obstetric, gynecologic, and neonatal nursing : JOGNN, 46, 857-869, 2017	No relevant intervention
Coca, K. P., Pinto, V. L., Westphal, F., Mania, P. N. A., De Vilhena Abrao, A. C. F., Bundle of measures to support intrahospital exclusive breastfeeding: Evidence of systematic reviews, Revista Paulista de Pediatria, 36, 214-220, 2018	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary

Study	Reason for exclusion
	studies were included rather than the review
Collins CT, Ryan P, Crowther CA, McPhee AJ, Paterson S, Hiller JE., Effect of bottles, cups, and dummies on breast feeding in preterm infants: a randomised controlled trial. , BMJ 2004;329(7459):193â□“8., 2004	No relevant population
Collins, C. T., Does the use of artificial teats (dummy or bottle) affect breast feeding success in preterm infants? A randomised controlled trial and systematic review, PHD thesis. The university of adelaide., 2004	Dissertation
Coombs DW, Reynolds K, Joyner G, Blankson M., A self-help program to increase breastfeeding among low-income women., 1998	No relevant outcomes
Crossland, N., Thomson, G., Morgan, H., Dombrowski, S. U., Hoddinott, P., Bibs study team, Incentives for breastfeeding and for smoking cessation in pregnancy: an exploration of types and meanings, Social Science & Medicine, 128, 10-7, 2015	Not an RCT
de Jesus, P. C., de Oliveira, M. I., Fonseca, S. C., Impact of health professional training in breastfeeding on their knowledge, skills, and hospital practices: a systematic review, Jornal de Pediatria, 92, 436-50, 2016	Systematic review, all included studies were screened - none were relevant to this review
de Oliveira LD, Giugliani ER, do Espirito Santo LC, Franca MC, Weigert EM, Kohler CV, et al. , Effect of intervention to improve breastfeeding technique on the frequency of exclusive breastfeeding and lactation-related problems. , Journal of Human Lactation 2006;22(3):315â□“21., 2006	Study conducted in Brazil
Dennis CL. , A Randomized Controlled Trial Evaluating the Effect of Peer (Mother-to-Mother) Support on Breastfeeding Duration Among Primiparous Women, 1999	Thesis
Dennis, C. L., Breastfeeding peer support: maternal and volunteer perceptions from a randomized controlled trial, Birth, 29, 169-76, 2002	No relevant outcomes
Dennis, C. L., Kingston, D., A systematic review of telephone support for women during pregnancy and the early postpartum period, JOGNN - Journal of Obstetric, Gynecologic, & Neonatal Nursing, 37, 301-14, 2008	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Di Meglio GD, McDermott MP, Klein JD., A randomized controlled trial of telephone peer support's influence on breastfeeding duration in adolescent mothers., Breastfeeding Medicine, 5, 41-7, 2010	No relevant outcomes
Di Napoli A, Di L a llo D, Fortes C, Franceschelli C, Armeni E, Guasticchi G. , Home breastfeeding support by health professionals: findings of a randomised controlled trial in a population of Italian women. , Acta Paediatrica , 93, 1108â□“14, 2004	No relevant outcomes
Dias de Oliveira, L., Justo Giugliani, E. R., Cordova do Espirito Santo, L., Meirelles Nunes, L., Counselling sessions increased duration of exclusive breastfeeding: a randomized clinical trial with adolescent mothers and grandmothers, Nutrition Journal, 13, 73, 2014	Study conducted in Brazil
Doherty T, Sanders D, Jackson D, Swanevelder S, Lombard C, Zembe W, et al. , Early cessation of breastfeeding amongst women in South Africa: an area needing urgent attention to improve child health. , BMC Pediatrics , 12, 105, 2012	Study conducted in South Africa

Study	Reason for exclusion
Dyson, L., McCormick, F., Renfrew, M. J., Interventions for promoting the initiation of breastfeeding, Cochrane Database of Systematic Reviews, CD001688, 2005	Cochrane review that has since been updated
Edwards, R. A., Bickmore, T., Jenkins, L., Foley, M., Manjourides, J., Use of an interactive computer agent to support breastfeeding, Maternal and Child Health Journal, 17, 1961-1968, 2013	No relevant outcomes
Ehrlich SF, Hedderson MM, Feng J, Crites Y, Quesenberry CP, Ferrara A. , Lifestyle intervention improves postpartum fasting glucose levels in women with gestational diabetes. , Diabetes, 63(Suppl 1):A95, Abstract no: 363-OR. , 2014	Conference abstract
Eksioglu, A., Yesil, Y., Demir Gungor, D., Ceber Turfan, E., The Effects of Different Breastfeeding Training Techniques Given for Primiparous Mothers before Discharge on the Incidence of Cracked Nipples, Breastfeeding Medicine, 12, 311-315, 2017	This study was conducted in Turkey
Ekstrom A, Nissen E., A mother's feelings for her infant are strengthened by excellent breastfeeding counseling and continuity of care., Pediatrics , 118, e309-14, 2006	No relevant outcomes
Ekstrom, A. C., Thorstensson, S., Nurses and midwives professional support increases with improved attitudes - design and effects of a longitudinal randomized controlled process-oriented intervention, BMC Pregnancy and Childbirth, 15 (1) (no pagination), 2015	No relevant outcomes
Ekstrom, A., Abrahamsson, H., Eriksson, R. M., Martensson, B. L., Women's use of nipple shields-Their influence on breastfeeding duration after a process-oriented education for health professionals, Breastfeeding Medicine: The Official Journal of the Academy of Breastfeeding Medicine, 9, 458-66, 2014	No relevant outcomes
Ekstrom, A., Widstrom, A. M., Nissen, E., Process-oriented training in breastfeeding alters attitudes to breastfeeding in health professionals, Scandinavian journal of public health, 33, 424-431, 2005	No relevant outcomes
Engebretsen I, Nankunda J, Nankabirwa V, Diallo A, Fadnes L, Doher ty T, et al. , Early infant feeding practices in the Promise-EBF trial: promotion of exclusive breastfeeding by peer counsellors in three countries in Africa., Annals of Nutrition & Metabolism 2013;63(Suppl 1):709, Abstract no: PO940., 2013	Conference abstract
Engebretsen IM , Jackson D, Fadnes LT, Nankabirwa V, Diallo AH , Doher ty T, et al. , Growth effects of exclusive breastfeeding promotion by peer counsellors in sub-Saharan Africa: the cluster-randomised PROMISE EBF trial. , BMC Public Health 2014;14(1):633., 2014	Study conducted in Burkina Faso, Uganda and South Africa
Engebretsen IM, Jackson D, Fadnes LT, Nankabirwa V, Diallo AH , Doherty T, et al., Is promotion of exclusive breastfeeding safe in sub-Sharan Africa with respect to child growth? Results from the cluster-randomised PROMISE EBF-trial., Proceedings of the 16th ISRHML Conference â€• Breastfeeding and the Use of Human Milk. Science and Practiceâ□œ; 2012 September 27-October 1; Trieste, Italy. 2012., 2012	Conference abstract
Engebretsen IMS, Nankabirwa V, Doher ty T, Diallo AH, Nankunda J, Fadnes LT, et a l. , Early infant feeding practices in three African countries: the PROMISE-EBF trial promoting exclusive breastfeeding by peer counsellors. , International Breastfeeding Journal , 9, 19, 2014	Study conducted in Burkina Faso, Uganda and South Africa
Ericson, J., Eriksson, M., Hellstrom-Westas, L., Hoddinott, P., Flacking, R., Proactive telephone support provided to breastfeeding mothers of preterm infants after discharge: a randomised controlled trial, Acta Paediatrica, 06, 06, 2018	Not relevant population

Study	Reason for exclusion
Ericson, J., Eriksson, M., Hoddinott, P., Hellstrom-Westas, L., Flacking, R., Breastfeeding and risk for ceasing in mothers of preterm infants-Long-term follow-up, Maternal and Child Nutrition., 2018	Not relevant population
Fallon, A. B., Hegney, D., O'Brien, M., Brodribb, W., Crepinsek, M., Doolan, J., An evaluation of a telephone-based postnatal support intervention for infant feeding in a regional Australian city, Birth (Berkeley, Calif.), 32, 291-298, 2005	Not an RCT
Fangupo LJ, Heath A M, Williams SM , Somerville MR, Lawrence JA, Gray AR, et al, Impact of an early-life intervention on the nutrition behaviors of 2-y-old children: A randomized controlled trial. , American Journal of Clinical Nutrition 2015;102(3):704â□“12., 2015	No relevant outcomes
Feferbaum, R., Interventions for promoting the initiation of breastfeeding, Sao Paulo Medical Journal = Revista Paulista de Medicina, 132, 68, 2014	Study Design - commentary to a Cochrane review
Finch M, Yoong SL, Thomson RJ, Seward K, Cooney M, Jones J, et al. , A pragmatic randomised controlled trial of an implementation intervention to increase healthy eating and physical activity-promoting policies, and practices in centre-based childcare services: study protocol. , BMJ Open, 5(5):e006706., 2015	Study protocol
Flaherman, V., Aby, J., Burgos, A., Lee, K., Cabana, M., Newman, T., Randomized Trial of Early Limited Formula To Reduce Formula Use at 1 Week and Promote Breastfeeding at 3 Months in Infants with High Early Weight Loss, Pediatric Academic Societies Annual Meeting, 2012	Conference abstract
Flax V, Negerie M, Usman A, Leatherman S, Daza E, Bentley M., Nigerian women participating in an integrated microcredit and mhealth breastfeeding promotion intervention were more likely to adopt international breastfeeding recommendations., Annals of Nutrition & Metabolism 2013;63(Suppl 1):885, Abstract no: PO1294., 2013	Conference abstract
Flax VL, Negerie M, Ibrahim AU, Leatherman S, Daza EJ, Bentley ME., Integrating group counseling, cell phone messaging, and participant-generated songs and dramas into a microcredit program increases Nigerian women's adherence to international breastfeeding recommendations., Journal of Nutrition, 144, 1120-4, 2014	Study conducted in Nigeria
Flohr, C., John Henderson, A., Kramer, M. S., Patel, R., Thompson, J., Rifas-Shiman, S. L., Yang, S., Vilchuck, K., Bogdanovich, N., Hameza, M., Martin, R. M., Oken, E., Effect of an intervention to promote breastfeeding on asthma, lung function, and atopic eczema at age 16 years follow-up of the probit randomized trial, JAMA Pediatrics, 172, 2018	This study was conducted in Belarus
Forster D, McLachlan H, L umley J, Beanland C, Waldenstrom U, Harris H, et al., A BFAB. Attachment to the breast and family attitudes to breastfeeding. The effect of breastfeeding education in the middle of pregnancy on the initiation and duration of breastfeeding: a randomised controlled trial., BMC Pregnancy Childbirth 2003;3:5., 2003	Description of study protocol
Forster D, Mclachlan H., Supporting breastfeeding in local communities (SILC): a cluster randomised controlled trial in Victoria, Australia., International Confederation of Midwives 30th Triennial Congress. Midwives: Improving Womenâ□™s Health; 2014 June 1-4; Prague, Czech Republic. 2014:C138., 2014	Conference abstract
Forster DA, McLachan HL , Lumley J. , Factors associated with breastfeeding at six months pos tpartum in a group of Australian women. , International Breastfeeding Journal 2006; 1:18., 2006	No relevant comparison
Forster DA, McLachlan HL, Lumley J, Beanland CJ, Waldenstrom U, Short RV, et al., ABFAB: attachment to the breast and family attitudes towards breastfeeding. The effect of breastfeeding education in the	Conference abstract

Study	Reason for exclusion
middle of pregnancy on the duration of breastfeeding: a randomised controlled trial. [abstract]., Perinatal Society of Australia and New Zealand 7th Annual Congress; 2003 March 9-12; Tasmania, Australia. 2003:A70., 2003	
Forster DA, McLachlan HL, Lumley J., Risk factors for early cessation of breastfeeding: results from a randomised controlled trial., Perinatal Society of Australia and New Zealand 10th Annual Congress; 2006 April 3-6; Perth, Australia. 2006:149., 2006	Conference abstract
Forster, D, McLardie-Hore, F, McLachlan, H, Davey, Ma, Amir, Lh, Gold, L, Mortensen, K, Moorhead, Am, Grimes, H, Shaifei, T, Ringing up about breastfeeding: a random controlled trial exploring early telephone peer support for breastfeeding (RUBY) â□“ primary outcomes, Women and Birth, 30, 8, 2018	Conference abstract
Franco-Antonio, C., Calderon-Garcia, J. F., Vilar-Lopez, R., Portillo-Santamaria, M., Navas-Perez, J. F., Cordovilla-Guardia, S., A randomized controlled trial to evaluate the effectiveness of a brief motivational intervention to improve exclusive breastfeeding rates: Study protocol, Journal of advanced nursing, 75, 888-897, 2019	Study design - protocol
Frank DA, Wirtz SJ, Sorensen JR, Heeren T., Commercial hospital discharge packs and breastfeeding counseling: effects on infant feeding practices in a randomized trial., Pediatrics 1987;80(6):845â□“54., 1987	Publication date pre-1995
Frick D, Pugh C, Milligan A. , Costs related to promoting breastfeeding among urban low-income women., JOGNN: Journal of Obstetric, Gynecologic & Neonata l Nursing 2012; 41(1):144â□“51., 41, 144-51, 2012	No relevant outcomes
Froozani MD, Permehzadeh K, Motlagh AR, Golestan B., Effect of breastfeeding education on the feeding pattern and health of infants in their first 4 months in the Islamic Republic of Iran. , Bulletin of the World Health Organizati on 1999;77 (5):381â□“5., 1999	Study conducted in Iran
Furman, L. M., Dickinson, C., Community health workers: Collaborating to support breastfeeding among high-risk inner-city mothers, Breastfeeding Medicine, 8, 73-78, 2013	Study design - qualitative review
Galipeau, R., Baillot, A., Trottier, A., Lemire, L., Effectiveness of interventions on breastfeeding self-efficacy and perceived insufficient milk supply: A systematic review and meta-analysis, Maternal and Child Nutrition, 14 (3) (no pagination), 2018	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Gallegos, D., Russell-Bennett, R., Previte, J., Parkinson, J., Can a text message a week improve breastfeeding?, BMC Pregnancy and Childbirth, 14, 374, 2014	Not an RCT
Garcia-Montrone, V. V., Rose, J. C., [An education experience for promoting breast-feeding and infant stimulation by low-income women: a preliminary study], Cad Saude Publica Cadernos de saude publica, 12, 61-68, 1996	Language
Gavine, A, MacGillivray, S, Renfrew, M. J, Siebelt, L, Haggi, H, McFadden, A., Education and training of healthcare staff in the knowledge, attitudes and skills needed to work effectively with breastfeeding women: a systematic review, International Breastfeeding Journal, 12, 6, 2016	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review

Study	Reason for exclusion
Giglia, R., Binns, C., The effectiveness of the internet in improving breastfeeding outcomes: a systematic review, Journal of Human Lactation, 30, 156-60, 2014	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Giglia, R., Cox, K., Zhao, Y., Binns, C. W., Exclusive breastfeeding increased by an internet intervention, Breastfeeding Medicine, 10, 20-25, 2015	No relevant outcomes
Gijsbers B, Mesters I, Knottnerus JA, Kester AD, Van Schayck CP. , The success of an educational program to promote exclusive breastfeeding for 6 months in families with a history of asthma: a randomized controlled trial, Pediatric Asthma, 19, 214â□“22, 2006	No relevant outcomes
Gill, S. L., Reifsnider, E., Lucke, J. F., Effects of support on the initiation and duration of breastfeeding, Western journal of nursing research, 29, 708-723, 2007	Not an RCT
Girish M, Mujawar N, Gotmare P, Paul N, Punia S, Pandey P. , Impact and feasibility of breast crawl in a tertiary care hospital., Journal of Perinatology, 33(4):288â□“91. , 2013	Study conducted in India
Grossman LK, Harter C, Kay A. , The effect of postpartum lactation counseling on the duration of breastfeeding in low-income women. , American Journal of Diseases in Childhood 1990;14 4(4):471â□“4., 1990	Publication date pre-1995
Grossman LK, Harter C, Kay A. , Postpartum lactation counseling for low-income women., 1987	Publication date pre-1995
Guise, J. M., Evidence is not yet clear on impact of pacifiers on breastfeeding, Journal of Pediatrics, 155, 449-450, 2009	Conference abstract
Haider R, Ashworth A, Kabir I, Huttly S. , Effects of community-based peer counsellors on exclusive breastfeeding practices in Dhaka, Bangladesh: a randomised controlled trial. , Lancet 2000;356:1643â□“7., 2000	Study conducted in Bangladesh
Haider R, Kabir I, Huttley SRA, Ashworth A. , Training peer counselors to promote and support exclusive breastfeeding in Bangladesh., Journal of Human Lactation 2002;18 (1):7-12., 2002	Study conducted in Bangladesh
Hall JM. , Influencing breastfeeding success. , Journal of Obstetric , Gynecologic and Neonatal Nursing 1978;7: 28â□“32., 1978	Publication date pre-1995
HanafiMI, Shalaby SA, Falatah N, El-Ammari H., Impact of health education on knowledge of, attitude to and practice of breastfeeding among women attending primary health care centres in Almadinah Almunawwarah, Kingdom of Saudi Arabia: controlled pre-post study., Journal of Taibah University Medical Sciences, 9(3):187âå¬93., 2014	No relevant outcomes
Hannula, L. S., Kaunonen, M. E., Puukka, P. J., A study to promote breast feeding in the Helsinki Metropolitan area in Finland, Midwifery, 30, 696-704, 2014	Not an RCT
Hanson C, Manzi F, Mkumbo E, Shirima K, Penfold S, Hill Z, et al. , Effectiveness of a home-based counselling strategy on neonatal care and survival: a cluster-randomised trial in six districts of rural Southern Tanzania, PLOS Medicine , 12, e1001881, 2015	Study conducted in Tanzania
Harari N, Rosenthal MS, Griswold M, Goeschel L, Bozzi V, Fenick AM, et al., Impact of a text message intervention used as an adjunct tool by WIC breastfeeding counselors: the LATCH project., Pediatric Academic Societies and Asian Society for Pediatric Research Joint Meeting, Vancouver, Canada. 2014:Abstract no: 2195.6., 2014	Conference abstract

Study	Reason for exclusion
Haroon, S., Das, J. K., Salam, R. A., Imdad, A., Bhutta, Z. A., Breastfeeding promotion interventions and breastfeeding practices: a systematic review, BMC public health, 13, S20, 2013	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Hauck YL, Dimmock JE. , Evaluation of an information booklet on breastfeeding duration: a clinical trial. , Journal of Advanced Nursing, 20(5):836â□“43. , 1994	Publication date pre-1995
Hauck,Y., Hall,W.A., Jones,C., Prevalence, self-efficacy and perceptions of conflicting advice and self-management: effects of a breastfeeding journal, Journal of Advanced Nursing, 57, 306-317, 2007	Not an RCT
Hayes, D. K., Prince, C. B., Espinueva, V., Fuddy, L. J., Li, R., Grummer-Strawn, L. M., Comparison of manual and electric breast pumps among WIC women returning to work or school in Hawaii, Breastfeeding medicine : the official journal of the Academy of Breastfeeding Medicine, 3, 3-10, 2008	No relevant comparison
Hill PD. , Effects of education on breastfeeding success., Maternal-Child Nursing Journal 1987;16(2):145â□“6., 1987	Publication date pre-1995
Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L., Process evaluation for the Feeding Support Team (FEST) randomised controlled feasibility trial of proactive and reactive telephone support for breastfeeding women living in disadvantaged areas. , BMJ Open 2012;2(2):e001039., 2012	No relevant outcomes
Hoddinott P. , A randomised controlled trial to evaluate the clinical and cost effectiveness of breastfeeding peer support groups in improving breastfeeding initiation, duration and satisfaction., www.nrr.nhs.uk (accessed 13 Aug 2007).	Unavailable
Hoddinott P., A randomised controlled trial to evaluate the clinical and cost effectiveness of breastfeeding peer support groups in improving breastfeeding initiation, duration and satisfaction. National Research Register (www.nrr.nhs.uk) (accessed 6 July 2006) 2006.	Clinical trial citation
Hopkinson J, Konefal Gallagher M. , Assignment to a hospital-based breastfeeding clinic and exclusive breastfeeding among immigrant Hispanic mothers: a randomized, controlled trial. , Journal of Human Lactation, 25, 287â□“96, 2009	No relevant outcomes
Howard, C. R., Howard, F. M., Lanphear, B., Eberly, S., DeBlieck, E. A., Oakes, D., Lawrence, R. A., Randomized clinical trial of pacifier use and bottle-feeding or cupfeeding and their effect on breastfeeding, Pediatrics, 111, 511-518, 2003	No relevant outcomes
Howell EA, Bodnar-Deren S, Balbierz A, Parides M, Bickell N. , An intervention to extend breastfeeding among black and Latina mothers after delivery., American Journal of Obstetrics & Gynecology , 210, e1â□“5, 2014	No relevant intervention
Huang, M. Z., Kuo, S. C., Avery, M. D., Chen, W., Lin, K. C., Gau, M. L., Evaluating effects of a prenatal web-based breastfeeding education programme in Taiwan, Journal of Clinical Nursing, 16, 1571-1579, 2007	Not an RCT
Ickovics JR, Earnshaw V, Lewis JB, Kershaw TS, Magriples U, Stas ko E, et al., Cluster randomized controlled trial of group prenatal care: perinatal outcomes among adolescents in New York City health centers., American Journal of Public Health 2016;106(2):359âå,¬65., 2016	No relevant intervention

Study	Reason for exclusion
Ickovics JR, Kershaw TS, Westdahl C, Magriples U, Massey Z, Reynolds H, et al., Group prenatal care and perinatal outcomes: a randomized controlled trial. , Obstetrics and Gynecology 2007;110(2 Pt 1):15., 2007	No relevant intervention
Inch S, Law S,Wallace L., Hands off! The breastfeeding best start project (2). , Practising Midwife, 6(11):24â□“5., 2003	No relevant outcomes
Isselmann KF, Collins B, McCoy A., A prospective efficacy trial of a brief breastfeeding promotion intervention to prevent postpartum smoking relapse., American Public Health Association 134th Annual Meeting & Exposition, Nov 4-8; Boston, MA. 2006., 2006	Conference abstract
Jaafar, S. H, Ho, J. J, Jahanfar, S, Angolkar, M., Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding, Cochrane Database of Systematic Reviews, 2016 (8) (no pagination), 2016	Cochrane systematic review - used to identify studies for this review
Jaafar, S. H, Ho, J. J, Lee, K. S., Rooming-in for new mother and infant versus separate care for increasing the duration of breastfeeding, Cochrane Database of Systematic Reviews, 2016 (8) (no pagination), 2016	No relevant intervention
Jacobsen, N., Antenatal Breastfeeding Education and Support: Summary and Analysis of 2 Cochrane Publications, The Journal of perinatal & neonatal nursing, 32, 144-152, 2018	Summary and analysis of 2 Cochrane reviews included in the present review, Balogun 2016 and Lumbiganon 2016
Jakobsen MS, Sodemann M, Biai S, Nielsen J, Aaby P., Promotion of exclusive breastfeeding is not likely to be cost effective in West Africa. A randomized intervention study from Guinea-Bissau. , Acta Paediatrica, 97:68â□“75, 2008	Study conducted in Guinea-Bissau
Jenik A., Influence of pacifiers on breastfeeding duration. ClinicalTrials.gov (http://clinicaltrials.gov/) (accessed 20 February 2008)., 2008	Clinical trial registration
Jenner S. , The influence of additional information, advice and support on the success of breast feeding in working class primiparas. , Child Care, Health and Development 1988;14 (5):319â□“28., 1998	Publication date pre-1995
Johnston, B. D., Huebner, C. E., Anderson, M. L., Tyll, L. T., Thompson, R. S., Healthy steps in an integrated delivery system: child and parent outcomes at 30 months, Archives of Pediatrics & Adolescent Medicine, 160, 793-800, 2006	Not an RCT
Jones DA, West RR. , Lactation nurse increases duration of breastfeeding., 1985	Publication date pre-1995
Jones E, Jones P, Spencer A. , Breastfeeding and returning to work. , Practising Midwife, 7(11):17-8, 20, 22. , 2004	No relevant ooutcomes
Jones, D. A., West, R. R., Effect of a lactation nurse on the success of breast-feeding: A randomised controlled trial, Journal of Epidemiology and Community Health, 40, 45-49, 1986	Publication date pre-1995
Joshi, A., Amadi, C., Meza, J., Aguire, T., Wilhelm, S., Evaluation of a computer-based bilingual breastfeeding educational program on breastfeeding knowledge, self-efficacy and intent to breastfeed among rural Hispanic women, International Journal of Medical Informatics, 91, 10-19, 2016	No relevant outcomes
Junior WS, Martinez FE . , Effect of intervention on the rates of breastfeeding of very low birth weight newborns., 2007	Study conducted in Brazil
Kamau-Mbuthia E, Mbugua S, Webb Girard A , Kalungu S, Sarange C, Lou W, et al. , Cell phone based peer counseling to support exclusive breastfeeding is associated with more frequent help and decreased	Conference abstract

Study	Reason for exclusion
breastfeeding problems. , Annals of Nutrition & Metabolism 2013;63(Suppl 1):196-7, Abstract no: O079., 2013	
Kang, N. M., Song, Y., Hyun, T. H., Kim, K. N., Evaluation of the breastfeeding intervention program in a Korean community health center, International journal of nursing studies, 42, 409-413, 2005	Not an RCT
Kaojuri DM, Sakakky M, Hosseini F, Kherkhah M., Comparison of the effect of two methods of home visit for the promotion of exclusive breastfeeding in caesarean section mothers in Iran university of medical sciences 2008. , International Journal of Gynecology & Obstetric s 2009;107 (Suppl 2):S150., 2008	Study conducted in Iran
Kaplowitz DD, Olson CM. , The effect of an educational program on the decision to breastfeed. , Journal of Nutrition Education 1983;15(2):61â□“5., 1983	Publication date pre-1995
Karimi, F. Z., Sadeghi, R., Maleki-Saghooni, N., Khadivzadeh, T., The effect of mother-infant skin to skin contact on success and duration of first breastfeeding: A systematic review and meta-analysis, Taiwanese Journal of Obstetrics and Gynecology, 58, 1-9, 2019	No relevant intervention
Karp, S. M., Howe-Heyman, A., Dietrich, M. S., Lutenbacher, M., Breastfeeding initiation in the context of a home intervention to promote better birth outcomes, Breastfeeding Medicine, 8, 381-387, 2013	No relevant intervention
Keith, D. R., Weaver, B. S., Vogel, R. L., The effect of music-based listening interventions on the volume, fat content, and caloric content of breast milk-produced by mothers of premature and critically ill infants, Advances in Neonatal Care, 12, 112-119, 2012	No relevant population
Khoury, A. J., Mitra, A. K., Hinton, A., Carothers, C., Sheil, H., An innovative video succeeds in addressing barriers to breastfeeding among low-income women, Journal of Human Lactation, 18, 125-31, 2002	Not an RCT
Khresheh R, Suhaimat A, Jalamdeh F, Barclay L., The effect of a postnatal education and support program on breastfeeding among primiparous women: a randomized controlled trial., 2011	Study conducted in Jordan
Kim, J. H., Shin, J. C., Donovan, S. M., Effectiveness of Workplace Lactation Interventions on Breastfeeding Outcomes in the United States: An Updated Systematic Review, Journal of human lactation : official journal of International Lactation Consultant Association, 35, 100-113, 2019	Systematic review, included studies checked and none relevant
Kim, S. K., Park, S., Oh, J., Kim, J., Ahn, S., Interventions promoting exclusive breastfeeding up to six months after birth: A systematic review and meta-analysis of randomized controlled trials, International Journal of Nursing StudiesInt J Nurs Stud, 80, 94-105, 2018	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Kim, Y., The effects of a breastfeeding campaign on adolescent Korean women, Pediatric Nursing, 24, 235-40, 1998	Not an RCT
Kind C, Schubiger G, Schwarz U, Tonz O. , Provision of supplementary fluids to breast fed infants and later breast feeding success. , Advances in Experimental Medicine & Biology 2000;478:347â□“54., 2000	This is a secondary publication of Schubiger 1997, which was included in the present review. Insufficient information is provided in relation to the results of the study
Kirkwood BR, Manu A, ten Asbroek AH, Soremekun S, Weobong B, Gyan T, et al., Effect of the Newhints home-visits intervention on	Study conducted in Ghana

Study	Reason for exclusion
neonatal mortality rate and care practices in Ghana: a cluster randomised controlled trial., Lancet 2013;381(9884):2184âå,¬92, 2013	
Kistin N, Benton D, Rao S, Sullivan M., Breast-feeding rates among black urban low-income women: effect of prenatal education. , Pediatrics 1990;86(5):741â□“6., 1990	Publication date pre-1995
Kluka SM., A Randomized Controlled Trial to Test the Effect of an Antenatal Educational Intervention on Breastfeeding Duration Among Primiparous Women [thesis]., Vancouver: University of British Columbia, 2004., 2004	Thesis
Kramer 2001, Kramer 2001 {published and unpublished data} Kramer M, Matush L, Vanilovich I, Platt R, Mazer B. Does breastfeeding help prevent asthma and allergy? Evidence from a randomized trial in Belarus. , American Journal of Epidemiology 2006;163(Suppl 11):S85., 2001	Study conducted in Belarus
Kramer MS , Chalmers B, Hodnett E, Sevkovskaya Z, Dzikovich I, Shapiro S, et al. , Promotion of breastfeeding intervention trial (PROBIT): a randomized trial in the Republic of Belarus. , JAMA 2001;285(4):413â□“20., 2001	Study conducted in Belarus
Kramer MS , Matush L, Bogdanovich N, Aboud F, Mazer B, Fombonne E, et al. , Health and development outcomes in 6.5-y-old children breastfed exclusively for 3 or 6 mo. , American Journal of Clinical Nutrition 2009;90(4):1070â□“4, 2009	Study conducted in Belarus
Kramer MS ., Breast is best: the evidence., Early Human Development , 86, 729-32, 2010	Study conducted in Belarus
Kramer MS, Aboud F, Mironova E, Vanilovich I, Platt RW, Matush L, et al., Breastfeeding and child cognitive development: new evidence from a large randomized trial., Archives of General Psychiatry , 65, 578-84, 2000	Study conducted in Belarus
Kramer MS, Barr RG, Jane R, Yang H, Dagenais S, Jones P, et al. , Pacifier use, breastfeeding, and infant CRY/FUSS behavior: a randomized trial. , Pediatric Research 2000;47(4): 203A, 2000	Conference abstract
Kramer MS, Fombonne E, Igumnov S, Vanilovich I, Matush L, Mironova E, et al. , Effects of prolonged and exclusive breastfeeding on child behavior and maternal adjustment: evidence from a large, randomized trial. , Pediatrics 2008;121(3):e435â□“40., 2008	Study conducted in Belarus
Kramer MS, Matush L, Va nilovich I, Platt RW, Bogdanovich N, Sevkovskaya Z, et al., A randomized breast-feeding promotion intervention did not reduce child obesity in Belarus., Journal of Nutrition 2009;139(2):417Sâå,¬21S., 2009	Study conducted in Belarus
Kramer MS, Matush L, Vanilovich I , Platt R, Bogdanovich N, Sevkovskaya Z, et al. , Effect of prolonged and exclusive breast feeding on risk of allergy and asthma: cluster randomised trial. , BMJ 2007;335(7624):815., 2007	Study conducted in Belarus
Kramer MS, Vanilovich I, Matush L, Bogdanovich N, Zhang X, Shishko G, et al., The effect of prolonged and exclusive breast-feeding on dental caries in early school-age children. New evidence from a large randomized trial. , Caries Research 2007;41(6):484â□“8., 2007	Study conducted in Belarus
Kronborg, H, Vaeth, M, Olsen, J, Iversen, L, Harder, I., Effect of early postnatal breastfeeding support: A cluster-randomized community based trial, Acta Paediatrica, International Journal of Paediatrics, 96, 1064-1070, 2007	No relevant outcomes
Kronborg, H, Vaeth, M., How Are Effective Breastfeeding Technique and Pacifier Use Related to Breastfeeding Problems and Breastfeeding Duration?, Birth, 36, 34-42, 2009	No relevant outcomes

Study	Reason for exclusion
Kruske, S., Schmied, V., Cook, M., The 'Earlybird' gets the breastmilk: Findings from an evaluation of combined professional and peer support groups to improve breastfeeding duration in the first eight weeks after birth, Maternal and Child Nutrition, 3, 108-119, 2007	Study conducted in Inida
Kupratakul, J., Taneepanichskul, S., Voramongkol, N., Phupong, V., A randomized controlled trial of knowledge sharing practice with empowerment strategies in pregnant women to improve exclusive breastfeeding during the first six months postpartum, Journal of the Medical Association of Thailand, 93, 1009-1018, 2010	Study conducted in Thailand
Kvist, L. J., Persson, E., Lingman, G. K., A comparative study of breast feeding after traditional postnatal hospital care and early discharge, Midwifery, 12, 85-92, 1996	Not an RCT
Labarere J, Gelbert-Baudino N, Laborde L, Arragain D, Schelstraete C, Francois P. , CD-ROM-based program for breastfeeding mothers. , Maternal & Child Nutrition, 7 (3):263â□“72., 2011	Not an RCT
Lavender T., Breastfeeding: expectations versus reality., International Conference of Maternity Care Researcher, 2004 June 13-16; Lund, Sweden. 2., 2004	Conference abstract
Lavender, T., Richens, Y., Milan, S. J., Smyth, R. M. D., Dowswell, T., Telephone support for women during pregnancy and the first six weeks postpartum, Cochrane Database of Systematic Reviews, 2013 (7) (no pagination), 2013	Systematic review - all include studies checked for relevance
Lawrence RA. , Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. , Journal of Pediatrics 2001;139(1):164â□“5., 2001	Study conducted in Belarus
Leite AJ, Puccini RF, Atallah AN, A lves da Cunha AL, Machado MT. , Effectiveness of home-based peer counselling to promote breastfeeding in the northeast of Brazil: a randomised clinical trial. , Acta Paediatrica 2005;94:741â□“6., 2005	Study conducted in Brazil
Leite AJM, Puccini R, Atallah A, Cunha A, Machado M, Capiberibe A, et al., Impact on breastfeeding practices promoted by lay counselors: a randomized and controlled clinical trial., 1998	Conference abstract
Lewycka S, M wa nsambo C, Rosato M, Kazembe P, Phiri T, Mganga A, et al., Effect of women's groups and volunteer peer counselling on rates of mortality, morbidity, and health behaviours in mothers and children in rural Malawi (MaiMwana): a factorial, cluster-randomised controlled trial., Lancet , 381, 1721-35, 2013	Study conducted in Malawi
Lewycka S, Mwansambo C, Kazembe P, Phiri T, Mganga A, Rosato M, et al. , A cluster randomised controlled trial of the community effectiveness of two interventions in rural Malawi to improve health care and to reduce maternal, newborn and infant mortality. , Trials 2010;11:88., 2010	Study conducted in Malawi
Li, G., Cong, J., Li, L., Li, Y., Effects of nursing with information support and behavior intervention on lactation and breastfeeding success rate for primiparas, International Journal of Clinical and Experimental Medicine, 11, 2617-2623, 2018	Study presumed to be conducted in China (not clear)
Lieu, T. A., Wikler, C., Capra, A. M., Martin, K. E., Escobar, G. J., Braveman, P. A., Clinical outcomes and maternal perceptions of an updated model of perinatal care, Pediatrics, 102, 1437-44, 1998	Not an RCT
Lin, S. S., Chien, L. Y., Tai, C. J., Lee, C. F., Effectiveness of a prenatal education programme on breastfeeding outcomes in Taiwan, Journal of clinical nursing, 17, 296-303, 2008	Not an RCT
Lindenberg CS, Ar tola RC, Jimenez V. , The effect of early post-partum mother-infant contact and breast-feeding promotion on the	Study conducted in Nicaragua

Study	Reason for exclusion
incidence and continuation of breast-feeding., International Journal of Nursing Studies 1990;27 (3):179â□“86, 1990	
Long, D. G., Funk-Archuleta, M. A., Geiger, C. J., Mozar, A. J., Heins, J. N., Peer counselor program increases breastfeeding rates in Utah Native American WIC population, Journal of human lactation: official journal of International Lactation Consultant Association, 11, 279-284, 1995	Not an RCT
Louzada ML, Campagnolo PD, Rauber F, Vitolo MR. , Long-term effectiveness of maternal dietary counseling in a low-income population: a randomized field trial. , Pediatrics, 129(6):e1477â□“e1484, 2012	Study conducted in Brazil
Lovera, D., Sanderson, M., Bogle, M. L., Vela Acosta, M. S., Evaluation of a breastfeeding peer support program for fathers of hispanic participants in a texas special supplemental nutrition program for women, infants, and children, Journal of the American Dietetic Association, 110, 1696-1702, 2010	Not an RCT
Lucchini C, Uribe TC, Villarroel PL, Rojas RA., Randomized controlled clinical trial evaluating determinants of successful breastfeeding: follow-up two months after comprehensive intervention versus standard care delivery [Determinantes para una lactancia materna exitosa: Interv encion integral as cuidado estandar. Ensayo clinico aleatorio controlado]., Revista Chilena de Pediatria 2013;84(2):138âå,¬44., 2013	Language
Lumbiganon, P, Martis, R, Laopaiboon, M, Festin, M. R, Ho, J. J, Hakimi, M., Antenatal breastfeeding education for increasing breastfeeding duration, Cochrane Database of Systematic Reviews, 2016 (12) (no pagination), 2016	Cochrane systematic review - used to identify studies for this review
Lynch SA, Koch AM, Hislop TG, Coldman AJ., Evaluating the effect of a breastfeeding consultant on the duration of breastfeeding. , Canadian Journal of Public Health 1986;77 (3):190â□“5., 1986	Publication date pre-1995
MacVicar, S., Humphrey, T., Forbes-McKay, K. E., Breastfeeding and the substance-exposed mother and baby, Birth (Berkeley, Calif.), 45, 450-458, 2018	No relevant population
MacVicar, S., Kirkpatrick, P., The effectiveness and maternal satisfaction of breast-feeding support for women from disadvantaged groups: A comprehensive systematic review, JBI Database of Systematic Reviews and Implementation Reports, 12, 420-476, 2014	Systematic review - included studies checked and non relevant
Mahesh, P. K. B., Gunathunga, M. W., Arnold, S. M., Jayasinghe, C., Pathirana, S., Makarim, M. F., Manawadu, P. M., Senanayake, S. J., Effectiveness of targeting fathers for breastfeeding promotion: systematic review and meta-analysis, BMC public health, 18, 1140, 2018	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Martens, P. J., Does breastfeeding education affect nursing staff beliefs, exclusive breastfeeding rates, and Baby-Friendly Hospital Initiative compliance? The experience of a small, rural Canadian hospital, Journal of human lactation : official journal of International Lactation Consultant Association, 16, 309-18, 2000	Not an RCT
Martin RM, Patel R, Kramer MS, Guthrie L, Vilchuck K, Bogdanovich N, et al., Effects of promoting longer-term and exclusive breastfeeding on adiposity and insulin-like growth factor-I at age 11.5 years: a randomized trial. , JAMA, 309, 1005â□“13, 2013	Study conducted in Belarus
Martin RM, Patel R, Kramer MS, Vilchuck K, Bogdanovich N, Sergeichick N, et al. , Effects of promoting longer-term and exclusive breastfeeding on cardiometabolic risk factors at age 11.5 years: a	Study conducted in Belarus

Study	Reason for exclusion
cluster-randomized, controlled trial. , Circulation 2014;129(3):321â□“9., 2014	
Martin, J., MacDonald-Wicks, L., Hure, A., Smith, R., Collins, C. E., Reducing postpartum weight retention and improving breastfeeding outcomes in overweight women: a pilot randomised controlled trial, Nutrients, 7, 1464-79, 2015	No relevant outcomes
Mattar CN, Chan YS, Chong YS., Breastfeeding: it's an important gift., Obstetrics and Gynecology, 102, 1414, 2003	Letter to editor
Mbugua S, Kamau-Mbuthia E, Webb A, Kalungu S, Sarange C, Lou W, et a l. , Process indicators for a randomized trial of cell phone based peer counseling to support exclusive breastfeeding in Kenya. , Annals of Nutrition & Metabolism 2013;63(Suppl 1):693, Abstract no: PO905., 2013	Conference abstract
Mbugua S, Kamau-Mbuthia E, Webb Girard A , Kalungu S, Sarange C, Lou W, et a l., Process indicators for a randomized trial of cell phone based peer counseling to support exclusive breastfeeding in Kenya., Annals of Nutrition & Metabolism 2013;63(Suppl 1):751, Abstract no: PO1033., 2013	Conference abstract
McDonald SJ, Henderson JJ, Evans SF, Faulkner S, Hagan R., Effect of an extended midwifery support program on the duration of breastfeeding: a randomised controlled trial. [abstract]., Perinatal Society of Australia and New Zealand 7th Annual Congress; 2003 March 9-12; Tas mania, Australia. 2003:A68., 2003	Conference abstract
McFadden, A, Gavine, A, Renfrew, M. J, Wade, A, Buchanan, P, Taylor, J. L, Veitch, E, Rennie, A. M, Crowther, S. A, Neiman, S, Macgillivray, S., Support for healthy breastfeeding mothers with healthy term babies, Cochrane Database of Systematic Reviews, 2017 (2) (no pagination), 2017	Cochrane systematic review - used to identify studies for this review
McKie, A., Young, D., MacDonald, P. D., Does monitoring newborn weight discourage breast feeding?, Archives of Disease in Childhood, 91, 44-6, 2006	Not an RCT
McLachlan H, Forster D, Amir L, Small R, Cullinane M, Watson L, et al., Supporting breastfeeding in local communities (silc): results of a cluster randomised trial., Journal of Paediatrics and Child Health, 51, 2015	Conference abstract
McLachlan HL, Forster DA, Amir LH, Small R, Cullinane M, Watson LF, et al. , Supporting breastfeeding In Local Communities (SILC): protocol for a cluster randomised controlled trial. , BMC Pregnancy and Childbirth 2014;14 (1):346., 2014	Protocol
McQueen KA., Improving Breastfeeding Outcomes: a Pilot Randomized Controlled Trial of a Self-Efficacy Intervention with Primiparous Mothers [thesis]. , Toronto: University of Toronto, 2009., 2009	Thesis
Meedya, S., Fernandez, R., Fahy, K., Effect of educational and support interventions on long-term breastfeeding rates in primiparous women: A systematic review and meta-analysis, JBI Database of Systematic Reviews and Implementation Reports, 15, 2307-2332, 2017	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Mejdoubi J, van den Heijkant SC, v a n Leerdam FJ, Crone M, Crijnen A, HiraSing RA., Effects of nurse home visitation on cigarette smoking pregnancy outcomes: a randomized controlled trial., 2014	No relevant intervention
Memmott MM, Bonuck KA., Mother's reactions to a skills-based breastfeeding promotion intervention., Maternal & Child Nutrition , 2, 40-50, 2006	Qualitative study design

Study	Reason for exclusion
Mikami, F. C., de Lourdes Brizot, M., Tase, T. H., Saccuman, E., Vieira Francisco, R. P., Zugaib, M., Effect of Prenatal Counseling on Breastfeeding Rates in Mothers of Twins, JOGNN - Journal of Obstetric, Gynecologic, & Neonatal Nursing, 46, 229-237, 2017	Study conducted in Brazil
Mitchell-Box, K. M., Braun, K. L., Impact of male-partner-focused interventions on breastfeeding initiation, exclusivity, and continuation, Journal of human lactation : official journal of International Lactation Consultant Association, 29, 473-479, 2013	Systematic review - included studies checked for relevance
Mohd Shukri, N. H., Wells, J. C. K., Fewtrell, M., The effectiveness of interventions using relaxation therapy to improve breastfeeding outcomes: A systematic review, Maternal and Child Nutrition, 14 (2) (no pagination), 2018	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Molinero Diaz, P., Burgos Rodríguez, M. J., Mejía Ramírez de Arellano, M., Results of a health education intervention in the continuity of breastfeeding, Enfermeria clinica, 25, 232â€• 238, 2015	Language not in English
Mongeon M, Allard R., A controlled study with regular telephonic support given by volunteers on the progress and outcome of breast-feeding [Essai controle d'un soutien telephonique regulier donne par une benevole sur le deroulment et l'issus de l'allaitment]., Revue Canadienne de Sante Publique , 86, 124-7, 1995	Language not in English
Mongeon, M., Allard, R., Controlled study of a regular telephone support program given by volunteers on the establishment of breastfeeding, Canadian journal of public health = revue canadienne de sante publique, 86, 124â€• 127, 1995	Language not in English
Mongeon, M., Allard, R., A controlled assay with regular telephonic support given by volunteers on the progress and outcome of breast-feeding. ESSAI CONTROLE D'UN SOUTIEN TELEPHONIQUE REGULIER DONNE PAR UNE BENEVOLE SUR LE DEROULEMENT ET L'ISSUE DE L'ALLAITEMENT, Canadian Journal of Public Health. Revue Canadienne de Sante PubliqueCan J Public Health, 86, 124â€• 127, 1995	Language not in English
Moon, R. Y., Hauck, F. R., Colson, E. R., Kellams, A. L., Geller, N. L., Heeren, T., Kerr, S. M., Drake, E. E., Tanabe, K., McClain, M., Corwin, M. J., The Effect of Nursing Quality Improvement and Mobile Health Interventions on Infant Sleep Practices: A Randomized Clinical Trial, Jama, 318, 351-359, 2017	No relevant outcomes
Moon, R. Y., Mathews, A., Joyner, B. L., Oden, R. P., He, J., McCarter, R., Impact of a Randomized Controlled Trial to Reduce Bedsharing on Breastfeeding Rates and Duration for African-American Infants, Journal of community health, 42, 707-715, 2017	No relevant intervention
Moore, E. R, Bergman, N, Anderson, G. C, Medley, N., Early skin-to-skin contact for mothers and their healthy newborn infants, Cochrane Database of Systematic Reviews, 11, CD003519, 2016	No relevant intervention
Moran, V. H., Morgan, H., Rothnie, K., MacLennan, G., Stewart, F., Thomson, G., Crossland, N., Tappin, D., Campbell, M., Hoddinott, P., Incentives to promote breastfeeding: a systematic review, Pediatrics, 135, e687-702, 2015	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Morel K, Chapman DJ, Kyer N, Bermudez-Millan A, Young S, Perez-Escamilla R. , Peer counselors improve breastfeeding technique	Conference abstract

Study	Reason for exclusion
among low-income, obese women. , FASEB Journal 2010;24(Suppl):[Abstract no. 91.7]., 2010	
Morgan, H., Hoddinott, P., Thomson, G., Crossland, N., Farrar, S., Yi, D., Hislop, J., Moran, V. H., MacLennan, G., Dombrowski, S. U., Rothnie, K., Stewart, F., Bauld, L., Ludbrook, A., Dykes, F., Sniehotta, F. F., Tappin, D., Campbell, M., Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy (BIBS): a mixed-methods study to inform trial design, Health Technology Assessment (Winchester, England)Health Technol Assess, 19, 1-522, vii-viii, 2015	This publication presents three evidence syntheses and primary qualitative and survey research (no relevant study design). Studies included in the breastfeeding review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Morrell, C. J., Spiby, H., Stewart, P., Walters, S., Morgan, A., Costs and benefits of community postnatal support workers: a randomised controlled trial, Health Technology Assessment (Winchester, England), 4, 1-100, 2000	No relevant intervention
Morrell,C.J, Spiby,H, Stewart,P, Walters,S, Morgan,A., Costs and effectiveness of community postnatal support workers: randomised controlled trial, BMJ, 321, 593-598, 2000	No relevant intervention
Morrow AL, Lourdes Guerrero M, Shults J, Calva JJ, Lutter C, Ruiz-Palacios GM, et al. , Efficacy of home-based peer counselling to promote exclusive breastfeeding: a randomised controlled trial., Lancet 1999;353(9160): 1226â□“31., 1999	Study conducted in Mexico
Morrow AL, Lourdes Guerrero M., From bio-active substances to research on breastfeeding promotion. In: Newburg editor(s)., Bioactive Components of Human Milk. New York: Kluwer Academic/Plenum Publishers, 2001: 447â□“55., 2001	Study conducted in Mexico
Mottl-Santiago,J., Walker,C., Ewan,J., Vragovic,O., Winder,S., Stubblefield,P., A hospital-based doula program and childbirth outcomes in an urban, multicultural setting, Maternal & Child Health Journal, 12, 372-377, 2008	Not an RCT
Nankabirwa V, Tylleskar T, Nankunda J, Engebretsen IM, Sommerfelt H, Tumwine JK, et al. , Malaria parasitaemia among infants and its association with breastfeeding peer counselling and vitamin A supplementation: a secondary analysis of a cluster randomized trial.. , PLOS ONE 2011;6 (7):e21862., 2011	Study conducted in West Africa
Nankunda J, Turnwine JK, Nakabirwa V, Tylleskar T, PROMISE-EBF SG., "She would sit with me": woman experiences of individual peer support for exclusive breastfeeding in Uganda, 2010	Study conducted in Uganda
Nichols, J., Schutte, N. S., Brown, R. F., Dennis, C. L., Price, I., The impact of a self-efficacy intervention on short-term breast-feeding outcomes, Health Education and Behavior, 36, 250-258, 2009	No relevant outcomes
Nielsen, P. E., Group prenatal care and perinatal outcomes: a randomized controlled trial, Obstetrics & Gynecology, 111, 993, author reply 993-4, 2008	Letter to the editor and author's reply
Nolan A, Lawrence C. , A pilot study of a nursing intervention protocol to minimize maternal-infant separation after Cesarean birth. , Journal of Obstetric, Gynecologic, and Neonatal Nursing 2009;38(4):430â□“42., 2009	No relevant intervention
Nommsen-Rivers,L.A., Mastergeorge,A.M., Hansen,R.L., Cullum,A.S., Dewey,K.G., Doula care, early breastfeeding outcomes, and breastfeeding status at 6 weeks postpartum among low-income	Not an RCT

Study	Reason for exclusion
primiparae, JOGNN - Journal of Obstetric, Gynecologic, and Neonatal Nursing, 38, 157-173, 2009	
Novick G, Reid E, Lewis J, Kershaw S, Rising SS, Ickovics R., Group prenatal care: model fidelity and outcomes., American Journal of Obstetrics & Gynecology, 209, 112.e1-112.e6, 2013	No relevant comparison
Novick G, Reid E, Lewis J, Kershaw T, Rising S, Ickovics R., Group prenatal care: model fidelity and outcomes. , Journal of Midwifery & Womenâ□™s Health, 58, 586â□“7, 2013	Conference abstract
Ochola A, Labadarios D, Nduati W., Impact of counselling on exclusive breast-feeding practices in a poor urban setting in Kenya: a randomized controlled trial. , Public Health Nutrition 2013;16(10):1732â□“40., 2013	Study conducted in Kenya
O'Connor, N. R., Tanabe, K. O., Siadaty, M. S., Hauck, F. R., Pacifiers and breastfeeding: A systematic review, Archives of Pediatrics and Adolescent Medicine, 163, 378-382, 2009	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Oken E, Patel R, Guthrie LB, Vilchuck K, Bogdanovich N, Sergeichick N, et al. , Effects of an intervention to promote breastfeeding on maternal adiposity and blood pressure at 11.5 y postpartum: results from the Promotion of Breastfeeding Intervention Trial, a cluster-randomized controlled trial., American Journal of Clinical Nutrition, 98, 1048â□“56, 2013	Study conducted in Belarus
Olenick P, Berens P., The effect of structured group prenatal education on breastfeeding confidence, duration, and exclusivity to 12 weeks postpartum., Breastfeeding Medicine 2010;5(6):334., 2010	Conference abstract
Olenick PL. , The effect of structured group prenatal education on breastfeeding confidence, duration, and exclusivity to 12 weeks postpartum., 2011	Conference abstract
Olenick PL. , The Effect of Structured Group Prenatal Education on Breastfeeding Confidence, Duration and Exclusivity to Twelve Weeks Postpartum [Dissertation]. , San Francisco: Touro University, 2006., 2006	Dissertation
Olenick PL. , The effect of structured group prenatal education on breastfeeding confidence, duration and exclusivity to 12 weeks postpartum. , Journal of Obstetrics, Gynecologic, and Neonatal Nursing 2010;39(Suppl S1): S104-S105., 2010	Conference abstract
Oliveira, I. B., Leal, L. P., Coriolano-Marinus, M. W., Santos, A. H., Horta, B. L., Pontes, C. M., Meta-analysis of the effectiveness of educational interventions for breastfeeding promotion directed to the woman and her social network, Journal of advanced nursing, 73, 323-335, 2017	Studies included in the meta analysis were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the meta analysis
Olson, B. H., Haider, S. J., Vangjel, L., Bolton, T. A., Gold, J. G., A quasi-experimental evaluation of a breastfeeding support program for low income women in Michigan, Maternal & Child Health Journal, 14, 86-93, 2010	Not an RCT
Pate BL. , Effectiveness of Web-based Programs in Improving Breastfeeding Self-efficacy [PhD thesis]. , Little Rock: University of Arkansas for Medical Sciences, 2009., 2009	Thesis
Patel, S., The Effectiveness of Lactation Consultants and Lactation Counselors on Breastfeeding Outcomes, Journal of human lactation:	Studies included in the systematic review were

Study	Reason for exclusion
official journal of International Lactation Consultant Association, 32, 530-541, 2016	assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Patnode, C. D., Henninger, M. L., Senger, C. A., Perdue, L. A., Whitlock, E. P., Primary care interventions to support breastfeeding: Updated evidence report and systematic review for the US preventive services task force, JAMA - Journal of the American Medical Association, 316, 1694-1705, 2016	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Paul I M, Beiler JS, Schaefer EW, Hollenbeak CS, Alleman N, Sturgis SA., A randomized trial of nurse home visits vs. office-based care after nursery/maternity discharge., Pediatric Academic Societies and Asian Society for Pediatric Research Joint Meeting; 2011 April 30-May 3; Denver, Colorado, USA. 2011:2300.6., 2011	Conference abstract
Paul IM, Beiler JS, Schaefer EW, Hollenbeak CS, Alleman N, Sturgis SA., A randomized trial of nurse home visits vs. office-based care after nursery/maternity discharge., Pediatric Academic Societies and Asian Society for Pediatric Research Joint Meeting, 2011 April 30-May 3; Denver, Colorado, USA. 2011:2300.6	Conference abstract
Penfold S, Manzi F, M kumbo E, Temu S, Jaribu J, Shamba DD, et al. , Effect of home-based counselling on newborn care practices in southern Tanzania one year after implementation: a cluster-randomised controlled trial., BMC Pediatrics, 14, 187, 2014	Study conducted in Tanzania
Perez-Blasco J, Viguer P, Rodrigo MF. , Effects of a mindfulness-based intervention on psychological distress, well-being, and maternal self-efficacy in breast-feeding mothers: results of a pilot study. , Archives of Womenâ□™s Mental Health, 16(3):227â□“36., 2013	No relevant outcomes
Perez-Escamilla, R., Martinez, J. L., Segura-Perez, S., Impact of the Baby-friendly Hospital Initiative on breastfeeding and child health outcomes: a systematic review, Maternal and Child Nutrition, 12, 402-417, 2016	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Phillips RM, Merritt TA, Goldstein MR, Deming DD, Slater LE, Angeles DM. , Supporting mother-infant bonding increases the duration of breastfeeding in mothers with newborns in the neonatal intensive care unit. , Breastfeeding Medicine, 6 Suppl 1:Sâ□“3-S-4., 2011	Conference abstract
Pisacane,A., Continisio,P., Filosa,C., Tagliamonte,V., Continisio,G.I., Use of baby carriers to increase breastfeeding duration among term infants: the effects of an educational intervention in Italy, Acta Paediatrica, 101, e434-e438, 2012	No relevant intervention
Pobocik RS, Benavente JC, Schwab AC, Boudreau N, Morris CH, Sue Houston M:, Effect of a breastfeeding education and support program on breastfeeding initiation and duration in a culturally diverse group of adolescents. , Journal of Nutrition Education, 32, 139-45., 2000	Not an RCT
Pollard DL., The Effect of Self-Regulation on Breastfeeding Duration in Primiparous Mothers, [Thesis]. University of Pittsberg, 1998	Thesis
Porteous R, Kaufman K, Rush J. , The effect of individualized professional support on duration of breastfeeding: a randomized controlled trial. , Journal of Human Lactation, 16, 303-8, 2000	No relevant outcomes

Study	Reason for exclusion
Pugh LC, Nanda JP, Frick KD, Sharps PW, Spatz DL, Serwint JR, et al., A randomized controlled community-based trial to improve breastfeeding among urban low-income mothers., Pediatric Academic Societies Annual Meeting; 2007 May 5-8; Toronto, Canada 2007., 2007	Conference abstract
Pugh, L. C., Milligan, R. A., Brown, L. P., The breastfeeding support team for low-income, predominantly-minority women: a pilot intervention study, Health Care for Women International, 22, 501-15, 2001	Not an RCT
Raeisi K, Shariat M, Nayeri F, Raji F, Dalili H., A single center study of the effects of trained fathers' participation in constant breastfeeding., Acta Medica Iranica, 52, 694-6, 2014	Study conducted in Iran
Ransjo-Arvidson AB, Chintu K, Ngââ,¬â„¢andu N, Eriksson B, Susu B, Christenss on K, et al., Maternal and infant health problems after normal childbirth: a randomised controlled study in Zambia., Journal of Epidemiology & Community Health, 52, 385-91, 1998	Study conducted in Zambia
Rea MF, Venancio SI, Martines JC, Savage F., Counselling on breastfeeding: assessing knowledge and skills. , Bulletin of the World Health Organization, 77(6):492â□“8. , 1999	Study conducted in Brazil
Rempel, L. A., Rempel, J. K., The breastfeeding team: the role of involved fathers in the breastfeeding family, Journal of Human Lactation, 27, 115-21, 2011	Not an RCT
Renfrew, M. J., McCormick, F. M., Wade, A., Quinn, B., Dowswell, T., Support for healthy breastfeeding mothers with healthy term babies, Cochrane database of systematic reviews (Online), 5, CD001141, 2012	Systematic review - included studies checked for eligibility in this review
Rishel, P. E., Sweeney, P., Comparison of breastfeeding rates among women delivering infants in military treatment facilities with and without lactation consultants, Military Medicine, 170, 435-8, 2005	Not an RCT
Roberts, A., Hoddinott, P., Heaney, D., Bryers, H., The use of video support for infant feeding after hospital discharge: A study in remote and rural Scotland, Maternal and Child Nutrition, 5, 347-357, 2009	Study design - not a systematic review
Rossiter JC. , The effect of a culture-specific education program to promote breastfeeding among Vietnamese women in Sydney. , International Journal of Nursing Studies 1994;31(4):369â□“79., 1994	Publication date pre-1995
Ryser FG., Breastfeeding Attitudes, Intention and Initiation in Low-income Women: the Effect of the ââ,¬Å“Best Startâ€¬Â• Program. Texas, Texas Woman's University, 1999., 1999	Thesis
Sakha K, Behbahan AG. , Training for perfect breastfeeding or metoclopramide: which one can promote lactation in nursing mothers?. , Breastfeeding Medicine, 3(2):120â□“3. , 2008	Study conducted in Iran
Santiago LB, Bettiol H , Barbieri MA, Guttierrez M R, Del Ciampo LA. , Promotion of breastfeeding: the importance of pediatricians with specific training [Incentivo ao aleitamento materno: a importancia do pediatra com treinamento especifico]., 2003	Study conducted in Brazil
Schafer, E., Vogel, M. K., Viegas, S., Hausafus, C., Volunteer peer counselors increase breastfeeding duration among rural low-income women, Birth (Berkeley, Calif.), 25, 101-106, 1998	Not an RCT
Schlickau JM., Prenatal breastfeeding education: an intervention for pregnant immigrant Hispanic women [thesis]., Omaha: University of Nebraska, 2005., 2005	Thesis
Schneidrova, D., Mullerova, D., Janout, V., Paulova, M., Kudlova, E., Impact of breast-feeding promotion on infant feeding in the Czech Republic, Journal of Nutrition Education & BehaviorJ Nutr Educ Behav, 35, 228-35, 2003	Not an RCT

Study	Reason for exclusion
Schreck, P. K., Solem, K., Wright, T., Schulte, C., Ronnisch, K. J., Szpunar, S., Both Prenatal and Postnatal Interventions Are Needed to Improve Breastfeeding Outcomes in a Low-Income Population, Breastfeeding Medicine, 12, 142-148, 2017	Not an RCT
Schwartz, R., Vigo, A., De Oliveira, L. D., Giugliani, E. R. J., The effect of a pro-breastfeeding and healthy complementary feeding intervention targeting adolescent mothers and grandmothers on growth and prevalence of overweight of preschool children, PLoS ONE, 10 (7) (no pagination), 2015	Study conducted in Brazil
Schy DS, Maglaya CF, Mendelson SG, Race KE, Ludwig-Beymer P. , The effects of in-hospital lactation education on breastfeeding practice., 12 (2):117â□“22., 1996	Insufficient information relating to the results of the study
Sciacca, J. P., Dube, D. A., Phipps, B. L., Ratliff, M. I., A breast feeding education and promotion program: Effects on knowledge, attitudes, and support for breast feeding, Journal of community health, 20, 473-489, 1995	No relevant outcomes
Sellen D, Mbugua S, Webb Girard A, Kalungu S, Sarange C, Lou W, et al. , A randomized controlled trial indicates benefits of cell phone based peer counseling to support exclusive breastfeeding in Kenya. , Annals of Nutrition & Metabolism 2013;63(Suppl 1):751, Abstract no: PO1032., 2013	Conference abstract
Sellen D, Mbugua S, Webb-Girard A, Lou W, Duan W, Kamau-Mbuthia E., Cell phone based peer counselling can support exclusive breastfeeding: A randomized controlled trial in Kenya. , FASEB Journal, 28, [Abstract no. 119.5], 2014	Conference abstract
Sellen DW, Kamau-Mbuthia E, Mbugua S, Webb Girard AL, Lou W, Dennis CL, et al., Lessons learned in providing peer support through cell phones and group meetings to increase exclusive breastfeeding in Kenya. Breastfeeding and the use of human milk. Science and Practice., Proceedings of the 16th ISRHML Conference; 2012 September 27th-October 1st; Trieste, Italy. 2012:Abstract no. A18., 2012	Conference abstract
Serafino-Cross P, Donovan P. , Effectiveness of professional breastfeeding home-support., Society for Nutrition Education 1992;24 (3):117â□“22., 1992	Publication date pre-1995
Serrano, M. S., Doren, F. M., Wilson, L., Teaching Chilean mothers to massage their full-term infants: effects on maternal breast-feeding and infant weight gain at age 2 and 4 months, Journal of Perinatal & Neonatal Nursing, 24, 172-81, 2010	Not an RCT
Shakya, P., Kunieda, M. K., Koyama, M., Rai, S. S., Miyaguchi, M., Dhakal, S., Sandy, S., Sunguya, B. F., Jimba, M., Effectiveness of community-based peer support for mothers to improve their breastfeeding practices: A systematic review and meta-analysis, PLoS ONE, 12 (5) (no pagination), 2017	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Shaw, E., Kaczorowski, J., The effect of a peer counseling program on breastfeeding initiation and longevity in a low-income rural population, Journal of human lactation: official journal of International Lactation Consultant Association, 15, 19-25, 1999	Not an RCT
Sikander S , Maselko J, Z a far S, Haq Z, Ahmad I, Ahmad M, et al. , Cognitive-behavioral counseling for exclusive breastfeeding in rural pediatrics: a cluster RCT., 2015	Study conducted in Pakistan

Study	Reason for exclusion
Sjolin S, Hofvander Y, Hillervik C. , A prospective study of individual courses of breastfeeding. , Acta Paediatrica Scandinavica, 68, 521â□“9, 1979	Publication date pre-1995
Skouteris, H., Bailey, C., Nagle, C., Hauck, Y., Bruce, L., Morris, H., Interventions Designed to Promote Exclusive Breastfeeding in High-Income Countries: A Systematic Review Update, Breastfeeding Medicine, 12, 604-614, 2017	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Skugarevsky O, Wade KH, Richmond RC, Mar tin RM, Tilling K, Patel R, et al. , Effects of promoting longer-term and exclusive breastfeeding on childhood eating attitudes: a cluster-randomized trial. , International Journal of Epidemiology 2014;43(4):1263â□“71., 2014	Study conducted in Belarus
Soltani, H., Fair, F. J., Interventions for supporting the initiation and continuation of breastfeeding among women who are overweight or obese, Cochrane Database of Systematic Reviews, 2016 (2) (no pagination), 2016	Protocol for a review
Spiby, H., McCormick, F., Wallace, L., Renfrew, M. J., D'Souza, L., Dyson, L., A systematic review of education and evidence-based practice interventions with health professionals and breast feeding counsellors on duration of breast feeding, Midwifery, 25, 50-61, 2009	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Spinelli, M. G., Endicott, J., Goetz, R. R., Increased breastfeeding rates in black women after a treatment intervention, Breastfeeding Medicine: The Official Journal of the Academy of Breastfeeding Medicine, 8, 479-84, 2013	No relevant comparison
Srinivas GL, Worley S., Effect of office-based peer counselor on breastfeeding rates in an urban low-income clinic., Pediatric Academic Societies Annual Meeting; 2013 May 4-7; Washington DC, USA. 2013., 2013	Conference abstract
Stevens B, Guerriere D, McKeever P, Croxford R, Miller KL, Watson-MacDonell J, et al., Economics of home vs. hospital breastfeeding support for newborns., Journal of Advanced Nursing 2006;53(2):233â□“43., 2006	No relevant outcomes
Stevens B, McKeever P, Coyte P, Daub S, Dunn M, Gibbins S, et al., The impact of home versus hospital support of breastfeeding on neonatal outcomes. , Pediatric Research 2001;49 Suppl(4):261A., 2001	Conference abstract
Susin, L. R., Giugliani, E. R., Kummer, S. C., Maciel, M., Simon, C., da Silveira, L. C., Does parental breastfeeding knowledge increase breastfeeding rates?, Birth (Berkeley, Calif.), 26, 149-156, 1999	Study conducted in Brazil
Svensson KE, Velandia MI,Matthiesen AS,Welles-Nystrom BL, Widstrom AM. , Effects of mother-infant skin-to-skin contact on severe latch-on problems in older infants: a randomized trial. , International Breastfeeding Journal, 8(1):1., 2013	No relevant intervention
Szucs KA, Ahmed AH. The effect of interactive webbased, The effect of interactive webbased breastfeeding monitoring on maternal breastfeeding self-efficacy and satisfaction: a randomized control trial., Pediatric Academic Socieities Annual Meeting, San Diego, California, USA, 2015	Conference abstract
Szucs, K. A., Ahmed, A. H., The effect of interactive web-based breastfeeding monitoring on maternal breastfeeding self-efficacy and	Conference abstract

Study	Reason for exclusion
satisfaction: a randomized control trial, Pediatric academic societies (PAS) annual meeting; 2015 apr 25 - 28; san diego, USA, 2015	
Tahir NM, Al-Sadat N., Does telephone lactation counselling improve breastfeeding practices? A randomised controlled trial. , International Journal of Nursing Studies 2013;50 (1):16â□“25., 2013	Study conducted in Malaysia
Tarrant M, Fong DY, Heys M, Lee IL, Sham A, Hui Choi EW. , Professional breastfeeding support to increase the exclusivity and duration of breastfeeding: a randomised controlled trial. , Hong Kong Medical Journal = Xianggang Yi Xue Za Zhi / Hong K ong Academy of Medicine 2014;20(6 Suppl 7):34â□“5., 2014	Conference abstract
Taveras, E. M., Blackburn, K., Gillman, M. W., Haines, J., McDonald, J., Price, S., Oken, E., First steps for mommy and me: a pilot intervention to improve nutrition and physical activity behaviors of postpartum mothers and their infants, Maternal & Child Health Journal, 15, 1217-27, 2011	Not an RCT
Tully KP, Ball HL. , Postnatal unit bassinet types when rooming-in after cesarean birth: implications for breastfeeding and infant safety., 28(4):495â□“505. , 2012	No relevant intervention
Tylleskar T, Jackson D, Meda N, Engebretsen IM, Chopra M, Diallo AH, et al. , Exclusive breastfeeding promotion by peer counsellors in sub-Saharan Africa (PROMISE-EBF): a cluster-randomised trial., 2011	Not a high-income country setting
Tylleskar T., PROMISE EBF: safety and efficacy of exclusive breastfeeding promotion in the era of HIV in sub-Saharan Africa. ClinicalTrials.gov (clinicaltrials.gov/) (accessed 20 February 2008).	Not a high-income country setting
Valdes, V., Pugin, E., Schooley, J., Catalan, S., Aravena, R., Clinical support can make the difference in exclusive breastfeeding success among working women, Journal of tropical pediatrics, 46, 149-54, 2000	Not an RCT
Vianna MN, Barbosa AP, Carvalhaes AS, Cunha AJ. Music, Music therapy may increase breastfeeding rates among mothers of premature newborns: a randomized controlled trial [A musicoterapia pode aumentar os indices de aleitamento materno entre maes de recemâ€• nascidos prematuros: um ensaio clinico randomizado controlado], Jornal de Pediatria, 87, 206-12, 2011	Study conducted in Brazil
Vitolo MR, Bortolini GA , Feldens CA, Drachler Mde L, Impacts of the 10 Steps to Healthy Feeding in Infants: a randomized field trial [Impactos da implementacao dos dez passos da alimentacao saudavel para criancas: ensaio de campo randomizado]. , Cadernos de Saude Publica 2005;21 (5):1448â□“57., 2005	Study conducted in Brazil
Vitolo MR, Bortolini GA, Campagnolo PD, Hoffman DJ. , Maternal dietary counseling reduces consumption of energy-dense foods among infants: a randomized controlled trial., 44 (2):140â□“7., 2012	Study conducted in Brazil
Vitolo MR, Bortolini GA, Dal Bo Campagnolo P, Feldens CA. , Effectiveness of a nutrition program in reducing symptoms of respiratory morbidity in children: a randomized field trial., 2008	Study conducted in Brazil
Vitolo MR, Louzada ML, Rauber F, Grechi P, Gama CM., The impact of health workers' training on breastfeeding and complementary feeding practices., Cadernos De Saude Publica, 30, 1695-707, 2014	Study conducted in Brazil
Vitolo MR, Rauber F, Campagnolo PD, Feldens CA, Hoffman DJ. , Maternal dietary counseling in the first year of life is associated with a higher healthy eating index in childhood. , Journal of Nutrition 2010;140 (11):2002â□“7., 2010	Study conducted in Brazil
Wade, D., Haining, S., Day, A., Breastfeeding peer support: are there additional benefits?, Community practitioner : the journal of the	Not an RCT

Study	Reason for exclusion
Community Practitioners' & Health Visitors' Association, 82, 30-33, 2009	
Walkup,J.T., Barlow,A., Mullany,B.C., Pan,W., Goklish,N., Hasting,R., Cowboy,B., Fields,P., Baker,E.V., Speakman,K., Ginsburg,G., Reid,R., Randomized controlled trial of a paraprofessional-delivered in-home intervention for young reservation-based American Indian mothers, Journal of the American Academy of Child and Adolescent Psychiatry, 48, 591-601, 2009	No relevant outcomes
Wallace, L. M., Dunn, O. M., Law, S., Bryce, C., A new approach to breastfeeding training, Practising Midwife, 12, 47-9, 2009	No relevant outcomes
Walsh, A., Moseley, J., Jackson, W., The effects of an infant-feeding classroom activity on the breast-feeding knowledge and intentions of adolescents, Journal of School Nursing, 24, 164-9, 2008	Not an RCT
Walshaw, C. A., Owens, J. M., Scally, A. J., Walshaw, M. J., Does breastfeeding method influence infant weight gain?, Archives of Disease in Childhood, 93, 292-6, 2008	Not an RCT
Wambach K, Rojjanasrirat W, Williams Domian E, Aaronson L, Breedlove G, Yeh HW., Effects of a peer counselor and lactation consultant on breastfeeding initiation and duration. , Journal of Human Lactation 2009; 25(1):101â□“2., 2009	Conference abstract
Wambach K. , Kansas University Teen Mothers Project. , clinicaltrials.gov/ct2/show/NCT00222118 (first received 13 September 2005).	Clinical trial registration
Wan H, Hu S, Thobaben M, Hou Y, Yin T. , Continuous primary nursing care increases satisfaction with nursing care and reduces postpartum problems for hospitalized pregnant women., Contemporary Nurse, 37(2):149â□“59., 2011	Study conducted in China
Webb Girard A, Kamau-Mbuthia E, Mbugua S, Kalungu S, Sarange C, Lou W, et al., Infant medication, illness and growth in a randomized controlled trial of exclusive breastfeeding support in Kenya., Annals of Nutrition & Metabolism 2013;63(Suppl 1):752, Abstract no: PO1034., 2013	Conference abstract
Wen LM, Baur LA, Rissel C, Simpson JM. , A randomized controlled trial of an early intervention on childhood obesity: results from the first 12 months., Obesity (Silver Spring, Md.)., 19, S67, 2011	Conference abstract
Wen LM, Baur LA, Simpson JM, Rissel C, Wardle K, Flood VM., Effectiveness of home based early intervention on children's BMI at age 2: randomised controlled trial., BMJ (Online), 345, e3732, 2012	No relevant outcomes
Wen, L. M., Baur, L. A., Rissel, C., Simpson, J. M., A randomized controlled trial of an early intervention on childhood obesity: Results from the first 12 months, Obesity, 1), S67, 2011	Conference abstract
Westdahl CM, Kershaw T, Schindler-Rising S, Ickovics J., Group prenatal care improves breastfeeding initiation and duration: results from a two-site randomized controlled trial. , Journal of Human Lactation, 24, 96â□“7, 2008	Conference abstract
Westphal MF, Taddei JA, Venancio SI, Bogus CM. , Breast-feeding training for health professionals and resultant institutional changes. , Bulletin of the World Health Organization, 73(4):461â□“8., 1995	Study conducted in Brazil
Whitford, H. M, Wallis, S. K, Dowswell, T, West, H. M, Renfrew, M. J., Breastfeeding education and support for women with twins or higher order multiples, Cochrane Database of Systematic Reviews, 2017 (2) (no pagination), 2017	Cochrane systematic review - used to identify studies for this review
Wilhelm, S. L., Rodehorst, T. K., Stepans, M. B., Hertzog, M., Berens, C., Influence of intention and self-efficacy levels on duration of	Not an RCT

Study	Reason for exclusion
breastfeeding for midwest rural mothers, Appl Nurs ResApplied nursing research : ANR, 21, 123-30, 2008	
Williams A, Chantry C, Dentz H, Kiprotich M, Null C, Stewart C. , Effectiveness of behavior change communication on maternal nutrition and breastfeeding practices within a cluster randomized trial in rural Western Kenya. , Journal of Human Lactation, 31(3):534â□“5., 2015	Study conducted in Kenya
Winterburn S, Moyez J, Thompson J. , Maternal grandmothers and support for breastfeeding. , Journal of Community Nursing 2003;17(12):4â□“9., 2003	No relevant outcomes
Wong, E. H., Nelson, E., Choi, K. C., Wong, K. P., Ip, C., Ho, L. C., Evaluation of a peer counselling programme to sustain breastfeeding practice in Hong Kong, International Breastfeeding Journal, 2, 12, 2007	Not an RCT
Wood, N. K., Woods, N. F., Outcome Measures in Interventions That Enhance Breastfeeding Initiation, Duration, and Exclusivity: A Systematic Review, Mcn, The American journal of maternal child nursing. 43, 341-347, 2018	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Wood, N. K., Woods, N. F., Blackburn, S. T., Sanders, E. A., Interventions that Enhance Breastfeeding Initiation, Duration, and Exclusivity: A Systematic Review, 41, 299-307, 2016	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Wouk, K., Tully, K. P., Labbok, M. H., Systematic Review of Evidence for Baby-Friendly Hospital Initiative Step 3, Journal of human lactation : official journal of International Lactation Consultant Association, 33, 50-82, 2017	Studies included in the systematic review were assessed for inclusion in the present review. If relevant, the primary studies were included rather than the review
Wrenn SE., Effects of a model-based intervention on breastfeeding attrition [dissertation]. , San Antonio: University of Texas, 1997., 1997	Dissertation
Wu DS, Hu J, McCoy TP, Efird JT., The effects of a breastfeeding self-efficacy intervention on short-term breastfeeding outcomes among primiparous mothers in Wuhan, China., 2014	Study conducted in China
Yang S, Platt RW, Dahhou M, Kramer M S., Do population-based interventions widen or narrow socioeconomic inequalities? The case of breastfeeding promotion. , International Journal of Epidemiology, 43, 1284â€“92, 2014	Study conducted in Belarus
Yotebieng M, Labbok M, Soeters HM, Chalachala JL, Lapika B, Vitta BS, et al. , Ten steps to successful breastfeeding programme to promote early initiation and exclusive breastfeeding in dr congo: a cluster-randomised controlled trial. , Lancet Global Health, 3, e546â□“55, 2015	Study conducted in DR Congo

1 Economic studies

2 Table 43 Excluded studies and reasons for their exclusion

Study	Reason for exclusion
DelliFraine J, Langabeer J 2nd, Delgado R, Williams JF, Gong A. A transition strategy for	Non-comparative; not an economic evaluation. Explores the organisational costs (Baby-Friendly

Study	Reason for exclusion
becoming a baby-friendly hospital: exploring the costs, benefits, and challenges. Breastfeed Med. 2013; 8:170-5.	Initiative [BFI] application and certification process; formula and related supplies; organisational training; personnel and staffing; organisational structuring and process) of implementing BFI in a tertiary teaching hospital in the US
Frick KD, Milligan RA, White KM, Serwint JR, Pugh LC. Nurse-supported breastfeeding promotion: a framework for economic evaluation. Nurs Econ 2005; 23(4):165-72, 206, 147.	Not an economic evaluation. General description of methodology for economic evaluation.
Holla-Bhar R, Iellamo A, Gupta A, Smith JP, Dadhich JP. Investing in breastfeeding - the world breastfeeding costing initiative. Int Breastfeed J. 2015; 10:8.	Not an economic evaluation. Aims to determine the financial investment that is necessary to implement the WHO and UNICEF Global Strategy for infant and young child feeding, and to introduce a tool to estimate the costs for individual countries.
Nkonki L, Tugendhaft A, Hofman K. A systematic review of economic evaluations of CHW interventions aimed at improving child health outcomes. Hum Resour Health 2017; 15(1):19.	Systematic review – checked for references to primary economic evaluations of interventions aimed at promoting breastfeeding.
Pham CT, Karnon JD, Middleton PF, Bloomfield FH, Groom KM, Crowther CA, Mol BW. Randomised clinical trials in perinatal health care: a cost-effective investment. Med J Aust 2017; 207(7):289-293.	Estimation of investment costs of interventions assessed in published RCTs, including 1 RCT on intervention aiming at promoting breastfeeding (Maycock 2013), in Australia. Reports cost-savings over 6 weeks associated with a reduction in formula feeding resulting from implementation of trial findings [not relevant to NHS/PSS perspective].
Wiggins M, Oakley A, Roberts I, Turner H, Rajan L, Austerberry H, Mujica R, Mugford M. The Social Support and Family Health Study: a randomised controlled trial and economic evaluation of two alternative forms of postnatal support for mothers living in disadvantaged inner-city areas. Health Technol Assess 2004; 8(32)	Initiating / maintaining breastfeeding not the main purpose of the intervention

1
2

Appendix L – Research recommendations

Research recommendations for review questions:

What interventions are effective in starting and maintaining breastfeeding (single births)?

What interventions are effective in starting and maintaining breastfeeding (twins and triplets)?

No research recommendations were made for these review questions.

Appendix M – Pairwise meta-analysis and meta-regression results

Introduction – overview of meta-regression

Due to the large volume of included studies for intervention 2 'education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth' and the variability of the interventions across the studies, meta-regression was conducted in addition to the pair-wise meta-analysis. Meta-regression allows for the analysis of the effectiveness of the different variables that made up each study's intervention and would determine what component of an intervention was effective irrespective of all other components that made up the intervention. Meta-regression was implemented in WinBUGS 1.4.3 (Spiegelhalter 2003).

For the purpose of the meta-regression analysis, each study under this intervention category was categorised using the following variables:

- number of contact visits
  - 0 contacts, code in WinBUGS: contact0
  - 1 contact, code in WinBUGS: contact1
  - 2 to 3 contacts, code in WinBUGS: contact23
  - 4 to 8 contacts, code in WinBUGS: contact48
  - 9 or more contacts, code in WinBUGS: contact9
- how delivered
  - Face-to-face on an individual basis, code in WinBUGS: Individual
  - Face-to-face in a group, code in WinBUGS: Group
  - Remote, code in WinBUGS: Remote
  - Self-help, code in WinBUGS: Selfhelp
- duration of contact
  - contact with the intervention lasted more than 8 weeks, code in WinBUGS: contactmore8
  - contact with the intervention lasted less than 8 weeks, code in WinBUGS: contactless8
- where the intervention was delivered
  - at the woman's home, code in WinBUGS: Home
  - in a healthcare setting code in WinBUGS: healthcaresetting
  - combination of both home and healthcare setting code in WinBUGS: Mixed

Individual models were first run for each of the variable categories (number of contacts, how delivered, duration of contact and where the intervention was delivered). A final 'combined' model was then run incorporating as many of the variables as possible without the model crashing. The model crashing was dependent on the amount of data identified. The final model of each outcome incorporated the number of contacts, how delivered and where the intervention was delivered. Duration of contact was not incorporated as this destabilised the model; in addition, it was felt that this variable was in part captured by the number of contacts variable.

WinBUGS code, goodness of fit assessment and outputs of the analysis

A sample WinBUGS code for the analysis of any breastfeeding at 16 to 26 weeks is given in Table 44 for the following variables: how the intervention was delivered, the number of contacts for the intervention and where the intervention was delivered. The code was adapted from Welton 2009. Other analyses used the same substantive code, but were modified to include the relevant predictor variables for the model under consideration.

Goodness of fit was assessed by the deviance information criterion (DIC); the combined model was deemed to have a good fit if the DIC was lower or within 3 points of the individual models. Each WinBUGS model was run with an initial burn-in period of 50,000 iterations, followed by 50,000 further iterations.

Results were reported as RRs with 95% CIs of each intervention component versus standard care. Moreover, for the combined model, the probability that each intervention component was the best, second best, third best, etc. was recorded.

Table 44. Sample WinBUGS code for the analysis of any breastfeeding at 16 to 26 weeks for the following variables: how the intervention was delivered, the number of contacts for the intervention and where the intervention was delivered

Sample WinBUGS code

```
model{
for (i in 1:ndata){
        r[i]~dbin(p[i],n[i])
        logit(p[i])<- mu[s[i]] + delta[i]*(1-equals(trt[i],1))
        delta[i]~dnorm(md[i],taud[i])
        md[i] <-c[2]*(1-equals(Individual[i],0)) + c[3]*(1-equals(Group[i],0)) + c[4]*(1-
equals(Selfhelp[i],0))+ d[2]*(1-equals(healthcaresetting[i],0)) + d[3]*(1-equals(Home[i],0)) + b[2]*(1-
equals(contact1[i],0)) + b[3]*(1-equals(contact23[i],0)) +  b[4]*(1-equals(contact48[i],0)) + b[5]*(1-
equals(contact9[i],0)) + sw[i]*equals(m[i],3)
        taud[i]<- tau*(1+equals(m[i],3)/3)
#Deviance contribution
    rhat[i] <- p[i] * n[i]
    dev[i] <- 2 * (r[i] * (log(r[i])-log(rhat[i]))  +  (n[i]-r[i]) * (log(n[i]-r[i]) - log(n[i]-rhat[i])))
}
        resdev<- sum(dev[])
sw[1]<- 0
for (i in 2:ndata){
sw[i]<- (delta[i-1] - (c[2]*(1-equals(Individual[i],0)) + c[3]*(1-equals(Group[i],0)) + c[4]*(1-
equals(Selfhelp[i],0))+ d[2]*(1-equals(healthcaresetting[i],0)) + d[3]*(1-equals(Home[i],0)) +b[2]*(1-
equals(contact1[i],0)) + b[3]*(1-equals(contact23[i],0)) +  b[4]*(1-equals(contact48[i],0)) + b[5]*(1-
equals(contact9[i],0))))/2}
for (j in 1:nstudy){
        mu[j]~dnorm(0,.01)
}
tau<- 1/(sd*sd)
sd~dunif(0,2)
A ~ dnorm(-0.305847485, 1285.55347)

d[1]<-0
for (k in 2:ntrtd){
        d[k]~dnorm(0,.01)
        ord[k]<- exp(d[k])
}
for (k in 1:ntrtd) { logit(Td[k]) <- A + d[k] }
rrd[1]<-1
for (k in 2:ntrtd) {
rrd[k] <- Td[k]/Td[1]
}
c[1]<-0
```

Sample WinBUGS code

```
for (k in 2:ntrtc){
        c[k]~dnorm(0,.01)
        orc[k]<- exp(c[k])
}
for (k in 1:ntrtc) { logit(Tc[k]) <- A + c[k] }
rrc[1]<-1
for (k in 2:ntrtc) {
rrc[k] <- Tc[k]/Tc[1]
}
b[1]<-0
for (k in 2:ntrtb){
        b[k]~dnorm(0,.01)
        orb[k]<- exp(b[k])
}
for (k in 1:ntrtb) { logit(Tb[k]) <- A + b[k] }
rrb[1]<-1
for (k in 2:ntrtb) {
rrb[k] <- Tb[k]/Tb[1]
}
dum1<- usual[1]
dum2<-contactmore8[1]
dum3<-contactless8[1]
dum4<-contact0[1]
dum5<-Mixed[1]
dum6<-Remote[1]
}
```

Results

Initiation of breastfeeding

Table 45 reports the results of the pairwise meta-analysis for the comparison of education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus standard care as calculated in Rev Man, the meta-regression results of intervention 2 versus standard care as calculated for each variable in WinBUGS (from individual models), and the combined meta-regression model results as calculated in WinBUGS. Results in **bold** indicate a statistically significant result.

Table 45: Initiation of breastfeeding

	RR	95% CI lower	95% CI upper	DIC	Calculated
Int 2 vs standard care	**1.05**	**1.01**	**1.09**	NA	RevMan
Subgroup: General population	1.01	0.99	1.03	NA	RevMan
Subgroup: Low income	**1.16**	**1.03**	**1.31**	NA	RevMan
Subgroup: Obese women	0.99	0.90	1.08	NA	RevMan
Subgroup: Young women	1.10	0.83	1.46	NA	RevMan
Subgroup Obese + low income women	1.00	0.96	1.04	NA	RevMan

Subgroup: Young + low income women	**1.29**	**1.03**	**1.61**	NA	RevMan
Int 2 vs standard care (Int to HCP)	1.04	0.98	1.10	NA	RevMan
Int 1 v Int 2	0.96	0.92	1.01	NA	RevMan
Int 2 vs Int 2 (home visits vs printed materials)	1.04	0.91	1.18	NA	RevMan
How					
Face2Face – individual vs standard care	**1.09**	**1.02**	**1.15**	247.41	WinBUGS
Face2Face – group vs standard care	NA	NA	NA		WinBUGS
Remote vs standard care	0.99	0.78	1.12		WinBUGS
Self-help vs standard care	1.02	0.68	1.22		WinBUGS
Number of Contacts					
0 - 1 vs standard care	0.96	0.55	1.19	245.09	WinBUGS
2 - 3 vs standard care	1.01	0.91	1.10		WinBUGS
4 - 8 vs standard care	1.07	0.95	1.17		WinBUGS
9+ vs standard care	**1.11**	**1.05**	**1.16**		WinBUGS
Duration of contact					
Less than 8 weeks vs standard care	1.05	0.99	1.12	245.92	WinBUGS
More than 8 weeks vs standard care	**1.10**	**1.03**	**1.15**		WinBUGS
Where delivered					
Heathcare setting vs standard care	1.10	0.96	1.19	241.95	WinBUGS
Home vs standard care	1.02	0.96	1.08		WinBUGS
Mixed vs standard care	**1.14**	**1.08**	**1.19**		WinBUGS
Meta regression combined model results					
Contacts 2 - 3 vs standard care	1.00	0.82	1.15	241.16	WinBUGS
Contacts 4 - 8 vs standard care	1.03	0.84	1.17		WinBUGS
Contacts 9+ vs standard care	**1.10**	**1.01**	**1.18**		WinBUGS
Face2Face individual vs standard care	1.10	0.99	1.18		WinBUGS
Self-help vs standard care	1.13	0.93	1.25		WinBUGS
Healthcare setting vs standard care	0.86	0.61	1.07		
Home vs standard care	**0.84**	**0.69**	**0.97**		WinBUGS

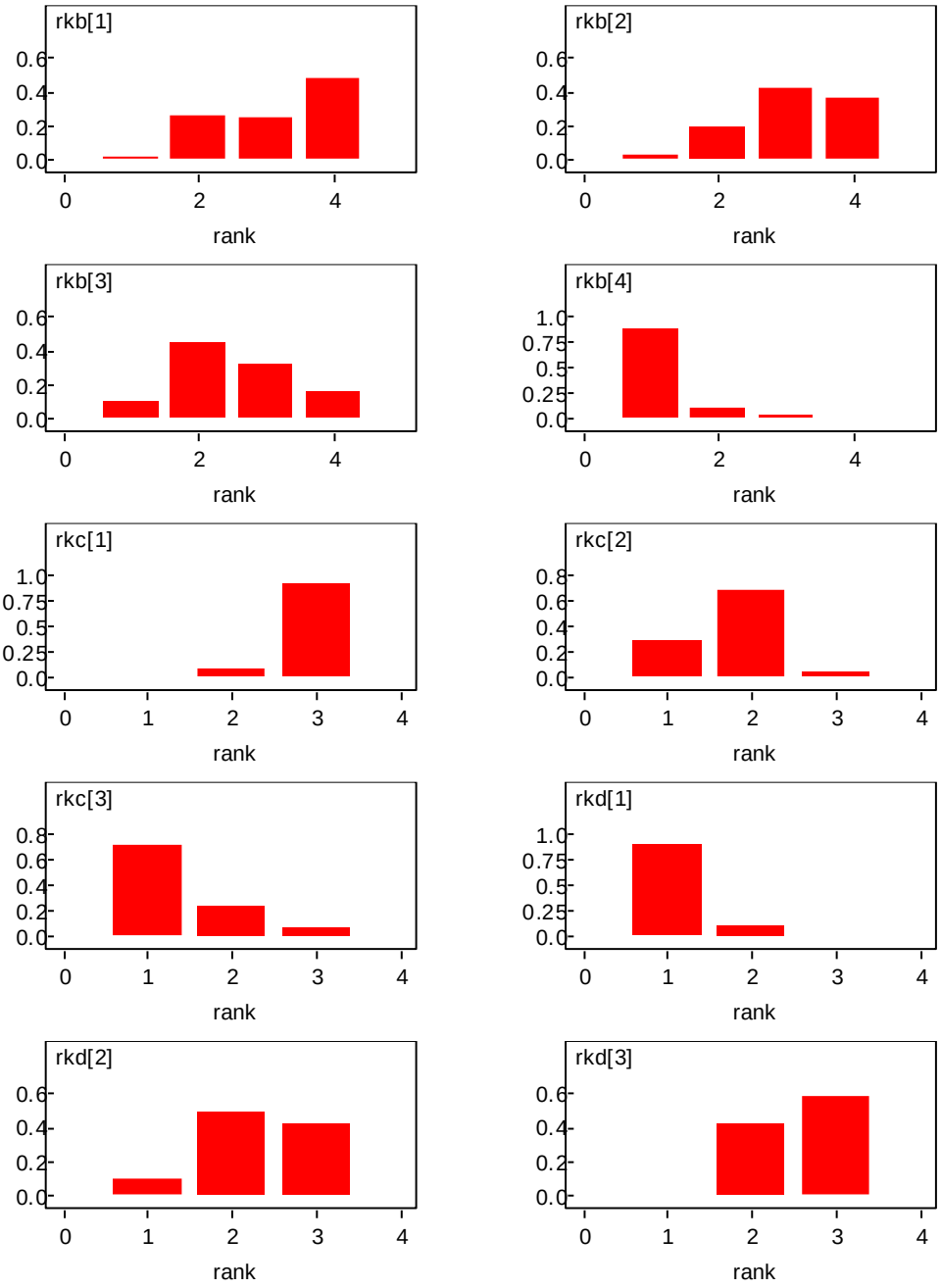
Note: No studies using a group design were identified. Data for 0 contacts and 1 contact needed to be merged to make the data fit into the model (due to the low number of studies identified for these variables)General population in this case means any study that was relevant to this outcome but not classified within another subgroup.

Figures: Probability that the intervention component [1, 2, 3, 4] is the most effective, 2nd most effective, 3rd most effective, or 4th most effective, as relevant, for each variable rkb, rkc, rkd.

rkb[1] standard care; rkb[2] Contacts 2 - 3; rkb[3] Contacts 4 - 8; rkb[4] Contacts 9+

rkc[1] standard care; rkc[2] Face2face individual contact; rkc[3] Self-help

rkd[1] standard care; rkd[2] healthcare setting; rkd[3] home setting



Any breastfeeding 3 to 14 days

Table 46 reports the results of the pairwise meta-analysis for the comparions of education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus standard care as calculated in Rev Man, the meta-regression results of intervention 2 versus standard care as calculated for each variable in WinBUGS (from individual models), and the combined meta-regression model results as calculated in WinBUGS. Results in bold indicate a statistically significant result.

1 **Table 46: Any breastfeeding 3 to 14 days**

	RR	95% CI lower	95% CI upper	DIC	Calculated
Int 2 vs standard care	**1.10**	**1.04**	**1.16**	NA	RevMan
Subgroup: General population	**1.04**	**1.02**	**1.07**	NA	RevMan
Subgroup: Low income	**1.52**	**1.05**	**2.20**	NA	RevMan
Subgroup: Obese and low income women	1.10	0.99	1.23	NA	RevMan
Int 2 vs standard care (area)	-0.00*	-0.03	0.03	NA	RevMan
Int 1 vs Int 2	0.96	0.92	1.01	NA	RevMan
Subgroup: General population	0.96	0.92	1.01	NA	RevMan
Subgroup: Low income	0.85	0.50	1.43	NA	RevMan
Int 2 vs Int 2 (home visit vs telephone call)	1.01	0.94	1.09	NA	RevMan
Int 2 vs Int 2 (home visits vs printed materials)	1.04	0.90	1.20	NA	RevMan
Int 2 versus Int 2 (home versus clinic contact)	1.00	0.96	1.03	NA	RevMan
How					
Face2Face – individual vs standard care	**1.15**	**1.08**	**1.22**	194.98	WinBUGS
Face2Face – group vs standard care	**1.31**	**1.21**	**1.36**		WinBUGS
Remote vs standard care	1.10	0.94	1.23		WinBUGS
Self-help vs standard care	1.07	0.77	1.26		WinBUGS
Number of Contacts					
0 vs standard care	1.13	0.63	1.32	196.61	WinBUGS
1 vs standard care	1.10	0.81	1.27		WinBUGS
2 - 3 vs standard care	**1.16**	**1.01**	**1.27**		WinBUGS
4 - 8 vs standard care	1.11	0.88	1.26		WinBUGS
9+ vs standard care	**1.21**	**1.11**	**1.28**		WinBUGS
Duration of contact					
Less than 8 weeks vs standard care	**1.11**	**1.02**	**1.20**	196.27	WinBUGS
More than 8 weeks vs standard care	**1.19**	**1.13**	**1.26**		WinBUGS
Where delivered					
Healthcare setting vs standard care	**1.19**	**1.12**	**1.26**	195.42	WinBUGS
Home vs standard care	1.07	0.99	1.16		WinBUGS
Mixed vs standard care	**1.20**	**1.12**	**1.26**		WinBUGS
Meta regression combined model results					
Contact 1 vs standard care	0.95	0.41	1.28	195.69	WinBUGS
Contacts 2 - 3 vs standard care	0.89	0.40	1.26		WinBUGS
Contacts 4 - 8 vs standard care	0.85	0.29	1.26		WinBUGS
Contacts 9+ vs standard care	0.98	0.46	1.29		WinBUGS

Face2Face individual vs standard care	1.22	0.84	1.33		WinBUGS
Face2Face group versus standard care	**1.31**	**1.13**	**1.36**		WinBUGS
Remote versus standard care	1.17	0.70	1.32		WinBUGS
Self-help versus standard care	1.22	0.94	1.32		WinBUGS
Healthcare setting versus standard care	0.82	0.50	1.11		WinBUGS
Home versus standard care	**0.67**	**0.40**	**0.96**		WinBUGS

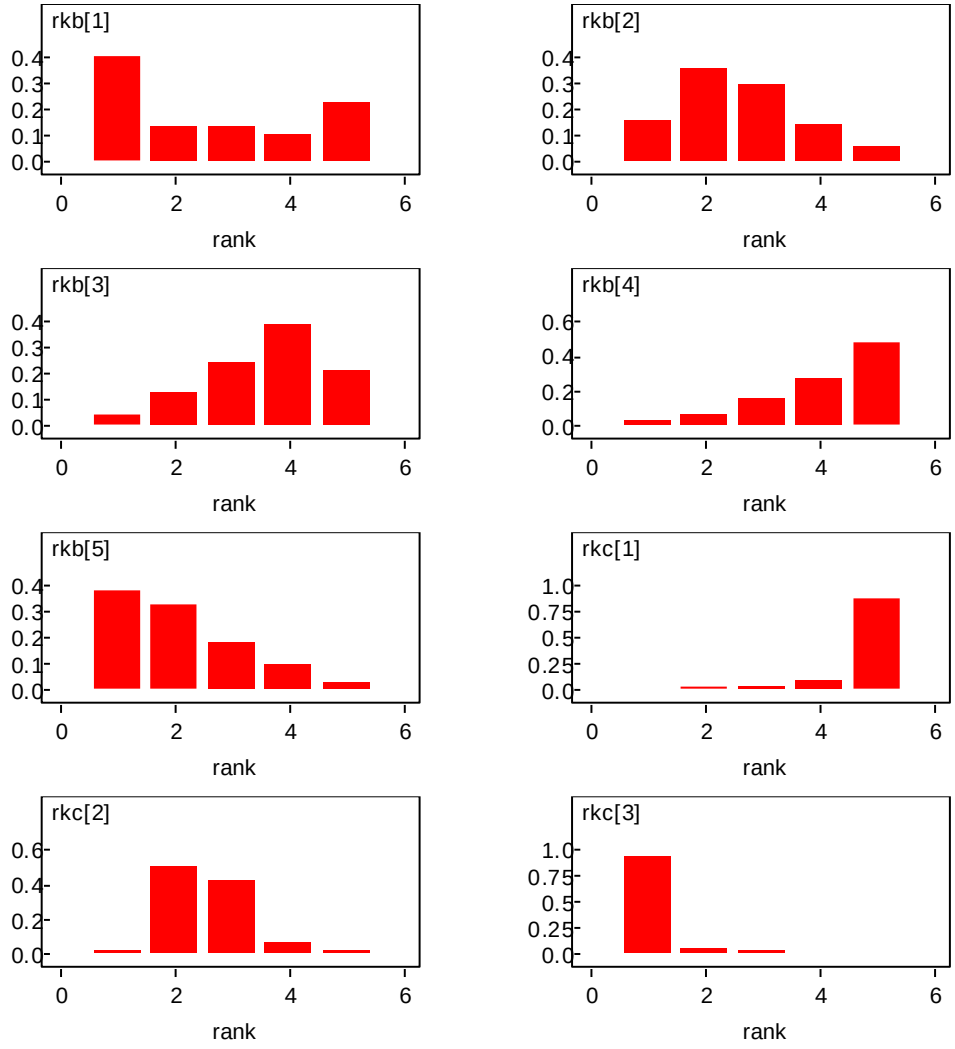
*Note: * mean difference, not risk ratio*

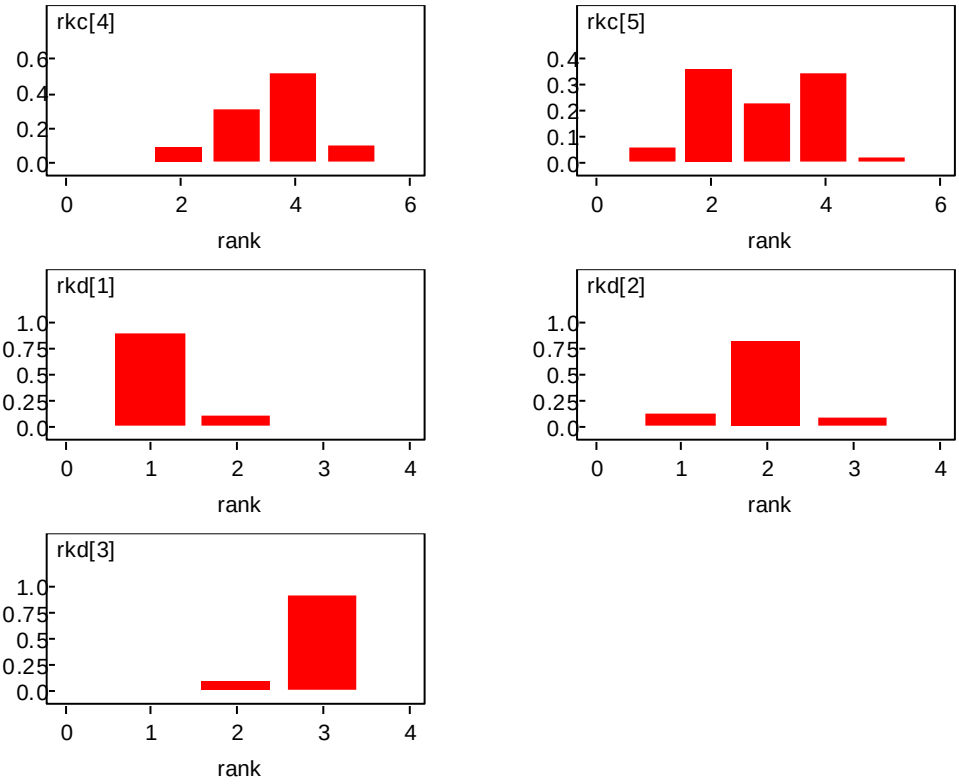
General population in this case means any study that was relevant to this outcome but not classified within another subgroup.**Figures:** Probability that the intervention component [1, 2, 3, 4, 5] is the most effective, 2nd most effective, 3rd most effective, 4th most effective, or 5th most effective, as relevant, for each variable b, c, d.

rkb[1] standard care; rkb[2] Contact 1; rkb[3] Contacts 2-3; rkb[4] Contacts 4-8; rkb[5] Contacts 9+

rkc[1] standard care; rkc[2] Face2Face individual; rkc[3] Face2Face group; rkc[4] Remote; rkc[5] Self-help

rkd[1] standard care; rkd[2] Healthcare setting; rkd[3] Home





Exclusive breastfeeding 3 to 14 days

Table 47 reports the results of the pairwise meta-analysis for the comparison of education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus standard care as calculated in RevMan, the meta-regression results of intervention 2 versus standard care as calculated for each variable in WinBUGS (from individual models), and the combined meta-regression model results as calculated in WinBUGS. Results in bold indicate a statistically significant result.

Table 47: Exclusive breastfeeding 3 to 14 days

	RR	95% CI lower	95% CI upper	DIC	Calculated
Int 2 vs standard care	**1.23**	**1.07**	**1.41**	NA	RevMan
Subgroup: General population	1.15	0.98	1.36	NA	RevMan
Subgroup: Low income	**1.41**	**1.07**	**1.86**	NA	RevMan
Subgroup: Obese women	1.11	0.74	1.65	NA	RevMan
Subgroup: Obese and low income women	1.37	0.69	2.70	NA	RevMan
Int 1 vs Int 2	0.72	0.50	1.03	NA	RevMan
Int 2 vs Int 2 (home visits vs printed materials)	**2.27**	**1.05**	**4.91**	NA	RevMan
Int 2 vs Int 2 (home vs clinic contact)	1.05	0.93	1.18	NA	RevMan
How					
Face2Face – individual vs standard care	**1.12**	**1.00**	**1.27**	217.93	WinBUGS
Face2Face – group vs standard care	**1.73**	**1.39**	**1.94**		WinBUGS
Remote versus standard care	1.17	0.95	1.37		WinBUGS

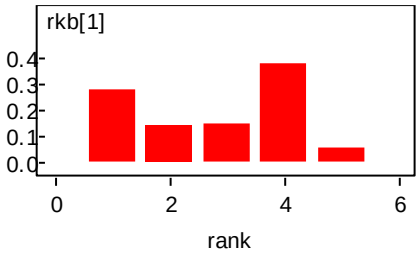
Self-help vs standard care	0.75	0.42	1.14		WinBUGS
Number of Contacts					
0 vs standard care	0.88	0.31	1.53	219.85	WinBUGS
1 vs standard care	0.45	0.03	1.43		WinBUGS
2 - 3 vs standard care	**1.17**	**1.00**	**1.36**		WinBUGS
4 - 8 vs standard care	1.10	0.85	1.36		WinBUGS
9+ vs standard care	**1.34**	**1.13**	**1.54**		WinBUGS
Duration of contact					
Less than 8 weeks vs standard care	1.16	1.01	1.32	219.70	WinBUGS
More than 8 weeks vs standard care	**1.28**	**1.08**	**1.48**		WinBUGS
Where delivered					
Healthcare setting vs standard care	**1.29**	**1.06**	**1.51**	219.57	WinBUGS
Home vs standard care	1.20	0.98	1.41		WinBUGS
Mixed vs standard care	1.13	0.89	1.38		WinBUGS
Meta regression combined model results					
Contact 1 vs standard care	0.33	0.01	1.38	218.83	WinBUGS
Contacts 2 - 3 vs standard care	1.15	0.43	1.75		WinBUGS
Contacts 4 - 8 vs standard care	1.05	0.31	1.74		WinBUGS
Contacts 9+ vs standard care	0.99	0.25	1.73		WinBUGS
Face2Face individual vs standard care	0.91	0.25	1.64		WinBUGS
Face2Face group vs standard care	1.60	0.70	1.96		WinBUGS
Remote vs standard care	1.08	0.32	1.75		WinBUGS
Self-help vs standard care	0.51	0.11	1.25		WinBUGS
Healthcare setting vs standard care	1.17	0.83	1.47		WinBUGS
Home vs standard care	1.16	0.76	1.51		WinBUGS

1 General population in this case means any study that was relevant to this outcome but not
2 classified within another subgroup.**Figures:** Probability that the intervention component [1, 2,
3 3, 4, 5] is the most effective, 2nd most effective, 3rd most effective, 4th most effective, or 5th
4 most effective, as relevant, for each variable b, c, d.

5 rkb[1] standard care; rkb[2] Contact 1; rkb[3] Contacts 2 - 3; rkb[4] Contacts 4 - 8; b[5]
6 Contacts 9+

7 rkc[1] standard care; rkc[2] Face2Face individual; rkc[3] Face2Face group; rkc[4] Remote;
8 rkc[5] Self-help

9 rkd[1] standard care; rkd[2] Healthcare setting; rkd[3] Home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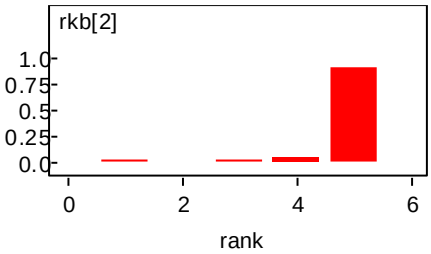
0.3
0.2
0.1
0.0
0
2
4
6
rank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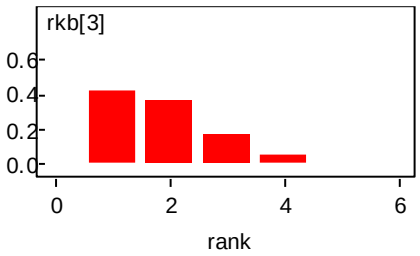
0.5
0.25
0.0
0
2
4
6
rank

1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0.2
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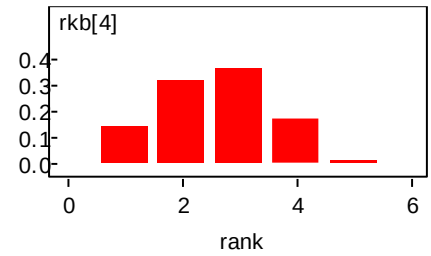
0
2
4
6
rank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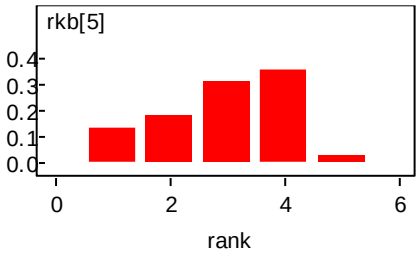
0
2
4
6
rank

2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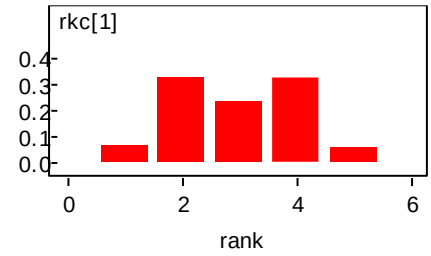
0.2
0.1
0.0
0
2
4
6
rank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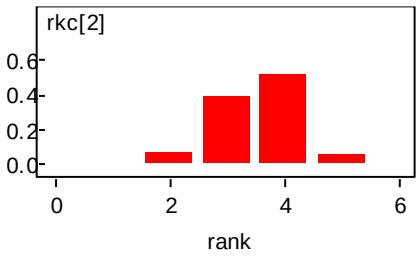
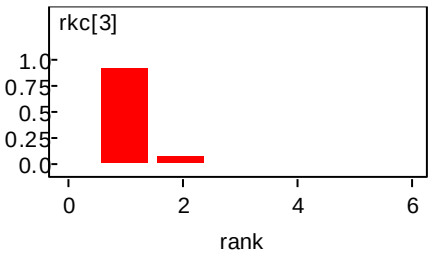
0.3
0.2
0.1
0.0
0
2
4
6
rank

3


rkc[2]
0.6
0.4
0.2
0.0
0
2
4
6
rank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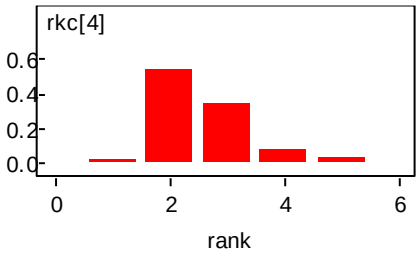
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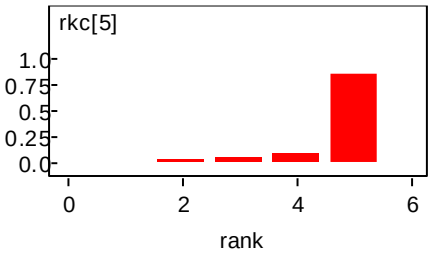
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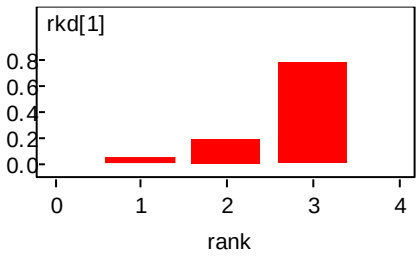
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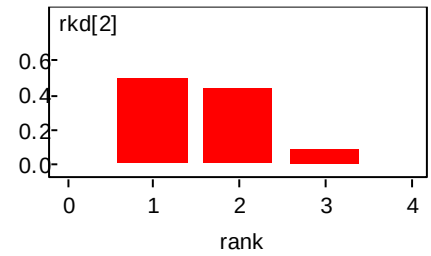
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rank

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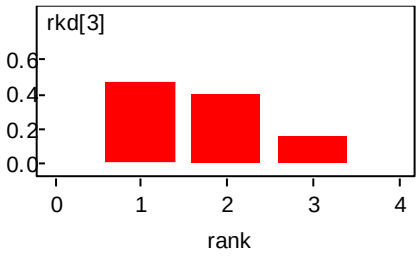
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2
3
4
rank

7

Any breastfeeding 6 to 12 weeks

Table 48 reports the results of the pairwise meta-analysis for the comparison of education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus standard care as calculated in RevMan, the meta-regression results of intervention 2 versus standard care as calculated for each variable in WinBUGS (from individual models), and the combined meta-regression model results as calculated in WinBUGS. Results in bold indicate a statistically significant result.

Table 48: Any breastfeeding 6 to 12 weeks

	RR	95% CI lower	95% CI upper	DIC	Calculated
Int 2 vs standard care	**1.09**	**1.05**	**1.13**	NA	RevMan
Subgroup: General population	**1.06**	**1.03**	**1.10**	NA	RevMan
Fathers	**1.30**	**1.21**	**1.39**	NA	RevMan
Int 2 vs standard care (area)	-0.02*	-0.04	0.00	NA	RevMan
Int 1 vs Int 2	0.89	0.77	1.02	NA	RevMan
Subgroup: General population	0.99	0.80	1.22	NA	RevMan
Subgroup: Low income	0.82	0.68	0.99	NA	RevMan
Int 2 vs Int 2 (video + feeding log vs video)	1.34	0.86	2.09	NA	RevMan
Int 2 vs Int 2 (home visits vs printed materials)	0.96	0.79	1.17	NA	RevMan
Int 2 vs Int 2 (proactive vs reactive calls)	1.29	0.87	1.93	NA	RevMan
How					
Face2Face – individual vs standard care	**1.10**	**1.04**	**1.15**	522.08	WinBUGS
Face2Face – group vs standard care	**1.52**	**1.20**	**1.71**		WinBUGS
Remote vs standard care	**1.15**	**1.07**	**1.24**		WinBUGS
Self-help vs standard care	1.05	0.77	1.31		WinBUGS
Number of Contacts					
0 vs standard care	1.08	0.90	1.26	519.91	WinBUGS
1 vs standard care	1.09	0.99	1.19		WinBUGS
2 - 3 vs standard care	1.04	0.97	1.12		WinBUGS
4 - 8 vs standard care	**1.19**	**1.11**	**1.27**		WinBUGS
9+ vs standard care	**1.18**	**1.10**	**1.26**		WinBUGS
Duration of contact					
Less than 8 weeks vs standard care	**1.08**	**1.03**	**1.14**	519.72	WinBUGS
More than 8 weeks vs standard care	**1.17**	**1.12**	**1.24**		WinBUGS
Where delivered					
Home vs standard care	**1.10**	**1.04**	**1.17**	524.62	WinBUGS
Healthcare setting vs standard care	**1.13**	**1.04**	**1.23**		WinBUGS
Mixed vs standard care	**1.16**	**1.06**	**1.26**		WinBUGS

Meta regression combined model results					
Contact 1 vs standard care	1.03	0.69	1.31	521.31	WinBUGS
Contacts 2 - 3 vs standard care	0.92	0.58	1.21		WinBUGS
Contacts 4 - 8 vs standard care	1.07	0.74	1.33		WinBUGS
Contacts 9+ vs standard care	1.05	0.73	1.31		WinBUGS
Face2Face individual vs standard care	1.15	0.85	1.43		WinBUGS
Face2Face group vs standard care	**1.49**	**1.07**	**1.71**		WinBUGS
Remote vs standard care	1.19	0.91	1.45		WinBUGS
Self-help vs standard care	1.12	0.83	1.37		WinBUGS
Healthcare setting vs standard care	0.99	0.85	1.13		WinBUGS
Home vs standard care	0.89	0.77	1.02		WinBUGS

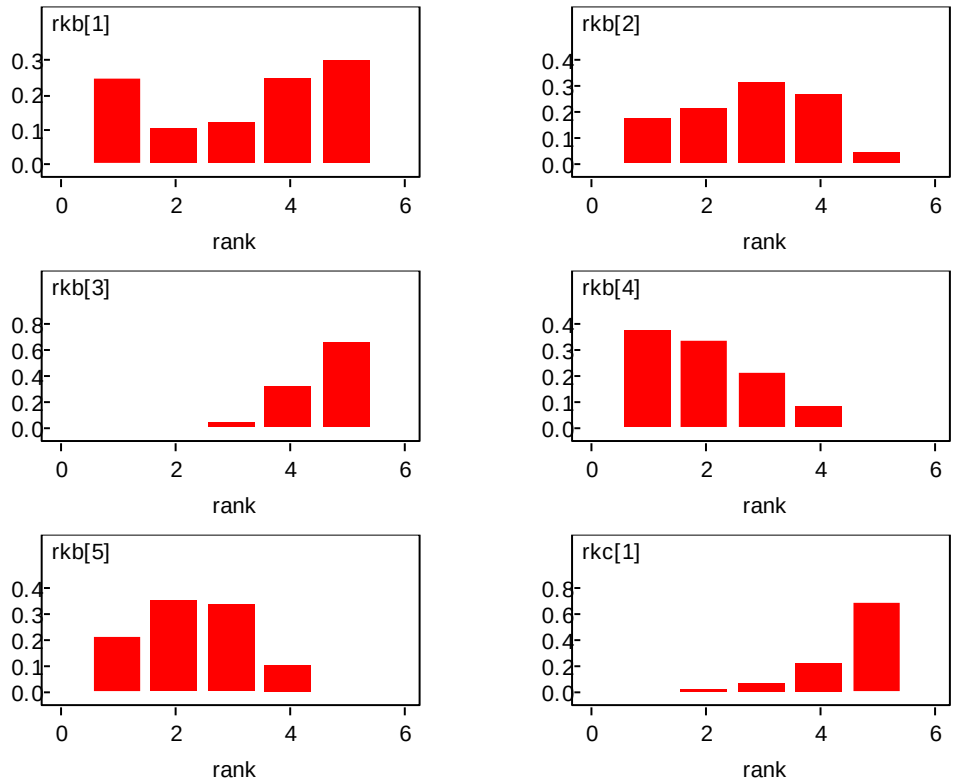
*Note: * mean difference, not risk ratio*

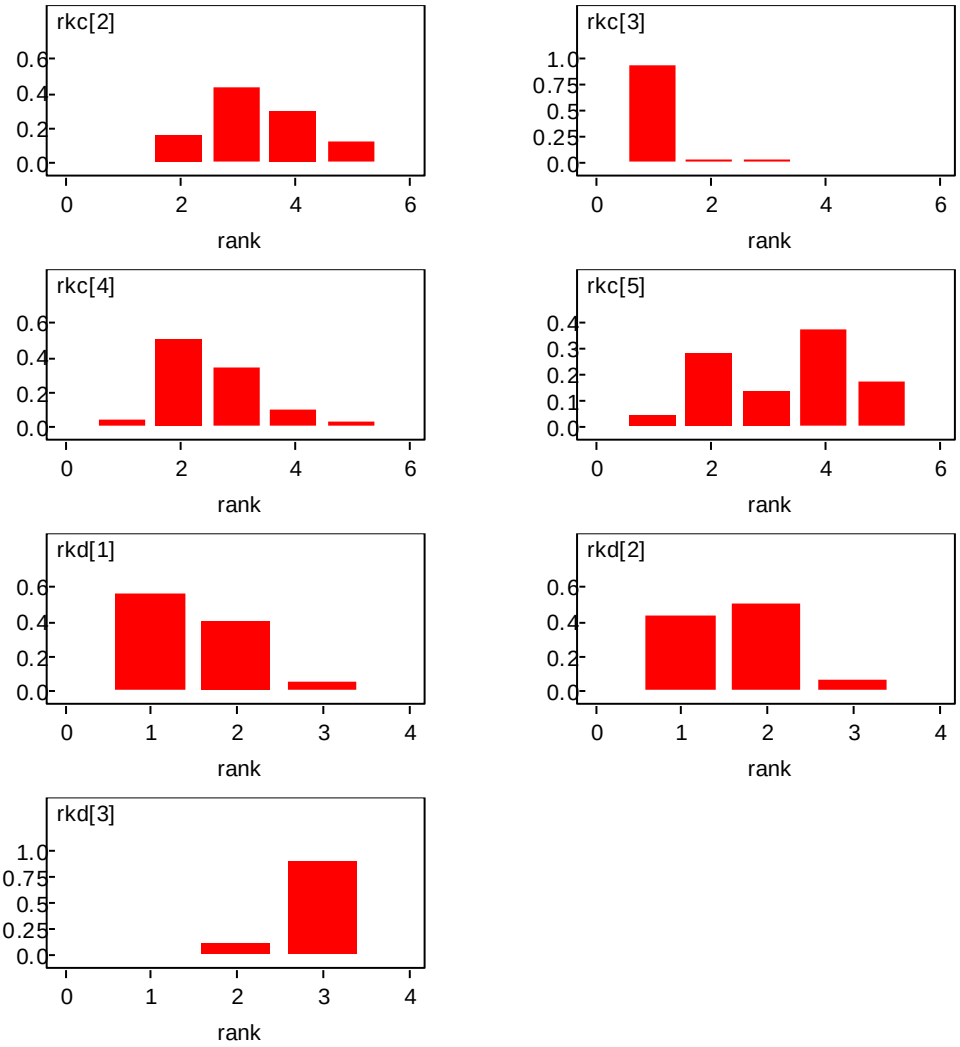
General population in this case means any study that was relevant to this outcome but not classified within another subgroup.**Figures:** Probability that the intervention component [1, 2, 3, 4, 5] is the most effective, 2nd most effective, 3rd most effective, 4th most effective, or 5th most effective, as relevant, for each variable b, c, d.

rkb[1] standard care; rkb[2] Contact 1; rkb[3] Contacts 2 - 3; rkb[4] Contacts 4 - 8; rkb[5] Contacts 9+

rkc[1] standard care; rkc[2] Face2Face individual; rkc[3] Face2Face group; rkc[4] Remote; rkc[5] Self-help

rkd[1] standard care; rkd[2] Healthcare setting; rkd[3] Home





Exclusive breastfeeding 6 to 12 weeks

Table 49 reports the results of the pairwise meta-analysis for the comparison of education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus standard care as calculated in Rev Man, the meta-regression results of intervention 2 versus standard care as calculated for each variable in WinBUGS (from individual models) and the combined meta-regression model results as calculated in WinBUGS. Results in bold indicate a statistically significant result.

Table 49: Exclusive breastfeeding 6 to 12 weeks

	RR	95% CI lower	95% CI upper	DIC	Calculated
Int 2 vs standard care	**1.34**	**1.19**	**1.51**	NA	RevMan
Subgroup: General population	**1.36**	**1.17**	**1.58**	NA	RevMan
Subgroup: Low income	**1.39**	**1.06**	**1.83**	NA	RevMan
Subgroup: Obese women	**1.42**	**1.09**	**1.85**	NA	RevMan
Subgroup: Obese and low income	0.54	0.14	2.07	NA	RevMan
Fathers	**1.25**	**1.06**	**1.47**	NA	RevMan

Int 1 vs Int 2	0.63	0.31	1.28	NA	RevMan
Subgroup: General population	1.03	0.66	1.60	NA	RevMan
Subgroup: Low income	**0.41**	**0.20**	**0.83**	NA	RevMan
Int 2 vs Int 2 (home visits vs printed materials)	1.91	0.18	20.69	NA	RevMan
Int 2 vs Int 2 (proactive vs reactive calls)	1.73	0.89	3.35	NA	RevMan
How					
Face2Face – individual vs standard care	**1.08**	**1.02**	**1.15**	323.52	WinBUGS
Face2Face – group vs standard care	**1.51**	**1.20**	**1.70**		WinBUGS
Remote vs standard care	**1.18**	**1.10**	**1.28**		WinBUGS
Self-help vs standard care	1.13	0.80	1.42		WinBUGS
Number of Contacts					
0 vs standard care	1.17	0.93	1.38	326.21	WinBUGS
1 vs standard care	0.93	0.69	1.16		WinBUGS
2 - 3 vs standard care	1.06	0.97	1.16		WinBUGS
4 - 8 vs standard care	**1.18**	**1.10**	**1.27**		WinBUGS
9+ vs standard care	**1.20**	**1.10**	**1.30**		WinBUGS
Duration of contact					
Less than 8 weeks vs standard care	**1.09**	**1.02**	**1.18**	326.88	WinBUGS
More than 8 weeks vs standard care	**1.17**	**1.09**	**1.26**		WinBUGS
Where delivered					
Home vs standard care	**1.11**	**1.02**	**1.19**	327.52	WinBUGS
Healthcare setting vs standard care	1.10	0.99	1.21		WinBUGS
Mixed vs standard care	**1.21**	**1.10**	**1.32**		WinBUGS
Meta regression combined model results					
Contact 1 vs standard care	0.90	0.48	1.31	323.38	WinBUGS
Contacts 2 - 3 vs standard care	1.07	0.73	1.39		WinBUGS
Contacts 4 - 8 vs standard care	1.10	0.80	1.39		WinBUGS
Contacts 9+ vs standard care	1.10	0.79	1.40		WinBUGS
Face2Face individual vs standard care	1.09	0.71	1.38		WinBUGS
Face2Face group vs standard care	**1.49**	**1.06**	**1.70**		WinBUGS
Remote vs standard care	1.26	0.91	1.50		WinBUGS
Self-help vs standard care	1.23	0.91	1.48		WinBUGS
Healthcare setting vs standard care	0.92	0.74	1.11		WinBUGS
Home vs standard care	0.79	0.62	0.97		WinBUGS

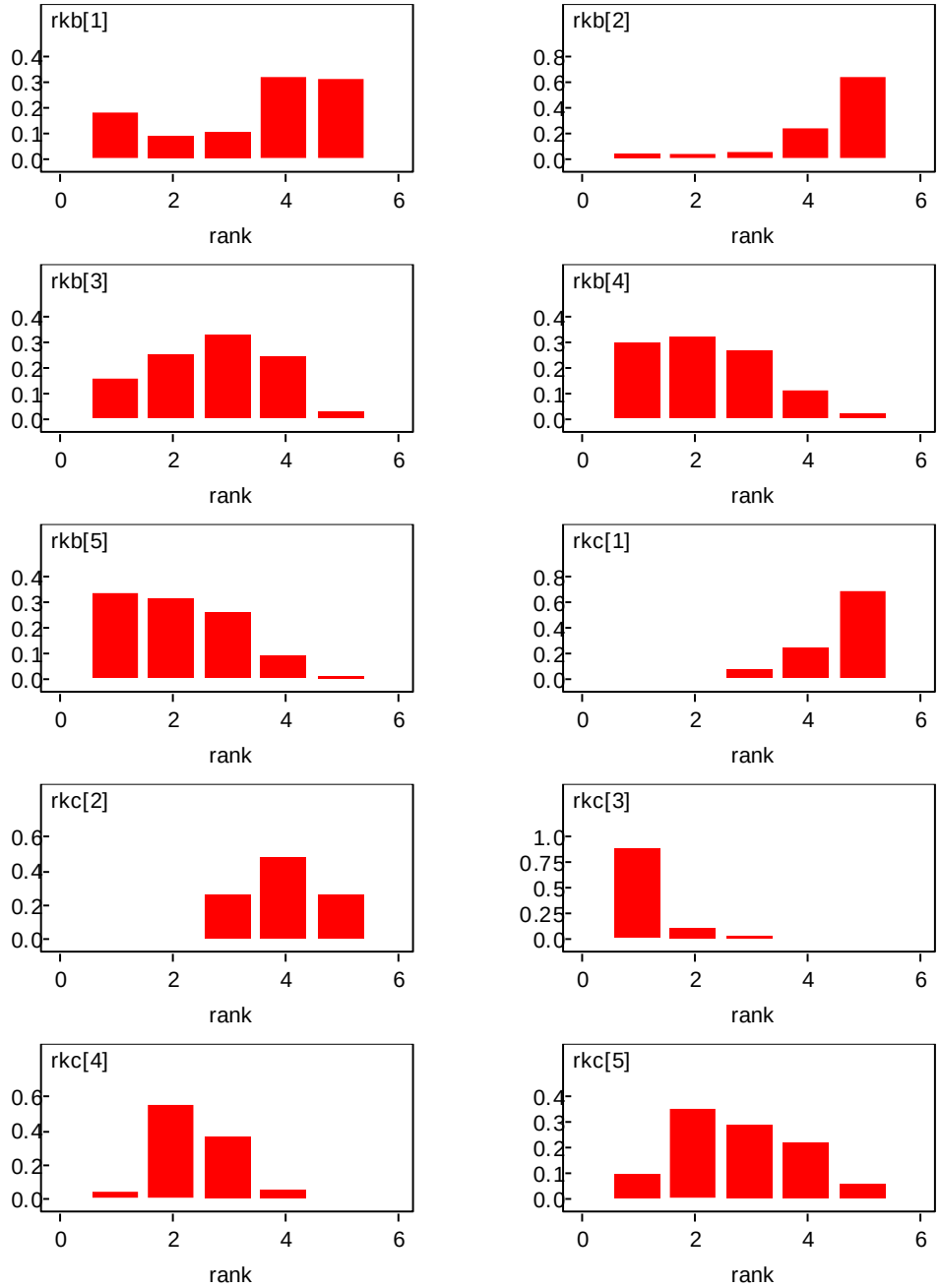
1 General population in this case means any study that was relevant to this outcome but not
2 classified within another subgroup.**Figures:** Probability that the intervention component [1, 2,

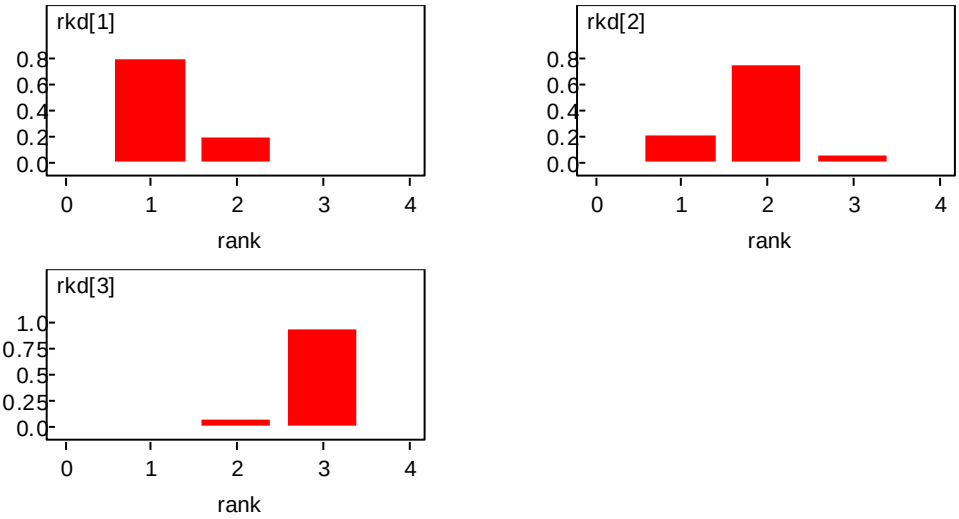
3, 4, 5] is the most effective, 2nd most effective, 3rd most effective, 4th most effective, or 5th most effective, as relevant, for each variable b, c, d.

rkb[1] standard care; rkb[2] Contact 1; rkb[3] Contacts 2 - 3; rkb[4] Contacts 4 - 8; rkb[5] Contacts 9+

rkc[1] standard care; rkc[2] Face2Face individual; rkc[3] Face2Face group; rkc[4] Remote; rkc[5] Self-help

rkd[1] standard care; rkd[2] Healthcare setting; rkd[3] Home





Any breastfeeding 16 to 26 weeks

Table 50 reports the results of the pairwise meta-analysis for the comparison of education, advice or support from peer or professional provided postnatally and initiated either antenatally or within the first eight weeks after birth (Intervention 2) versus standard care as calculated in Rev Man, the meta-regression results of intervention 2 versus standard care as calculated for each variable in WinBUGS (from individual models), and the combined meta-regression model results as calculated in WinBUGS. Results in bold indicate a statistically significant result.

Table 50: Any breastfeeding 16 to 26 weeks

	RR	95% CI lower	95% CI upper	DIC	Calculated
Int 2 vs Standard care	**1.08**	**1.03**	**1.13**	NA	RevMan
Fathers	1.19	0.82	1.74	NA	RevMan
Int 1 vs Int 2	0.96	0.79	1.16	NA	RevMan
Subgroup: Low income	1.06	0.78	1.43	NA	RevMan
Subgroup: Obese women	0.90	0.70	1.14	NA	RevMan
Int 2 vs Int 2 (counselling + book vs Counselling)	1.15	0.89	1.48	NA	RevMan
Int 2 vs Int 2 (video + feeding log vs video)	1.12	0.62	2.03	NA	RevMan
Int 2 vs Int 2 (home visit vs telephone call)	1.04	0.89	1.20	NA	RevMan
Int 2 vs Int 2 (home visits vs printed materials)	1.01	0.75	1.36	NA	RevMan
How					
Face2Face – individual vs standard care	**1.07**	**1.01**	**1.14**	529.03	WinBUGS
Face2Face – group vs standard care	**1.95**	**1.45**	**2.27**		WinBUGS
Remote vs standard care	**1.15**	**1.05**	**1.26**		WinBUGS
Self-help vs standard care	1.06	0.74	1.40		WinBUGS
Number of Contacts					
0 vs standard care	1.18	0.96	1.39	531.92	WinBUGS
1 vs standard care	1.05	0.95	1.14		WinBUGS

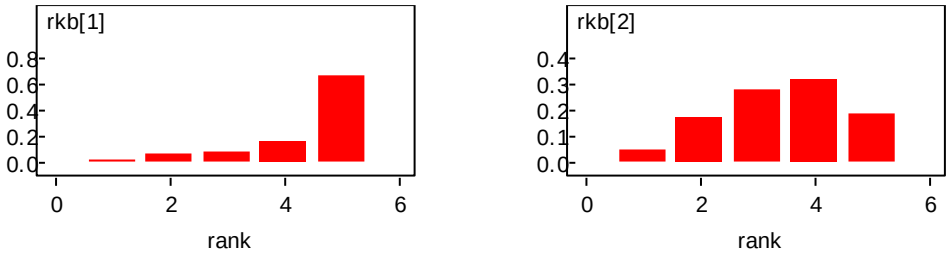
2 - 3 vs standard care	1.07	0.97	1.17		WinBUGS
4 - 8 vs standard care	**1.19**	**1.10**	**1.30**		WinBUGS
9+ vs standard care	**1.13**	**1.00**	**1.26**		WinBUGS
Duration of contact					
Less than 8 weeks vs standard care	1.04	0.97	1.10	525.37	WinBUGS
More than 8 weeks vs standard care	**1.20**	**1.11**	**1.29**		WinBUGS
Where delivered					
Home vs standard care	1.12	1.05	1.19	533.15	WinBUGS
Healthcare setting vs standard care	**1.06**	**0.96**	**1.17**		WinBUGS
Mixed vs standard care	**1.16**	**1.03**	**1.30**		WinBUGS
Meta regression combined model results					
Contact 1 vs standard care	1.09	0.87	1.35	534.57	WinBUGS
Contacts 2 - 3 vs standard care	1.12	0.90	1.38		WinBUGS
Contacts 4 - 8 vs standard care	1.18	0.99	1.40		WinBUGS
Contacts 9+ vs standard care	1.11	0.93	1.34		WinBUGS
Face2Face individual vs standard care	0.96	0.81	1.10		WinBUGS
Face2Face group vs standard care	**1.88**	**1.24**	**2.25**		WinBUGS
Self-help vs standard care	1.05	0.64	1.46		WinBUGS
Healthcare setting vs standard care	0.97	0.80	1.13		WinBUGS
Home vs standard care	1.01	0.84	1.16		WinBUGS

General population in this case means any study that was relevant to this outcome but not classified within another subgroup.**Figures:** Probability that the intervention component [1, 2, 3, 4, 5] is the most effective, 2nd most effective, 3rd most effective, 4th most effective, or 5th most effective, as relevant, for each variable b, c, d.

rkb[1] standard care; rkb[2] Contact 1; rkb[3] Contacts 2 - 3; rkb[4] Contacts 4 - 8; rkb[5] Contacts 9+

rkc[1] standard care; rkc[2] Face2Face individual contact ; rkc[3] Face2Face group; rkc[4] Remote; rkc[5] Self-help

rkd[1] standard care; rkd[2] Healthcare setting; rkd[3] Home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rank

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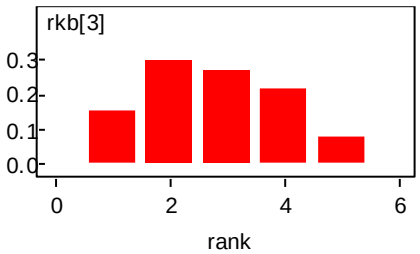
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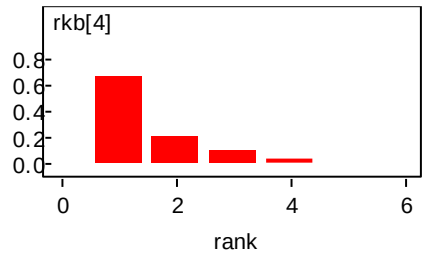
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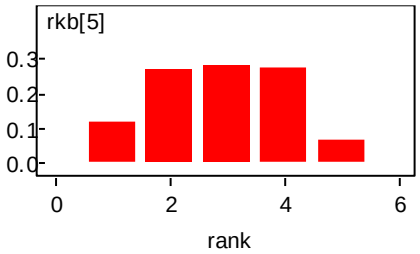
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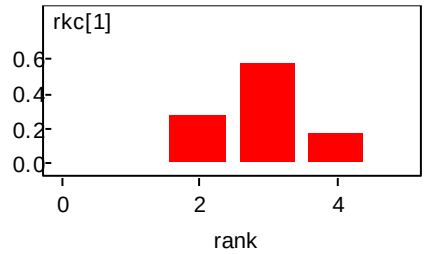
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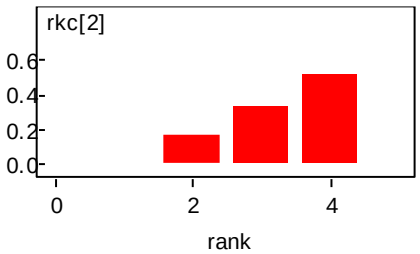
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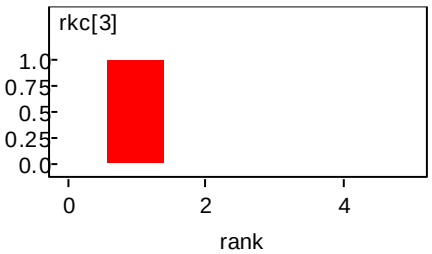
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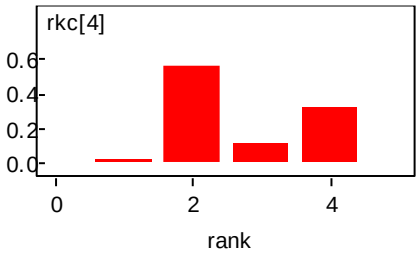
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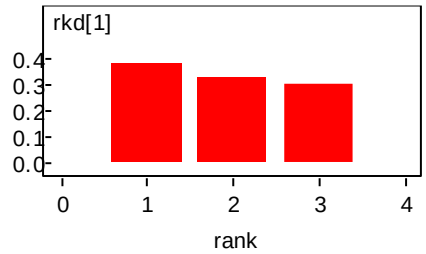
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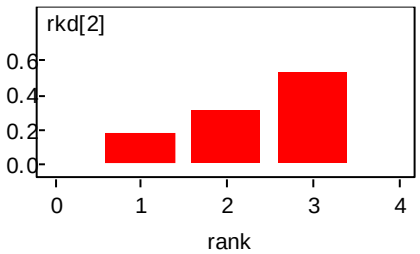
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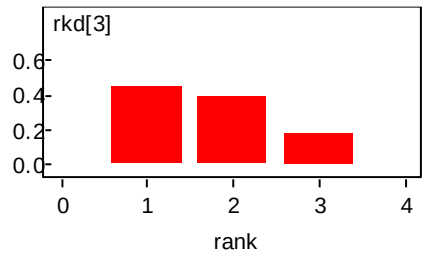
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6

Appendix N – Modelling studies on the benefits and costs associated with breastfeeding, considered as part of the guideline economic modelling

List of included modelling studies and overview of study characteristics of interest

Included study full reference	Country and outcomes considered
Bartick M, Reinhold A. The burden of suboptimal breastfeeding in the United States: a pediatric cost analysis. Pediatrics 2010; 125(5): e1048-56.	US study Outcomes for the baby: NEC, otitis media, gastroenteritis, hospitalisation for lower respiratory tract infection, atopic dermatitis, SIDS, childhood leukaemia, childhood asthma, type 1 diabetes mellitus, obesity. Study was considered by Renfrew 2012
Bartick M. Breastfeeding and the U.S. economy. Breastfeed Med 2011; 6: 313-8.	US study Further analysis to Bartick (2010); additional data on formula feeding costs, cost of extra food for lactating women, paid leave.
Bartick MC, Stuebe AM, Schwarz EB, Luongo C, Reinhold AG, Foster EM. Cost analysis of maternal disease associated with suboptimal breastfeeding. Obstet Gynecol 2013; 122(1): 111-9.	US study Outcomes for the mother: breast cancer, ovarian cancer, hypertension, type 2 diabetes, myocardial infarction. Data sources were either considered in Renfrew 2012 or included in systematic reviews reported by Victora 2016
Bartick MC, Schwarz EB, Green BD, Jegier BJ, Reinhold AG, Colaizy TT, Bogen DL, Schaefer AJ, Stuebe AM. Suboptimal breastfeeding in the United States: Maternal and pediatric health outcomes and costs. Maternal and Child Nutrition 2017a; 13(1).	US study Outcomes for the baby: acute lymphoblastic leukaemia, acute otitis media, Crohn's disease, ulcerative colitis, gastrointestinal infection, lower respiratory tract infection requiring hospitalisation, obesity, NEC, SIDS. Outcomes for the mother: breast cancer, pre-menopausal ovarian cancer, hypertension, type 2 diabetes, myocardial infarction. Data sources were either considered in Renfrew 2012 or included in systematic reviews reported by Victora 2016
Bartick MC, Jegier BJ, Green BD, Schwarz EB, Reinhold AG, Stuebe AM. Disparities in Breastfeeding: Impact on Maternal and Child Health Outcomes and Costs. J Pediatr 2017b; 181: 49-55.e6.	US study Sub-group analysis of Batrick 2017a.
Bartick M. Mothers' costs of suboptimal breastfeeding: implications of the maternal disease cost analysis. Breastfeed Med. 2013; 8(5):448-9.	US study Secondary analysis of Bartick 2013; cost analysis of maternal disease associated with suboptimal breastfeeding.
Büchner FL, Hoekstra J, van Rossum CTM. Health gain and economic evaluation of breastfeeding policies: Model simulation. Bilthoven, Netherlands: RIVM, 2007.	Dutch study. Outcomes for the baby: gastrointestinal infection, otitis media, respiratory infection, asthma, eczema, Crohn's disease, obesity, leukaemia.

Included study full reference	Country and outcomes considered
	Outcomes for the mother: breast cancer, ovarian cancer, rheumatoid arthritis for the mother. Study was considered by Renfrew 2012
Chola L, Fadnes LT, Engebretsen IM, Nkonki L, Nankabirwa V, Sommerfelt H, Tumwine JK, Tylleskar T, Robberstad B; PROMISE-EBF Study Group. Cost-Effectiveness of Peer Counselling for the Promotion of Exclusive Breastfeeding in Uganda. PLoS One 2015; 10(11):e0142718.	Ugandan study Outcomes for the baby: diarrhoea. Data on association between breastfeeding and diarrhoea based on SR of studies in developing countries.
Colchero MA, Contreras-Loya D, Lopez-Gatell H, González de Cosío T. The costs of inadequate breastfeeding of infants in Mexico. Am J Clin Nutr 2015; 101(3):579-86.	Mexican study Outcomes for the baby: respiratory infection, otitis media, gastroenteritis, NEC, SIDS. Data sources on association between breastfeeding and diarrhoea were considered in Renfrew 2012
Ma P, Brewer-Asling M, Magnus JH. A case study on the economic impact of optimal breastfeeding. Matern Child Health J. 2013; 17(1):9-13.	US study Outcomes for the baby: respiratory tract infection, gastroenteritis, NEC, SIDS. Data sources on association between breastfeeding and the 4 infant diseases were considered in Renfrew 2012
McIsaac KE, Moineddin R, Matheson FI. Breastfeeding as a means to prevent infant morbidity and mortality in Aboriginal Canadians: A population prevented fraction analysis. Can J Public Health. 2015; 106(4):e217-22.	Canadian study Outcomes for the baby: SIDS, gastrointestinal infection, respiratory tract infection, otitis media. Data sources on association between breastfeeding and the outcomes for the baby were considered in Renfrew 2012
Pokhrel S, Quigley MA, Fox-Rushby J, McCormick F, Williams A, Trueman P, Dodds R, Renfrew MJ. Potential economic impacts from improving breastfeeding rates in the UK. Arch Dis Child 2015; 100(4): 334-40.	UK study Secondary publication to Renfrew 2012
Renfrew M, Pokhrel S, Quigley M, et al. Preventing disease and saving resources: the potential contribution of increasing breastfeeding rates in the UK. London: Unicef UK, 2012.	UK study Outcomes for the baby: gastrointestinal infection, respiratory tract infection, otitis media, NEC Outcomes for the mother: breast cancer In addition, narrative description of economic benefits for the following outcomes for the baby: SIDS, cognitive outcomes, obesity Epidemiological and resource use data relevant to guideline analysis
Rollins NC, Bhandari N, Hajeebhoy N, Horton S, Lutter CK, Martines JC, Piwoz EG, Richter LM, Victora CG, Lancet Breastfeeding Series Group. Why invest, and what it will take to improve breastfeeding practices? Lancet 2016; 387(10017):491-504.	Global analysis Outcomes for the baby: diarrhoea, pneumonia, bronchiolitis, NEC, otitis media, asthma, leukaemia, type 1 diabetes, obesity, cognitive outcomes Data on association between breastfeeding and outcomes for the baby were obtained from Victora 2016; epidemiological and resource use data for the UK were obtained from Renfrew 2012.
Stuebe AM, Jegier BJ, Schwarz EB, Green BD, Reinhold AG, Colaizy TT, Bogen DL, Schaefer AJ, Jegier JT,	US study Estimation of population benefits and costs was made using the model and data reported by Bartick 2017

Included study full reference	Country and outcomes considered
Green NS, Bartick MC. An Online Calculator to Estimate the Impact of Changes in Breastfeeding Rates on Population Health and Costs. Breastfeed Med 2017; 12(10):645-658	
Straub N, Grunert P, Northstone K, Emmett P. Economic impact of breast-feeding-associated improvements of childhood cognitive development, based on data from the ALSPAC. Br J Nutr 2016; 22:1-6.	UK study Outcomes for the baby: attainment at school KS4, linked to individual gross income
Unar-Munguía M, Meza R, Colchero MA, Torres-Mejía G, de Cosío TG. Economic and disease burden of breast cancer associated with suboptimal breastfeeding practices in Mexico. Cancer Causes Control 2017; 28(12): 1381-1391.	Mexican study Outcomes for the mother: breast cancer Data source for the association between breastfeeding and breast cancer: Unar-Munguía M, Torres-Mejía G, Colchero MA, González de Cosío T. Breastfeeding Mode and Risk of Breast Cancer: A Dose-Response Meta-Analysis. J Hum Lact. 2017; 33(2):422-434. Data source was more recent than both Renfrew 2012 and Victora 2016.
Victora CG, Bahl R, Barros AJ, França GV, Horton S, Krasevec J, Murch S, Sankar MJ, Walker N, Rollins NC. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. Lancet 2016; 387 (10017): 475–90.	Global analysis. Outcomes for the baby: death due to infectious disease and due to prematurity, occurring after the 1st week of life Outcomes for the mother: breast cancer Study reports results of 28 systematic reviews and meta-analyses [22 of which were commissioned by WHO] on the association between breastfeeding and outcomes to mothers and babies
Walters D, Horton S, Siregar AY, Pitriyan P, Hajeebhoy N, Mathisen R, Phan LT, Rudert C. The cost of not breastfeeding in Southeast Asia. Health Policy Plan 2016; 31(8):1107-16.	Southeast Asian study. Outcomes for the baby: cognitive outcomes, child mortality, diarrhoea and pneumonia Outcomes for the mother: breast cancer Data on association between breastfeeding baby outcomes specific to developing countries; data on association between breastfeeding and breast cancer obtained from Victora 2016.
Walters DD, Phan LTH, Mathisen R. The cost of not breastfeeding: global results from a new tool. Health Policy Planning 2019; 34(6):407-417.	Global analysis Outcomes for the baby: diarrhoea, pneumonia, mortality due to diarrhoea and pneumonia, obesity, cognitive outcomes Outcomes for the mother: breast cancer, ovarian cancer, type 2 diabetes Formula feeding costs Data on association between breastfeeding and outcomes for the mother and the baby obtained from Victora 2016

NEC: necrotising enterocolitis
SIDS: sudden infant death syndrome

List of excluded modelling studies and reasons for exclusion

Excluded study full reference	Reason for exclusion
Berridge K, Hackett AF, Abayomi J, Maxwell SM. The cost of infant feeding in Liverpool, England. Public Health Nutr. 2004; 7(8):1039-46.	Not a modelling study. Reports costs to the mother relating to feeding a baby (e.g. bottles, nursing bras etc).
Hansen K. Breastfeeding: a smart investment in people and in economies. Lancet 2016; 387(10017):416.	Commentary
Langabeer J. Applications of microcosting economic analysis in breastfeeding. Journal of Human Lactation 2018; 34(1):: 84-85	Commentary
Michie C. Breastfeeding will reduce many NHS budgets. London Journal of Primary Care 2015; 7(4), 61-65.	Opinion paper. Includes references to modelling studies that have been checked.
Noonan MC, Rippeyoung PL. The economic costs of breastfeeding for women. Breastfeed Med 2011; 6:325-7.	Study of women's employment status and fathers' involvement associated with breastfeeding; no costs reported.
Phelps CE. Economics of healthcare financing: implications for breastfeeding. Breastfeed Med 2010; 5(5):191-9	Discussion on healthcare financing in US and priorities; refers to Bartick (2010) which has been included in the review
Phelps CE. Economic issues of breastfeeding. Breastfeed Med 2011; 6:307-11.	Discussion of family /employer /insurer perspectives relating to breastfeeding
Santacruz-Salas E, Aranda-Reneo I, Hidalgo-Vega Á, Blanco-Rodriguez JM, Segura-Fragoso A. The Economic Influence of Breastfeeding on the Health Cost of Newborns. Journal of Human Lactation 2019; 35(2): 340-348.	Not a modelling study – observational cohort study
Saunders JB. The economic benefits of breastfeeding. NCSL legisbrief 2010; 18(1): 1-2	Editorial
Smith JP. "Lost milk?": Counting the economic value of breast milk in gross domestic product. J Hum Lact 2013; 29(4):537-46.	Assessment of the economic value of lost breast milk
Smith JP, Forrester R. Who pays for the health benefits of exclusive breastfeeding? An analysis of maternal time costs. J Hum Lact 2013; 29(4):547-55.	Reports maternal time costs of exclusive breastfeeding
Smith JP. Counting the cost of not breastfeeding is now easier, but women's unpaid health care work remains invisible. Health Policy Planning 2019; 34(6):479-481.	Commentary on costs relating to women's unpaid time caring for sick children
Walters D, Eberwein JD, Sullivan LM1, D'Alimonte MR, Shekar M. Reaching the Global Target to Increase Exclusive Breastfeeding: How Much Will It Cost and How Can We Pay for It? Breastfeed Med 2016; 11:413-5.	Assessment of the cost of investment to achieve exclusive breastfeeding targets – low and middle income countries; benefits and cost-savings from breastfeeding not modelled