



**University of Dundee**

## **Support for healthy breastfeeding mothers with healthy term babies**

McFadden, Alison; Gavine, Anna; Renfrew, Mary J.; Wade, Angela ; Buchanan, Phyll; Taylor, Jane L.

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## Support for healthy breastfeeding mothers with healthy term babies (Review)

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[Intervention Review]

# Support for healthy breastfeeding mothers with healthy term babies

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## ABSTRACT

### Background

There is extensive evidence of important health risks for infants and mothers related to *not* breastfeeding. In 2003, the World Health Organization recommended that infants be breastfed exclusively until six months of age, with breastfeeding continuing as an important part of the infant's diet until at least two years of age. However, current breastfeeding rates in many countries do not reflect this recommendation.

### Objectives

To describe forms of breastfeeding support which have been evaluated in controlled studies, the timing of the interventions and the settings in which they have been used.

To examine the effectiveness of different modes of offering similar supportive interventions (for example, whether the support offered was proactive or reactive, face-to-face or over the telephone), and whether interventions containing both antenatal and postnatal elements were more effective than those taking place in the postnatal period alone.

To examine the effectiveness of different care providers and (where information was available) training.

To explore the interaction between background breastfeeding rates and effectiveness of support.

### Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register (29 February 2016) and reference lists of retrieved studies.

### Selection criteria

Randomised or quasi-randomised controlled trials comparing extra support for healthy breastfeeding mothers of healthy term babies with usual maternity care.

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Support for healthy breastfeeding mothers with healthy term babies (Review)

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## Data collection and analysis

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

## Main results

This updated review includes 100 trials involving more than 83,246 mother-infant pairs of which 73 studies contribute data (58 individually-randomised trials and 15 cluster-randomised trials). We considered that the overall risk of bias of trials included in the review was mixed. Of the 31 new studies included in this update, 21 provided data for one or more of the primary outcomes. The total number of mother-infant pairs in the 73 studies that contributed data to this review is 74,656 (this total was 56,451 in the previous version of this review). The 73 studies were conducted in 29 countries. Results of the analyses continue to confirm that all forms of extra support analyzed together showed a decrease in cessation of 'any breastfeeding', which includes partial and exclusive breastfeeding (average risk ratio (RR) for stopping any breastfeeding before six months 0.91, 95% confidence interval (CI) 0.88 to 0.95; *moderate-quality evidence, 51 studies*) and for stopping breastfeeding before four to six weeks (average RR 0.87, 95% CI 0.80 to 0.95; *moderate-quality evidence, 33 studies*). All forms of extra support together also showed a decrease in cessation of exclusive breastfeeding at six months (average RR 0.88, 95% CI 0.85 to 0.92; *moderate-quality evidence, 46 studies*) and at four to six weeks (average RR 0.79, 95% CI 0.71 to 0.89; *moderate quality, 32 studies*). We downgraded evidence to moderate-quality due to very high heterogeneity.

We investigated substantial heterogeneity for all four outcomes with subgroup analyses for the following covariates: who delivered care, type of support, timing of support, background breastfeeding rate and number of postnatal contacts. Covariates were not able to explain heterogeneity in general. Though the interaction tests were significant for some analyses, we advise caution in the interpretation of results for subgroups due to the heterogeneity. Extra support by both lay and professionals had a positive impact on breastfeeding outcomes. Several factors may have also improved results for women practising exclusive breastfeeding, such as interventions delivered with a face-to-face component, high background initiation rates of breastfeeding, lay support, and a specific schedule of four to eight contacts. However, because within-group heterogeneity remained high for all of these analyses, we advise caution when making specific conclusions based on subgroup results. We noted no evidence for subgroup differences for the any breastfeeding outcomes.

## Authors' conclusions

When breastfeeding support is offered to women, the duration and exclusivity of breastfeeding is increased. Characteristics of effective support include: that it is offered as standard by trained personnel during antenatal or postnatal care, that it includes ongoing scheduled visits so that women can predict when support will be available, and that it is tailored to the setting and the needs of the population group. Support is likely to be more effective in settings with high initiation rates. Support may be offered either by professional or lay/peer supporters, or a combination of both. Strategies that rely mainly on face-to-face support are more likely to succeed with women practising exclusive breastfeeding.

## PLAIN LANGUAGE SUMMARY

### Support for breastfeeding mothers

#### What is the issue?

The World Health Organization recommends that infants should be breastfed exclusively until six months of age with breastfeeding continuing as an important part of the infant's diet until he or she is at least two years old. We know that breastfeeding is good for the short-term and long-term health of both infants and their mothers. Babies are less likely to develop infections in the digestive tract, lungs or airways, and ears. They are also less likely to become overweight and develop diabetes later in life. The mothers are less likely to develop diabetes and to experience breast or ovarian cancer. Many mothers may stop breastfeeding before they want to as a result of the problems they encounter. Good care and support may help women solve these problems so that they can continue to breastfeed.

#### Why is this important?

By knowing what kind of support can be provided to help mothers with breastfeeding, we can help them solve any problems and continue to breastfeed for as long as they want to, wherever they live. Stopping breastfeeding early may cause disappointment and distress for mothers and health problems for themselves and their infants. Support can be in the form of giving reassurance, praise, information, and the opportunity for women to discuss problems and ask questions as needed. This review looked at whether providing extra organised support for breastfeeding mothers would help mothers to continue to breastfeed when compared with standard maternity

care. We were interested in support from health professionals including midwives, nurses and doctors, or from trained lay workers such as community health workers and volunteers.

### **What evidence did we find?**

We searched for evidence on 29 February 2016 and identified a further 31 new trials for inclusion in the review. This updated review now includes 100 randomised controlled studies involving more than 83,246 women. The 73 trials that contributed to the analyses were from 29 countries and involved 74,656 women. Some 62% of the women were from high-income countries, 34% from middle income countries and 4% from low-income countries

All forms of extra organised support analyzed together showed an increase in the length of time women continued to breastfeed, either with or without introducing any other types of liquids or foods. This meant that fewer women stopped any breastfeeding or exclusively breastfeeding (moderate quality evidence) before four to six weeks and before six months. Both trained volunteers and doctors and nurses had a positive impact on breastfeeding.

Factors that may have contributed to the success for women who exclusively breastfed were face-to-face contact (rather than contact by telephone), volunteer support, a specific schedule of four to eight contacts and high numbers of women who began breastfeeding in the community or population (background rates).

The term 'high-quality evidence' means that we are confident that further studies would provide similar findings. No outcome was assessed as being 'high-quality'. The term 'moderate-quality evidence' means that we found wide variations in the findings with some conflicting results in the studies in this review. New studies of different kinds of support for exclusive breastfeeding may change our understanding of how to help women to continue with exclusive breastfeeding.

The methodological quality of the studies was mixed and the components of the standard care interventions and extra support interventions varied a lot and were not always well described. Also, the settings for the studies and the women involved were diverse.

### **What does this mean?**

Providing women with extra organised support helps them breastfeed their babies for longer. Breastfeeding support may be more helpful if it is predictable, scheduled, and includes ongoing visits with trained health professionals including midwives, nurses and doctors, or with trained volunteers. Different kinds of support may be needed in different geographical locations to meet the needs of the people within that location. We need additional randomised controlled studies to identify what kinds of support are the most helpful for women.

## SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

All forms of support versus usual care						
<b>Patient or population:</b> healthy breastfeeding mothers with healthy term babies						
<b>Setting:</b> outpatient settings in multiple countries (8% low- or lower-middle income; 30% upper-middle income; 60% high-income countries)						
<b>Intervention:</b> all forms of support						
<b>Comparison:</b> usual care						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments <sup>1</sup>
	Risk with usual care	Risk with all forms of support				
Stopping breastfeeding (any) before last study assessment up to 6 months	Study population		average RR 0.91 (0.88 to 0.95)	21418 (51 RCTs)	⊕⊕⊕○ MODERATE <sup>2</sup>	We have not downgraded evidence for lack of blinding. However, no trial had adequate blinding of pregnant women or staff
	573 per 1000	510 per 1000 (487 to 532)				
Stopping exclusive breastfeeding before last study assessment up to 6 months	Study population		average RR 0.88 (0.85 to 0.92)	18591 (46 RCTs)	⊕⊕⊕○ MODERATE <sup>3,4</sup>	
	823 per 1000	732 per 1000 (707 to 765)				
Stopping breastfeeding (any) at up to 4-6 weeks	Study population		average RR 0.87 (0.80 to 0.95)	11264 (33 RCTs)	⊕⊕⊕○ MODERATE <sup>5</sup>	
	353 per 1000	304 per 1000 (279 to 329)				
Stopping exclusive breastfeeding at up to 4-6 weeks	Study population		RR 0.79 (0.71 to 0.89)	10960 (32 RCTs)	⊕⊕⊕○ MODERATE <sup>4,6</sup>	
	642 per 1000	507 per 1000 (443 to 571)				

\* **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; RR: risk ratio

#### **GRADE Working Group grades of evidence**

**High quality:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

<sup>1</sup> Sensitivity analyses restricted to trials of low risk of bias for allocation concealment showed similar effects for all four outcomes, with a reduction in effect size of (0 to 0.08) and minimal differences in confidence intervals.

<sup>2</sup> Statistical heterogeneity, downgraded one level ( $I^2 = 55\%$ ).

<sup>3</sup> Statistical heterogeneity, downgraded one level ( $I^2 = 96\%$ ).

<sup>4</sup> There is some evidence of funnel plot asymmetry due to small studies with large effect sizes. Not downgraded.

<sup>5</sup> Statistical heterogeneity, downgraded one level ( $I^2 = 54\%$ ).

<sup>6</sup> Statistical heterogeneity, downgraded one level ( $I^2 = 97\%$ ).

## BACKGROUND

### Description of the condition

Breastfeeding has a fundamental impact on the short-, medium- and long-term health of children and has an important impact on women's health (Victora 2016). For children, good quality evidence demonstrates that in both low-, middle- and high-income settings *not* breastfeeding contributes to mortality due to infectious diseases (Sankar 2015), hospitalisation for preventable disease such as gastroenteritis, and respiratory disease (Horta 2013), otitis media (Bowatte 2015), increased rates of childhood diabetes and obesity (Horta 2015a), and increased dental disease (Peres 2015; Tham 2015). For women, there is good quality evidence that *not* breastfeeding is associated with increased risks of breast and ovarian cancer, and diabetes (Chowdhury 2015). Lactational amenorrhoea is associated with exclusive/predominant breastfeeding and increases birth spacing when other forms of contraception are not available (Chowdhury 2015). Not being breastfed has an adverse impact on intelligence quotient (IQ), and educational and behavioural outcomes for the child (Heikkilä 2014; Heikkilä 2011; Horta 2015b; Quigley 2012). For many outcomes a dose-response relationship exists, with the greatest benefit resulting from breastfeeding exclusively, with no added food or fluids, for around six months, with breastfeeding continuing thereafter as an important component of the infant's diet (Kramer 2012). The negative impact of not breastfeeding has been demonstrated in a range of settings and population groups, though the balance of risks and benefits varies from setting to setting; for example, gastroenteritis will result in much higher mortality in low-income countries (Horta 2013).

Few health behaviours have such a broad-spectrum and long-lasting impact on population health, with the potential to improve life chances, health and well-being. Victora 2016 estimated that each year, 823,000 deaths in children under five years and 20,000 deaths from breast cancer could be prevented by near universal breastfeeding. The cost burden of not breastfeeding was estimated by Rollins 2016 to represent 0.49% of world gross domestic product. The cost burden includes the cost of caring for children and women with chronic disease as well as short-term illness (Bartick 2010; Smith 2010).

The established negative impact on a population of not breastfeeding has resulted in global and national support for encouraging the initiation and continuation of breastfeeding. The World Health Organization (WHO) recommends that, wherever possible, infants should be fed exclusively on breastmilk until six months of age (WHO 2003), with breastfeeding continuing as an important part of the infant's diet until at least two years of age. Other agencies and countries have endorsed the recommendation to breastfeed exclusively to around six months of age (EFSA Panel 2009; National Center for Health Statistics 2012).

Due to the lack of standardised infant feeding indicators in high-income countries, it is difficult to compare rates of breastfeeding across high-income countries, or between high-income, and low- and middle-income countries. Therefore reported rates of breastfeeding need to be treated with caution. Victora 2016 suggest that, in general, there is an inverse relationship between breastfeeding rates and national wealth, though this relationship does not necessarily hold at the level of population subgroups. In high-income countries, for example, the relationship is often seen to be the opposite, with rates higher among more affluent women (McAndrew 2012).

Although some high-income countries such as, Norway and Finland have high rates of both initiation and continuation of breastfeeding (Cattaneo 2010), rates in many high-income countries are low. Initiation rates have risen in some high-income countries in recent years (NHS England 2014; U.S. Department of Health and Human Services 2011), but there remains a marked decline in breastfeeding within the first few weeks after initiation, and exclusive breastfeeding to six months is rare (Cattaneo 2010; McAndrew 2012).

In middle- and low-income countries, while breastfeeding initiation and duration are generally higher than in high-income countries, the average rate of exclusive breastfeeding for children younger than six months is only 37% (Victora 2016). However, rates of exclusive breastfeeding for children younger than six months vary widely; Peru and Rwanda report rates of 72% and 85% respectively (UNICEF 2012), while in Nigeria the rate is only 17%. In some low- and middle-income countries, cultural practices such as prelacteal feeds, and giving water or teas alongside breastfeeding, account for the low rates of exclusive breastfeeding (Kimani-Murage 2011). This is particularly important as when breastfeeding continues for long periods of time, infant and young child mortality are reduced in the second year of life in low- and middle-income countries (Victora 2016).

Infant feeding is strongly related to inequalities in health, and, far from being an individual decision made by each woman, is influenced most strongly by structural determinants of health. The range of different rates of initiation and continuation of breastfeeding in different settings globally demonstrates that the key factors influencing infant feeding rates are likely to be sociocultural and related to societal and subgroup norms, public policy, and the availability of appropriate care and support, both professional and lay (EU Project on Promotion of Breastfeeding 2004; Rollins 2016). In high-income countries, for example, young mothers and women in low-income groups, or women who ceased full-time education at an early age, are least likely either to start breastfeeding or to continue for a period of time sufficient to benefit from the greatest health gain (McAndrew 2012). Migrant women have been shown to adopt breastfeeding practices that are more similar to the country in which they live, than the country of their birth (McLachlan 2006).

The early discontinuation of breastfeeding is not a decision that

is taken lightly by women; it is associated with a high prevalence of problems such as painful breasts and nipples, concern about adequacy of milk supply and about the baby's behaviour, and, in some settings, embarrassment related to breastfeeding in public. Many mothers report distress related to the decision to discontinue breastfeeding (McAndrew 2012), even in cultures where breastfeeding rates are high (Almqvist-Tangen 2012). A key factor is the widespread lack of appropriate education for health professionals in the prevention and treatment of breastfeeding problems, which means that in a wide range of settings women commonly do not receive the quality of care needed from the health services (Cattaneo 2010; Renfrew 2006). Enkin 2000 notes that industrial societies, on the whole, do not provide women with the opportunity to observe other breastfeeding women before they attempt breastfeeding themselves. In such societies, where breastfeeding is not normative behaviour and women may find it socially challenging to breastfeed, women are at particular risk of finding a serious lack of support to continue breastfeeding.

## Description of the intervention

'Support' is complex and can include several elements such as emotional and esteem-building support (including reassurance and praise), practical help, informational support (including the opportunity to discuss and respond to women's questions) and social support (including signposting women to support groups and networks) (Dykes 2006; Schmied 2011). It can be offered in a range of ways, by health professionals or lay people, trained or untrained, in hospital and community settings. It can be offered to groups of women or one-to-one, it can involve mother-to-mother support, and it can include family members (typically fathers or grandmothers) and wider communities. Support can be offered proactively by contacting women directly, or reactively, by waiting for women to get in touch. It can be provided face-to-face, by telephone or through social media. It can involve only one contact or regular, ongoing contact over several months.

Support is a complex intervention that tackles the multifaceted challenge of enabling women to breastfeed, and it should not be surprising that it varies from setting to setting and from study to study. However, it is likely that different forms of support in different contexts will be differentially effective. The global Baby Friendly Hospital Initiative (Baby Friendly Initiative in some countries), which is a complex intervention incorporating 10 steps to successful breastfeeding, has been shown to be associated with increased breastfeeding rates (Labbok 2012; Pérez-Escamilla 2016; Venancio 2011). Over 21,000 facilities in 198 countries have ever been accredited, representing 27.5% of maternities worldwide (Labbok 2012), but most babies are still not born in a Baby Friendly environment.

In many settings, the health professionals who provide standard maternity care lack in-depth knowledge of the prevention and treatment of breastfeeding problems. Therefore training and edu-

cation of health professionals and others who provide breastfeeding support is critical. To address this, WHO and UNICEF (the United Nations Children's Fund) have developed two breastfeeding training programmes: the 40-hour Breastfeeding Counselling, and the five-day Infant and Young Child Feeding Counselling, to train a cadre of health workers that can provide skilled support to breastfeeding mothers and help them overcome problems (WHO/UNICEF 1993; WHO/UNICEF 2006).

## How the intervention might work

Support for breastfeeding women can work in different ways for different women. Timely, skilled support will help women to avoid or overcome breastfeeding problems that may lead to cessation of breastfeeding. In settings where breastfeeding is not the social norm, support can increase women's belief in breastfeeding, and give them confidence to continue breastfeeding in the face of societal and family pressures that might undermine breastfeeding. In settings where exclusive breastfeeding is rare, support can dispel myths about the need for additional foods or fluids alongside breastfeeding to meet babies' nutritional needs.

## Why it is important to do this review

It is fundamentally important to examine the support that mothers receive when breastfeeding to determine what might be effective in helping women continue to breastfeed, whatever setting they live in. There is evidence that effective breastfeeding support interventions are cost-effective and likely to realise a return on investment within a few years (Renfrew 2012a).

The purpose of this review is to examine interventions which provide extra support for mothers who are breastfeeding or considering breastfeeding; and to assess their impact on breastfeeding duration and exclusivity and, where recorded, on health outcomes and maternal satisfaction. This review is an update of the previously published version Renfrew 2012b. The focus of this review is support for mothers and babies who are part of the general healthy population of their countries; mothers of premature and sick babies and mothers with some medical conditions have additional issues with breastfeeding, and interventions to support these mothers need to be reviewed separately. A Cochrane Review of breastfeeding education and support for mothers with multiple pregnancies is in progress (Whitford 2015). Whilst many support interventions include breastfeeding education for mothers, our review excludes interventions described as solely educational in nature and interventions with no postnatal component. A Cochrane Review of antenatal breastfeeding education for increasing breastfeeding duration has been published (Lumbiganon 2012).

Specific objectives of this review are to describe forms of support which have been evaluated in controlled studies, and the settings in which they have been used. It was also of interest to examine

the effectiveness of different modes of offering similar supportive interventions (for example, face-to-face or over the telephone), whether interventions containing both antenatal and postnatal elements were more effective than those taking place in the postnatal period alone, and whether the support was offered proactively to women, or whether they needed to seek it out. We also planned to examine the effectiveness of different care providers, and the possible impact of background breastfeeding rates in the countries or areas where the trials took place on the effectiveness of supportive interventions. It is important to note that the support interventions offered were in addition to standard care, which varied from setting to setting, though there are few settings in which standard care is consistently offered by people with training and skill in enabling women to breastfeed.

## OBJECTIVES

1. To describe forms of breastfeeding support which have been evaluated in controlled studies, the timing of the interventions and the settings in which they have been used.
2. To examine the effectiveness of different modes of offering similar supportive interventions (for example, whether the support offered was proactive or reactive, face-to-face or over the telephone), and whether interventions containing both antenatal and postnatal elements were more effective than those taking place in the postnatal period alone.
3. To examine the effectiveness of different care providers and (where information was available) training.
4. To explore the interaction between background breastfeeding rates and effectiveness of support.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

All randomised or quasi-randomised controlled trials, with or without blinding. Cluster-randomised controlled trials were also eligible for inclusion.

#### Types of participants

Participants were healthy pregnant women considering or intending to breastfeed or healthy women who were breastfeeding healthy babies. Healthy women and babies were considered those who did

not require additional medical care (e.g. women with diabetes, women with HIV/AIDS, overweight or obese women) or surgical care (e.g. women who required a Caesarean Section). Studies which focused specifically on women with additional care needs were excluded.

#### Types of interventions

Contact with an individual or individuals (either professional or volunteer) offering support which is supplementary to the standard care offered in that setting. 'Support' interventions eligible for this review could include elements such as reassurance, praise, information, and the opportunity to discuss and to respond to the mother's questions, and could also include staff training to improve the supportive care given to women. It could be offered by health professionals or lay people, trained or untrained, in hospital and community settings. It could be offered to groups of women or one-to-one, including mother-to-mother support, and it could be offered proactively by contacting women directly, or reactively, by waiting for women to get in touch. It could be provided face-to-face or over the phone, and it could involve only one contact or regular, ongoing contact over several months. Studies were included if the intervention occurred in the postnatal period alone or also included an antenatal component. Interventions taking place in the antenatal period alone were excluded from this review, as were interventions described as solely educational in nature.

#### Types of outcome measures

The main outcome measure was the effect of the interventions on stopping breastfeeding by specified points in time. Primary outcomes were recorded for stopping any or exclusive breastfeeding before four to six weeks and before six months postpartum. Other outcomes of interest in previous versions of this review were stopping any or exclusive breastfeeding at other time points (two, three, four, nine and 12 months), measures of neonatal and infant morbidity (where available) and measures of maternal satisfaction with care or feeding method. Secondary outcomes were not considered in this update so that the review could be completed in time to inform the World Health Organisation's review of the evidence and update of the WHO recommendations on breastfeeding in maternity facilities. A new set of core outcomes for Cochrane pregnancy and childbirth breastfeeding reviews is currently being developed and the outcomes from this core set may influence future outcomes chosen for this review.

#### Primary outcomes

1. Stopping breastfeeding before six months postpartum.
2. Stopping exclusive breastfeeding before six months postpartum.
3. Stopping any breastfeeding before four to six weeks postpartum.

4. Stopping exclusive breastfeeding before four to six weeks postpartum.

### Secondary outcomes

We did not consider secondary outcomes in this 2016 update.

### Search methods for identification of studies

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

#### Electronic searches

We searched the Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (29 February 2016).

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

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

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

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

(For details of search methods used in previous versions of this review, please see: [Britton 2007](#); [Renfrew 1995](#); [Renfrew 2012b](#); [Sikorski 1999](#); [Sikorski 2002](#))

### Searching other resources

We searched the reference lists of retrieved studies.

We did not apply any language or date restrictions.

### Data collection and analysis

For methods used in the previous version of this review, see [Renfrew 2012b](#).

For this update, the following methods (based on a standard template used by Cochrane Pregnancy and Childbirth) were used for assessing the 162 reports that were identified as a result of the updated search.

#### Selection of studies

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

#### Data extraction and management

We designed and piloted a form to extract data. For eligible studies, two review authors extracted information using the agreed form. We resolved discrepancies through discussion. Data were entered into Review Manager 5 software ([RevMan 2014](#)), and checked for accuracy.

When information regarding study methods and results was unclear, we attempted to contact authors of the original reports to provide further details.

#### Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (the *Handbook*) ([Higgins 2011](#)). Any disagreement was resolved by discussion or by involving a third assessor.

##### (1) Random sequence generation (checking for possible selection bias)

For each included study, we described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

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

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

For each included study, we described the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

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

## **(3.1) Blinding of participants and personnel (checking for possible performance bias)**

For each included study, we described the method used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

1. low, high or unclear risk of bias for participants;
2. low, high or unclear risk of bias for personnel.

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

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

We assessed methods used to blind outcome assessment as:

1. low, high or unclear risk of bias.

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

For each included study, and for each outcome or class of outcomes, we described the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis

at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we planned to re-include missing data in the analyses that we undertook.

We assessed methods as:

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

## **(5) Selective reporting (checking for reporting bias)**

For each included study, we described how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

1. low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
2. high risk of bias (where not all the study's prespecified outcomes have been reported; one or more reported primary outcomes were not prespecified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
3. unclear risk of bias.

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

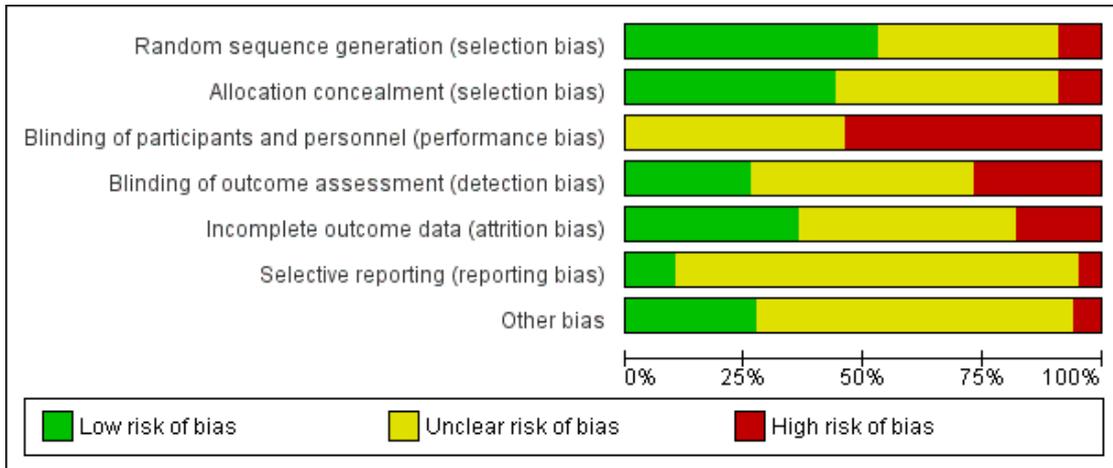
We described for each included study any important concerns we had about other possible sources of bias.

## **(7) Overall risk of bias**

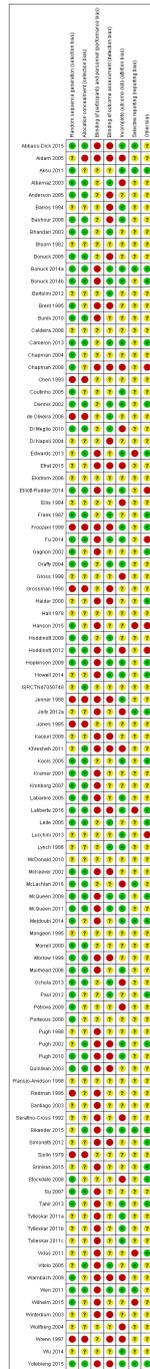
We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011).

Overall findings for our assessment of risk of bias in the included studies are set out in [Figure 1](#) and [Figure 2](#).

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



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



## Assessment of the quality of the evidence using the GRADE approach

For this update the quality of the evidence was assessed using the GRADE approach as outlined in the [GRADE handbook](#) in order to assess the quality of the body of evidence relating to the following primary outcomes for the comparison, *All forms of support versus usual care*.

1. Stopping breastfeeding before six months postpartum.
2. Stopping exclusive breastfeeding before six months postpartum.
3. Stopping any breastfeeding before four to six weeks postpartum.
4. Stopping exclusive breastfeeding before four to six weeks postpartum.

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

## Measures of treatment effect

### Dichotomous data

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

### Continuous data

There are no continuous data in this review.

## Unit of analysis issues

### Cluster-randomised trials

There are 15 cluster-randomised trials in the analyses. Their sample sizes have been adjusted using the methods described in the *Handbook* and by [Donner 2000](#) incorporating an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible). Where cluster adjusted confidence limits were presented

but not the ICC, the design effect was estimated from comparison with limits based on the raw numbers. However, for [Ochola 2013](#), outcome one of [Elliott-Rudder 2014](#), arm two of [Yotebieng 2015](#), adjusting for clustering based on the summary statistic made the standard error larger and the width of the confidence interval increased which resulted in a design of <1. Therefore, the adjustment for clustering resulted in an increase of the error sum of squares for the raw numbers given. As this was nonsensical, no adjustment for clustering was made for these studies. We have synthesised the findings from individually- and cluster-randomised trials provided that there was little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit was considered to be unlikely. We have carried out sensitivity analyses to investigate the effect of including cluster-randomised trials where no adjustment was possible. For all trials where ICCs were not reported, study authors will be contacted in the next version of the review.

### Trials with multiple groups

In order to avoid 'double counting' in studies involving one control group and two different interventions groups, we split the control group number of events and participants in half, so that we could include two independent comparisons, as per methods described the *Handbook* [section 16.5.4].

### Dealing with missing data

For all outcomes, analyses were carried out, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

For included studies, we have noted levels of attrition. We have not included outcomes in the analyses where more than 25% of the data were missing.

### Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the Tau<sup>2</sup>, I<sup>2</sup> and Chi<sup>2</sup> statistics. We regarded heterogeneity as substantial if I<sup>2</sup> was greater than 30% and either Tau<sup>2</sup> was greater than zero, or there was a low P value (less than 0.10) in the Chi<sup>2</sup> test for heterogeneity. If we identified substantial heterogeneity (above 30%), we planned to explore it by prespecified subgroup analysis.

### Assessment of reporting biases

For all outcomes we have ordered studies in terms of weight, where a sufficient number of studies contributed data, we have generated

funnel plots. We examined plots visually to see whether there was any evidence of asymmetry that might suggest different treatment effects in smaller studies, which may indicate publication bias (Harbord 2006). We note however, that there are many other reasons for asymmetry in Funnel Plots such as heterogeneity.

### Data synthesis

We carried out statistical analysis using Review Manager 5 software (RevMan 2014). At the outset, we had anticipated that there would be some heterogeneity between studies in terms of the interventions and the populations studied, we therefore decided to use random-effects meta-analysis for combining data. Random-effects meta-analysis estimates the average treatment effect, and this may not always be clinically meaningful. Furthermore, where there is high heterogeneity the applicability of the overall effect estimate is likely to vary in different settings and we therefore advise caution in the interpretation of results. The random-effects summary was treated as the average of the range of possible treatment effects and we discuss the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we planned not to combine trials. Since we used random-effects analyses, the results were presented as the average treatment effect with 95% confidence intervals, and the estimates of  $Tau^2$  and  $I^2$ .

### Subgroup analysis and investigation of heterogeneity

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

We carried out the following subgroup analyses for the four primary outcomes.

1. By type of supporter (professional versus lay person, or both).
2. By type of support (face-to-face versus telephone support).
3. By timing of support (antenatal and postnatal versus postnatal alone).
4. By whether the support was proactive (scheduled contacts) or reactive (women needed to request support).
5. By background breastfeeding initiation rates (low, medium or high background rates).
6. By intensity of support (number of scheduled contacts).

### Sensitivity analysis

We have carried out sensitivity analysis for primary outcomes by study quality; we did this by dividing the studies into subgroups according to whether they were at low risk of bias as opposed to unclear or high risk of bias. We have performed this for allocation

concealment. Because we have excluded studies from any analyses if they had more than 25% attrition, we have not conducted sensitivity analyses for this item.

## RESULTS

### Description of studies

#### Results of the search

In this updated version, we assessed 162 reports and have subsequently included a further 31 studies. We excluded 68 studies and have assigned the remainder as either an additional report of another study in the review, a study awaiting classification or an ongoing study (see [Studies awaiting classification](#) and [Characteristics of ongoing studies](#)). This review now therefore includes 100 studies and has excluded 147 studies.

This updated review is only focused on two primary outcomes each at two different time points. Of the 31 new studies included in this update, 21 studies provided data for one or more of the primary outcomes (see [Table 1](#)). Ten new trials met the inclusion criteria for this review but were excluded from the analyses either because they did not present data in a useable form or because of attrition rates >25%. Eleven studies provided data for outcome 1.1; 13 studies for outcome 1.2; eight studies for outcome 1.3; and eight studies for outcome 1.4. The addition of these studies to the studies included in the previous version of the review meant that for this 2016 update a total of 51 studies contributed data for outcome 1.1; 46 studies for outcome 1.2; 33 studies for outcome 1.3; and 32 studies for outcome 1.4.

In the results section we will not discuss further those studies that did not contribute data to the review, but additional information about these trials is provided in the [Characteristics of included studies](#) table and further details about the eleven new trials from the update is also provided in [Table 1](#).

#### Included studies

This updated review includes 100 trials involving more than 83,246 mother-infant pairs of which 73 studies contribute data (58 individually-randomised trials and 15 cluster-randomised trials).

#### Description of included studies (n = 73)

Seventy-three of the 100 included studies contribute data to this 2016 update of the review. It should be noted that two of the included trials were obtained via a single publication ([Bonuck 2014a](#)); one trial is called the BINGO trial and the other called the PAIRING trial. In order to differentiate between these two

trials in this review the BINGO trial is identified via the reference (Bonuck 2014a) and the PAIRING trial via the reference (Bonuck 2014b).

The total number of mother-infant pairs in these studies is 74,656 (this total was 56,451 in the previous version of this review (Renfrew 2012b)). The 73 studies were published/conducted between 1979 and 2016 and show increases over time both in number of studies (five studies are dated before 1990, 10 between 1990 and 1999, 40 between 2000 and 2011, and 18 are dated between 2012 and 2016), and range of country settings (the seven studies with dates before 1994 were all undertaken in high-income countries, and the eight studies from low-/low-middle income countries were published in 2000 or later). The data in this review come from participants living in 29 countries. Using the World Bank classification of countries by income (<http://data.worldbank.org/about/country-classifications/country-and-lending-groups>, accessed 30 June 2016):

- four studies with 3260 participants (4.4% of the total number of participants) were conducted in low-income countries (Bangladesh, Haider 2000; Burkina Faso and Uganda, Tylleskar 2011a and Tylleskar 2011b; and the Democratic Republic of the Congo, Yotebieng 2015);
- four studies with 2534 participants (3.4%) were conducted in low-middle income countries (India, Bhandari 2003; Kenya, Ochola 2013; Pakistan, Sikander 2015; and Syria, Bashour 2008);
- 15 studies with 22,477 participants (30.1%) were conducted in upper-middle income countries (Belarus, Kramer 2001; Brazil, Albernaz 2003, Barros 1994, Bortolini 2012, Coutinho 2005, de Oliveira 2006, Leite 2005, Santiago 2003, and Vitolo 2005; China, Wu 2014; Iran, Froozani 1999; Malaysia, Tahir 2013; Mexico, Morrow 1999; Turkey, Aksu 2011; and South Africa, Tylleskar 2011c<sup>1</sup>);
- 52 studies with 46,390 participants (62.1%) were conducted in high-income countries (Australia, Elliott-Rudder 2014, McLachlan 2016, McDonald 2010, Quinlivan 2003, and Wen 2011; Canada, Abbass-Dick 2015, Dennis 2002, Gagnon 2002, Laliberte 2016, Lynch 1986, Mongeon 1995, McQueen 2011, and Porteous 2000; Croatia, Vidas 2011; Denmark, Kronborg 2007; France, Labarere 2005, and McQueen 2009; Hong Kong, Wu 2014; Italy, Di Napoli 2004; Netherlands, Kools 2005, and Mejdoubi 2014; Singapore, Su 2007; Sweden, Ekstrom 2006, and Sjolín 1979; UK, Graffy 2004, Hoddinott 2009, Jones 1985, Jenner 1988, Morrell 2000, Muirhead 2006, ISRCTN47056748, and Winterburn 2003; USA, Bonuck 2014a, Bonuck 2014b, Bonuck 2005, Brent 1995, Bunik 2010, Chapman 2004, Di Meglio 2010, Edwards 2013, Frank 1987, Grossman 1990, Hopkinson 2009, Howell 2014, Paul 2012, Petrova 2009, Pugh 1998, Pugh 2002, Pugh 2010, Serafino-Cross 1992, Wilhelm 2015, and Wrenn 1997).

<sup>1</sup> Note: The Tylleskar study, Tylleskar 2011a, Tylleskar 2011b, and Tylleskar 2011c, was undertaken in three countries, two are in

the low-income and one in the upper-middle income World Bank category. In this review, we have entered data into the analyses separately for each country.

### Methods used in trials

The 73 studies include 58 individually-randomised trials and 15 cluster-randomised trials (Bhandari 2003; Ekstrom 2006; Elliott-Rudder 2014; Fu 2014; Haider 2000; Hoddinott 2009; Kools 2005; Kramer 2001; Kronborg 2007; McLachlan 2016; Morrow 1999; Ochola 2013; Sikander 2015; Tylleskar 2011a; Tylleskar 2011b; Tylleskar 2011c; Yotebieng 2015).

### Participants and setting

#### Socioeconomic and health status

Participants were women from the general healthy population of their countries. However, 28 of the 73 studies were undertaken with women from low-income groups within their country. These 28 studies include 16 of the 20 USA studies, with four other studies from high-income countries (Jones 1985; Mejdoubi 2014; Quinlivan 2003; Wen 2011), three of the studies from Brazil (Barros 1994; Coutinho 2005; Vitolo 2005), three of the studies from low-middle income countries (Ochola 2013; Sikander 2015; Yotebieng 2015), and the two studies from low-income countries. In one of these (Haider 2000, Bangladesh), participants were mainly of lower-middle and low socioeconomic status. In the other (Tylleskar 2011a; Tylleskar 2011b; Tylleskar 2011c), participants came from three countries in sub-Saharan Africa, with those in one country (Uganda) from low-income groups within that country. With regard to health of the general population of countries, Tylleskar 2011a; Tylleskar 2011b; Tylleskar 2011c reported local HIV prevalence rates of 10% to 34% in the South Africa study sites; during recruitment, women who had not been HIV tested were encouraged to visit the antenatal clinic, and those who had HIV-positive status were recruited into another study.

#### *Background rates of breastfeeding initiation/ever breastfed*

Among the 73 studies, World Bank country income group shows an inverse relationship with background rates of breastfeeding initiation ('ever breastfed'). All the studies with intermediate (60% to < 80%, n = 18) or low (< 60%, n = 11) background rates of breastfeeding initiation were undertaken in high-income countries. Nine of the 11 studies with low background rates recruited women from low-income groups in the USA (Brent 1995; Bonuck 2005; Bunik 2010; Chapman 2004; Di Meglio 2010; Frank 1987; Grossman 1990; Pugh 2002; Serafino-Cross 1992); the remaining two (UK) studies were from areas of Scotland with lower breastfeeding initiation rates than the Scottish average (Hoddinott 2009; Muirhead

2006). All the country income groups are represented among the 24 studies with high ( $\geq 80\%$ ) rates, however the seven studies from low-/low-middle income countries all had high rates. Where background rates of 'ever breastfed' were not reported, we have used either rates published in the WHO Global Data Bank on Infant and Young Child Feeding ([www.who.int/nutrition/databases/infantfeeding/countries/en/index](http://www.who.int/nutrition/databases/infantfeeding/countries/en/index); accessed July 2016), or those published in the supplementary material to *Victoria 2016*, and for the two studies from Scotland (*Hoddinott 2009*; *Muirhead 2006*), we used [www.isdscotlandarchive.scot.nhs.uk/isd/1914](http://www.isdscotlandarchive.scot.nhs.uk/isd/1914) (accessed November 2016). For one study that was conducted in China (*Wu 2014*), data were not presented in the paper or available in the WHO Global Data Bank on Infant and Young Child Feeding and so were therefore excluded from the sensitivity analysis.

## Interventions

### Level of the intervention

In 64/73 studies, women received the intervention. In eight studies the intervention was additional training in breastfeeding support for staff (five cluster-randomised trials; *Bhandari 2003*; *Ekstrom 2006*; *Elliott-Rudder 2014*; *Kramer 2001*; *Yotebieng 2015*; and three individually-randomised trials; *Labarere 2005*; *Santiago 2003*; *ISRCTN47056748*). One cluster-randomised trial evaluated a policy for providing breastfeeding groups (*Hoddinott 2009*).

### Breastfeeding support: proactive/indirect

In 58 of the 64 studies where women received the intervention and seven of the eight studies of staff training, breastfeeding support was delivered directly to women. However, in two of these studies although the support was offered proactively initially, it was up to the women to request follow-up support (*Bonuck 2014a*; *Laliberte 2016*). In five other studies (*Graffy 2004*; *Hoddinott 2009*; *Labarere 2005*; *Morrell 2000*; *Winterburn 2003*), breastfeeding support was not offered proactively; women were encouraged to access it, but breastfeeding support was not delivered directly to women as part of these interventions. One study evaluated a multi-faceted intervention, of which breastfeeding support delivered directly to women was one component (*Kools 2005*). For two studies it was not clear if the support was offered proactively or not (*Edwards 2013*; *Vidas 2011*).

### One-to-one/group support

In 57 of the 73 studies there was individual, one-to-one contact between the breastfeeding supporter and the breastfeeding mother. Two studies offered group support (*Hoddinott 2009*; *Vidas 2011*), one offered both individual and group support (*Ekstrom 2006*), one study offered support to couples (*Abbass-Dick 2015*), and

in two studies this aspect of support was unclear (*Kools 2005*; *Kramer 2001*).

### Breastfeeding support from professional/lay supporters

In the previous version of this review, the people providing breastfeeding support were categorised as 'professional', 'lay and professional' or 'lay'. Using those categories, the 73 studies in this update comprise 49 studies of professional support, nine of lay and professional support and 15 of lay support. In view of the growing body of work evaluating breastfeeding peer support, we have distinguished between this and other kinds of lay support, following the definition by *Dennis 2002*: "Peer support is provided by lay individuals who are not part of the client's own embedded network, who possess experiential knowledge of the targeted behaviour (i.e. successful breastfeeding skills) and similar qualities (i.e. age, socioeconomic status, ethnicity, residency etc.) in order to aid the client during a time of actual or potential stress (i.e. the initiation and continuation of breastfeeding)."

#### Professional

In 49 of the 73 studies a variety of medical, nursing and allied professionals (for example, nutritionists, lactation consultants and researchers) provided the breastfeeding support (*Abbass-Dick 2015*; *Albernaz 2003*; *Bashour 2008*; *Barros 1994* *Bonuck 2005*; *Bonuck 2014a*; *Bonuck 2014b*; *Bortolini 2012*; *Brent 1995*; *Bunik 2010*; *de Oliveira 2006*; *Di Napoli 2004*; *Ekstrom 2006*; *Elliott-Rudder 2014*; *Frank 1987*; *Froozani 1999*; *Fu 2014*; *Gagnon 2002*; *Grossman 1990*; *Howell 2014*; *Jones 1985*; *Kramer 2001*; *Kronborg 2007*; *Laliberte 2016*; *Lynch 1986*; *McLachlan 2016*; *McDonald 2010*; *McQueen 2009*; *McQueen 2011*; *Mejdoubi 2014*; *Paul 2012*; *Petrova 2009*; *Porteous 2000*; *Pugh 1998*; *Quinlivan 2003*; *Santiago 2003*; *Serafino-Cross 1992*; *Sikander 2015*; *ISRCTN47056748*; *Sjolin 1979*; *Su 2007*; *Tahir 2013*; *Vidas 2011*; *Vitolo 2005*; *Wen 2011*; *Wilhelm 2015*; *Wrenn 1997*; *Wu 2014*; *Yotebieng 2015*).

#### Professional and lay

Professionals provided breastfeeding support with other people in a further nine studies; para-professionals (*Kools 2005*; *Morrell 2000*), peer supporters (*Bhandari 2003*; *Hopkinson 2009*; *Pugh 2002*; *Pugh 2010*), and lay people (employees who had to be mothers in *Barros 1994*; someone chosen by the mother in *Winterburn 2003*; and a group of mothers in *Hoddinott 2009*).

#### Lay

Lay people provided breastfeeding support in 17 studies. In twelve of these, the lay people were peer supporters (Chapman 2004; Dennis 2002; Di Meglio 2010; Edwards 2013; Haider 2000; Leite 2005; Morrow 1999; Muirhead 2006; Ochola 2013; Tylleskar 2011a; Tylleskar 2011b; Tylleskar 2011c). The other five studies did not report that the lay supporters met the Dennis 2002 criteria for us to classify them as peer supporters (Aksu 2011; Coutinho 2005; Graffy 2004; Jenner 1988; Mongeon 1995).

### Training in breastfeeding support

Overall, 50 of the 73 studies reported that the people providing breastfeeding support had additional training to provide breastfeeding support (33/49 professional, 3/9 professional and lay, and 14/15 peer/lay). In 10 studies the professionals were International Board Certified Lactation Consultants (IBCLC) (Bonuck 2014a; Bonuck 2014b; Bortolini 2012; Brent 1995; Fu 2014; Laliberte 2016; Petrova 2009; Pugh 1998; Tahir 2013; Yotebieng 2015).

In one of the studies of support from professionals and paraprofessionals, the professionals were lactation consultants (Kools 2005), and in the other they were midwives not stated to have had extra training in breastfeeding support (Morrell 2000); in both these studies the para-professionals were trained to refer women with breastfeeding problems to the professionals. Two of the four studies of support from professionals and peers reported training; in Bhandari 2003 peer supporters received WHO-based training, and in Hopkinson 2009 the professionals were IBCLCs and the peer supporters had three days' training in lactation management, 20 hours' training in peer counselling and at least one year's work experience. One of the three studies study of professional and lay support stated that lay supporters received breastfeeding support training (Barros 1994).

All 10 studies of peer support (alone) reported that peer supporters were trained. The training was WHO 20 hours (Leite 2005), 40 hours (Haider 2000; Ochola 2013) or one week (Tylleskar 2011a; Tylleskar 2011b; Tylleskar 2011c); La Leche League (LLL) 30 hours (Chapman 2004), 20 hours (Di Meglio 2010); over 30 weeks (Edwards 2013), or not specified (Morrow 1999). Two studies reported the length but not the type of training; 2.5 hours and more than two days (Dennis 2002; Muirhead 2006, respectively). Three of the five studies of lay support (alone) reported breastfeeding training; WHO 18 hours plus five days (Coutinho 2005), WHO 18 hours (Aksu 2011), and National Childbirth Trust training (Graffy 2004).

### Mode of support (face-to-face or by telephone, or both)

Forty-seven of the 73 studies offered telephone support and all but two of these were undertaken in countries classified as high-income countries by the World Bank (Albernaz 2003, Brazil; Wu 2014, China). Four studies offered breastfeeding support only by telephone (Bunik 2010; Dennis 2002; Di Meglio 2010; Fu 2014).

Thirty offered both face-to-face and telephone support, with telephone support either predominating (e.g. Muirhead 2006; Petrova 2009), or as backup (e.g. Chapman 2004). In some studies (e.g. Kools 2005; Pugh 1998), telephone contact with the breastfeeding support specialist came after the women had been visited by someone else. Across the 27 studies examining telephone support, details about whether or not the telephone support was proactively offered by the peer or professional supporter were not reported consistently. Thirty-eight studies offered only face-to-face support. In the one remaining study (Winterburn 2003), the support was not proactive and the mode of support was not specified.

### Support with an antenatal component and intention to breastfeed

The outcomes of interventions intended to promote longer duration of breastfeeding could be expected to differ according to whether women were recruited before or after they started to breastfeed. Two-thirds of the studies (49/73) included postnatal women at or after initiation of breastfeeding. In the one study of breastfeeding in groups (Hoddinott 2009), pregnant women and breastfeeding mothers could be invited to attend groups. The remaining 24 studies recruited women before the birth, not all of whom went on to initiate breastfeeding. Six of the 24 studies included only women who intended to breastfeed (Kramer 2001 in Belarus; Jenner 1988 and Winterburn 2003 in the UK; Serafino-Cross 1992 in the USA; Mongeon 1995 in Canada; Tylleskar 2011a; Tylleskar 2011b; Tylleskar 2011c in Burkina Faso, Uganda and South Africa). In the Tylleskar 2011 study, this inclusion criterion was related to HIV/AIDS prevention and management in the country and study populations. The other studies that recruited before the birth did not specify that participants had to intend to breastfeed.

### Intensity of the intervention

Sixty of the 73 studies reported the intensity of the intervention in terms of the number of postnatal contacts the mother could have for breastfeeding support. Twenty-four studies specified three or fewer contacts, 21 specified four to eight contacts, and the remaining 17 studies specified nine or more contacts. We have performed a subgroup analysis and the results are described in the text.

### Control group care

Seven of the 73 studies were undertaken in hospital settings with Baby Friendly accreditation (Aksu 2011; Chapman 2004; Coutinho 2005; de Oliveira 2006; ISRCTN47056748; Tahir 2013; Yotebieng 2015). However, in the study by Yotebieng 2015, the intervention was the Baby Friendly Hospital Initiative (BFHI) so the control group did not access this. For the other six studies

undertaken in settings with Baby Friendly accreditation, study interventions were additional to care that met Baby Friendly standards and were received by everyone at the hospital including all the study participants in the intervention and control groups. In two community-based cluster-randomised trials (Hoddinott 2009; Kronborg 2007), most of the maternity hospitals in which the participants had given birth had Baby Friendly accreditation. In 29 studies control group care was not specified (n = 9) or stated to be standard care but not described (n = 20). In the remaining studies there was some description of control group care (see [Characteristics of included studies](#)). Standard postnatal care varies both between and within countries. Care may have differed within the study period and may also have differed from that which is offered at the present time.

## Outcomes

### Level of data collection

In 66 of the 73 studies outcome data were collected from the women who had received the intervention. In the other seven studies, the relationship between the recipients of the intervention and the source of the outcome data varied. In the three individually-randomised trials of staff training (ISRCTN47056748; Labarere 2005; Santiago 2003), outcome data came from all the women randomised to receive, or not to receive, a support intervention from trained staff. In one of the three cluster-randomised trials of staff training (Ekstrom 2006), data came from mothers of singleton term healthy infants at centres where staff had been randomised, or not randomised, to receive training. In another (Bhandari 2003), trained staff visited all families in the intervention villages and outcome data were collected from all infants in the intervention and control villages, and in the third (Kramer 2001), staff in all intervention sites were trained and data were collected from mothers who intended to breastfeed in the intervention and control sites. In the cluster-randomised trial that evaluated a policy for providing breastfeeding groups (Hoddinott 2009), the policy intervention was made at locality level. Pregnant or postnatal women could be invited to groups in intervention clusters; however, only 1310 pregnant or breastfeeding women out of more than 9000 births in the intervention localities attended any group.

### Duration of any and/or exclusive breastfeeding

Breastfeeding duration was most commonly assessed at six months. A total of 51 studies measured any breastfeeding at six months and 46 studies measured exclusive breastfeeding at six months. For the other primary outcomes, 33 studies measured any breastfeeding at four to six weeks and 32 measured exclusive breastfeeding at four to six weeks. When data on both seven-day and 24-hour recall were provided, we selected the data for 24-hour recall.

The breastfeeding outcomes reported reflect World Bank country income group of the countries in which the 73 studies were undertaken. Most studies (29/52) reported the effect of the intervention on rates of both any and exclusive breastfeeding. Some studies report details about data collection that make it clear that duration of exclusive breastfeeding at specific time points was not necessarily measured from birth (Tylleskar 2011a; Tylleskar 2011b; Tylleskar 2011c; Vitolo 2005); most studies did not report this level of detail.

### Secondary outcomes

Details of secondary outcomes were not collected for this update but will be included in the next update in two years time.

In the previous version of this review (Renfrew 2012b), a few studies reported various infant morbidity and maternal satisfaction with feeding and care outcomes by intervention group: infant morbidity was reported in 11 studies (Bashour 2008; Bhandari 2003; Bunik 2010; Frank 1987; Froozani 1999; Kramer 2001; Morrow 1999; Petrova 2009; Pugh 2002; Quinlivan 2003; Tylleskar 2011a; Tylleskar 2011b; Tylleskar 2011c); maternal satisfaction with feeding in 11 studies (Bashour 2008; de Oliveira 2006; Dennis 2002; Hoddinott 2009; Hopkinson 2009; Kronborg 2007; Labarere 2005; McDonald 2010; McQueen 2011; Petrova 2009; Pugh 1998), and maternal satisfaction with care in six studies (Bashour 2008; Ekstrom 2006; Graffy 2004; Jones 1985; Kools 2005; Morrow 1999).

### Excluded studies

The previous version of this review excluded 79 studies from the review and we have excluded a further 68 studies. Thus 147 studies have been excluded with reasons (see [Characteristics of excluded studies](#)). The main reason for exclusion was because studies were not randomised trials, or it was not clear that allocation to groups had been carried out randomly; we excluded 18 studies identified by the search for this reason (Caulfield 1998; Davies-Adetugbo 1996; Ebbeling 2007; Garcia-Montrone 1996; Hall 2007; Jang 2008; Kistin 1994; McInnes 2000; Moreno-Manzanares 1997; Neyzi 1991; Nor 2009; Pascali-Bonaro 2004; Perez-Escamilla 1992; Segura-Millan 1994; Sisk 2006; Susin 2008; Thussanasupap 2006; Valdes 2000). A further two papers were reviews rather than reports of a randomised controlled trials (Guise 2003; Lewin 2005).

We excluded 72 trials because the intervention was not relevant to this review. We excluded 42 trials on the grounds that studies examined educational interventions where the focus was on instruction rather than on support to women to encourage breastfeeding (Ahmed 2016; Beiler 2011; Benitez 1992; Bolam 1998; Cattaneo 2001; Christie 2011; Edwards 2013a; Ehrlich 2014; Finch 2015; Flax 2014; Forster 2004; Giglia 2015; Girish

2013; Hanafi 2014; Harari 2014; Hauck 1994; Henderson 2001; Isselmann 2006; Jakobsen 2008; Jones 2004; Labarere 2003; Labarere 2011; Lavender 2004; Louzada 2012; Mattar 2003; Perez-Blasco 2013; Phillips 2011; Pollard 1998; Rea 1999; Rossiter 1994; Sakha 2008; Schy 1996; Svensson 2013; Szucs 2015; Tully 2012; Vianna 2011; Vitolo 2012; Vitolo 2014; Wallace 2006; Wan 2011; Westphal 1995; Williams 2014). We excluded a further 13 trials as the intervention was not designed to support continued breastfeeding; these studies examined more general interventions in the postnatal period (Ball 2011; Barlow 2006; Barnett 2002; Black 2001; Gagnon 1997; MacArthur 2002; Peterson 2002; Pollard 2011; Ratner 1999; Rush 1991; Serrano 2010; Thomson 2009; Wiggins 2005); a further trial by Baqui 2008 focused on breastfeeding initiation only, rather than on postnatal support to encourage continuation. Eleven of the studies examined interventions carried out in the antenatal period only, and had no postnatal support component (Forster 2006; Jahan 2014; Johnston 2001; Katepa-Bwalya 2011; Kronborg 2012; MacArthur 2009; Olenick 2011; Otsuka 2012; Noel-Weiss 2006; Reeve 2004; Wockel 2009).

We excluded 25 of the studies that we assessed for inclusion as they did not focus on healthy mothers with healthy, term infants. Five trials examined interventions for low birthweight babies (Agrasada 2005; Brown 2008; Junior 2007; Pinelli 2001; Thakur 2012), while the Ahmed 2008 study recruited only mothers of premature babies. The Davies-Adetugbo 1997 and Haider 1996 studies recruited the mothers of babies with severe diarrhoea, the Merewood 2006, Phillips 2010 and Phillips 2012 studies recruited only mothers of babies admitted to neonatal intensive care units, and the Pound 2015 study only included babies with jaundice. The Ferrara 2008 and Stuebe 2016 trials focused on an intervention for mothers with diabetes, the Martin 2015 and Carlsen 2013 studies focused on overweight women, and the Gijbers 2006 and Mesters 2013 trials on families with a history of asthma, while Moore 1985 looked at infants with a parent with eczema or asthma. Three other trials recruited only women in high-risk groups (Chapman 2011; McLeod 2003; Rasmussen 2011). Two studies focused providing support for fathers (Byas 2011; Tohotoa 2012), and one study concerned training for student nurses (Davis 2014).

The remaining trials were excluded for other reasons (Bica 2014; Finch 2002; Haider 2014; Hives-Wood 2013; Hoddinott 2012a; Lieu 2000; Mannan 2008; Nkonki 2014; Nor 2012; Ochola 2013a; Penfold 2014; Rasmussen 2011; Rowe 1990; Sciacca 1995; Steel O'Connor 2003; Thakur 2012; Wasser 2015). Further details of these, and other excluded studies, can be found in the [Characteristics of excluded studies](#) tables.

## Risk of bias in included studies

Each trial was assessed for methodological quality as outlined in the [Methods](#) section (see [Figure 1](#) and [Figure 2](#)).

## Allocation

Random sequence generation: we considered that a little over half of the studies included in the review used methods that were at low risk of bias to generate the randomisation sequence: we deemed 54 studies to be at low risk; nine studies at high risk and 38 studies to be at unclear risk.

Allocation concealment: we considered that a little less than half of the studies included in the review used methods that were at low risk of bias to conceal allocation to experimental groups: we deemed 44 studies to be at low risk; nine studies at high risk and 48 studies to be at unclear risk.

## Blinding

Blinding participants and personnel: with interventions of this type, it is very difficult to assess risk of bias associated with blinding. Both the mothers and the staff providing care would probably be aware that they were either receiving or delivering an intervention. In studies where there was randomisation at the clinic level, all women may have been exposed to the same intervention, and contamination between groups would thereby be reduced, but there may still have been a risk of response bias if outcomes were reported to staff providing care. Therefore, we assessed no studies as being at a low risk of bias for this domain.

Blinding of outcome assessment: we assessed approximately one-quarter of studies as being at low risk of bias for blinding of outcome assessment: we deemed 27 studies to be at low risk, 27 studies to be at high risk, and 47 studies at unclear risk.

## Incomplete outcome data

We had prespecified that we would not include data for any outcome where there were missing data for more than 25% of the randomised group. Loss to follow-up was a particular problem in studies where women were recruited in the antenatal period and, as we have described above, we have not included any outcome data from studies that were otherwise eligible for inclusion in the review because of high levels of attrition for all outcomes. For some of those studies that contributed data there was still considerable loss to follow-up, and loss was not always balanced across randomisation groups. When assessing incomplete outcome data, reasons for loss of data were not taken into consideration.

We judged approximately one-third of studies to be at low risk of bias for incomplete outcome data: we deemed 36 studies to be at low risk; 18 studies at high risk and 47 studies to be at unclear risk.

## Selective reporting

We assessed bias in most of the studies included in the review from published study reports. In most cases we did not have access to the trial registration or protocol. Under these circumstances

assessing risk of bias due to selective reporting bias is very difficult. For this reason in the last version of this review all of the studies were deemed to be at unclear risk of bias for this domain. In this update we were able to access some protocols for newly included studies. Only 10 studies have been assessed as being at low risk of bias; five studies as high risk of bias and 86 studies as unclear.

### Other potential sources of bias

We have noted any other concerns about bias (including any apparent baseline imbalance between randomised groups) in the [Characteristics of included studies](#) tables along with further information about the judgements we made about risk of bias for each included study. The quality of the studies was very mixed and most of the studies had some methodological weakness, or did not provide good information about methods. It is important that the mixed quality of the evidence is taken into account in the interpretation of results. We judged 28 studies to be at low risk of other potential sources of bias; six studies at high risk of bias and 67 studies at unclear risk.

### Effects of interventions

See: [Summary of findings for the main comparison All forms of support versus usual care](#)

### Interventions to support breastfeeding versus usual care: 73 studies

#### Primary outcomes

#### Outcome 1.1: Stopping any breastfeeding up to six months postpartum

The main summary outcome measure was cessation of any breastfeeding at the time of the last study assessment up to six months ([Analysis 1.1](#)).

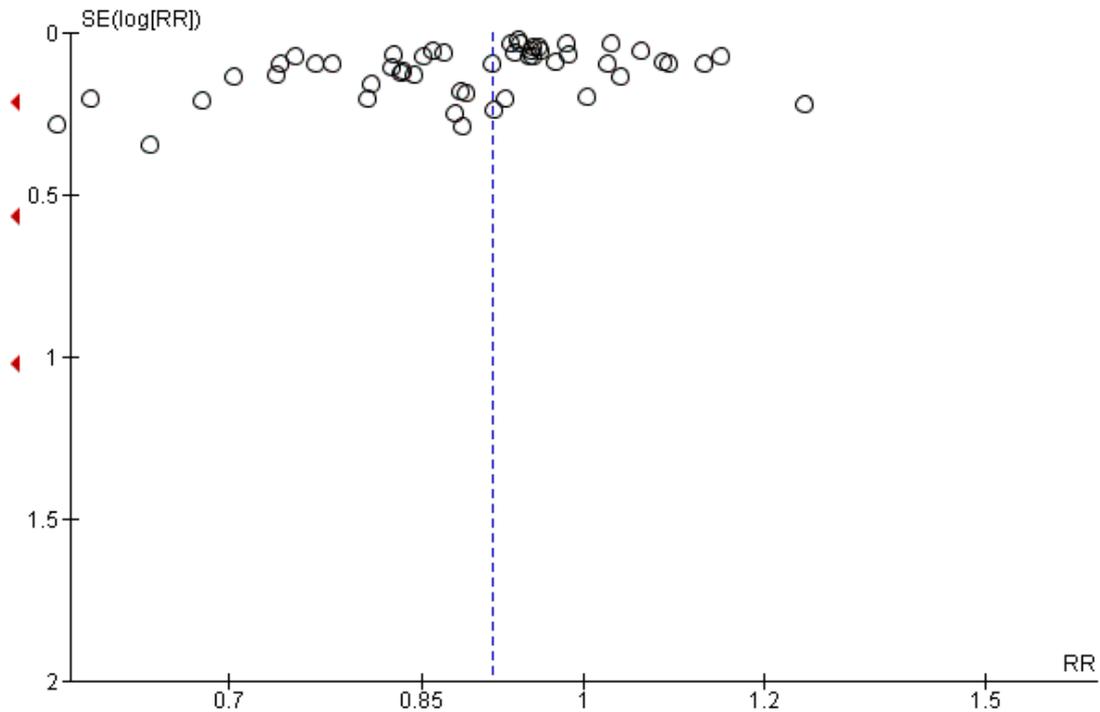
In the meta-analysis for this outcome the previous version of this review we included 40 trials with 14,227 women (effective sample size). With the new studies we added in this update, there are now 51 studies with 21,418 women included. One new study (the BINGO trial, [Bonuck 2014a](#)), contributes two intervention arms to the analysis and the control group was split to avoid double counting. One of the cluster-randomised trials ([McLachlan 2016](#)) also contributed two intervention arms and splitting over the control group was included in the adjustment for clustering.

Interventions to support breastfeeding appear to have a beneficial effect on the number of women who continue breastfeeding beyond six months, with fewer women in the groups that receive support stopping breastfeeding by this time (average risk ratio (RR) 0.91, 95% confidence interval (CI) 0.88 to 0.95; *moderate-quality evidence*). Overall, 52.59% of those receiving support interventions had stopped any breastfeeding by six months compared with 56.64% of controls (unweighted percentages). However, there was high heterogeneity for this outcome and results should therefore be interpreted with caution (heterogeneity:  $\text{Tau}^2 = 0.01$ ,  $I^2 = 55\%$ ,  $\text{Chi}^2 = 116.09$ ,  $P < 0.00001$ ).

Sensitivity analysis using only studies assessed as having a low risk of bias for allocation concealment demonstrated a similar positive treatment effect on breastfeeding at up to six months ([Analysis 1.5](#)). A sensitivity analysis omitting the cluster-randomised study ([Elliott-Rudder 2014](#)) for which a design effect could not be calculated demonstrated a similar positive treatment effect (average RR 0.91, 95% CI 0.88 to 0.94).

Visual inspection of the funnel plot generated for this outcome suggested that there was some asymmetry with results from smaller studies tending to show a greater positive treatment effect ([Figure 3](#)).

**Figure 3. Funnel plot of comparison: I All forms of support versus usual care, outcome: I.1 Stopping breastfeeding (any) before last study assessment up to 6 months**



**Outcome 1.2: Stopping exclusive breastfeeding up to six months postpartum**

In the previous version of this review we included 33 studies with 11,961 women in the analysis of women who had stopped exclusive breastfeeding at up to six months. With the new studies we added in this update, there are now 46 studies with 18,591 women included. Two new studies (the BINGO trial, [Bonuck 2014a](#); [Yotebieng 2015](#)), contribute two intervention arms to the analysis; we split the control group to avoid double-counting.

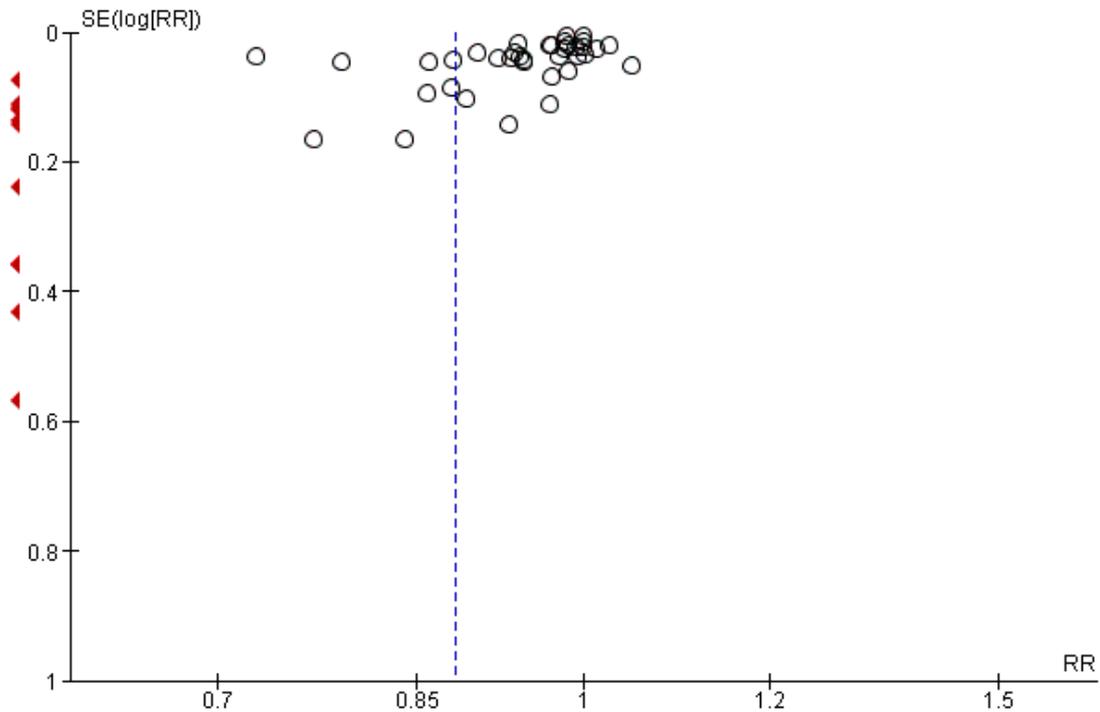
Women in the intervention groups were less likely to have stopped exclusive breastfeeding before six months (average RR 0.88, 95% CI 0.85 to 0.92; *moderate-quality evidence*) (Heterogeneity:  $\tau^2 = 0.01$ ,  $I^2 = 96\%$ ,  $\text{Chi}^2 = 1076.75$ ,  $P < 0.00001$ ; [Analysis 1.2](#)); although 74.9% of women in the intervention groups had stopped exclusive breastfeeding by this time, a greater proportion of women

in the control groups had stopped (83.4%; unweighted percentages).

Sensitivity analysis using only those studies assessed as having a low risk of bias for allocation concealment revealed that results still significantly favoured the intervention groups ([Analysis 1.6](#)), although the effect size was reduced in the studies at low risk of bias (average RR 0.93, 95% CI 0.89 to 0.96). A sensitivity analysis omitting the one arm of the cluster-randomised study ([Yotebieng 2015](#)) for which a design effect could not be calculated demonstrated the same positive treatment effect (average RR 0.88, 95% CI 0.84 to 0.91).

Visual examination of a funnel plot for this outcome suggested that the treatment effect may have been more pronounced in smaller studies ([Figure 4](#)).

**Figure 4. Funnel plot of comparison: I All forms of support versus usual care, outcome: I.2 Stopping exclusive breastfeeding before last study assessment up to 6 months**



**Outcome 1.3: Stopping any breastfeeding before four to six weeks postpartum**

In the previous version of this review we included 25 studies with 8513 women in the analysis of women stopping breastfeeding before four to six weeks. With the new studies we added in this update, there are now 33 studies with 10,776 women included. Two new studies (the BINGO trial, [Bonuck 2014a](#); [Fu 2014](#)), contribute two intervention arms to the analysis, and we have split the control arm to avoid double-counting.

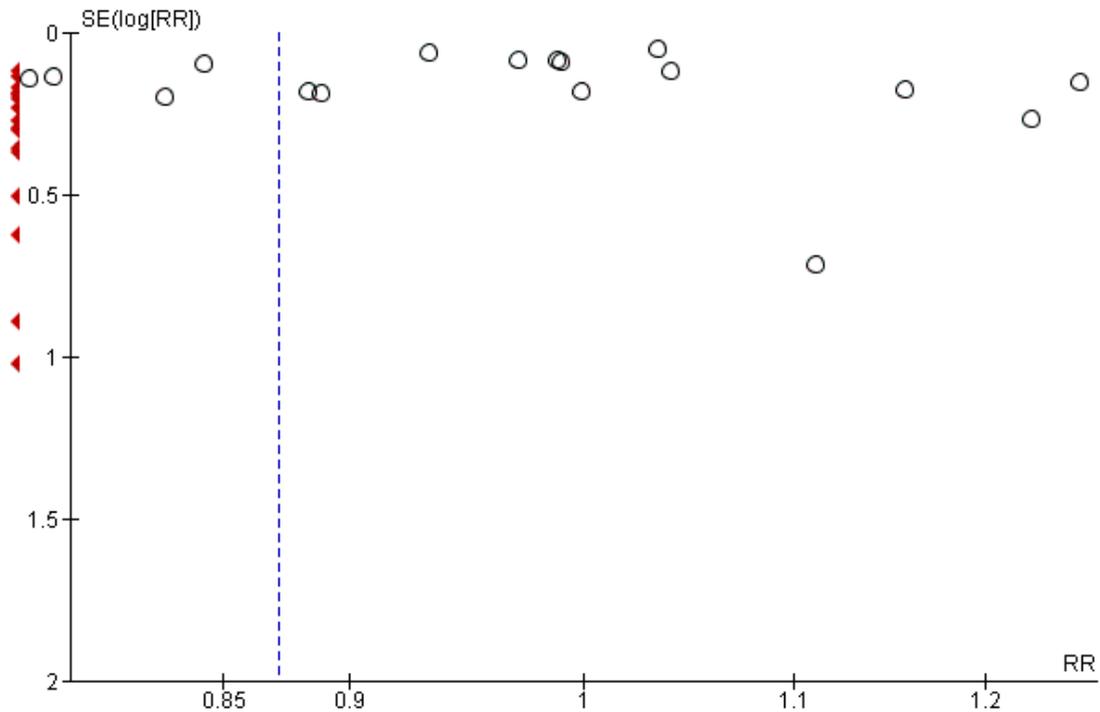
Women receiving support interventions were less likely to stop breastfeeding before six weeks (average RR 0.87, 95% CI 0.80 to 0.95; *moderate-quality evidence*): while 31.3% of women in the intervention groups had stopped exclusive breastfeeding by

this time, 34.8% of women in control groups had also stopped (unweighted percentages). There was considerable variation in the results from individual studies (heterogeneity:  $\text{Tau}^2 = 0.02$ ,  $I^2 = 54\%$ ,  $\text{Chi}^2 = 74.65$ ,  $P = 0.0001$ ; [Analysis 1.3](#)).

Sensitivity analysis using only those studies assessed as having a low risk of bias for allocation concealment revealed that results still significantly favoured the intervention groups ([Analysis 1.7](#)), although the effect size was reduced in the studies at low risk of bias (average RR 0.88, 95% CI 0.81 to 0.96).

Visual examination of a funnel plot for this outcome suggested that the treatment effect may have been more pronounced in smaller studies ([Figure 5](#)).

**Figure 5. Funnel plot of comparison: I All forms of support versus usual care, outcome: I.3 Stopping breastfeeding (any) at up to 4-6 weeks**



**Outcome 1.4: Stopping exclusive breastfeeding before four to six weeks postpartum**

In the previous version of this review, we included 24 studies with 7693 women in the analysis of women who had stopped exclusive breastfeeding before four to six weeks. With the new studies we added in this update, there are now 32 studies with 10,960 women included. Two new studies (the BINGO trial, [Bonuck 2014a](#); [Fu 2014](#)), contribute two intervention arms to the analysis, and we have split the controls to avoid double-counting.

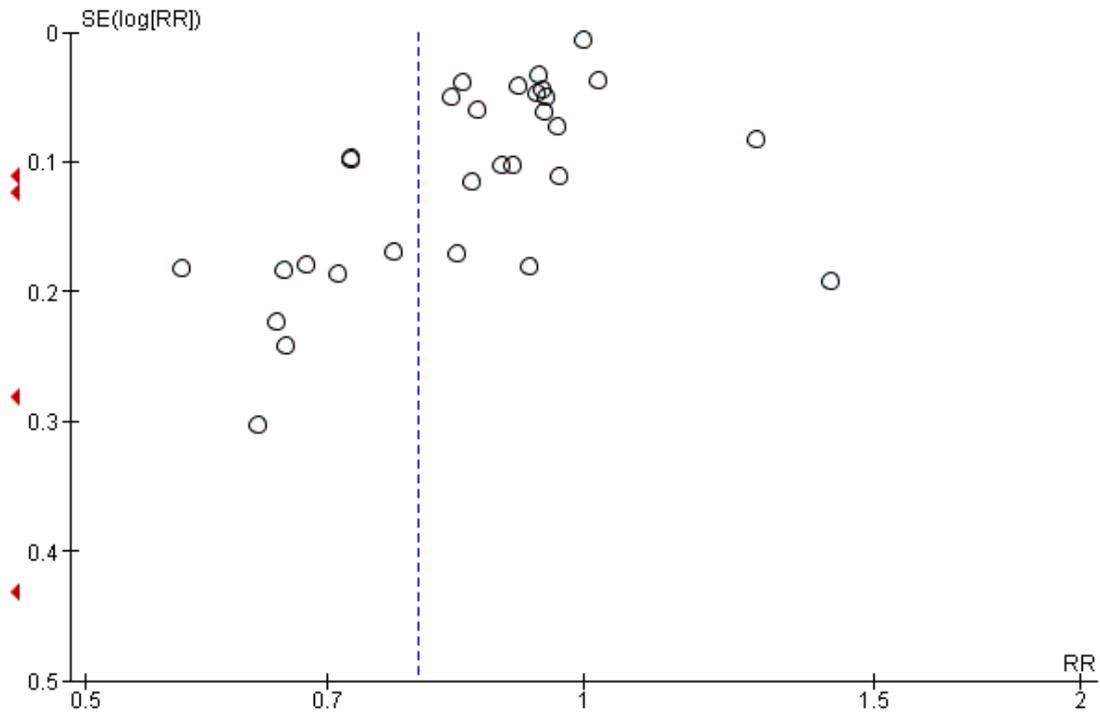
Women in the intervention groups were less likely to stop exclusive breastfeeding by six weeks compared with women in the control groups (average RR 0.79, 95% CI 0.71 to 0.89; *moderate-quality evidence*); and while 57.2% of women in the intervention groups had stopped exclusive breastfeeding by this time, 65.0% of women in control groups had also stopped (unweighted percent-

ages); (heterogeneity:  $Tau^2 = 0.10$ ,  $I^2 = 97%$ ,  $Chi^2 = 1160.22$ ,  $P < 0.00001$ ; [Analysis 1.4](#)).

Again, there was some evidence that the treatment effect may be partly due to bias; sensitivity analysis including only those studies assessed as being at low risk of bias for allocation concealment showed that results still favoured the intervention group although the treatment effect was less pronounced in the studies at lower risk of bias ([Analysis 1.8](#)). A sensitivity analysis omitting the cluster-randomised study ([Ochola 2013](#)) for which a design effect could not be calculated demonstrated a similar positive treatment effect (average RR 0.80, 95% CI 0.71 to 0.89).

Visual examination of the funnel plot for this outcome suggested that the treatment effect may have been more pronounced in smaller studies and that there may be smaller studies missing which do not find an effect in favour of the intervention ([Figure 6](#)).

**Figure 6. Funnel plot of comparison: I All forms of support versus usual care, outcome: I.4 Stopping exclusive breastfeeding at up to 4-6 weeks**



### Secondary outcomes

This update of the review does not include an analysis of secondary outcomes.

Secondary outcomes were not considered in this update so that the review could be completed in time to inform the World Health Organisation's review of the evidence and update of the WHO recommendations on breastfeeding in maternity facilities. A new set of core outcomes for Cochrane pregnancy and childbirth breastfeeding reviews is currently being developed and the outcomes from this core set may influence future outcomes chosen for this review.

### Subgroup analysis

There was considerable variation between the trials in terms of the interventions examined, the standard care offered to women, and the background breastfeeding initiation rates in the various study settings. We wanted to explore whether different types of support and settings were associated with different or more pronounced treatment effects. Therefore, for the review's four primary outcomes we carried out subgroup analysis to explore the impact of

interventions involving different types of supporter (professional versus lay person, or both); types of support (face-to-face versus telephone support or both); timing of support (antenatal and postnatal versus postnatal alone); whether the support was proactive (scheduled contacts) or reactive (women needed to request support); and whether support interventions had similar effects in settings with different background breastfeeding initiation rates (low, medium or high background rates).

For all subgroup analyses, the covariate chosen does little to explain the high heterogeneity; most within-group heterogeneity remains high.

### Who delivered the support

For our four primary outcomes, we examined whether the treatment effect was similar where the support was delivered by professionals as opposed to non-professionals (lay support) or both. It should be noted that most studies involved delivery of the intervention by professionals (37 of the 51 studies).

For cessation of any breastfeeding at up to six months it appeared that support from non-professionals was associated with a broadly similar treatment effect to that for support from professionals (

Analysis 2.1).

The test for subgroup differences suggests a differential treatment effect according to who delivers the support, but we are not confident in this result due to very different subgroup sizes and high within-group heterogeneity in two of three groups and zero heterogeneity in the other (test for subgroup differences:  $\text{Chi}^2 = 6.02$ , degrees of freedom (df) = 2 (P = 0.05),  $I^2 = 66.8\%$ ). When the smaller, mixed support group is removed from the analysis, there is no evidence of a difference between lay and professional support (test for subgroup differences:  $\text{Chi}^2 = 2.89$ , df = 1 (P = 0.09),  $I^2 = 65.4\%$ ).

For cessation of exclusive breastfeeding at up to six months the treatment effect appears to be greater when the intervention was delivered by non-professionals (lay support) compared with professionals or mixed support (test for subgroup differences:  $\text{Chi}^2 = 7.74$ , df = 2 (P = 0.02),  $I^2 = 73.1\%$ ; Analysis 2.2). The confidence intervals for professional and lay support do not overlap, but due to the high heterogeneity remaining within the subgroups, we advise caution when interpreting this result.

For cessation of any breastfeeding by four to six weeks there is no evidence for a differential effect when professionals, lay or both deliver support (test for subgroup differences:  $\text{Chi}^2 = 1.47$ , df = 2 (P = 0.48),  $I^2 = 0\%$ ; Analysis 2.3).

For cessation of exclusive breastfeeding by four to six weeks the test for subgroup differences indicates a possible differential treatment effect (test for subgroup differences:  $\text{Chi}^2 = 7.12$ , df = 2 (P = 0.03),  $I^2 = 71.9\%$ ). However, we are not confident in this result, because the mixed subgroup is disproportionately small. When this third group is removed from the analysis there is no evidence for a differential effect between professional and lay support test for subgroup differences:  $\text{Chi}^2 = 2.31$ , df = 1 (P = 0.13),  $I^2 = 56.7\%$ ; Analysis 2.4).

### Type of support

We compared different types of intervention (support provided predominantly by face-to-face contact, predominantly by telephone, or by both face-to-face and telephone contact) for our primary outcomes.

For cessation of any breastfeeding at up to six months there was no evidence of a differential effect according to type of support (test for subgroup differences:  $\text{Chi}^2 = 0.40$ , df = 2 (P = 0.82),  $I^2 = 0\%$ ; Analysis 3.1).

For cessation of exclusive breastfeeding at up to six months face-to-face interventions may be associated with greater effects than other types of support; however, very high within-group heterogeneity remains in the analysis, and we advise caution when interpreting this result (test for subgroup differences:  $\text{Chi}^2 = 37.55$ , df = 2 (P < .00001,  $I^2 = 94.7\%$ ; Analysis 3.2).

For cessation of any breastfeeding by four to six weeks, there is no evidence of a differential effect according to type of support (test for subgroup differences:  $\text{Chi}^2 = 0.91$ , df = 2 (P = 0.64),  $I^2 = 0\%$ ;

Analysis 3.3).

For cessation of exclusive breastfeeding at up to four to six weeks, face-to-face interventions may be associated with greater effects than other types of support; however very high within-group heterogeneity remains in the analyses, and we advise caution when interpreting this result (test for subgroup differences:  $\text{Chi}^2 = 10.63$ , df = 2 (P = 0.005),  $I^2 = 81.2\%$ ; Analysis 3.4).

### When the support was offered

We examined whether offering support with an antenatal component rather than postnatal support alone was associated with any difference in treatment effect. The results were similar in both subgroups for all of our four primary outcomes and there were no significant subgroup differences according to the interaction tests (Analysis 4.1 test for subgroup differences: test for subgroup differences:  $\text{Chi}^2 = 0.15$ , df = 1 (P = 0.70),  $I^2 = 0\%$ ); (Analysis 4.2 test for subgroup differences:  $\text{Chi}^2 = 1.54$ , df = 1 (P = 0.21),  $I^2 = 35.1\%$ ); (Analysis 4.3 test for subgroup differences:  $\text{Chi}^2 = 1.05$ , df = 1 (P = 0.31),  $I^2 = 4.4\%$ ); (Analysis 4.4 test for subgroup differences:  $\text{Chi}^2 = 2.07$ , df = 1 (P = 0.15),  $I^2 = 51.6\%$ ).

### Proactive versus reactive support

We had planned to carry out formal subgroup analysis by whether support was proactive or reactive, but due to the fact that most interventions included at least one scheduled contact (proactive), we did not think that this way of categorising studies would shed light on types of interventions that were effective or ineffective.

### Background breastfeeding initiation rates in study settings

We were interested in whether or not background rates of breastfeeding in different settings had any impact on the success of interventions. We divided the studies into three groups: those carried out in settings where 80% or more women initiated breastfeeding (high background initiation), where between 60% to 80% initiated breastfeeding (intermediate) or where breastfeeding initiation rates were less than 60% (low). These groups showed an inverse relationship with World Bank country income groups. The studies with high background rates of breastfeeding initiation were set in countries from all the World Bank country income groups, however, the four studies from low-/low-middle income countries had the highest rates (more than 95%). All the studies with intermediate or low background rates of breastfeeding initiation were undertaken in high-income countries.

We found the interventions had a greater effect of preventing women stopping exclusive breastfeeding at both time points in countries where background rates were already high; there was no similar effect on any breastfeeding. Because within-group heterogeneity remains high in all analyses, we advise caution when interpreting this result.

For cessation of any breastfeeding at up to six months, there is no evidence of a difference in the effectiveness of the intervention according to the background breastfeeding rate (test for subgroup differences:  $\text{Chi}^2 = 0.56$ ,  $\text{df} = 2$  ( $P = 0.76$ ),  $I^2 = 0\%$ ; [Analysis 5.1](#)). For cessation of exclusive breastfeeding at up to six months, the intervention effect appears greater in studies where breastfeeding initiation rates were high (test for subgroup differences:  $\text{Chi}^2 = 30.73$ ,  $\text{df} = 2$  ( $P < .00001$ ,  $I^2 = 93.5\%$ ; [Analysis 5.2](#)). However, within-group heterogeneity remains very high, and we advise caution when interpreting this result.

For cessation of any breastfeeding by four to six weeks, there is no evidence that the interventions worked differently in trials with different background rates of breastfeeding (test for subgroup differences:  $\text{Chi}^2 = 2.72$ ,  $\text{df} = 2$  ( $P = 0.26$ ),  $I^2 = 26.6\%$ ; [Analysis 5.3](#)). For cessation of exclusive breastfeeding at up to four to six weeks, the intervention effect appears stronger in studies where initiation rates were high (test for subgroup differences:  $\text{Chi}^2 = 9.24$ ,  $\text{df} = 2$  ( $P = 0.010$ ),  $I^2 = 78.4\%$ ; [Analysis 5.4](#)). However, within-group heterogeneity remains very high in all subgroups, and we advise caution when interpreting this result.

### **Intensity of the intervention: the number of postnatal contacts**

We examined whether different numbers of postnatal contacts were associated with any difference in treatment effect. We divided the studies into four subgroups: unspecified or no direct contacts (for example in studies that involved staff training rather than direct contacts with women); less than four postnatal contacts; between four and eight contacts; and more than eight contacts. Trials including antenatal contacts are included here, and we used the number of postnatal contacts to determine the appropriate subgroup.

For cessation of any breastfeeding at the final study assessment up to six months, there was no evidence of subgroup differences (test for subgroup differences:  $\text{Chi}^2 = 1.45$ ,  $\text{df} = 3$  ( $P = 0.69$ ,  $I^2 = 0\%$ ; [Analysis 6.1](#)).

For cessation of exclusive breastfeeding at up to six months, there appears to be a differential effect of the number of postnatal contacts, with four to eight contacts performing best. The confidence intervals for this subgroup do not overlap with any other subgroup, but within-group heterogeneity for all subgroups remains very high, and we advise caution when interpreting this result ([Analysis 6.2](#); test for subgroup differences:  $\text{Chi}^2 = 13.78$ ,  $\text{df} = 3$  ( $P = 0.003$ ),  $I^2 = 78.2\%$ ).

For cessation of any breastfeeding by four to six weeks, there was no evidence of a differential treatment effect according to the number of postnatal contacts (test for subgroup differences:  $\text{Chi}^2 = 1.59$ ,  $\text{df} = 3$  ( $P = 0.66$ ),  $I^2 = 0\%$ ; [Analysis 6.3](#)).

For cessation of exclusive breastfeeding at up to four to six weeks there appears to be differential treatment effect according to the number of support contacts, with four to eight contacts the most

effective schedule. However, within-group heterogeneity remains very high in all subgroups, and we advise caution when interpreting this result (test for subgroup differences:  $\text{Chi}^2 = 7.62$ ,  $\text{df} = 3$  ( $P = 0.05$ ),  $I^2 = 60.6\%$ ; [Analysis 6.4](#)).

## **DISCUSSION**

### **Summary of main results**

This update of the review considered the evidence of the effect of breastfeeding support interventions on primary outcomes of stopping any or exclusive breastfeeding before four to six weeks and at up to six months postpartum. The review includes 100 trials published from 1979 to 2016, 73 of which contributed data to the analyses. The 73 trials that contributed data to the analyses were conducted in 29 countries; 52 studies (62.1% of participants) in high-income countries, 15 (30.1% of participants) in upper-middle income countries, four (3.4% of participants) in lower-middle income countries, and four (4.4% of participants) in low-income countries. The numbers of trials include one ([Tylleskar 2011a](#); [Tylleskar 2011b](#); [Tylleskar 2011c](#)) that was conducted in three countries; two low-income and one upper-middle income countries. This number and location of trials indicates that the challenge of supporting women to breastfeed is both longstanding and international; this is also reflected in the continuing low rates of duration and exclusivity of breastfeeding in many countries, despite increasing availability of good-quality evidence of the scale of its public health impact.

This updated review provides evidence that interventions to support breastfeeding appear to reduce the risk of women stopping any breastfeeding at up to six months and exclusive breastfeeding at up to six months. Similarly the review provides evidence that women receiving breastfeeding support interventions were less likely to stop any breastfeeding before six weeks and exclusive breastfeeding at up to four to six weeks. The size of the treatment effects varied considerably in different trials, and average treatment effects may not be applicable in different settings. The subgroup analyses suggested that face-to-face support was associated with a greater treatment effect for exclusive breastfeeding than either telephone support alone or mixed telephone and face-to-face support. Similarly, support interventions were associated with greater effect on exclusive breastfeeding in settings with high background breastfeeding initiation rates compared to settings with low or intermediate breastfeeding initiation rates. Lay support and more contact in the form of scheduled visits (4 to 8 visits) were also associated with greater treatment effects. However, for all of these subgroup results, the within-group heterogeneity remains high, and we advise caution when interpreting these results.

A striking aspect of this updated review is the heterogeneity of the support interventions, and the diversity of settings and of standard care. Interventions deemed by researchers to be 'supportive'

included some where it was difficult to see how women might actually feel supported, especially when the support service provided was one they had to ask for, or travel a distance to get to (Graffy 2004; Hoddinott 2009), or where there was only one scheduled contact with the support person. However, this updated review, like the previous update (Renfrew 2012b), has shown that the effect of supportive interventions is robust across settings and population groups, and results from a wide range of interventions.

### Overall completeness and applicability of evidence

This review adds 21 trials contributing data to its evidence base compared to its predecessors (Britton 2007; Renfrew 2012b; Sikorski 2002). The number of mother-infant pairs in these studies has increased to 74,656 from 56,451 in Renfrew 2012b. The reporting of the included studies was, however, often not comprehensive - lacking, for example, in terms of a description of the components of the support intervention, details of the training and qualifications of the supporters, the definitions used of the extent of breastfeeding and in the description of adherence to the support protocol. There was also a failure to present details of the interventions and of the standard care available to both intervention and comparison groups. Very few of the trials described a theoretical basis for the intervention tested, with the result that the findings are difficult to explain or to replicate. There has been slight improvement in study reporting or quality, with 44 out of the 73 trials that contributed data (60%) reporting an approach to allocation concealment that we considered to be at low risk of bias compared to 26 of the 52 trials (50%) in the previous review (Renfrew 2012b).

It is possible that not all existing trials have been included in this meta-analysis. Funnel plot analyses conducted for the primary outcomes all show marked asymmetry, with each suggesting that smaller studies showing a less beneficial effect of the intervention may be missing. This may be the result of publication bias although it is also possible that few or no such trials exist. Nevertheless, caution should be taken when interpreting the evidence as funnel plot asymmetry can also be the result of heterogeneity.

Interventions offered across all included studies were very diverse, as was the provision of standard care. Interventions included, for example, one individual session in hospital, offering women the opportunity to attend a group session in community settings, telephone support, and multiple one-to-one visits at home over several months. Five studies offered the intervention in the context of Baby Friendly accreditation of the hospital, and are unlikely to be generalisable to settings where this standard of care is not available to all women.

Study endpoints also varied widely, with some substantial gaps of many months between the completion of the intervention and the last study outcome assessed. Many only offered support in the early days or weeks. These factors, together with the range of

different settings and population subgroups studied, should urge caution in the interpretation of the analysis of pooled data.

Despite this caution, the overall benefit identified from all forms of support interventions has been explored with subgroup and sensitivity analyses and is moderately robust following exclusion of the methodologically weaker trials. In this review, the greatest effect of breastfeeding support interventions on reducing cessation of exclusive breastfeeding before six months occurred in communities with high (over 80%) levels of breastfeeding initiation. This suggests that work to promote breastfeeding at a population level should continue as one strategy to increase breastfeeding duration and exclusivity (Dyson 2009; Rollins 2016).

While the effect size of support interventions on reducing the cessation of any breastfeeding is modest, there is evidence of a greater effect on the prolongation of exclusive breastfeeding. There was a reduction in the cessation of exclusive breastfeeding within the first six months and at up to four to six weeks when lay support was used, although in view of considerable within-subgroup heterogeneity, these findings should be interpreted with caution.

We have explored a range of possible reasons to explain the significant heterogeneity in the findings. As noted above, included studies were very varied in setting, population group studied, content, timing and intensity of the intervention, whether it was proactively offered to women or available only if they asked for it, the standard care available, staff training programmes, and the type and timing of the outcomes measured.

Strategies that depend mainly on face-to-face support appear more effective than those that rely primarily on telephone contact for women who practice exclusive breastfeeding. The duration of the intervention also seems to be an important factor for exclusive breastfeeding. Interventions that relied on one session in hospital are very different from interventions where women receive repeated home visits. We attempted to examine this by assessing the intensity of the intervention, and we found studies with four to eight visits to be associated with a more pronounced treatment effect on exclusive breastfeeding at final study assessment. However there was some evidence that more pronounced treatment effects were associated with studies at higher risk of bias; this could potentially confound any differences between subgroups. Caution is also needed in the interpretation of this finding as there is inconsistent reporting due to variations in the timing of outcome assessments, and the settings of studies and the population groups included in studies with more face-to-face visits. There was no evidence found for a difference between solely postnatal interventions and those interventions with both an antenatal and postnatal component.

It is likely that support will be most effective when it reflects the local needs of the population. It was notable that none of the five studies where women were expected to access support without any proactive element found a difference in outcomes between control and intervention groups. Four of these five were UK-based studies, which may help to explain the lack of effect seen in recent UK trials (Hoddinott 2011).

The findings of the subgroup analysis that suggests that interventions with four to eight contacts are best compared to those with either fewer contacts or nine or more contacts seems counter-intuitive. Given the heterogeneity of the somewhat complex interventions being tested, however, we might assume that it is other aspects of the interventions that may be responsible. One of the ways to test this would be to conduct meta-regression of the effects of the number of contacts; thus ensuring that the exact number of contacts is used for each study rather than the categorization we have used. This is something we will explore in a future update of this review. We will also consider, in a future update, adopting an analysis strategy which would treat the outcomes as time-to-event data (i.e. 'time to breastfeeding cessation' and 'time to cessation of exclusive breastfeeding'). However, whilst some studies do provide such data, many currently do not.

### Quality of the evidence

We considered that the overall risk of bias of trials included in the review was mixed. We graded fewer than half of the studies (44/100) as being at low risk of bias for allocation concealment. However, when we carried out sensitivity analysis which included only those studies at low risk of bias for allocation concealment, the results were not substantially different. A potentially important source of bias in these studies was the general lack of blinding. However, given the nature of the intervention it is unlikely that participants or personnel, or both, would be blinded, as for the support interventions, trialists would face considerable difficulties in blinding staff and women. We graded blinding of outcome assessment as being at low risk in about a quarter of studies. However, even where an attempt is made to blind outcome assessment, there is still a risk of response bias for outcomes relying on self-report such as any or exclusive breastfeeding. A further possible source of bias was loss to follow-up and missing outcome data. In the 17 studies with an attrition of more than 25%, the reasons for attrition were unclear, and these studies did not contribute data to the review. However, we are aware that even lower levels of attrition are problematic, particularly where loss was not balanced across different arms of trials. To avoid problems associated with attrition, we carried out intention-to-treat analysis for our primary outcomes; that is, we assumed that all women who were lost to follow-up had stopped breastfeeding by given time points. This is likely to have diluted overall treatment effects but these estimates may be more appropriate given the possibility of response bias and the increased likelihood of women who stopped breastfeeding dropping out before those who continued.

We assessed the four primary outcomes with GRADE criteria. We did not downgrade any evidence for lack of blinding during this assessment; neither did we downgrade trials for other risk of bias domains (our sensitivity analyses were robust, as reported above). We judged all outcomes to be of moderate quality - stopping 'any' breastfeeding at up to six months; 'any' breastfeeding between four

to six weeks; stopping exclusive breastfeeding at up to six months; or stopping exclusive breastfeeding between four to six weeks; all analyses had substantial heterogeneity even with a random-effects model. An assessment of moderate quality highlights our uncertainty in the summary estimate presented here. Included trials of breastfeeding support had mixed results for preventing women from stopping exclusive breastfeeding.

In meta-analyses with a large number of trials, as is the case in this review, there is a strong possibility that a large number of small and possibly poor quality trials will have a substantial influence on the result. In such circumstances it is preferable, therefore, to conduct a sensitivity analysis confined to the trials of the best methodological quality, which would be assumed to be the most reliable and unbiased. Apart from allocation concealment, we have not performed such an analysis, since none of the studies were assessed as being low risk of bias across all of the domains of bias we assessed.

### Potential biases in the review process

There is a potential for bias to be introduced at any stage of the review process. In order to minimise the bias in the review process, two review authors independently screened studies for inclusion and any disagreements were resolved by a third review author. Data extraction and risk of bias assessment was performed by one reviewer and then checked by a second review author. Again any discrepancies were resolved by a third review author. It must be stressed that 'Risk of bias' assessment is subjective in nature and therefore another team of review authors may have graded studies differently. It is also worth noting that we did not formerly assess risk of bias in the 15 included cluster-randomized trials. Particular biases are unique to cluster designs, as described in the *Handbook* [section 16.3.2] and formal assessments will be made of these in future updates. To minimise language bias any study not reported in English was translated into English and included in the review provided it met the inclusion criteria. This update was limited to primary outcomes so that it could be completed in time to inform important international guidance on infant feeding. All primary and secondary outcomes will be considered in the next update of this review. The development of a core outcome set for breastfeeding reviews is currently underway and this may influence the choice of outcomes in subsequent updates. This update, consistent with the previous versions of the review, combined different levels of interventions, so that trials in which breastfeeding mothers received the intervention were combined with trials where the intervention was directed at the staff providing the support. We will reconsider this approach in the next update. It is also of concern that there was missing data for 28 studies. Whilst we attempted to identify all the evidence on interventions to support breastfeeding (including published abstracts from conference proceedings) and followed-up ongoing studies, it is feasible that relevant research

that is unpublished or not registered in a clinical trials register could have been missed.

### **Agreements and disagreements with other studies or reviews**

The overall findings of this review, that breastfeeding support interventions have been shown to be effective in reducing the risk of cessation of any breastfeeding and of exclusive breastfeeding, are similar to the findings of other reviews (Rollins 2016; Sinha 2015). We concur with others, e.g. Hoddinott 2011 and Renfrew 2007, that it is critically important to identify the characteristics of support that may make this important but heterogeneous intervention more or less effective in different circumstances and settings. For example, Jolly 2012b found that peer support had a greater effect on reducing the risk of non-exclusive breastfeeding in low- and middle-income countries compared to high-income countries, especially in the UK. Other recent reviews have found that interventions to increase breastfeeding duration and exclusivity are more effective when delivered as multi-component structured programmes such as the Baby Friendly Hospital Initiative/Baby Friendly Initiative (BFHI/BFI), in a combination of settings (Beake 2012; Pérez-Escamilla 2016; Rollins 2016; Sinha 2015).

## **AUTHORS' CONCLUSIONS**

### **Implications for practice**

When breastfeeding support is offered to women, the duration and exclusivity of breastfeeding is increased. Characteristics of effective support include: that it is offered as standard by trained personnel during antenatal or postnatal care, that it includes ongoing scheduled visits so that women can predict when support will be available, and that it is tailored to the setting and the needs of the population group. Support is likely to be more effective in settings with high initiation rates. Support may be offered either by professional or lay/peer supporters, or a combination of both. Strategies that rely mainly on face-to-face support are more likely to succeed with women practising exclusive breastfeeding.

### **Implications for research**

There is a very large number of trials in this field and this number continues to grow. This has resulted in a great deal of research time, energy and funding. While there are still questions to address about how best to provide support, the key messages are clear - we have ample evidence to know that women need support to be available and to be provided using the characteristics we have identified to increase the duration and exclusivity of breastfeeding. The key research question for the future is to identify how such support can best be provided consistently, for all women, in all countries.

This becomes a scaling-up issue, which needs implementation and quality improvement approaches rather than effectiveness studies.

Any future studies should describe in detail the attributes of the intervention (who delivered it, setting, intensity, proactive or reactive); standard care (Baby Friendly accreditation or not, staff trained in breastfeeding or not); the population group studied (low- versus high-income, any selection criteria); and the background breastfeeding rates in the population studies. Studies should also examine the potential for synergy between support and other interventions that aim to increase breastfeeding rates, as it may be that a package of interventions is more effective than single interventions in tackling the multifaceted challenge of increasing breastfeeding rates. Packages to be tested could include peer and professional support along with, for example, antenatal education, staff training, and mother-to-mother support. Studies should also assess the effectiveness of lay, professional and combined support in different settings - in particular in those communities with low rates of breastfeeding initiation. Implementation of the Baby Friendly Initiative should be accompanied by the continued monitoring of breastfeeding rates to explore whether its effect is similar in countries with differing rates of initiation and prevalence of breastfeeding.

Further study is also required to:

- test the effectiveness of different training programmes (which should be well-defined and reproducible) and should attempt to address impact on both exclusive and any breastfeeding where possible;
- analyse and develop the theoretical basis for their approach, and analyse the elements of their approach that appear to have an impact, including training, timing, and intensity of the intervention, and differential impact on different population subgroups;
- establish the cost-effectiveness of different interventions;
- investigate appropriate strategies for supporting women who wish to breastfeed for longer than six months;

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

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

#### Abbass-Dick 2015

Methods	2-arm RCT, single-site, n = 214
Participants	<p>Large urban teaching hospital in Toronto, Canada</p> <p>Background rates of breastfeeding initiation: 89%</p> <p>Inclusion criteria: primiparous mothers in the first 2 days postpartum, singleton birth, <math>\geq 18</math> years old, <math>\geq 37</math> weeks' gestation at delivery, able to speak and read English, and living with a male partner</p> <p>Exclusion criteria: women sharing a hospital room with a current study participant, a medical problem that could interfere with breastfeeding, infant not discharged from hospital with them, no access to the Internet or a telephone, planning to breastfeed for <math>&lt; 12</math> weeks, and had a partner who would not be available to participate in the study</p>
Interventions	<p>Intervention: the trial intervention was a multifaceted coparenting breastfeeding support intervention, provided face-to-face on the postpartum unit, at which time the couples were provided with breastfeeding information, the information package was reviewed, and couples were given the option of watching a video. The session took 15 min in the majority of cases. Couples had a take-home breastfeeding booklet, developed by Best Start: Ontarios Maternal, Newborn and Early Child Development Resource Centre, access to a secure study web site that consisted of extensive information on breastfeeding and coparenting and contained links to related information and resources on the Internet including a copy of the video to watch at home. The couples were followed up at home with emails at 1 and 3 weeks postpartum and a telephone call at 2 weeks postpartum to answer any questions or concerns about the information provided</p> <p>Control: couples received usual care, which included standard in-hospital breastfeeding support and any breastfeeding assistance that was proactively sought in the community</p>
Outcomes	<p>Primary:</p> <p>Exclusive breastfeeding at 6 weeks and 12 weeks postpartum</p> <p>Secondary:</p> <p>Breastfeeding duration at 6 and 12 weeks postpartum</p> <p>Maternal perceptions of breastfeeding support</p> <p>Maternal perception of the coparenting relationship at 12 weeks postpartum</p>
Notes	

#### *Risk of bias*

#### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Intervention group by sequentially numbered randomly generated numbers
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes

Abbass-Dick 2015 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Envelopes were constructed by a research assistant who was not involved in any other trial procedure. Participants not blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Participants in intervention group were known to assessors because they were interviewed
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data were < 25%. Complete follow-up data were collected from 87.9% (n = 188) of fathers at 6 weeks and 88.3% (n = 189) of mothers at 6 weeks and 91.6% (n = 196) at 12 weeks
Selective reporting (reporting bias)	Low risk	Primary and secondary outcomes detailed in the study protocol were reported
Other bias	Unclear risk	There were no significant differences in baseline characteristics between the groups except prenatal education. However, there was a non-significant difference between the 2 groups in attendance at a prenatal breastfeeding class

Aidam 2005

Methods	3-arm RCT, with individual randomisation n=231
Participants	<p>The study was carried out in the Tema area of Ghana (sub-Saharan Africa). Women were recruited in prenatal clinics in 2 hospitals (1 government and 1 private) that served urban areas (an industrial city and a commercial town)</p> <p>High baseline prevalence of breastfeeding in Ghana, the median duration of breastfeeding was reported as being 22 months and 53.4% of women with babies &lt; 6 months breastfed exclusively. It was reported that "almost all" mothers initiated breastfeeding</p> <p>231 women randomized (136 eligible at the beginning of the intervention period)</p> <p>Inclusion criteria: pregnant women in the last trimester planning delivery in the study hospitals and to stay in study area for 6 months after delivery. After delivery: singleton babies with normal birthweight (&gt; 2500 g) and Apgar scores <math>\geq</math> 6 at 1 min and 5 min</p> <p>Exclusion criteria: multiple birth, low Apgar score or planning to move out of area</p> <p>Participant characteristics:</p> <p>38% of the women had only primary level or no formal education; 90% were married or living with a partner; 46% were primiparous; 73% had vaginal birth; 24% lived in households with access to a car; 74% were described as trader/artisan</p>
Interventions	<p>All 3 groups (intervention 1, intervention 2 and control) were allocated to 2 educational group sessions during pregnancy by trained nurses and 9 proactive home visits by trained nurse counsellors at 1, 2, 4, 6, 8, 12, 16, 20 and 24 weeks postpartum. These were in addition to standard care. The content of the sessions differed between the 3 groups. 63% of intervention 1, 73% of intervention 2 and 65% of the control group women received all 9 scheduled home follow-up visits</p>

	<p>Intervention 1 (n = 74): 43 followed up. Content of sessions was breastfeeding and exclusive breastfeeding. Trained local nurses with experience of breastfeeding gave 2 educational sessions, of approximately 20 min each, to groups of 2-4 women during their third trimester. At postpartum home visits women received individual counselling and nurses were advised to respond to concerns. Materials were developed from WHO/ UNICEF breastfeeding counselling training manual</p> <p>Intervention 2 (n = 72): 44 followed up. Content of the pregnancy sessions was general health and childcare as for control group. Content of the postpartum home visits was breastfeeding and exclusive breastfeeding as for intervention 1</p> <p>Control (n = 85): 49 followed up. Content of sessions was general health and childcare topics such as immunisation, HIV/AIDS, nutrition and family planning</p>
Outcomes	Breastfeeding status at 1, 2, 3, 4, 5, and 6 months, exclusive breastfeeding up to 6 months, infant morbidity and growth
Notes	We have not included data from this study in the review due to high levels of attrition (> 25% loss to follow-up). Most data were reported in graphs and difficult to interpret. Several measures of exclusive breastfeeding were reported; at 1 and 6 months women were asked about breastfeeding since birth, during previous month and on previous day. In this review we have reported figures for exclusive breastfeeding since birth for both time points. Figures in the paper were expressed as percentage of women still exclusively breastfeeding; in order to use the data we used subtraction to calculate a figure for women who had stopped breastfeeding

*Risk of bias**Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization was achieved by writing numbers 1 to 3 on folded pieces of paper."
Allocation concealment (selection bias)	High risk	Quote: "The numbers were not viewed by either study staff or mothers and the pieces of paper looked the same on the outside. Before offering papers to mothers, they were shuffled in the interviewer's palm." Quote: "The randomisation scheme used was not a formal one. It was one that could be conducted easily in the field. Despite this, it functionally produced balanced groups with no evidence of bias."
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was stated that women were informed only that they would receive "health education" that would be beneficial to their infants and themselves, but were not aware of their group allocation or of differences in the content of the health education. How-

**Aidam 2005** (Continued)

		ever, it is not possible to blind
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "It was impossible to keep counsellors unaware of study design.... research assistants [collecting outcome data] were aware of mothers group allocation."
Incomplete outcome data (attrition bias) All outcomes	High risk	231 women randomized during the third trimester. At delivery 95 women were excluded as they were no longer eligible (41% lost before the intervention). A further 13 women were lost to follow-up during the intervention period. 123 completed the final follow-up at 6 months (i.e. 53% of the original randomized sample but 90% of those still eligible at delivery) Results were reported in graphs and percentages and it was not clear how many women commenced breastfeeding, so group denominators are not clear Loss to follow-up appeared balanced across groups.
Selective reporting (reporting bias)	Unclear risk	Failure to provide denominators for results means that they are very difficult to interpret
Other bias	Unclear risk	Women in the 3 arms of the trial appeared similar at baseline. Analysis was according to group allocation

**Aksu 2011**

Methods	RCT, single site, a Baby-Friendly hospital, March-July 2008, n = 66
Participants	Urban state maternity hospital in Turkey Background rates of breastfeeding initiation: high Inclusion criteria: primiparous, live vaginal birth, healthy term singleton infant, living in study area, able to speak Turkish, no history of chronic diseases, non-smoker, intending to breastfeed Exclusion criteria: infant birthweight < 2500 g, Apgar score ≤ 7, congenital anomalies, serious disease or needing intensive care Baseline prevalence of "ever breastfed" in Turkey: 96.7% (WHO Global data bank 2010, accessed 6 October 2011)
Interventions	Intervention: women received standard breastfeeding support plus support from trained lay supporters who had undergone WHO/UNICEF 18-h training. The intervention was a single home visit on day 3 after the birth (in hospital), by 2 lay breastfeeding

**Aksu 2011** (Continued)

	supporters, that lasted about 30 min and covered the same topics as routine support Control: at this Baby-Friendly hospital, a standard breastfeeding education session lasting 20-30 min was provided to all mothers before standard discharge home at 24 h after the birth. The session included the topics covered by the 18-h WHO/Unicef training
Outcomes	Exclusive breastfeeding at 2 and 6 weeks and 6 months postpartum; breastfeeding duration (any/exclusive) to 18 months; breastfeeding knowledge scores at 2 and 6 weeks postpartum
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to enable a judgement to be made
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Women were contacted either through home visits or via the phone and data on breastfeeding was collected, however, not reported whether the assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	82% follow-up at 18 months. Reasons for loss were explained and were balanced across groups
Selective reporting (reporting bias)	Low risk	Not apparent
Other bias	Low risk	Groups appeared similar at baseline.

**Albernaz 2003**

Methods	Primary care facilities, recruitment over 5 months, n = 169
Participants	3 hospitals in the city of Pelotas, in southern Brazil Background rates of breastfeeding initiation: 88% Ethnic composition not described. Inclusion criteria: term healthy baby, family income ≥ USD 500 per month (no economic constraints to baby's growth), mother intended to breastfeed and did not smoke Exclusion criteria: multiple birth, gestational age not 37-42 weeks, significant perinatal morbidity, maternal smoking and family income USD 500 per month

**Albernaz 2003** (Continued)

Interventions	Intervention: hospital visit, home visits at 5, 15, 30, 45, 90 and 120 days, and 24-h telephone hotline for help or to arrange visits. 2 members of the lactation support team had received the 40-h WHO lactation support training course Control: attended paediatric clinics where general advice on advantages of breastfeeding may have been offered, but specific lactation counselling was not provided
Outcomes	Breastfeeding pattern and duration up to age of 4 months. Breastmilk intake for a subgroup of 68 infants at 4 months
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Computer-generated code
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to enable a judgement to be made
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The interviewers were not informed about the intervention or control status of each mother, and did not know the study's objectives
Incomplete outcome data (attrition bias) All outcomes	High risk	188 women were randomized. 21 were excluded after 2 weeks as they had introduced formula milk. A further 26 withdrew (some data were available for some of these women). 141 women completed the trial (75%)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Excluding women who introduced formula within 2 weeks of randomisation is likely to have introduced bias although similar numbers were excluded from both groups (9 women lost from the intervention group for this reason and 11 women from the control group and an additional control was withdrawn for smoking)

## Anderson 2005

Methods	2-arm RCT, with individual randomisation N=135
Participants	<p>Hartford area of Connecticut, USA in a hospital providing care for predominantly Latina low-income women</p> <p>Inclusion criteria: age <math>\geq 18</math> years; gestational age <math>&lt; 32</math> weeks at first approach; healthy, considering breastfeeding, planning delivery at study hospital and resident in area for 3 months after the birth, 185% of the federal poverty level, available for telephone contact and willing to participate</p> <p>Exclusion criteria for mothers: medical conditions such as diabetes or hypertension; drug use that could impair breastfeeding</p> <p>Exclusion criteria for infants: preterm, low birthweight (<math>&lt; 2500</math> g), any complications requiring admission to special care, Apgar score <math>&lt; 7</math> at 1 min and 5 min</p> <p>Participant characteristics: at baseline: intervention n = 63; control n = 72</p> <p>Participant characteristics:</p> <p>Married/cohabiting: intervention 40%; control 26%</p> <p>Hispanic race: intervention 81%; control 64%</p> <p>Education less than high school: intervention 31%; control 38%</p> <p>Received welfare: intervention 31%; control 38%</p> <p>Primiparous: intervention 92%; control 89%</p> <p>Planned breastfeeding duration <math>&lt; 6</math> months: intervention 20%; control 46%</p> <p>Planned breastfeeding duration 6-12 months or longer: intervention 80%; control 54%</p>
Interventions	<p>Intervention: in addition to standard care, women received 3 prenatal home visits, daily in-hospital visits and 9 postpartum home visits from peer counsellors: 3 in first week, 2 in second week and 1 in each week for weeks 3-6. Women could also phone peer counsellors. Peer counsellors were mothers from the area with experience of successful breastfeeding and training from a lactation consultant (LC)</p> <p>Control: women received what would have been standard care for private patients (these women may not have normally qualified to receive this care as many were participating in welfare programmes). This consisted of: breastfeeding support line open to mothers after delivery staffed by a lactation specialist. Usual in-patient care and support for breastfeeding was provided by hospital staff</p>
Outcomes	Infant feeding practices (weekly for first month) breastfeeding and exclusive breastfeeding. Infant morbidity (diarrhoea and ear infection). Breastfeeding outcomes measured in 3 different ways - over the past 24 h, over the past week and since the birth (ever given)
Notes	We have not included data from this study in the review due to high levels of attrition ( $> 25\%$ loss to follow-up)

### *Risk of bias*

### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	SPSS software was used to randomly assign subjects to study groups

**Anderson 2005** (Continued)

Allocation concealment (selection bias)	Low risk	Quote: “Recruited subjects were entered into the database at the end of every week” and then random allocation by computer software
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated if women or peer counsellors were blinded, but unlikely
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not a double-blind study and the interviewer knew the study hypotheses. Steps were taken to prevent interviewer bias by asking questions regarding peer counsellor contact at the very end of each follow-up interview session
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	182 women were recruited and randomized. 162 were still eligible at delivery and 135 completed the trial (84% of those still eligible at delivery and 74% of the total randomized)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Groups appeared similar at baseline although women in the control group were more likely (46%) to plan to breastfeed for < 6 months than women in the intervention group (20.4%). This difference in breastfeeding intentions means that the results are more difficult to interpret

**Barros 1994**

Methods	2-arm RCT, single-site, n = 900
Participants	Urban setting in Brazil: in-patient maternity unit Background rates of breastfeeding initiation: high Ethnic composition not described Inclusion criteria: family income < twice the minimum Brazilian wage; hospital stay < 5 days; wanting to breastfeed: living within the city of Pelotas Baseline prevalence in Pelotas (1993) for any breastfeeding: 85% at 1 month, 66% at 3 months and 38% at 6 months
Interventions	Intervention: 3 home visits at 5, 10 and 20 days postpartum by a social assistant or nutritionist. The visitor was required to have a personal history of successfully breastfeeding

**Barros 1994** (Continued)

	a child and received training in breastfeeding physiology and common breastfeeding problems and their solutions Control: usual care, a social assistant would not normally make routine home visits but would visit only when requested to do so by the hospital team
Outcomes	Breastfeeding at monthly intervals to 6 months and median duration of breastfeeding Time to introduction of artificial feeds Difficulties encountered during breastfeeding and reasons for weaning also recorded
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Record in Portuguese and no information in the translation regarding blinding of participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	High risk	The nurse collecting outcome data was not aware of previous contacts, but the authors stated that s/he may have been made aware of group assignment as women were likely to talk about the intervention
Incomplete outcome data (attrition bias) All outcomes	Low risk	900 randomized, approximately 8% lost to follow-up in the intervention and control groups
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	No baseline imbalance apparent. Assessment of risk of bias was made from translation notes. The original paper is in Portuguese

**Bashour 2008**

Methods	3-arm RCT, with individual randomisation N=903
Participants	Recruited from Maternity Teaching Hospital in Damascus, Syria Background rates of breastfeeding initiation: high Inclusion criteria: consenting women who delivered a healthy newborn by vaginal delivery or caesarean section, who lived within 30 km from hospital, and were available for follow-up for the next 6 months

	<p>Exclusion criteria for infants: premature, low birthweight (&lt; 2500 g), with apparent congenital anomalies</p> <p>Participant characteristics:</p> <p>Age not clear.</p> <p>Approximately 37% primiparous</p> <p>90% had normal labour</p> <p>&gt; 99% of the women were married</p> <p>Home conditions were described as bad (number of rooms, poor sanitation or water, etc.) in 28.5% of control group and approximately 20% of the intervention groups</p> <p>Few of the women (approximately 5%) worked outside the home.</p>
Interventions	<p>Intervention 1 (n = 301): 4 structured home visits from trained midwives at 1, 3 and 7 days and 4 weeks after the birth. Midwives examined mothers and infants and provided and advice and support on a range of healthcare issues including breastfeeding support and education</p> <p>Intervention 2 (n = 301): a single postnatal visit from a trained midwife at 3 days which included advice and education on breastfeeding</p> <p>Control (n=301): received standard care in Syria (no postnatal visits)</p>
Outcomes	<p>Primary:</p> <p>Maternal postpartum morbidities, postnatal care uptake, contraceptive uptake and type, infant morbidities, infant immunisation according to the national schedule at 3 months and Infant feeding (specifically exclusive breastfeeding during the first 4 months of life)</p> <p>Secondary:</p> <p>Women's perceptions of their health, impressions about the home visit and perceptions of its quality</p>
Notes	Some baseline imbalance, women in the control groups were more likely to have poor home conditions and were less likely to have received antenatal care

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Participants were randomized into blocks to either of the intervention groups (4 home visits or 1 home visit) or to the control group (no home visits). Randomisation was in blocks of 7 where a caseload of 21 eligible deliveries per day was assumed, based on the average daily number of deliveries in the hospital (ranging from 30 to 35) after excluding non-eligible cases
Allocation concealment (selection bias)	Low risk	Quote: "Numbered, opaque and sealed envelopes.." Group allocation was carried out by a senior midwife not involved in the rest of the study

**Bashour 2008** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The midwives carrying out the intervention were not blinded. It was not stated whether the participants were blinded, but this is unlikely
Blinding of outcome assessment (detection bias) All outcomes	High risk	The interviewers carrying out outcome assessment were not informed of groups, but would be aware of which group women were in from the interviews
Incomplete outcome data (attrition bias) All outcomes	Low risk	903 women met the inclusion criteria. After randomisation (301 in each arm), 27 women were excluded (18 due to lack of address detail and 9 refusals). A total of 876 women were followed up in the 3 study groups: Intervention 1 (285 women), Intervention 2 (294 women) and Control (297 women). Incomplete data were addressed
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Some baseline imbalance, women in the control groups were more likely to have poor home conditions and were less likely to have received antenatal care. Outcome data were collected at 4 months, but it is likely that there may have been recall bias for some outcomes, e.g. breast engorgement - women in the intervention groups would have discussed this and maybe it was recorded at the time it occurred, women in the control group would not have been asked until 4 months postpartum. Outcome data were collected for a large number of variables, so any differences may have occurred by chance

**Bhandari 2003**

Methods	Cluster-randomised study with 8 sites, n = 1115
Participants	8 village communities located 3 km-5 km from the main highway in Haryana, India Background rates of breastfeeding initiation: high Inclusion criteria: born in a study village within 9 months of start of intervention Exclusion criteria: not reported Baseline breastfeeding prevalence stated to be high

**Bhandari 2003** (Continued)

Interventions	Intervention: health and nutrition workers in the intervention communities received training based on Integrated Management of Childhood Illnesses Training Manual on Breastfeeding Counseling (WHO 1997). Messages - feed only breast milk for first 6 months of life; breastfeed the infant day and night, at least 8 times in 24 h; possible adverse effects of other foods and fluids given to breastfeeding infants - given to mothers at birth, plus monthly home visits, immunisation clinics and neighbourhood meetings Control: at the control sites, the research team provided routine services, in which, according to national policy, workers are required to advise exclusive breastfeeding for 4-6 months
Outcomes	Feeding at 3 months Anthropometry and diarrhoea prevalence at 3 and 6 months
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Communities were paired on the basis of similar scores for socioeconomic, mortality and morbidity indicators. 1 of each pair was allocated to the intervention using a random number table. 8 areas were randomized (4 to each condition)
Allocation concealment (selection bias)	Low risk	Statistician independent of project carried out randomisation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated whether participants and peer counsellors were blinded but unlikely
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Authors state "we attempted to keep to a minimum reporting bias by use of a separate team for assessment of outcomes; this team did not take part in the intervention and was unaware of the hypothesis being tested"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reasons for drop-out recorded. 1151 births within the study period (not clear how many in each area). 588 families received the intervention and 527 no intervention. 895 completed 3 months follow-up (80%) and 880 6 months (79%)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol

**Bhandari 2003** (Continued)

Other bias	Unclear risk	Areas were paired, but it was not clear whether this achieved similar baseline characteristics between groups. Results were reported to have been adjusted for clustering
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**Bloom 1982**

Methods	2-arm RCT, with individual randomisation (although the study also included a non-randomised comparison group)	
Participants	100 breastfeeding mothers randomized; recruited 3 days after the birth Inclusion criteria: married, primiparous with healthy infants born at a maternity hospital in Nova Scotia, Canada Exclusion criteria: infants with birthweight < 2500 g, with Apgar scores < 5, twins, women having operative deliveries, women who did not speak English	
Interventions	Women in both groups received a pamphlet on breastfeeding. Intervention: weekly telephone calls beginning 10 days after the birth made by a nurse interviewer, offering support and advice and referral if necessary. Calls lasted 5-10 min and were described as friendly. Women received up to 3 calls up to 6 weeks postpartum. Calls ceased when women discontinued breastfeeding Control: women received usual care (not specified)	
Outcomes	Interviews at 6 weeks postpartum. Women were asked about infant behaviour and infant feeding and breastfeeding duration	
Notes	We have not included data from this study, because results in this paper were not reported in a form in which we could use them in the review. Most of the results were not reported according to randomisation group (rather authors described factors and associations with, e.g. breastfeeding). Breastfeeding in the randomized groups at 6 weeks was not reported and it was not possible to contact the authors to obtain this information. It was stated that average breastfeeding duration was 28.6 days in the intervention group vs 21.0 days for controls, but no SDs were reported. It was not clear when or how breastfeeding duration data were collected; if at the 6-week postpartum interviews this suggests that figures for average breastfeeding duration only apply to those women who had discontinued breastfeeding and denominators are therefore not clear	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Described as "randomly assigned".

**Bloom 1982** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The interviewer who recruited women also carried out the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The interviewer carrying out outcome assessment was reported not to be aware of the initial feeding choice (but may have been made aware of the intervention allocation by women)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Rates of follow-up at 6 weeks were high (97%). However, denominators for breastfeeding duration results were not reported
Selective reporting (reporting bias)	Unclear risk	Most results were not reported by randomisation group and are difficult to interpret
Other bias	Unclear risk	Unclear - no baseline characteristics table for randomized groups

**Bonuck 2005**

Methods	2-arm RCT, n = 382
Participants	<p>From 2 prenatal care centres in the Bronx, New York (reported to be the county in the USA with the highest poverty rate)</p> <p>Background rates of breastfeeding initiation: low</p> <p>Inclusion criteria: able to speak English or Spanish, singleton or twin pregnancy &lt; 24 weeks (twins subsequently excluded), intending to keep infant and attend for prenatal and postnatal care at centre and affiliated hospital, telephone contact numbers available</p> <p>Exclusion criteria: HIV-positive status, chronic disease with medication not compatible with breastfeeding, diabetes, serious illness, or breast reduction surgery</p> <p>Participant characteristics: 57% Hispanic, 36% African-American, 62% multiparous (70% of these had previous breastfeeding experience), mean age 25 years (SD 6.23), 51.5% married or living with a partner, 57% receiving Medicaid</p>
Interventions	<p>Intervention (n = 188): delivered by a trained LC. Women were recruited when &lt; 24 weeks pregnant, and had 2 prenatal LC visits scheduled. During late pregnancy there was telephone contact, and hospital and home visits and telephone support (up to 12 months postpartum) were planned for the postnatal period. In the postnatal period 25% of the intervention group received at least 1 hospital contact; approximately 50% had telephone and/or home visits; but 36% received no home or hospital visits and no telephone support</p> <p>Control (n = 194): women had no contact with the LC. Standard care varied between the sites and neither site followed an established protocol for breastfeeding. Women enrolled in women and child nutrition programmes (WIC) had the opportunity to visit a breastfeeding co-ordinator</p>

Outcomes	<p>Infant health outcomes:            Duration of breastfeeding and exclusive breastfeeding was presented mostly in graphical form and was difficult to interpret. Breastfeeding was categorised on a 7-point scale from 7 = exclusive breastfeeding (which was defined as no other milk or food, but infants may have received water and other liquids) through to exclusive formula, between these extremes of the scale there were various 'intensities' of breastfeeding (e.g. &gt; 50% breast milk). This meant that results were complicated and not easy to interpret. Women were followed up for up to 12 months and detailed (graphical) weekly data were reported for weeks 1-26 postpartum</p>
Notes	Results estimated from graphs.

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The project's biostatistical office generated and maintained a list of random codes for subjects... undisclosed blocking factor and stratification according to center."
Allocation concealment (selection bias)	Low risk	Sealed envelopes, numbered and opened sequentially.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It was not stated whether the women were blinded. The LC providing the intervention was not blinded with respect to treatment group
Blinding of outcome assessment (detection bias) All outcomes	High risk	The research assistant collecting breastfeeding outcome data was not blinded with respect to treatment group
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Women were recruited in the antenatal period. 382 women were randomized. Loss to follow-up included 10 women who miscarried or terminated the pregnancy. 304 women were followed up into the postnatal period (80% of those randomized). There were further missing data for longer term follow-up. Loss to follow-up was balanced across groups
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	The intervention did not appear to be standardised and many women in the intervention group (36%) did not receive any postnatal visits

**Bonuck 2014a**

Methods	Parallel 2-arm participant-level RCT, n = 666
Participants	<p>Women who attended an urban medical centre providing prenatal care to a low income population in the Bronx, New York City</p> <p>Background rates of breastfeeding initiation:79%</p> <p>Inclusion criteria: English- or Spanish-speaking women aged <math>\geq 18</math> years, in the first or second trimester of a singleton pregnancy</p> <p>Exclusion criteria: risk factors for premature birth maternal or infant conditions that would preclude or complicate breastfeeding (e.g. mother HIV-positive, infant congenital anomaly)</p>
Interventions	<p>666 women were randomized in a 1:3:3:1 ratio to: usual care, electronic prompt (EP) alone, Lactation Consultant (LC) + EP, or LC alone. Only the LC and EP+LC arms are included in this review as the EP arm (n=253) was antenatal only and therefore does not meet the review inclusion criteria for a breastfeeding support intervention</p> <p>LC intervention (n= 80): Two LCs were allocated to this intervention. The LC protocol included 2 prenatal sessions, a hospital visit, and regular phone calls postpartum for 3 months or until breastfeeding ceased. The prenatal sessions occurred in the examination room, during the 30-plus min of 'downtime' while waiting for the prenatal care provider. Attempts were made to complete interrupted sessions after the examination. The first session focused on rapport building and education, and the second was on the practical aspects of breastfeeding. The study provided nursing bras and breast pumps to LC group participants as needed. LCs met mothers and their infants at the 1-week routine paediatric visit, modelling practice on a recent review. Postpartum home visits were optional, based upon participant and LC preference and comfort</p> <p>LC + EP intervention (n=253): Included the LC protocol detailed above and electronic prompts for healthcare providers to ask three brief open-ended questions which portrayed breastfeeding as the norm. This was done during pre-natal care appointments</p> <p>Control (n=80): usual care</p>
Outcomes	<p>For BINGO, the prespecified primary outcome measure was 3-month breastfeeding intensity</p> <p>Quote: "We categorized breastfeeding intensity as &lt; 20% (low), 20% to 80% (medium) , and greater than 80% (high) of all feeds from breast milk consistent with previous studies and Infant Feeding Practices Survey II analyses</p> <p>Other analysis was planned. Power calculations were affected by the finding - "we found that breastfeeding intensity was not normally distributed, and most women stopped breastfeeding altogether during follow-up".</p> <p>Other outcomes:</p> <p>Quote: "Study staff assessed infant feeding at 1, 3, and 6 months postpartum during phone interviews using items adapted from the Infant Feeding Practices Survey II"; exclusive breastfeeding, breastfeeding intensity ("defined as the percentage of all feedings in the past 7 days that were breast milk"), breastfeeding initiation, and total duration data collected</p>
Notes	The paper reported 2 trials that appear in this review (PAIRINGS and BINGO)

*Risk of bias*

*Risk of bias*

**Bonuck 2014a** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Women were randomized using sequentially numbered opaque sealed envelopes, generated by the study's biostatistician" Quote: "Randomization incorporated an undisclosed blocking factor and nativity status (US-born vs foreign-born)."
Allocation concealment (selection bias)	Low risk	Sequentially numbered opaque sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "It was infeasible to blind participants and clinical staff to treatment group."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "we sought to minimize bias by restricting access to allocation assignment, stripping group assignment from study databases to which research staff had access, and omitting group identifiers from participant interview form."
Incomplete outcome data (attrition bias) All outcomes	Low risk	The BINGO analytic sample included 94% of those randomized (628 of 666 participants)
Selective reporting (reporting bias)	Low risk	We checked the Clinicaltrials.gov record and the key breastfeeding outcome data seemed to be reported in this paper
Other bias	Low risk	

**Bonuck 2014b**

Methods	Parallel 2-arm, participant-level RCT, (n=275)
Participants	Women who attended an urban medical centre providing prenatal care for a economically diverse population in the Bronx, New York City Background rates of breastfeeding initiation:79% Inclusion criteria: English- or Spanish-speaking women aged $\geq 18$ years, in the first or second trimester of a singleton pregnancy Exclusion criteria: risk factors for premature birth maternal or infant conditions that would preclude or complicate breastfeeding (e.g. mother HIV-positive, infant congenital anomaly)

Interventions	<p>Intervention (n=136): lactation counselling and electronic pumps. One LC was allocated to this intervention. The LC protocol included 2 prenatal sessions, a hospital visit, and regular phone calls postpartum for 3 months or until breastfeeding ceased. The prenatal sessions occurred in the examination room, during the 30-plus min of 'downtime' while waiting for the prenatal care provider. Attempts were made to complete interrupted sessions after the examination. The first session focused on rapport building and education, and the second was on the practical aspects of breastfeeding. The study provided nursing bras and breast pumps to LC group participants as needed. LCs met mothers and their infants at the 1-week routine paediatric visit, modelling practice on a recent review. Postpartum home visits were optional, based upon participant and LC preference and comfort. electronic prompts for healthcare providers to ask three brief open-ended questions which portrayed breastfeeding as the norm. This was done during pre-natal care appointments</p> <p>Control (n=139): usual practice.</p>
Outcomes	<p>For PAIRINGS, the prespecified primary outcome was exclusive breastfeeding at 3 months</p> <p>Other outcomes:</p> <p>Quote: "Study staff assessed infant feeding at 1, 3, and 6 months postpartum during phone interviews using items adapted from the Infant Feeding Practices Survey II"; exclusive breastfeeding, breastfeeding intensity ("defined as the percentage of all feedings in the past 7 days that were breast milk"), breastfeeding initiation, and total duration data collected</p>
Notes	The paper reported 2 trials that appear in this review (PAIRINGS and BINGO)

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Participants were randomized using sequentially numbered opaque sealed envelopes, generated by the study's biostatistician
Allocation concealment (selection bias)	Low risk	Sequentially numbered opaque sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "It was infeasible to blind participants and clinical staff to treatment group."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "we sought to minimize bias by restricting access to allocation assignment, stripping group assignment from study databases to which research staff had access, and omitting group identifiers from participant interview form."

**Bonuck 2014b** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Analytic sample included 95% of those randomized (262 of 275 participants)
Selective reporting (reporting bias)	Unclear risk	Breastfeeding outcomes reported in Clinicaltrials.gov were reported in this paper. Other outcomes on weight and length were not reported in this paper, but they are not included as outcomes in this systematic review
Other bias	Low risk	

**Bortolini 2012**

Methods	2-arm RCT, 1 site setting, n = 397 (unclear if this was the total number in the study overall)
Participants	Children recruited at birth at the Hospital Centenário (the only hospital in the city of São Leopoldo, state of Rio Grande do Sul, Brazil), only children in Brazilian National Health Service (Sistema Único de Saúde, SUS) wards were enrolled, between October 2001-June 2002 Background rates of breastfeeding initiation: 95.8% Inclusion criteria: newborn infants with birthweight $\geq$ 2500 g and gestational age $\geq$ 37 weeks Exclusion criteria: none noted
Interventions	Intervention: mothers provided with dietary counselling based on the guidance provided in the Ten Steps for Healthy Feeding of Children Younger Than Two Years Counseling took place through 10 home visits: one in the first 10 days after birth, monthly up to 6 months and then at 8, 10 and 12 months. The dietary recommendations that the mothers were given prioritised exclusive breastfeeding up to 6 months and introduction of complementary foods at the age of 6 months. Mothers were advised not to give their children bottles or pacifiers. 12 undergraduate students of nutrition conducted the home visits in pairs. The entire team was trained in the dietary guidelines and in techniques for counselling mothers about the Ten Steps for Healthy Feeding of Children Younger Than Two Years. Each dietary counselling session lasted 30 min-40 min Control: women were visited at 6 and 12 months for collection of anthropometric, dietary and sociodemographic data and to collect data on the infants' health status Interviewers, who were not involved in the intervention process and who were blinded to the group to which the children belonged, conducted home visits at 6 and 12 months in order to collect data on the study variables. Interviewers informed mothers about the anthropometric results and instructed them to attend the nearest health service if nutritional problems were detected
Outcomes	Following outcomes at 6 months of age for both groups: proportion of children exclusively breastfed for < 1 month; proportion of children exclusively breastfed for 4 months or more; proportion of children exclusively breastfed at 6 months; proportion of children receiving breastmilk at 6-12 months and age at introduction of cows milk

**Bortolini 2012** (Continued)

Notes		
<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Reported in another paper ( <a href="#">Vitolo 2005</a> ) which is in Spanish and needs to be translated.
Allocation concealment (selection bias)	Unclear risk	Reported in another paper <a href="#">Vitolo 2005</a> which is in Spanish and needs to be translated.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It is not stated whether the women and undergraduate students providing the intervention were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers who were not involved in the intervention process and were blind to the group to which the children belonged conducted home visits at 6 and 12 months in order to collect data on the study variables
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unable to assess with the information given.
Selective reporting (reporting bias)	Unclear risk	Outcomes not prespecified in clinicaltrials.gov record.
Other bias	Unclear risk	None noted.

**Brent 1995**

Methods	2-arm RCT with individual randomisation, single-site, duration not stated, n = 115
Participants	<p>Urban USA - ambulatory care centre and in-patient maternity unit</p> <p>Background rates of breastfeeding initiation: low</p> <p>Baseline prevalence of breastfeeding at birth in national WIC sample = 33% (1991)</p> <p>Inclusion criteria: English-speaking; nulliparous</p> <p>Exclusion criteria: separated from child at birth; preterm delivery; child in NICU &gt; 72 h</p> <p>Ethnic composition: described as 71% white</p> <p>90% of participants were eligible for WIC programmes for those on low income</p> <p>Study population not limited to those intending to breastfeed</p>

Interventions	Intervention: package of: 2-4 prenatal sessions with LC (10 min-15 min each); telephone call 48 h after discharge; visit to lactation clinic at 1 week postpartum (staffed by paediatrician or LC); contact with LC at each health supervision visit until weaning or 1 year; professional education of nursing and medical staff Control: women were offered optional prenatal breastfeeding classes, postpartum breastfeeding instruction by nurses and physicians and outpatient follow-up by nurses and physicians in the paediatric ambulatory department
Outcomes	Rates of breastfeeding at 2 months and median duration of breastfeeding
Notes	

**Risk of bias****Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sample stratified by age with block randomisation in blocks of 8
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and LC were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome data were collected by questionnaire administered by the LC who was not blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Follow-up 94%. It appeared that 115 women were randomized. It was stated that 7 in the intervention group were excluded as they did not receive the intervention. 8 women in the control group were subsequently excluded from the analysis for at least some outcomes as the treatment they received deviated from protocol
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Potential confounders: women were excluded from intervention group following randomisation if they had received fewer than 2 prenatal lactation consultations; ITT analysis not performed (8 women in control group who met LC excluded); intervention included input by staff caring

Brent 1995 (Continued)

	for both intervention and control groups
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Bunik 2010

Methods	2-arm RCT, with individual randomisation, with add-on qualitative study, n = 339
Participants	<p>Denver, USA; a clinic providing care for a predominantly Hispanic, medically underserved population</p> <p>Background rates of breastfeeding initiation: low</p> <p>Inclusion criteria: women <math>\geq</math> 18 years, primiparous with healthy, term, singleton baby who were willing to consider breastfeeding</p> <p>Exclusion criteria: primary language not English or Spanish, medical complication that interfered with breastfeeding, hospital stay &gt; 72 h following vaginal births or &gt; 96 h following caesarean section, baby with medical problems, admitted to NICU or had a hospital stay &gt; 72 h</p> <p>Participant characteristics:</p> <p>Mean age 22 years; 88% Hispanic or Latino; 77% vaginal delivery</p> <p>Planned to breastfeed only: intervention group 50%, control group 55% (other women planned to combine breastfeeding with formula)</p> <p>&gt; 60% were participating in WIC programmes at 1 month and 74% of these women were provided with formula at WIC clinics</p>
Interventions	<p>Intervention: daily telephone support, from the day following hospital discharge until 2 weeks postpartum, from trained nurses following a specific protocol covering advantages and disadvantages of breastfeeding, cultural issues, technique, problems and with referral for any lactation or medical problems</p> <p>Control: usual hospital care (pamphlets on breastfeeding, a breast pump, lanolin cream and a water bottle); usual discharge care (commercial discharge packs) and scheduled healthcare visits at 3-5 days and at 2 weeks at the local community health centre</p>
Outcomes	<p>Any breastfeeding or predominantly breastfeeding</p> <p>Maternal satisfaction</p> <p>Healthcare utilisation</p> <p>Reasons for stopping breastfeeding</p>
Notes	

<i>Risk of bias</i>			<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	Computer-generated block random allocation	
Allocation concealment (selection bias)	Low risk	Sequentially numbered opaque sealed envelopes	

**Bunik 2010** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding for participants or caregivers.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not described for outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	341 women were randomized. At 1 month there was approximately 8% loss to follow-up. By 6 months 27% loss. 73% were described as included in the analyses; women in the intervention group that did not receive the intervention as planned were not included
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Groups appeared similar at baseline.

**Caldeira 2008**

Methods	Study methods were not clear. This appeared to be a cluster-randomised trial in 35 clinics. The intervention was carried out with healthcare workers. Results were for women attending intervention and control clinics before and after the intervention period
Participants	Setting: family healthcare teams from Montes Claros city in South East Brazil Baseline prevalence of breastfeeding initiation in country/setting: not clear 1423 women recruited (unclear). Follow-up for 12 months Inclusion criteria: mothers with children between 0 and 2 years old registered with the family health teams Participant characteristics: Approximately 20% under 20 years, 38% primiparous, 27% vaginal deliveries, 90% with > 4 years' education
Interventions	Intervention: 20 healthcare teams received staff training to promote breastfeeding, based on the Baby Friendly Hospital Initiative. Duration of the intervention was unclear; there was an initial interview before the study and a second interview 12 months after the start of training. Control: healthcare teams (n = 15 - unclear) in control clinics did not receive the training
Outcomes	Number of exclusive breastfeeding days; survival curves
Notes	We have not included data from this study. Data were not reported in a way in which we could incorporate results into the review. Authors reported the number of days, not the number of participants, for exclusive breastfeeding. It is reported that the median duration of exclusive breastfeeding was 106 days before and 107 days after the intervention

**Caldeira 2008** (Continued)

period for the control group. For the intervention group the median duration of exclusive breastfeeding was reported to be 104 days before and 125 days after the intervention period; the difference was reported to be statistically significant

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Method not described; it was reported that half of the women were assigned to the Intervention group and the other half to the control group
Allocation concealment (selection bias)	Unclear risk	Not described; 20 intervention clinics and 15 control (not clear)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not described in translation form.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described in translation form.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear. Authors reported that dropouts were negligible because all children registered were contacted with the help of community health agent
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Data extraction from translation (original paper in Portuguese). Cluster trial with no apparent adjustment for design effect

**Cameron 2013**

Methods	4-arm RCT, 1 study site, n = 802
Participants	<p>Maternity hospital in Dunedin, New Zealand</p> <p>Background rates of breastfeeding initiation: not specified.</p> <p>Inclusion criteria: all mothers who had booked into the single maternity hospital (&gt; 97% of all births) serving the city of Dunedin, New Zealand, between May 2009-November 2010, as well as mothers who planned to give birth at home and were invited to participate by their midwife. Mothers were invited to participate at 28-30 weeks gestation and an 'opt out' recruitment strategy (eligible participants were contacted and excluded only when they said they were unwilling to participate) was used</p>

	<p>Exclusion criteria before birth: home address outside the greater Dunedin area, planning to move away from Dunedin in the next 2 years, booked into the maternity centre after 34-week gestation, or unable to communicate in English or Te Reo Maori [language of the indigenous (Maori) ethnic group of New Zealand]</p> <p>Exclusion criteria after birth: identification of a congenital abnormality that was likely to affect feeding or growth, or the infant being born before 36.5 weeks gestation. When a mother delivered twins, the oldest child was recruited into the study. There were no triplets born during the study recruitment period</p>
Interventions	<p>Interventions: various types of support:</p> <p>1) infant sleep education only intervention (sleep);</p> <p>2) Food, physical activity and breastfeeding (FAB) intervention: LC providing food, activity and breastfeeding help intervention;</p> <p>3) combination of both 1 and 2 (Combo), participants received both the sleep and FAB interventions</p> <p>Total number randomized: n = 802 (sleep 192, FAB 205, Combo 196)</p> <p>Control: usual care n = 209</p>
Outcomes	<p>Outcomes: delayed introduction of complementary foods at 5 months and preferably until 6 months</p> <p>Complementary foods were defined as foods other than breast milk or infant formula (p 1483)</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Used a computerised random-number generator, which assigned blocks of participants to the 4 arms
Allocation concealment (selection bias)	Low risk	Allocation was concealed and performed after application of the prebirth exclusion criteria, stratified by socioeconomic status with use of the New Zealand Deprivation Index 2006
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Group allocation was revealed to the participant after consent to participate had been obtained
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Most of the breastfeeding and other data were collected by a researcher who was not aware of the participants' group, and no data were collected by the LC who delivered the intervention. The statistician remained blinded to group allocation codes until primary analyses were conducted

**Cameron 2013** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	< 25% attrition
Selective reporting (reporting bias)	Unclear risk	This study is a sub-sample of results from a larger study and the outcomes reported in the trial registration document are not reported in this study. However, the full study results have not yet been published to be able to judge this outcome
Other bias	Low risk	Appears to be free of demographic variables, looks comparable across the groups

**Chapman 2004**

Methods	2-arm RCT, with individual randomisation; recruitment July 2000-August 2002 at an urban USA hospital with BFI accreditation, n = 219	
Participants	<p>Urban USA hospital prenatal clinic serving a low-income, predominantly Latina population</p> <p>Background rates of breastfeeding initiation: low</p> <p>Antenatal inclusion criteria: low-income women ≥ 18 years old, at ≤ 26 weeks' gestation, considering breastfeeding, not yet enrolled in peer counselling programme, resident in hospital area, available for telephone follow-up</p> <p>Postnatal inclusion criteria: healthy, full term singleton infants, no congenital abnormalities, no maternal history of HIV and no admission to NICU</p> <p>Exclusion criteria: none specified</p> <p>After birth, n = 165 women remained in the study, 90 in the intervention group and 75 controls</p> <p>Participant characteristics: ethnic composition 80% Hispanic (61% Puerto Rican origin), 9% African American, 3% white, 8% other</p>	
Interventions	<p>Intervention: 1 prenatal home visit, daily visits during postpartum hospitalisation, home visit within 24 h and at least 2 more home visits as requested, and telephone/pager contact. Intervention from peer counsellors with 30 h classroom training that covered La Leche League International Peer Counseling Program and Hispanic Health Council's curricula. Peer counsellors had to score 85% in a written exam and work for 3-6 months with experienced peer counsellors to demonstrate competence before working independently with clients. Peer counsellors had 1 h per month continuing education and were paid for their work</p> <p>Control: routine breastfeeding education offered by the study hospital, and the same breastfeeding services as women paying privately. A small amount of exposure to peer counsellors among the control group was reported</p>	
Outcomes	Breastfeeding rates at birth and 1, 3 and 6 months postpartum Subgroups most responsive to breastfeeding peer counselling	
Notes		

Chapman 2004 (Continued)

<i>Risk of bias</i>			<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>	
Random sequence generation (selection bias)	Low risk	By computer programme	
Allocation concealment (selection bias)	Unclear risk	Not described.	
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No detail provided about whether participants and personnel were blinded	
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not stated whether outcome assessors were blinded, but to minimise bias, data related to peer counsellor contact were collected at the end of each interview	
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Loss to follow-up appeared reasonably balanced although there was more loss from the control group. Reasons for loss to follow-up stated. 219 were randomized, 72% followed up at 1 month, 70% at 3 months and 66% at 6 months	
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol	
Other bias	Unclear risk	Groups appeared similar at baseline. It was reported that many women in the intervention group received less than half of the planned visits	

Chapman 2008

Methods	2-arm RCT , 1 site, n = 206
Participants	<p>Hartford Hospital prenatal clinic. Hospital with BFI status, the prenatal clinic serves a low-income, predominantly Latina population. Study population (82% Latina, with Puerto Ricans comprising 50% of Latinas)</p> <p>Background rates of breastfeeding initiation: not specified</p> <p>Inclusion criteria at prenatal recruitment: be considering breastfeeding and have a prepregnancy BMI <math>\geq 27</math>, <math>\geq 18</math> years of age, <math>\leq 36</math> weeks' gestation, singleton pregnancy, absence of medical conditions that would interfere with breastfeeding, planning to remain in the area for 6 months postpartum, income <math>&lt; 185\%</math> of the federal poverty level, and have telephone access</p> <p>Inclusion criteria at delivery: <math>\geq 36</math> weeks' gestation, birthweight <math>\geq 2.5</math> kg and <math>\leq 3.9</math> kg, 1 min and 5 min Apgar scores of <math>\geq 6</math>, and no NICU admission</p>

	Exclusion criteria: none stated
Interventions	<p>Intervention: specialised breastfeeding peer counsellor (SBFPC) made 3 prenatal visits, plus daily in-hospital support, and up to 11 postpartum home visits promoting exclusive breastfeeding and addressing potential obesity-related breastfeeding barriers. Prenatal visits involved assessment of previous breastfeeding experiences/knowledge, personalised education about breastfeeding logistics, the risks of formula feeding, and anticipatory guidance. During hospitalisation, women received 1 SBFPC visit per day, which were similar in content to those provided by 'Breastfeeding: Heritage and Pride' (BHP) peer counsellors. The SBFPC ensured that intervention participants received a manual breast pump before discharge</p> <p>Control: standard breastfeeding support and staff peer counsellors (see below), which involved routine access to breastfeeding support from hospital personnel, including staff peer counsellors, plus prenatal breastfeeding education that included brief breastfeeding discussions during routine clinic appointments and receipt of written educational materials. Staff nurses provided routine perinatal breastfeeding assistance, with LCs available as needed. After discharge, participants could call the hospital telephone hotline with breastfeeding questions</p> <p>Standard care also included optional breastfeeding support from Breastfeeding: Heritage and Pride (BHP) peer counsellors (PC), who provided the following: up to 3 prenatal visits (covering breastfeeding benefits, breastfeeding myths, positioning, and common breastfeeding problems and to educate with up to 7 personalised home visits during the first year postpartum; and telephone support. If available, electric breast pumps were loaned as needed. To receive prenatal PC visits, controls could self-refer or be referred to the BHP program</p>
Outcomes	<p>Primary: breastfeeding initiation and the rates of exclusive and any breastfeeding at 2 weeks, 1 month, 3 months, and 6 months postpartum</p> <p>Secondary: infant morbidity (diarrhoea, otitis media, emergency department visits, hospitalisation), maternal amenorrhoea, and breastfeeding intensity</p>
Notes	High attrition due to randomisation prior to birth resulting in high exclusion (Intervention n = 76, 26.2%; Control n = 78, 24.3%) with further study attrition at 6 months (intervention n = 55; control n = 53 (> 25% attrition for various stated reasons))

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	All participants provided written informed consent. Each week, the study co-ordinator used SPSS software (SPSS Inc, Chicago, IL) to randomly assign 50% of newly recruited participants to the intervention group, thus preserving allocation concealment
Allocation concealment (selection bias)	Unclear risk	Each week, the study co-ordinator used SPSS software (SPSS Inc, Chicago, IL) to randomly assign 50% of newly recruited participants to the intervention group, thus preserving allocation concealment (not sure how they did

**Chapman 2008** (Continued)

		this using SPSS)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants.
Blinding of outcome assessment (detection bias) All outcomes	High risk	The interviewer was not informed of participants' group assignment, but was not completely blinded because she collected participant contact data. To minimise potential bias, participant contact questions were asked at the end of each interview
Incomplete outcome data (attrition bias) All outcomes	High risk	All attrition > 25%
Selective reporting (reporting bias)	Unclear risk	The paper contains additional outcomes that were not included in the clinicaltrials.gov record
Other bias	High risk	The intervention group was significantly younger and differed in delivery mode, compared with the control group

**Chen 1993**

Methods	3-arm quasi-RCT, with sequential allocation, n = 180?
Participants	180 women (not clear) attending a hospital in Southern Taiwan Inclusion criteria: breastfeeding at hospital discharge, term, healthy infant, able to read Chinese (hospital discharge at approximately 5 days)
Interventions	Intervention 1 - telephone support: weekly phone calls for 2 weeks after hospital discharge then at 4 and 8 weeks postpartum by maternity nurse. The calls were to increase women's self confidence Intervention 2 - home visits intervention: same schedule as phone support group with visits at home by the maternity nurse Control: usual care
Outcomes	Breastfeeding duration and analysis of factors affecting duration of breastfeeding
Notes	We have not included data from this study in the review as data were not reported in a way that allowed us to enter them into <a href="#">RevMan 2014</a> for meta-analysis.

***Risk of bias***

***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Sequentially to 1 of 3 groups

**Chen 1993** (Continued)

Allocation concealment (selection bias)	High risk	In sequence (could be anticipated and changed by the person carrying out randomisation)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient detail provided to judge this.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient detail provided to judge this.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear: 180 women were followed up. It was not clear whether this number was randomized
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Baseline characteristics of 3 groups were similar.

**Coutinho 2005**

Methods	2-arm RCT, with individual randomisation N=350
Participants	The study was carried out in 2 hospitals serving urban areas and neighbouring small towns in the interior of the State of Pernambuco, north-eastern Brazil Background rates of breastfeeding initiation: high Inclusion criteria: singleton infants Exclusion criteria: infants with congenital anomalies or serious illness necessitating intensive care and those whose mothers had serious disease or mental illness or were planning to leave the area within 6 months Approximately 60% had an income lower than the minimum wage; 33% did not have access to a flush toilet, approximately 35% of the mothers were < 20 years, 39% primiparous, approximately 28% had a caesarean delivery
Interventions	90% of maternity staff in both hospitals received the 18-h UNICEF/WHO Baby Friendly Hospital Initiative training course. All participants in the intervention and control groups received their hospital postnatal care from these Baby-Friendly trained staff Intervention: women (N=175) received 10 postnatal home visits (mean duration 30 min); 4 during the first month, 2 during the second month and 1 per month during the third to sixth months. Each mother was given an illustrated booklet. At each visit the home visitors observed the positioning of the infant at the breast, flow of milk and the baby's satisfaction; encouraged exclusive breastfeeding for 6 months and continued breastfeeding for at least 2 years, and used the booklet as a basis for discussions of key topics relevant to the infant's age. If there were any difficulties home visitors could not resolve he/she referred the mother for more specialist help at the hospital. If other family

	members were present, their attitude towards exclusive breastfeeding was assessed and their support was sought, including help with household chores Control: (N=175) usual care with no postnatal home visits
Outcomes	Primary outcome: exclusive breastfeeding. Data collected prospectively at 1, 10, 30, 60, 90, 120,150 and 180 days after birth. Any breastfeeding at same time points. The type of other fluids introduced were also recorded at each time point
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Randomised in blocks of 10 per town by use of a random numbers table. The random numbers were generated by the project manager, and enrolment and group assignment were made by 2 maternity-based research assistants
Allocation concealment (selection bias)	Unclear risk	Concealment was achieved by drawing numbers from envelopes at the time of assignment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "Mothers in the trial were not close neighbours, so discussion with other mothers is unlikely, but we did not formally assess whether masking was maintained". It was not stated whether the personnel delivering the intervention were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data were collected in the trial by 4 researchers who were not aware of group allocation and were unconnected with the delivery of the interventions, however, authors did not formally assess whether masking was maintained
Incomplete outcome data (attrition bias) All outcomes	Low risk	350 women were randomized, 175 in each group. 20 women (6%) were lost to follow-up
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	The random numbers were generated by the project manager and so this may lead to bias

Coutinho 2005 (Continued)

	Results were presented in graphs and aggregated results were not simple to interpret
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de Oliveira 2006

Methods	2-arm RCT, with individual randomisation, methods unclear N=211
Participants	From maternity ward of the Hospital de Clinicas de Porto Alegre in Brazil, a university general hospital with Baby Friendly accreditation Background rates of breastfeeding initiation high, however median duration of exclusive breastfeeding 29 days Inclusion criteria: mothers living in the city of Porto Alegre, healthy non twin newborns with a birthweight $\geq$ 2500 g Exclusion criteria: mother-infant pairs that were unable to stay together due to a health concern for either the mother or infant Participant characteristics: $\geq$ 20 years old 76%, vaginal delivery 72%, white mothers 70%, > 8 years' education 64%, living with partner 83%
Interventions	Intervention (n=74) in hospital, 2 nurses reinforced the orientation about breastfeeding technique routinely given to mothers, following the WHO breastfeeding counselling principles, in a 30-min session with no more than 2 mother-infant pairs. Topics included comfortable and proper mother and infant positioning, correct attachment of the child to the breast and manual milk expression. Pictures, dolls and a model breast were used for demonstrating proper breastfeeding technique. Women also received 2 home visits from the same nurse, when the child reached 7 and 30 days of age. Infant feeding patterns, positioning, attachment, milk expression and breastfeeding problems were discussed, and breast examination performed Control (n=137): standard hospital care met Baby-Friendly standards. The control group appear not to have received home visits
Outcomes	Primary outcome: number of mothers who breastfed and exclusively breastfed on maternity ward and at 30 days Secondary outcome: frequency of breastfeeding-related problems
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Following interviews and feeding assessments, mother-infant pairs were randomly assigned by pulling coloured balls from a bag indicating either the control or experimental group. After the number of mothers for the experimental group were selected, all women eligible for the study were added to the control group until the sample was

de Oliveira 2006 (Continued)

		complete
Allocation concealment (selection bias)	High risk	By drawing coloured balls from bags - this could be changed and it was not clear that all women in the control group were randomly allocated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No detail provided regarding whether participants or personnel were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The researchers responsible for the breastfeeding evaluations did not participate in the intervention and were blinded to the group to which the mother infant pairs had been assigned."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	233 women were eligible, 211 followed up. (It was not clear how many were randomized.)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Groups were described as similar at baseline, although it appeared that more women in the control group that had had previous breastfeeding experience were more likely to feed for 6 months (65%) compared to women in the intervention group (47.5%) Unequal numbers in the intervention and control group. The groups were not balanced (74 in the intervention group and 137 controls). It was not clear that all the women in the control group were randomly allocated

Dennis 2002

Methods	2-arm RCT, with individual randomisation, single-site study, recruiting over 10 months, n = 258
Participants	Women at home in Toronto, Canada Background rates of breastfeeding initiation: intermediate Inclusion criteria: English-speaking, primiparous, ≥ 16 years, single full-term baby, intending to breastfeed, Exclusion criteria: none specified. Breastfeeding initiation 79%

Interventions	Intervention: telephone support by briefly-trained volunteers (2.5 h session) who had personal breastfeeding experience for at least 6 months. First contact within 48 h of hospital discharge and then as required. Mean number of contacts in those completing log-books = 5.4. Mean duration of telephone contact = 16.2 min. 97% of contacts by telephone, 3% at home Control: not described
Outcomes	Breastfeeding (any or exclusive) at 1, 2 and 3 months
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Randomly generated numbers were provided by a statistician who was not involved in the recruitment process
Allocation concealment (selection bias)	Low risk	Consecutively numbered, sealed opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not explicitly stated if peer counsellors were blinded but as they were recruited for the study, it is unlikely. No detail provided on blinding participants
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "A research assistant blinded to group allocation telephoned the participants to collect data regarding current infant feeding status, breast problems encountered and health services used."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Very little loss to follow-up. 258 women randomized and 2 women lost to follow-up
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Low risk	No apparent differences between groups at baseline.

Methods	2-arm RCT, with individual randomisation, n = 78
Participants	<p>Setting: 2 hospitals in Rochester, NY, USA</p> <p>Background rates of breastfeeding initiation: low</p> <p>Inclusion criteria: maternal age &lt; 20 years, uncomplicated postpartum, breastfeeding singleton infant born at gestational age &gt; 36 weeks and weighing &gt; 2000 g, mothers and infants discharged home together</p> <p>Exclusion criteria: maternal contraindications to breastfeeding (HIV, active substance abuse), postpartum transfusion or intensive care; infants in intensive or special care unit &gt; 6 h, infants with anomalies that interfered with breastfeeding (e.g. cleft lip or palate)</p> <p>Participant characteristics: mean age 18.3 years, approximately half were African Americans, approximately one-third had private or health maintenance organisation insurance, the rest were on Medicaid or with Medicaid health maintenance organisations, &gt; 80% were first time mothers and gave birth vaginally</p>
Interventions	<p>Intervention: telephone support from trained peer supporters (teen mothers who had breastfed for &gt; 4 weeks). Peer supporters telephoned the new teen mothers at 2, 4, 7 days and 2, 3, 4 and 5 weeks postdischarge. Peers introduced themselves and talked about the breastfeeding experience. No specific discussion topics were assigned. Peers offered their telephone numbers so that new mothers could call for support. They were advised to refer anyone with a problem to telephone resources for breastfeeding information or to their physician. Peers and women received gift voucher incentives to complete assessments and training</p> <p>Control: usual care included access to paediatric care providers and hospital LCs. The control group did not receive telephone peer support</p>
Outcomes	<p>Primary outcome: 'any breastfeeding' duration, as measured by the age in days at complete breastfeeding cessation</p> <p>Secondary outcome: exclusive breastfeeding duration, as measured by the time to the first introduction of any other supplement (water, juice, vitamins or formula)</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers
Allocation concealment (selection bias)	Low risk	Quote: "The assignment was recorded in a sealed and numbered envelope. Envelopes were sequentially opened."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "In order to blind subjects to the study hypothesis, recruiters explained that this study was about: how young mothers who breastfeed in the hospitals feed their babies at home; how young mothers make

Di Meglio 2010 (Continued)

		feeding decisions and who helps them make those decisions.” Not clear if this attempt was successful
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “a single research assistant conducted all the telephone interviews, using standardised, closed ended questionnaires. The interviewer had no knowledge of the study hypothesis or design.”
Incomplete outcome data (attrition bias) All outcomes	High risk	78 randomized (38 intervention, 40 control) In intervention group: 6 dropouts before first interview; 3 dropouts before 8-week interview; 7 dropouts between 8 and 37 weeks In control group: 5 dropouts before first interview; 2 dropouts before 8-week interview; 9 dropouts between 8 and 21 weeks Overall, 11 women dropped out immediately after recruitment (14%). By 8 weeks 21% lost to follow-up. 46/78 (61%) were successfully followed up to complete breastfeeding cessation (22 intervention and 24 control)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Of the 5 adolescents who completed peer support training, there was only 1 that remained involved for the entire duration of the study There was very poor compliance with possibly only half of the intervention group receiving the planned intervention. The analysis is presented in diagrams that are not simple to interpret Study results published in 2010, data collected 1996-1997

Di Napoli 2004

Methods	2-arm RCT, single-site study, mothers recruited March 2000-December 2001, n = 605
Participants	Urban Italy Background rates of breastfeeding initiation: intermediate Inclusion criteria: mothers in public maternity ward in Rome, intending to breastfeed Exclusion criteria: mothers who did not speak Italian, had no phone, breastfeeding

	medically contraindicated, baby in SCBU Ethnic composition not defined. Baseline national breastfeeding initiation rate 70%
Interventions	Intervention (home visit and telephone contact): home visit, from 1 of the 6 midwives from the maternity ward of the study hospital, took place within 7 days of hospital discharge. Telephone breastfeeding counselling session provided by the same midwife. These midwives had attended the UNICEF 18-h intensive training course on breastfeeding techniques and management Control: standard care (not described)
Outcomes	Any breastfeeding up to 60 days
Notes	Extra information about reported numbers requested and received from author

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Sample was stratified "for age and parity, and finally randomly assigned to either the intervention or control group"
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details were provided about blinding of participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	High risk	A trained interviewer conducted the interviews, but was not blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	605 women were randomized. Full data were available for 278 women (46%) and partial data available for a further 264 (44%). Follow-up rates for breastfeeding outcomes collected up to 180 days, but after 60 days follow-up rates were < 75% so only outcomes up to 60 days are included in this review. Reasons for drop-out were reported by group
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	Baseline characteristics similar and no apparent differences between those who refused intervention and those who received it, see Table 1

Edwards 2013

Methods	2-arm RCT, single site, n = 248
Participants	<p>A major USA urban university hospital community doula intervention</p> <p>Participant: low-income, African-American mothers &lt; 22 years old</p> <p>Breastfeeding rates: young African-American mothers continue to breastfeed at low rates, and commonly introduce complementary foods earlier than recommended. In the 2006 National Health and Nutrition Study, for example, only 30% of black adolescent mothers had ever attempted to breastfeed their infants</p> <p>Background rates of breastfeeding initiation:79%</p> <p>Inclusion criteria: women who were &lt; 34 weeks pregnant, &lt; 21 years of age, and planning to deliver at the affiliated hospital were eligible to participate in the study</p> <p>Exclusion criteria: mothers who were aware at the time of recruitment that they would require a surgical delivery, who planned to move from the area, or who planned to give up custody of the infant</p>
Interventions	<p>Intervention (n=124):</p> <p>Women received additional care from doulas who were women from the same communities as the women attending the clinic. During pregnancy women received weekly home visits (average = 10) where the doula focused on building a relationship with the mother and discussed pregnancy health, childbirth preparation, and bonding with the unborn infant. Doulas were present during labour to provide support and help initiate breastfeeding after birth. Doulas continued to provide face-to-face breastfeeding support in the post-natal period (average 12 home visits). Doulas undertook a 20-week doula training course provided by the Chicago Health Connection (Health Connect One) and a 10-week breastfeeding peer counsellor training programme from the same organisation</p> <p>Control (n=124): mothers received usual prenatal care; no doula input</p>
Outcomes	<p>Primary outcomes: data on breastfeeding attempts were collected by mother report at the hospital the second morning after the birth and from review of the nursing notes in the mothers medical chart after the mothers discharge. mothers were considered to have attempted breastfeeding if breastfeeding was indicated by either self report or nursing notes. At 4 months postpartum, the mothers participated in an interview on feeding practices. Mothers reported on whether they were currently breastfeeding and, if not, when they had stopped breastfeeding</p> <p>Secondary: mothers were also asked about whether they had started feeding their infants cereal, either in the bottle or by spoon, or other solid foods, and reported the infant age</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization took place in blocks of 4, 6, or 8, with equal numbers assigned to the intervention and control groups."

Edwards 2013 (Continued)

Allocation concealment (selection bias)	Low risk	Quote: "A biostatistician prepared a set of opaque envelopes, each labelled with a subject ID number and containing a group assignment. Envelopes were opened by the interviewer in the presence of the mother at the completion of the baseline interview."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data were collected by research staff through interviews with mothers and by chart review. Not stated whether research staff were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	A total of 221 mothers, 113 in the control group and 108 in the doula participated in the 4-month interview. Attrition < 25% for both groups
Selective reporting (reporting bias)	High risk	Breastfeeding at 12 months was reported as a secondary outcome in the Clinicaltrials.gov record, but this was not reported in the paper
Other bias	Low risk	Mothers in the 2 groups were compared on a variety of demographic, psychological, and health variables measured before randomisation and no significant differences were found

Efrat 2015

Methods	Parallel 2-arm RCT, single-site study, n = 298
Participants	<p>Community health centres in Los Angeles County, USA</p> <p>Participants: low-income, Hispanic women</p> <p>Breastfeeding rates: local breastfeeding rates not reported but authors state that within the Hispanic population the exclusive breastfeeding rate in hospital is 27.9% and at 1 week postpartum 33% of breastfeeding Hispanic women also give their babies formula</p> <p>Inclusion criteria: women 26-34 weeks pregnant, Medicaid recipient, self-identified Hispanic, available via telephone, not assigned to a WIC peer counsellor, gave birth to a healthy full-term singleton, absence of congenital abnormality, the infant was not admitted to a NICU</p> <p>Exclusion criteria: participants whose babies had medical conditions that could significantly interfere with breastfeeding. The researchers also avoided recruiting participants from health clinics located near WIC sites that offered peer support</p>
Interventions	Intervention (n = 146): WIC Supplemental Nutrition Programmes. The standard WIC programmes provide monthly food vouchers, nutrition education and breastfeeding support to women, infants and children aged ≤ 5 years. Breastfeeding support includes breastfeeding classes, access to a free breastfeeding helpline, breast pumps and LC ser-

	<p>vice. Some programmes also offered breastfeeding and support and education using peer counsellors. The intervention group received additional support from LCs who were undergraduate students who had completed a semester-long lactation education course and 10 h of postcourse training. The lactation education course included content knowledge on the normal breastfeeding process and cultural sensitivity training. The intervention entailed 4 prenatal and 17 postpartum phone calls (first call initiated when mothers were in the third trimester of pregnancy and the last call when mother was 6 months postpartum. The intervention participants were also provided with the lactation educator's phone number so they could contact her more frequently if need be. On occasion, text messages were used to implement phone contacts with participants</p> <p>Control (n = 143): standard WIC programme</p>
Outcomes	<p>Primary and secondary outcomes not distinguished.</p> <p>Exclusive breastfeeding at 72 h</p> <p>Any breastfeeding at 72 h</p> <p>Exclusive breastfeeding at 1 month</p> <p>Any breastfeeding at 1 month</p> <p>Exclusive breastfeeding at 3 months</p> <p>Any breastfeeding at 3 months</p> <p>Exclusive breastfeeding at 6 months</p> <p>Any breastfeeding at 6 months</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No details provided to enable judgement of this.
Allocation concealment (selection bias)	Unclear risk	No details provided to enable judgement of this.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome data collected by the research assistants who also acted as lactation educators and were not blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Follow-up varied between 61% and 38%.
Selective reporting (reporting bias)	Unclear risk	Outcomes not specified in trial registration document.
Other bias	Unclear risk	None noted.

**Ekstrom 2006**

Methods	Longitudinal study, 2-arm cluster-randomised trial, 10 Swedish municipalities randomized n=540
Participants	Setting: Antenatal Centres and Child Health Centres in 10 municipalities in southwest Sweden Background rates of breastfeeding initiation: high Inclusion criteria: Swedish-speaking mothers who gave birth to singleton, healthy, term infants spontaneously, by vacuum extraction or by caesarean section Participant characteristics: mean age approximately 27 years, married 61%-69%, vaginal delivery 70%-75%, university educated 36%
Interventions	Intervention: the intervention included continuity of care at the antenatal and child centres, and a process-oriented training program of 7 sessions for health professionals. The staff training included reflection on personal experience of breastfeeding and breastfeeding counselling, management and promotion. Staff were encouraged to develop a common breastfeeding policy between the antenatal and child health centres. The family classes were also kept together before and after childbirth Control: offered standard family classes, usually discontinued at birth
Outcomes	Maternal perceptions of the relationship with the infant, maternal feelings for the infant and duration of exclusive/any breastfeeding
Notes	10 centres randomized. A total of 540 women took part in the study (intervention group 206 women; 2 control groups 162 + 172 = 334 women). Data collection took place at different times for the 2 control groups. We have included data from 378 women; the intervention group (206 women) and 1 control group (172 women), from whom data were collected at the same time as from the intervention group

**Risk of bias**

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The 10 largest municipalities were classified in pairs that were similar in size and had similar figures of breastfeeding duration. The municipalities were randomized pair-wise to either an intervention or control group
Allocation concealment (selection bias)	Unclear risk	Trial report did not report.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No detail regarding blinding of participants or personnel, but appears unlikely
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Maternity staff distributed the first questionnaire. Follow-up questionnaires were sent to women. It was not stated whether there were any blinding procedures

**Ekstrom 2006** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The sample included women cared for in intervention clinics and then 2 control groups. However, data collection in 1 of the control groups was carried out before the intervention period, so in the analyses we have included only the control group data that were collected simultaneously with the intervention group (total 540 women, 378 included in analysis) Response rates at 3 days 84% and 93% in the intervention and control groups, by 9 months postpartum 64% and 73% There was no adjustment for cluster design.
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	No baseline imbalance was apparent, although duration of exclusive breastfeeding was presented as a baseline characteristic

**Elliott-Rudder 2014**

Methods	2-arm cluster-RCT, n = 330 in 15 clusters
Participants	NSW, Australia, primary care setting of general practice in rural agricultural settings. Maternity hospitals were not Baby Friendly accredited, although at each hospital an International Board Certified LC and registered midwives encouraged mothers to breastfeed 35.3% of infants were currently fed solids at 4 months, while 52.9% had received solids, infant formula or other nonhuman milk, at least once, by 4 months Background rates of breastfeeding initiation:92% Inclusion criteria: all pregnant women who had registered to give birth at 1 of the 3 local hospitals (n = 3127) over 14 months, had reached 24-36 weeks of pregnancy, who planned to have their postnatal care at a participating general practice and who were still breastfeeding at 8 weeks were randomised Exclusion criteria: not reported
Interventions	Intervention (n = 154): a structured conversation to support continuation of breastfeeding following a Conversation Tool flowchart that used a motivational interviewing approach. The Conversation Tool was used with each breastfeeding mother who attended a general practice intervention site for her infant to be immunised at 2, 4 or 6 months. Mothers were informed of the recommendation for breastfeeding exclusively to 6 months and maintenance to 1-2 years and asked 'How would that work for you?' According to the mother's response, the practice nurse provided a targeted proactive conversational action Intervention practice nurses attended 2 x 5-h training workshops that were delivered by a team of a midwife/LC/trainer and a family doctor/breastfeeding counsellor and based

	<p>on WHO-based resource that presented breastfeeding maintenance as appropriate and physiological. In addition, training addressed motivational interviewing and reflective practice. Information about local government and community breastfeeding support services, and handout literature for mothers, were provided</p> <p>Control (n = 176): mothers received usual care from nurses who had not received WHO breastfeeding support training, and who commonly asked whether the mother had any problems</p>
Outcomes	<p>Outcomes not clearly stated</p> <p>Exclusive and full/predominant (substitution of breastmilk with water-based substances allowed) breastfeeding at 4 and 6 months</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Clusters were coded, computer randomized and assigned to the intervention or control group
Allocation concealment (selection bias)	Low risk	Clusters randomized at same time, so concealment was not an issue
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding was not possible for the practice nurses. Participants were unaware of the group allocation process, but not clear if this was effective
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research assistants, who were not otherwise associated with the study, collected blinded outcome data by telephone interview
Incomplete outcome data (attrition bias) All outcomes	Low risk	2% attrition in intervention group and 3% in control group.
Selective reporting (reporting bias)	Unclear risk	The protocol did not state the predefined outcomes clearly.
Other bias	High risk	Difference in prenatal intentions to rejoin employment within 12 months between the 2 groups (70% intervention, 56% control)

**Ellis 1984**

Methods	2-arm RCT, with individual randomisation n=120
Participants	Setting not clear: women expecting to give birth in an urban maternity unit, Canada. 120 women recruited in late pregnancy.
Interventions	Intervention: in addition to usual care, prenatal breastfeeding class and postnatal drop-in breastfeeding session. Telephone follow-up by nurse at 2, 6 and 12 weeks postpartum. Control: usual care in hospital with assistance from nurses who had received breastfeeding education
Outcomes	Exclusive breastfeeding at 1 and 3 months and any breastfeeding at 3 and 6 months
Notes	We have not included data from this study in the review due to high levels of attrition (> 25% loss to follow-up). Recruitment to the study took place during pregnancy and by 1 month postpartum there was high loss to follow-up and loss was not balanced across groups. At 1 month 42% of controls and 22% of the intervention group were not available for follow-up. The high level and unbalanced attrition means that results from this study were difficult to interpret

***Risk of bias***

***Risk of bias***

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Described as "randomly assigned".
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details provided about blinding of participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Did not state who collected the data. No details provided about blinding of outcome assessment
Incomplete outcome data (attrition bias) All outcomes	High risk	Recruitment to the study took place during pregnancy and by 1 month postpartum there was high loss to follow-up and this was not balanced across groups. At 1 month 42% of controls and 22% of the intervention group were not available for follow-up. The high level and unbalanced attrition means that results from this study are difficult to interpret.
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol

Ellis 1984 (Continued)

Other bias	Unclear risk	There was very little information about study methods and most of the results in the paper were not reported by randomisation group
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Frank 1987

Methods	4-arm (factorial design) RCT, single site, recruiting over 17 months, n = 343	
Participants	<p>Urban USA: inpatient maternity unit</p> <p>Background rates of breastfeeding initiation: low</p> <p>Inclusion criteria: breastfed once in hospital; able to speak Spanish or English; baby needed &lt; 48 h on NICU; able to be contacted by telephone after discharge</p> <p>Participant characteristics:</p> <p>57% primiparous</p> <p>Ethnic composition: black 65%, Hispanic 19%, white 13%, other 4%</p> <p>Socioeconomic status defined by: &lt; 100% poverty level - 69%; 100%-200% poverty level - 21%; &gt; 200% poverty level - 10%</p> <p>Mean age of participants 25.7 years</p>	
Interventions	<p>Intervention: women received postpartum breastfeeding counselling in hospital by trained counsellor (20-40 min) and by telephone at 5, 7, 14, 21, 28, days and 6, 8 and 12 weeks, also 24-h advice by pager. Given research discharge pack in English and Spanish</p> <p>Routine care consisted of postpartum staff nursing contacts (including discharge teaching session on infant care), infrequent breastfeeding classes, written information on breastfeeding management and the opportunity to access a midwife-run telephone advice line</p>	
Outcomes	<p>Exclusive breastfeeding at 1, 2, 3 and 4 months</p> <p>Any breastfeeding at 4 months</p> <p>Median duration of breastfeeding</p> <p>Time to introduction of formula or solids</p> <p>Rehospitalisation of infants</p>	
Notes		

*Risk of bias*

*Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised block design (block size 8) with computer-generated list of random numbers
Allocation concealment (selection bias)	Low risk	Sequentially numbered opaque sealed envelopes

**Frank 1987** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were aware of the overall goal of the interventions but not aware of the study hypotheses. It is not detailed whether personnel were blinded but appears unlikely
Blinding of outcome assessment (detection bias) All outcomes	Low risk	For follow-up at 4 months it was stated that the investigator was not aware of group assignment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participants received a fee to minimise sample attrition. 343 women were recruited. There were a small number of protocol deviations (7 women received the wrong type of discharge pack and were analyzed according to treatment received rather than by randomisation group). 19 women were lost to follow-up. Attrition and reasons for attrition were described as similar across groups. Follow-up 94%. Appropriate randomisation procedures
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Low risk	No baseline imbalance apparent.

**Froozani 1999**

Methods	Single-site study recruiting over 7 months, n = 134
Participants	Urban Iran Background rates of breastfeeding initiation: high Inclusion criteria: women without breastfeeding experience or chronic disease giving birth normally at term to a healthy baby $\geq 2.5$ kg
Interventions	Intervention: nutritionist trained using WHO Breastfeeding Counseling training course (40 h). Contact in hospital immediately after birth, between 10 and 15 days, after 30 days and monthly to the fourth month at home or in a lactation clinic Control: standard care (not described)
Outcomes	Exclusive breastfeeding at 1, 2, 3 and 4 months Mean number of days illness with diarrhoea
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Allocation by day of the week of birth.
Allocation concealment (selection bias)	High risk	Allocation could be anticipated in advance and different days of the week may have had different characteristics (e.g. staff on duty)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women were not told directly which group they had been assigned to but would be aware of whether or not they had received the intervention. The nutritionist carrying out the intervention would have been aware of allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	The nutritionist carrying out the intervention also carried out all the measurements and noted breastfeeding pattern at each visit
Incomplete outcome data (attrition bias) All outcomes	Low risk	134 randomized and 120 followed up.
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Low risk	No baseline imbalance apparent.

**Fu 2014**

Methods	Multicentre, 3-arm cluster-RCT, n = 722 (clusters (hospitals) n = 3)
Participants	<p>Mother-infant pairs were recruited from the postnatal units of 3 geographically distributed public hospitals providing obstetrical services in Hong Kong</p> <p>Participants: 722 primiparous breastfeeding mothers with uncomplicated, full-term pregnancies</p> <p>Background rates of breastfeeding initiation: 80%</p> <p>In Hong Kong current breastfeeding patterns are similar to those of other developed countries, with &gt; 80% of women initiating breastfeeding, but with only 20% continuing to breastfeed exclusively for 3 months</p> <p>Inclusion criteria (mother): Hong Kong Chinese primiparas, ≥ 18 years old, intending to breastfeed, and without any major obstetric complications (i.e. severe postpartum haemorrhage) or serious medical problems (i.e. psychiatric illness)</p> <p>Inclusion criteria (baby): gestational age ≥ 37 weeks; birthweight ≥ 2500 g, 5-min</p>

	<p>Apgar score <math>\geq</math> 8, and no physical anomalies that would contraindicate or complicate breastfeeding</p> <p>Exclusion criteria: mothers who were planning to live in mainland China after delivery</p>
Interventions	<p>Intervention 1: standard care plus 3 in-hospital professional breastfeeding support sessions, of 30-45 min in duration</p> <p>Intervention 2: standard care plus weekly postdischarge breastfeeding telephone support, of 20-30 min duration, for 4 weeks</p> <p>Both interventions were delivered by 4 trained research nurses, who were either highly experienced registered midwives or certified LCs</p> <p>Control: standard postnatal maternity care that consisted of routine perinatal care according to the type of delivery, group postnatal lactation education provided by a midwife or LC, 1-on-1 assistance with breastfeeding if problems arose and time permitted, and postdischarge follow-up, either at the outpatient clinic of the delivery hospital or at the nearest Maternal and Child Health Centre. Information on available peer-support groups was also provided upon hospital discharge</p>
Outcomes	<p>Primary: prevalence of any and exclusive breastfeeding at 1, 2, and 3 months postpartum. Classified infant feeding status into 3 categories: exclusive breastfeeding; any breastfeeding; and exclusive formula feeding</p> <p>Secondary: overall duration of any and exclusive breastfeeding. Measured the duration of any and exclusive breastfeeding as the age of the infant in weeks when the participant completely stopped breastfeeding and first introduced infant formula, respectively</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	The allocation sequence was generated using an online program ( <a href="http://www.randomization.com">www.randomization.com</a> ). All participants at each study site were allocated to the intervention to which the hospital was randomly assigned for that week. Cluster-randomisation was used, with hospitals being the unit of randomisation. Each week, a study hospital was randomly assigned each study hospital to 1 of the 3 treatment groups
Allocation concealment (selection bias)	Low risk	Conducted by a person not involved in the subject recruitment or data collection. Assignments placed in sequentially numbered opaque sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	The blinding of either participants or those delivering the intervention was not possible for this type of study design. For the

**Fu 2014** (Continued)

		control and telephone support group, a research nurse not involved with delivering the intervention, recruited the participants. However, authors state that for the inpatients, the same nurse who recruited the participants also delivered the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	A study research assistant, who was blinded to the participants' treatment allocation, conducted the telephone follow-up
Incomplete outcome data (attrition bias) All outcomes	Low risk	97% of participants had complete follow-up.
Selective reporting (reporting bias)	Unclear risk	No evidence of predefined outcome measures so unable to make a judgement
Other bias	High risk	Not all intervention groups received the full intervention. Of the 191 participants allocated to the in-hospital support group, 137 (71.7%) received all 3 sessions, 52 (27.2%) received 2 sessions, and 2 (1.0%) received only 1 session before hospital discharge. Of the 268 participants in the telephone support group, 199 (74.3%) received all support sessions for which they were eligible; 27 (10.1%), 24 (9.0%), 13 (4.9%), and 5 (1.9%) Baseline characteristics and maternal and birth data were similar across the 3 groups although there were some minor variations in maternal education, family income, intention to exclusively breastfeed, and antenatal breastfeeding class attendance

**Gagnon 2002**

Methods	2-arm RCT, with individual randomisation, n = 586, 292 assigned to intervention and 294 to control
Participants	Study conducted at a university teaching hospital and affiliated community health centres in urban Quebec, Canada. Recruitment January 1997-September 1998 Background rates of breastfeeding initiation: intermediate Inclusion criteria: mothers participating in hospital short-stay programme Ethnic and socioeconomic composition of sample not reported Baseline prevalence of breastfeeding initiation in Canada (excluding territories) 1994-5 = 73%

Interventions	Intervention: home visit from community nurse 3-4 days postpartum. Nurses were Baccalaureate prepared, had a minimum of 3 years' clinical experience in maternal-child health, and had attended training to ensure assessment skills of maternal-newborn and breastfeeding support. Contact with the nurse continued if required Control: usual care was a 48-h postpartum contact and 1 postpartum hospital clinic visit (day 3) following a standard plan of care and lasting up to 45 min. Referral for continued care was available
Outcomes	Breastfeeding frequency and infant weight gain assessed at 2 weeks postpartum
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Block randomisation (block size 8) stratified by parity, by computer-generated random numbers
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "masking of the women and health professionals was not possible."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was reported that outcome data were collected by blind investigators. It was not clear whether planned blinding was effective, although investigators apparently asked women "not to divulge their group status"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	586 randomized. 21 protocol deviations, but analysis performed according to randomisation. 499 completed trial and provided information on primary outcome (15% attrition). Some further missing data for some outcomes
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so were unable to evaluate
Other bias	Low risk	Groups described as similar at baseline.

Graffy 2004

Methods	2-arm RCT with individual randomisation, conducted in 32 general practices in the UK; recruitment April 1995-August 1998, n = 720; 363 assigned to intervention and 357 to control
Participants	Urban south-east England Background rates of breastfeeding initiation: intermediate Inclusion criteria: mothers considering breastfeeding who had not breastfed a previous child for 6 weeks after birth Exclusion criteria: planning to contact a breastfeeding counsellor, address considered unsafe to visit, baby born before 36 weeks' gestation Ethnic composition of sample: 59% white (UK) participants, 11% white (other) participants, 16% African or Caribbean, 8% Indian subcontinent, 6% other Socioeconomic status on RG classification: 10% I, 26% II, 19% IIINM, 26% IIIM, 12% IV, 3% V, 5% other First baby: 74% National baseline prevalence 66% breastfeeding at birth
Interventions	Intervention: women received 1 antenatal visit from a National Childbirth Trust trained breastfeeding counsellor, who offered postnatal support by telephone or further visits if the mother requested this after the birth Control: standard care (UK standard care includes postnatal home visits from midwives and health visitors)
Outcomes	Prevalence of any breastfeeding to 6 weeks; duration of any breastfeeding to 4 months; time to introduction of formula feeds; maternal satisfaction and common feeding problems; mothers' perspectives on support from counsellors; association between counselling uptake and feeding behaviour
Notes	

**Risk of bias**

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Permuted block design stratified by GP practice and parity, randomisation schedule prepared by statistician
Allocation concealment (selection bias)	Low risk	Numbered sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Did not state whether participants or personnel were blinded, however, it seems unlikely due to the nature of the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Reported that responses to follow-up questionnaires were coded by blinded assessors

**Graffy 2004** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	720 women recruited and randomized. 97% available for follow-up at birth, 93% at 6 weeks and 86% at 4 months
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not evaluate this
Other bias	Unclear risk	Groups were similar at baseline although more women in the intervention group (16) than the control group (6) were undecided about breastfeeding intention at the antenatal assessment. It was reported that a sensitivity analysis was carried out to adjust for this possible confounder

**Gross 1998**

Methods	Cluster-randomised trial. 4 clinics were 'randomly assigned' to 4 different interventions n=548	
Participants	Setting: 4 WIC clinics in Baltimore USA Women were predominantly African American (> 90%) 548 women attending study clinics enrolled at between 6 and 24 weeks' gestation. Women were WIC eligible with singleton pregnancies, planning to keep the baby and to stay in study areas	
Interventions	The study was carried out in 4 clinics. Each clinic offered a different intervention Clinic 1: standard care (usual breastfeeding promotion by clinic staff) Clinic 2: standard care plus a motivational video (encouraging breastfeeding) that was played repeatedly in the clinic waiting area Clinic 3: peer support by a mother who had breastfed and undertaken training. Peer supporters contacted pregnant women and discussed breastfeeding. Women were offered a 1-h group breastfeeding support session in the WIC clinic before the birth. After the birth, peer counsellors contacted women and remained in contact with breastfeeding women (phone or visits) until 16 weeks after the birth Clinic 4: standard care plus video plus peer support	
Outcomes	Infant feeding method at 8 weeks and 16 weeks postpartum and maternal work status	
Notes	We were not able to include data from this study in the review due to very high levels of attrition. The study was at a high risk of bias. This was a cluster trial with 4 clinics each allocated to a different intervention and with no adjustment for study design effect Women were recruited in the antenatal period. 548 women enrolled but information was only available for 273 women at 7-10 days postpartum (50%); of the 275 women lost to follow-up 31% (74) were excluded due to pregnancy complications, the remaining 73% (201 women) refused or could not be contacted - these women represented 37% of the original randomized sample. It was not clear whether loss was similar in the 4 clinics	

Gross 1998 (Continued)

<i>Risk of bias</i>			<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>	
Random sequence generation (selection bias)	Unclear risk	Cluster trial. 4 clinics; method of randomisation not described	
Allocation concealment (selection bias)	Unclear risk	Not described	
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Did not state whether participants or personnel were blinded	
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Did not state who the interviewers were or if any attempt at blinding outcome assessment was made	
Incomplete outcome data (attrition bias) All outcomes	High risk	548 women were enrolled on the study, but information was only available for 273 women at 7 to 10 days postpartum (50%) ; of the 275 women lost to follow-up 31% (74) were excluded due to pregnancy complications, the remaining 73% (201 women) refused or could not be contacted - these women represented 37% of the original randomized sample. It was not clear whether loss was similar in the 4 clinics	
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not evaluate this	
Other bias	Unclear risk	Baseline characteristics: imbalance for educational status, employment and parity - although these were adjusted for in the analysis	

Grossman 1990

Methods	2-arm quasi-RCT, with individual randomisation, single-site study recruiting over 10 months, n = 97, follow-up 90%. Quasi-randomisation via coin toss, with women sharing same room allocated by 1 toss
Participants	Urban USA - inpatient maternity unit Background rates of breastfeeding initiation: low WIC breastfeeding prevalence at birth 1991 = 33% Inclusion criteria: women eligible for WIC programme services for those on low incomes; women intending to breastfeed

Grossman 1990 (Continued)

	Participant characteristics: approximately one-third were primiparous Ethnic composition described as 54% black. Mean age was 25.4 years.
Interventions	Intervention: package included 30-45 min face-to-face meeting in hospital with LC (a registered nurse) after birth - educational booklet given; telephone contacts on days 2, 4, 7, 10 and 21; a telephone help-line staffed by a nurse or paediatrician; and back-up support for those with problems from a lactation clinic Control: routine postnatal teaching on infant care and feeding by obstetric nursing staff
Outcomes	Rates of breastfeeding at 6 weeks and 3 and 6 months Median duration of breastfeeding

Notes

***Risk of bias***

***Risk of bias***

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	High risk	Coin toss at the point of randomisation.
Allocation concealment (selection bias)	High risk	Coin toss at the point of randomisation, so allocation could be altered. If 2 women occupied the same room they were allocated to the same group
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Did not state whether women or personnel were blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Some data were derived from medical records, but telephone outcome assessment was not blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	97 women randomized, by 6 weeks 4 control group women could not be contacted (> 90% follow-up but loss not balanced across groups)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not evaluate this
Other bias	Unclear risk	Groups appeared similar at baseline.

## Haider 2000

Methods	Community-based cluster-randomised study (40 adjacent areas randomized), recruitment over 10 months, n = 726
Participants	Setting: Dakka, Bangladesh Background rates of breastfeeding initiation: high Socioeconomic status: mainly lower-middle and low Inclusion criteria: women aged 16-35 years with $\leq 3$ children (or $\leq 6$ pregnancies) and no serious illness Exclusion criteria: multiple births, children with congenital abnormalities, and those weighing $< 1800$ g National baseline prevalence reported in paper was similar to the control group rates; UNICEF quoted higher rates - 53% exclusive breastfeeding at 0-3 months
Interventions	Intervention: peer counselling by women with personal breastfeeding experience trained over 40 h with the WHO/UNICEF Breastfeeding Counseling course. Paid honorarium. Supervised caseload of 12-25 mothers. 15 home visits: 2 in last trimester/4 in month 1/ 2-weekly in months 2-5. Duration of visits 20-40 min Control: not specified
Outcomes	Exclusive breastfeeding at birth, 4 days, 4 weeks, 2, 3, 4 and 5 months
Notes	

### *Risk of bias*

### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random number tables
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and counsellors aware of group assignment.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Interviewers collecting outcome data would also be aware of assignment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	40 areas randomized (20 intervention, 20 control) 726 women randomized. 653 available to follow-up at delivery (90%) . 573 available at 5 months (79%). Loss appeared balanced across groups. No ITT analysis
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not evaluate this

Haider 2000 (Continued)

Other bias	Low risk	No differences in baseline characteristics apparent. Stated that results were based on individual level analysis, but with adjustment for cluster level of randomisation
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Hall 1978

Methods	3-arm RCT n=49
Participants	49 women giving birth in a small community hospital in the USA planning to breastfeed for at least 6 weeks and breastfeeding for the first time. All women had healthy babies. Women were described as married and middle class aged 17-31 years
Interventions	3 groups: Intervention 1: 15 randomized, 13 followed up (not clear): usual care plus an educational session Intervention 2: 16 randomized, 15 followed up (not clear): usual care plus education plus daily visits by nurse while in hospital and telephone support 2 days after discharge and 1 week later and further support if necessary (up to 5 weeks postpartum) Control: 18 randomized, 12 followed up (not clear)
Outcomes	Outcomes were unclear, but included breastfeeding at 6 weeks and breastfeeding problems
Notes	We have not included data from this study in the review due to methodological weakness and high and unbalanced levels of attrition. More than 30% of the control group were lost to follow-up and results were therefore difficult to interpret. Most results were not reported according to randomisation group and the only result for breastfeeding duration was approximate, stating: "Approximately 50% of the control group and 50% of the group which received the teaching unit were still nursing at 6 weeks. Of the group who received the teaching plus support 80% were still nursing at 6 weeks."

*Risk of bias*

*Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Described as 'randomly assigned'.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessment was not by the same nurse as the 1 delivering the intervention, but unclear if they were blinded

**Hall 1978** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There was high attrition in this small study, > 30% of the control group were lost to follow-up and results were therefore difficult to interpret
Selective reporting (reporting bias)	Unclear risk	Most results were not reported by randomisation group.
Other bias	Unclear risk	No baseline characteristics reported.

**Hanson 2015**

Methods	2-arm cluster-RCT, whole population in 132 wards (clusters)	
Participants	<p>Setting: rural Tanzania. Most residents were subsistence farmers living in small settlements (subvillages) and 90% lived within 5 km of primary facilities</p> <p>Background rates of breastfeeding initiation: not stated</p> <p>Inclusion criteria: households in intervention and comparison wards with live births. If the village had fewer than 130 households, all households in the village were included</p> <p>Exclusion criteria: If the village had greater than 130 households, segmentation was used to limit the sample to a maximum of 131 households</p>	
Interventions	<p>Intervention: home-based counselling - this strategy, branded Mtnze Mtoto Mchanga, which means "protect your newborn baby" in Swahili, was developed in 2008-2009. The strategy was designed in consultation with the Ministry of Health and members of the WHO, UNICEF, and professional organisations. Key counselling messages were selected on the basis of the frequency of the behaviour in 2007 the feasibility of change, and the likely impact on survival on the basis of evidence published at the time. They included hygiene during childbirth, early and exclusive breastfeeding, and extra care for low-birthweight babies, including skin-to-skin care</p> <p>Control: usual practice</p>	
Outcomes	<p>Primary: all-cause neonatal mortality rate, per 1000 live births, defined as the proportion of all live births who died in the first 28 days of life</p> <p>Secondary:</p> <ul style="list-style-type: none"> <li>Breastfeeding within an hour of delivery;</li> <li>Soap or use of gloves for those attending home deliveries;</li> <li>Exclusive breastfeeding for 3 days after birth;</li> <li>Skilled attendance at birth;</li> <li>Birth preparedness;</li> <li>Immediate drying and covering of the baby;</li> <li>Clean cord care;</li> <li>Delayed bathing;</li> <li>Identification and extra care for small babies, including skin-to-skin care for small babies and referral to hospital for very small babies</li> </ul>	
Notes		

*Risk of bias*

*Risk of bias*

**Hanson 2015** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomisation was performed using STATA" (p.8).
Allocation concealment (selection bias)	Unclear risk	No information provided to enable us to judge this.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded to the intervention. Volunteers who provided the intervention were not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "The survey team was unaware of cluster allocation. The data analyst was masked to the cluster allocation until data cleaning was complete and a copy of the data lodged with the data and safety monitoring board". Unclear if these procedures were effective
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Probably high as the data were obtained retrospectively in the 2013 survey and results from the previous year were used in the data analysis. Six of the sampled sub-villages refused to participate. In 6% of households no one was present, 1% of households refused to participate
Selective reporting (reporting bias)	High risk	Breastfeeding was not a prespecified outcome in the clinicaltrials.gov record
Other bias	High risk	Risk of contamination, quote: "Methodological limitations include our inability to rule out some degree of leakage of the intervention into the comparison areas and response bias for newborn care behaviours"

**Hoddinott 2009**

Methods	2-arm cluster-RCT with prospective mixed method embedded case studies to evaluate implementation processes. 14 localities randomized; recruitment 2002-2004 n=18858
Participants	Setting: women registered at GP practices in 14 localities (of 66) in Scotland Background rates of breastfeeding initiation: low In Scotland, in 2005, only 44% of babies had received any breast milk at 6 weeks 14 clusters randomized, birth records supplied data for n = 9747 in intervention group and n = 9111 in control group Inclusion criteria: pregnant women and breastfeeding mothers

**Hoddinott 2009** (Continued)

	<p>Exclusion criteria: not stated</p> <p>In intervention localities 25.2% of the populations were in the most deprived social groups, compared with 32.1% in the control localities. Mean age of mothers at the first child health record was 28-29 years. In 7 areas (3 intervention, 4 control) women gave birth at Baby-Friendly hospitals</p>
Interventions	<p>Intervention: a policy intervention aimed at locality areas rather than at individual women. The policy aimed to double the number of local breastfeeding support groups and to make weekly support groups open to all pregnant women and breastfeeding mothers. These local breastfeeding support groups were facilitated by health professionals taking a woman-centred approach and aiming to provide breastfeeding support and social interaction for women.</p> <p>Control: control localities received no additional intervention; however, breastfeeding support groups existed in some control areas</p>
Outcomes	<p>Primary: number of babies receiving any breast milk at 6-8 weeks, as reported in routinely collected data for the 2 pretrial years and 2 trial years</p> <p>Secondary: any breastfeeding at birth, 5-7 days and 8-9 months, and maternal satisfaction</p> <p>Results were not presented in a way which allowed us to enter them into data and analysis tables, but we have summarised findings in the text</p>
Notes	<p>When we updated our search in October 2011, <a href="#">Hoddinott 2009</a> was the only evaluation we found: a) of a policy-level intervention; b) of breastfeeding in groups; and c) that used routinely collected locality-level outcome data</p>

**Risk of bias**

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Cluster-RCT; 14 localities randomized. Localities varied in size, baseline breastfeeding rates and numbers of pre-existing groups and how pregnancy and post-natal care were organised. Localities were matched on breastfeeding rates and existing support groups: quote: "An independent statistician used random number tables to randomise locality pairs to either intervention or control".
Allocation concealment (selection bias)	Low risk	Researchers analysing primary and secondary outcomes were blinded to allocation, ensured by coding of localities
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Cluster-randomised trial, so women may not have been aware of the study although they would be aware of the intervention. Not stated whether personnel were blinded

**Hoddinott 2009** (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers analysing primary and secondary outcomes were reported to be blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	According to flow chart no clusters discontinued the intervention or were lost to follow-up and there was follow-up of national data in all localities included in the trial. The amount of data missing varied for different outcomes (e.g. birth and 6 week postpartum records were available for most of the eligible population but child health records at 8-9 months were only available for approximately a quarter of the children)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Analysis took into account aspects of design effect. It appeared that there were some differences in the localities at baseline. Control localities may have had higher levels of social deprivation

**Hoddinott 2012**

Methods	2-arm RCT, single-site study, n = 69
Participants	<p>Setting: a maternity unit serving a mixed urban and rural population in Scotland</p> <p>Background rates of breastfeeding initiation: at hospital discharge, 54% of babies were exclusively breastfed and 6% were receiving breast and formula milk. In the most disadvantaged areas, 39% exclusively breastfed compared with 63% in the most advantaged areas</p> <p>Inclusion criteria: women admitted to the ward between 26 July-18 October 2010 who lived in the 3 most disadvantaged postcode area quintiles for the Scottish Index of Multiple Deprivation (SIMD 1-3) in 2009 and who were breastfeeding</p> <p>Exclusion criteria: women aged &lt; 16 years with serious medical or psychiatric problems or with insufficient spoken English to communicate by telephone</p>
Interventions	<p>Intervention (n = 35): proactive telephone calls (intervention) 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 proactive calls stopped 14 days after hospital discharge</p> <p>Control (n = 34): reactive telephone calls; women could telephone the feeding team at any point over the 2 weeks following discharge. Text and answer-phone messaging was</p>

	available
Outcomes	Any breastfeeding at 6-8 weeks
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "Using a website randomisation service set up by an independent statistician. Randomisation was stratified to ensure balance of primiparous and multiparous women across both trial arms."
Allocation concealment (selection bias)	Low risk	Performed by an independent statistician.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Although not informed of the randomisation outcome, women knew if they had been randomized to the proactive group as they received a phone call from the feeding team within 24 h of hospital discharge". Healthcare professionals providing intervention would have been aware of allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes were collected by telephone by a researcher who was blind to randomisation and who had no other contact with study women
Incomplete outcome data (attrition bias) All outcomes	High risk	3/35 in the intervention group and 8/34 of those in the control group did not have data at follow-up
Selective reporting (reporting bias)	Unclear risk	No evidence of outcomes being prespecified anywhere, so difficult to judge this
Other bias	High risk	Women in the proactive call group were a year older on average, with more living in the most disadvantaged postcode areas (SIMD 1). Hospital stays were half a day longer on average in the proactive call group; however, data were imbalanced by a small number of women with unusually long hospital stays. Otherwise the randomized groups were similar for parity, method of delivery, gestation and admission to the neonatal special care unit

## Hopkinson 2009

Methods	2-arm RCT, n = 522
Participants	<p>A large metropolitan hospital in Houston, Texas, USA, serving predominantly immigrant Hispanic women (85% monolingual Hispanic)</p> <p>Background rates of breastfeeding initiation were high in this study population</p> <p>Inclusion criteria: mothers of low-risk infants, mixed feeding in hospitals, had telephones and access to transportation</p> <p>Exclusion criteria: infants with elevated risk for hyperbilirubinaemia (preterm, discharged at &lt; 48 h old, jaundice within 24 h of birth, Rhesus-incompatibility, cephalohematoma, positive Coombs test, family history of disorders of red blood cell enzyme defects, or defects of red blood cell shape and size)</p> <p>Participant characteristics:</p> <p>Mean maternal age: intervention group 26.8 years, control group 27.1 years</p> <p>Mean parity: intervention group 1.5, control group 1.5</p> <p>Mothers born in the USA: intervention group 2.8%, control group 1.1% (most of the women were born in Mexico or Central America)</p>
Interventions	<p>Intervention: mothers were given an appointment to visit the hospital-based breastfeeding clinic at 3-7 days postpartum. At the breastfeeding clinic, peer counselling sessions included a breastfeeding history, breast examination, infant oral-motor assessment, measurement of infant weight, evaluation of latch and milk transfer, and discussion of the mother's concerns and support system. Additional visits and telephone consultations were provided if deemed necessary by the mother and the clinic staff. Women who missed appointments received a telephone call</p> <p>Control: received usual care, which included bedside breastfeeding assistance before hospital discharge and the phone number of the hospital breastfeeding clinic with instructions to call if needed</p>
Outcomes	<p>Primary: exclusive breastfeeding at 1 month</p> <p>Secondary: volume of formula given by mothers who were mixed feeding, and incidence of breastfeeding problems</p>
Notes	

### *Risk of bias*

### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Generated by random number table.
Allocation concealment (selection bias)	Low risk	After participants had given informed consent, the group was determined using opaque, sealed envelopes containing assignments generated by random table number. The envelope was opened by the mother
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded as the envelope was opened by the mother. Caregivers were also not blinded

**Hopkinson 2009** (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	For outcome assessors, outcomes were determined by telephone survey at 4 weeks postpartum by interviewers blinded to group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	522 randomized (255 in intervention group and 267 in control group. 55 women were lost to follow-up at 4 weeks (10.5%) . Loss was balanced in the 2 groups. Issues around incomplete data were addressed
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol so could not judge this
Other bias	Low risk	There were slight baseline differences between the control group and the experimental group. Women in the intervention group were more likely to have an emergency caesarean, and were taller. Due to low compliance with the intervention, secondary analysis was carried out, but we have reported data from the primary analysis (unadjusted)

**Howell 2014**

Methods	2-arm RCT, single site, n = 540
Participants	Black and Latina women who had delivered at a large tertiary hospital located in New York City, USA Background rates of breastfeeding initiation: not stated Inclusion criteria: participants were black/African American or Latina/Hispanic, spoke English or Spanish, had a working telephone, $\geq 18$ years old, and had infants with birthweights $> 2500$ g and 5-min Apgar scores $> 7$ Exclusion criteria: not specified
Interventions	Intervention (n = 270): The intervention used a behavioural educational approach and aimed to prepare and educate mothers about postpartum symptoms and experiences provide social support, and develop self management skills. The intervention was delivered in two parts. The first part was delivered whilst the women was in hospital by a social worker who reviewed an education pamphlet and partner summary sheet with each mother. Education materials provided information about post-partum care and included information on breastfeeding and breast/nipple pain.. Additional information was provided on social support. The second part was a 2-week postdelivery call, where the social worker assessed patients' symptoms, skills in symptom management, and other needs. Patients and the social worker created action plans to address current needs that included assessment of community resources Control: enhanced usual care; participants received a list of community resources and received a 2-week control call
Outcomes	Duration and exclusivity of breastfeeding at 6 months
Notes	

<i>Risk of bias</i>			<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>	
Random sequence generation (selection bias)	Unclear risk	Not reported	
Allocation concealment (selection bias)	Unclear risk	Not reported	
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible	
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data were collected in person at baseline and by telephone during follow-up interviews by bilingual clinical research co-ordinators who were blinded to intervention status	
Incomplete outcome data (attrition bias) All outcomes	Low risk	79.3% of intervention group and 77.4% of control group had data available at 6 month follow-up	
Selective reporting (reporting bias)	Unclear risk	Not clear	
Other bias	Low risk	Baseline sociodemographic, clinical, psychosocial, and breastfeeding characteristics were similar among intervention vs control subjects. There were no clinically important differences between intervention and control groups in baseline sociodemographic, clinical, and psychosocial characteristics, except that comorbid conditions were more prevalent among the control subjects than intervention subjects (27% vs 20%; $P < .05$ )	

**ISRCTN47056748**

Methods	2-arm RCT, single centre, single blind, recruitment 2005-2006 n=182
Participants	<p>Setting: maternity unit in Northern Ireland with Baby-Friendly accreditation</p> <p>Background rates of breastfeeding initiation: intermediate, one-fifth of women were reported to have stopped breastfeeding before hospital discharge</p> <p>Participants randomized n = 182</p> <p>Inclusion criteria: primigravid women who attended for antenatal care when 20 weeks pregnant, intended to give birth at the study hospital and consented to participate</p> <p>Exclusion criteria: women &lt; 20 years old who had commenced the 'young mums' parentcraft programme prior to the 20-week visit. Vulnerable women, e.g. women who neither spoke nor understood English. Mothers separated from their babies, for example when a baby was admitted to the neonatal unit, who did not receive routine instruction (postrandomisation exclusion)</p>

	<p>Sample characteristics for n = 144 who completed the research (not reported by randomized group):</p> <p>Age 21-30 years: 79/144 (55%)</p> <p>Age 31-40 years: 53/144 (37%)</p> <p>Socioeconomic status: 38 (26%) professionals; 20 (14%) not working</p>
Interventions	<p>All study participants received standard care at the study hospital, this met Baby-Friendly standards and complied with National Institute for Clinical Excellence (NICE) guidelines</p> <p>Intervention: staff training; women (n = 93) received a 'motivationally enhanced' version of control group care from staff who had been trained in a programme called 'Designer Breastfeeding'</p> <p>Control (n = 89): women received a 2-h antenatal infant feeding class, a breastfeeding book and midwife support for the first 3 postnatal weeks</p>
Outcomes	<p>Primary: women's motivational profile was measured, using 7-point Likert scales, in relation to 3 motivational factors: total value placed on breastfeeding, perceived midwife support, and expectancy for successful breastfeeding</p> <p>Secondary: breastfeeding behaviour on discharge from hospital and at 3 weeks postnatally. Breastfeeding initiation was defined according to the Department of Health as giving 1 breastfeed or 1 episode of expressed breast milk. Duration of breastfeeding was categorised in accordance with the Index of Breastfeeding Status, which classifies breastfeeding on a scale in accordance with the amount of breast milk the infant receives</p>
Notes	<p>Only 53/89 women randomized to the control group were known to have initiated breastfeeding. In the intervention group 57/93 women randomized initiated breastfeeding</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Quote: "Prior to recruitment a randomized table was created."
Allocation concealment (selection bias)	Low risk	The authors state: "Neither the researcher, nor the research participants could predict their allocated treatment"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Described as single blind. Women were said to be not aware of groups, but there were stickers on the notes so care providers would be aware of group assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details available about who collected outcome data to enable us to judge this

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	234 assessed for eligibility, 182 consented and 144 completed
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	There were some baseline differences between groups. Women in the control group were more likely to be discharged from hospital early and were less likely to attend antenatal infant feeding classes. It is not clear what impact these differences had on the results

**Jenner 1988**

Methods	Quasi-RCT, recruitment location/duration not stated, n = 38
Participants	UK white, working-class women 19-32 years old, living with partner and intending to breastfeed Background rates of breastfeeding initiation: intermediate: prevalence of breastfeeding in 1985 = 64% at birth and 26% at 4 months
Interventions	Intervention: 3 antenatal home visits/1 hospital visit/1 'immediate' home visit and 1 or 2 further home visits 'in the early weeks'; plus face-to-face and telephone support by a single lay supporter (mother/previous breastfeeding experience, but no indication of training) Control: 1 antenatal home visit and 1 postnatal hospital visit
Outcomes	Breastfeeding at 3 months. Partial breastfeeding grouped with formula feeding as 'breastfeeding failure'
Notes	Moderate-to-high risk of bias

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	High risk	Alternation
Allocation concealment (selection bias)	High risk	Alternate allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding was not attempted.

**Jenner 1988** (Continued)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding was not attempted.
Incomplete outcome data (attrition bias) All outcomes	Low risk	38 women included. It appeared that all were followed up.
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol to judge this
Other bias	Unclear risk	Very little information available about study methods.

**Jolly 2012a**

Methods	2-arm cluster-controlled trial, n = 1267
Participants	<p>Primary Care Trust health district (PCT) in Birmingham, UK</p> <p>Background rates of breastfeeding initiation: 58%, with continuation rates poorly collected, but considered to be lower than national average</p> <p>Inclusion criteria: all pregnant women registered with a GP within the PCT, with an estimated delivery date between 1 February 2007-31 July 2007</p> <p>Exclusion criteria: none stated</p>
Interventions	<p>Intervention (n = 1267): antenatal peer support offered to all women in intervention clusters to encourage breastfeeding initiation, and postnatal peer support for women who initiated breastfeeding to increase continuation. Community peer support workers were employed and trained by the breastfeeding personnel in the PCT in line with WHO/ UNICEF Baby Friendly breastfeeding management course. Antenatal support was aimed to be 2 support sessions (at least 1 at home, although almost all actually took place in the clinic/Children's Centre setting). The support workers were informed when the women were discharged from hospital so that they could contact and visit them within 24 h-48 h. Further contact would be needs-based, but with a minimum of 1 more contact in the first week. Additional needs-based contacts could be by telephone or home visits</p> <p>Number randomized = 1267 (416 consented to follow-up at 6 months, and 271 of these responded at 6 months)</p> <p>Control (n = 1370): routine maternity care.</p> <p>Number randomized = 1370 (432 consented to follow-up at 6 months, 301 responded at 6 months)</p>
Outcomes	Any breastfeeding and exclusive breastfeeding at 10-14 days, 6 weeks and 6 months and 6 months
Notes	<p>The numbers randomized in this paper do match the MacArthur paper which states:</p> <p>Intervention: n = 1140 deliveries</p> <p>Women with data on initiation of breastfeeding n = 1083</p> <p>Women who initiated breastfeeding n = 747</p> <p>Comparison: n = 1371 deliveries</p>

Women with data on initiation of breastfeeding n = 1315  
 Women who initiated breastfeeding n = 896

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Practices were "randomized by the trial statistician with stratification by midwifery team and numbers of deliveries per clinic". Unclear how the sequence was generated
Allocation concealment (selection bias)	Unclear risk	No details provided to allow us to assess this.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women were aware of allocation at recruitment.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Women's options for 6 month follow-up were by postal questionnaire in English, or by telephone in their language of choice by a researcher blinded to the trial allocation. Unclear whether the questionnaire would have contained identification related to allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	When based upon the number of women who consented to be followed up at 6 months, the follow-up was 69.7% in the intervention group and 65.1% in control group. When based on the number actually in the clusters this number is 21.4% in intervention group and 20.5% in the control group
Selective reporting (reporting bias)	Low risk	Outcomes in paper match those prespecified in ISRCTN registry
Other bias	Low risk	None identified

**Jones 1985**

Methods	Quasi-RCT, individual randomisation, single-site study; recruitment period 18 months, n = 678
Participants	Maternity department of UK district general hospital Background rates of breastfeeding initiation: intermediate Inclusion criteria: all women who attempted at least 1 breastfeed Exclusion criteria: birth of child overlapped intervention and control periods 55% of the sample were primiparous. Ethnic composition not stated. Socioeconomic

	status defined by UK census categories (I and II 22%, III 46%, IV and V 13%)
Interventions	Intervention (n = 228): individual support and problem solving by lactation nurse in hospital and at home. Duration of the intervention not specified Control (n = 355): not specified
Outcomes	Breastfeeding rates at 4 weeks, and 3, 6 and 12 months Satisfaction with care and intention to breastfeed after next pregnancy
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	High risk	Alternating 2 week periods (i.e. 2 week intervention recruitment period, 2 week control recruitment period)
Allocation concealment (selection bias)	High risk	The randomisation method did not achieve balanced group size; 228 in the intervention group vs 355 controls
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel not described.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Stated that 12 month follow-up was conducted by an independent interviewer
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	678 women randomized and 649 available to follow-up (96%). Potential confounder: late exclusion of 66 women because of overlap of recruitment periods, and group sizes were uneven
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	The method of recruiting intervention and control women appeared different; possibly face-to-face for intervention group but records not clear for the control group

**Kaojuri 2009**

Methods	Not clear; described as 'case control randomized trial', 2-armed n=120
Participants	Setting: Tehran, Iran; mothers and babies recruited in a Baby Friendly accredited hospital. 120 women (baseline characteristics not described) Inclusion criteria: women giving birth to singletons by caesarean section only Exclusion criteria: infants with congenital abnormalities or serious illness necessitating intensive care, and mothers who had a serious illness or were planning to leave the area within 6 months, infants weighing < 2500 g at birth
Interventions	Intervention: 4 postnatal home visits (not clear) Control: standard care (not clear)
Outcomes	Follow-up interviews by telephone on days 90, 120, 150 and 180 Results were not reported in a way in which we can include them in the review. Authors reported that "the patterns of exclusive breastfeeding in the 2 groups for days 3 to 180 differed significantly ( $P < 0.0001$ ) with a mean aggregated of 67.72% among the group assigned home visits compared with 31.78% for the group assigned none"
Notes	We have not included data from this study in the review. Results were difficult to interpret and data were not reported in a way that allowed us to include them in meta-analyses

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding of participants/professionals reported.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding of participants/professionals reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear, 120 women were recruited but it was not clear how many were followed up
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Did not state what was included in the telephone interview. Results reported on exclusive breastfeeding (not reported in a form we can use in the review)

**Khreshch 2011**

Methods	2-arm RCT, recruited August 2008-April 2009, n = 140
Participants	Recruitment from postnatal wards of 2 hospitals in South Jordan Prevalence of 'ever breastfed' in country: 93% (WHO Global Data Bank on Breastfeeding, accessed 12 Oct 2011). Paper stated that traditionally most women initiate breastfeeding and breastfeed for up to 2 years, with 32% fully breastfeeding for > 6 months Inclusion criteria: primiparous women following vaginal delivery with term infants Exclusion criteria: women who lived outside the study area or who could not be contacted by phone
Interventions	Intervention: women received a 1-h education session approximately 2 h after the birth. The session included demonstrations of breastfeeding. Mothers were encouraged to ask questions and were given a pamphlet on breastfeeding. At 2 and 4 months postpartum women were contacted by phone by the same researcher/nurse. The purpose of calls was to offer support, monitor breastfeeding practices and identify any problems Control: usual care; women were given an appointment for 6 weeks after discharge to attend the maternal and child health services for support and follow-up. Paper states most women did not return for these appointments and were not receiving any postnatal care. Control group women did not receive postnatal home visits from a midwife or a child health nurse
Outcomes	Primary: exclusive breastfeeding at 6 months and breastfeeding knowledge Secondary: infant hospital admissions for diarrhoea and vomiting or respiratory tract infections
Notes	Due to high levels of attrition (36%) we have not included outcome data from this study in the review

***Risk of bias***

***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Paper stated randomisation occurred by women selecting 1 envelope from a group of sealed opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	The researchers carried out the intervention and would have been aware of allocation. No details provided regarding whether mothers were blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding described and it appears that the same researchers who collected data also carried out recruitment and delivered the intervention

**Khreshch 2011** (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	Serious loss to follow-up. At 6 months, follow-up was 62.5% in the intervention group and 66.2% in the control group
Selective reporting (reporting bias)	Unclear risk	Not apparent
Other bias	Unclear risk	Data collection procedures varied at 6 months. Some women were visited at home while others were telephoned. It was not clear how many women in the control and intervention groups were telephoned vs visited. The different data collection procedures may have affected responses

**Kools 2005**

Methods	2-arm cluster-randomised study with 10 sites, divided into 2 groups, which had similar numbers of births and breastfeeding rates. Recruitment December 2000-December 2002, n = 781, 408 women in sites assigned to the intervention and 373 in sites assigned to the control
Participants	Child healthcare centres in Limbourg province, the Netherlands Background rates of breastfeeding initiation: high Inclusion criteria: mothers applying for maternity care at any of the 10 centres Exclusion criteria: birthweight < 2000 g Ethnic composition not defined. Baseline prevalence of breastfeeding initiation was 80% in the Netherlands in 2002
Interventions	Intervention: programme with 3 elements: structured health counselling by maternity and child healthcare nurses and physicians; booklet to transfer information between caregivers and between mother and caregivers and used at each consultation; lactation consultancy available via caregiver faxing consultant with details of problem (LC would then contact the caregiver or mother within 24 h of receiving the fax) Control: not specified
Outcomes	Exclusive and complementary breastfeeding rates at 3 months; determinants of breastfeeding at 3 months
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	By coin flip

**Kools 2005** (Continued)

Allocation concealment (selection bias)	Low risk	Clusters were randomized after sites were paired for similarity of breastfeeding rates and the number of births in each centre
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details provided about whether women and personnel were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details provided about whether the caregivers (who collected some of the data) or those responsible for conducting the questionnaires were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 centres and 781 women were randomized. Data available for 701 for the first follow-up (90%) and 683 (87%) at 6 months postpartum
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Low risk	Analyses adjusted for cluster effect by multi-level analysis. No baseline imbalance apparent

**Kramer 2001**

Methods	Multi-site cluster-randomised study, recruitment period 19 months, n = 17,046
Participants	Urban and rural sites within Belarus Background rates of breastfeeding initiation: high Inclusion criteria: intention to breastfeed, healthy mother, child $\geq$ 2500 g at term, Apgar $\geq$ 5 at 5 min Baseline breastfeeding prevalence 50% at 3 months
Interventions	Intervention: WHO/UNICEF BFI training for all staff dealing with mothers and babies in hospitals and community polyclinics. Infants seen monthly for polyclinic well-child visits and whenever ill Control: staff did not receive the training
Outcomes	Any breastfeeding at 3, 6, 9 and 12 months Incidence of respiratory, gastrointestinal infection, and atopic eczema in first year
Notes	

**Risk of bias** *Risk of bias*

Bias	Authors' judgement	Support for judgement
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**Kramer 2001** (Continued)

Random sequence generation (selection bias)	Low risk	Cluster-randomised trial with double randomisation procedure. Random number tables were used to ascribe numbers to sites and higher/lower numbers were used to allocate sites to A or B interventions. Then later, in public, a coin flip was used to determine whether A or B would be intervention or control sites
Allocation concealment (selection bias)	Low risk	2-stage randomisation procedure
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel working in the hospital were not blinded. It was not stated whether the women were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The paediatricians carrying out the interventions were aware of the status of the study infants. An audit was carried to assess data validity, but it was not clear what this identified
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	34 sites randomized, 2 of which refused to carry out allocated intervention and 1 clinic falsified outcome data and was excluded. 31 sites contributed data. In addition, follow-up data were missing for 3.3% of women
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	A steering group ensured that "control sites did not institute any changes that would render their maternity hospitals or polyclinics more baby friendly" Analysis took account of cluster design. Groups appeared similar at baseline.

**Kronborg 2007**

Methods	Cluster-randomised, 2-community-based trial; 22 municipalities randomized to intervention and control clusters n= 109 Health visitors and 1588 women
Participants	Western Denmark, urban and agricultural areas Background rates of breastfeeding initiation: high. The 5 hospitals serving the area had adopted UNICEF/ WHO Baby Friendly Hospital Initiative standards, and 3 of the 5 were accredited at the time of the study Inclusion criteria: Danish mothers who lived in the 22 municipalities and gave birth to a single child with gestational age of $\geq 37$ completed weeks

**Kronborg 2007** (Continued)

	Participant characteristics: 36% primiparous, 7.5% multiparous with previous short breastfeeding experience
Interventions	Usual care included hospital care at hospitals working to Baby-Friendly standards, and an existing Health Visitor service in all municipalities Intervention cluster: 1-3 structured home visits within the first 5 postnatal weeks from Health Visitors with additional training. Main topics for the first visit were effective breastfeeding technique and learning to know the baby; for the second visit, self-regulated feeding and interpretation of the baby's cues; for the third visit, sufficient milk and interaction with the baby. Mothers were also given a booklet about how to breastfeed and how to read the baby's cues Control cluster: Health Visitors' usual practice consisting of 1 or more non-standardised visits
Outcomes	Duration of exclusive breastfeeding and mother's satisfaction with breastfeeding
Notes	The authors did not adjust for cluster design effect. In our data and analysis tables we have adjusted the sample size and event rates to take account of the design effect. We calculated an effective sample size by dividing figures by the design effect - calculated using the ICC for breastfeeding cessation given in the paper: ICC = 0.02

***Risk of bias***

***Risk of bias***

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	The 22 clusters were stratified according to their number of births the year before the trial, and within 3 strata, 11 municipalities were randomized to the intervention group and 11 to the comparison group. The randomisation was computerised and done independently of the investigators
Allocation concealment (selection bias)	Low risk	As for the sequence generation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and caregivers were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The health visitors provided the mothers with questionnaires which appear to have been self-completed as the mothers were asked to return the questionnaire in a stamped addressed envelope. The identity of the health visitors was blinded to the investigators and it is not clear whether this partial blinding was effective

**Kronborg 2007** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	22 municipalities were randomized. 2186 women had babies during the study time period. 1760 women were followed up
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Reported that there were no significant differences between groups at baseline This was a cluster-randomised trial and authors stated they did not make allowance for clustering in the sample size calculation as the cluster effect was expected to be small. Elsewhere in the paper an ICC value was provided, which the authors said indicated that cluster effect was small. It was not clear that the cluster design effect was taken into account in any of the analyses

**Labarere 2005**

Methods	2-arm RCT, with individual randomisation, recruitment October 2001-May 2002, n = 231
Participants	<p>Setting: the maternity section at the Chambéry Teaching hospital in Chambéry, France</p> <p>Background rates of breastfeeding initiation: intermediate. Breastfeeding prevalence rates were 70.8% in hospital and 58.1% at 1 month of infant age</p> <p>Inclusion criteria: mothers of healthy singleton infants (gestational age: &gt; 37 completed weeks), breastfeeding on the day of discharge and consenting to participate in the study</p> <p>Exclusion criteria: infants admitted to neonatal unit, mothers transferred to ICU, mothers &lt; 18 years old, living outside the area, unable to speak French, or unable to complete follow-up monitoring because of psychosocial problems such as homelessness</p> <p>Participant characteristics:</p> <p>Age: mean (SD): intervention: 29.3 years (4.1); control: 29.7 years (4.8)</p> <p>Education beyond high school graduate level: intervention: 87 (75.0); control 84 (73.0)</p> <p>White collar worker: intervention: 92 (79.3); control 87 (75.6)</p> <p>Primiparous: intervention: 58 (50.0); control: 63 (54.8)</p>
Interventions	<p>Intervention (n = 116): in addition to standard care, mothers were invited to an outpatient visit in a primary care physician's office within 2 weeks of the birth to see a primary care doctor who had received special breastfeeding education. Topics covered included general health assessment, lactation physiology, feeding position and latch on assessment, management of common lactation problems (nipple pain, nipple cracks, sore nipples, mastitis, and maternal concern regarding low milk supply), management of infant problems (insufficient weight gain, breastfeeding jaundice, diarrhoea and dehydration), maternal medication use while breastfeeding and sources of support. The physicians' training programme was delivered through lectures, panel discussions, role playing exercises and printed educational materials</p>

	Control (n = 115): standard care; mothers received verbal encouragement from maternity ward staff to maintain breastfeeding. On discharge, the infant was examined by the paediatrician working in the department, for a general health assessment and an evaluation for evidence of successful breastfeeding behaviour. The mothers were also provided with the telephone number of a peer support group that they could call to ask questions and request help. The postdischarge follow-up monitoring consisted of routine, preventive, outpatient visits in a primary care physician's office at 1, 2, 3, 4, 5 and 6 months of infant age
Outcomes	Primary: exclusive breastfeeding at 4 weeks (exclusive breastfeeding defined as giving maternal milk as the only food source, with no other liquids or foods) Secondary: any breastfeeding at 4 weeks, median duration of breastfeeding, breastfeeding difficulties and maternal satisfaction with the infant feeding experience
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	The allocation sequence was generated by the statistical adviser of the study with random permuted blocks with a block size of 8
Allocation concealment (selection bias)	Low risk	The randomisation assignments were unknown to any of the investigators and were concealed in consecutively numbered, sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding of participants or personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcomes were assessed using self-completed questionnaires, however, it was not stated whether the investigators analysing the data were blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	(1080 women assessed for eligibility, 849 deemed not eligible) 231 women randomized, outcome data were available for all but 5 of the woman randomized, and a sensitivity analysis was carried out where the most conservative values were assumed for those women lost to follow-up
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not judge this

Labarere 2005 (Continued)

Other bias	Unclear risk	The majority of women assessed were not eligible for inclusion in this trial and so the results may not be generalisable
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Laliberte 2016

Methods	2-arm, RCT, single site, n = 472	
Participants	<p>Ottawa, Canada</p> <p>Background breastfeeding rates: not stated</p> <p>Inclusion criteria: women <math>\geq</math> 18 years, with no diagnosed medical problems, with a healthy singleton infant at a gestational age of over 36 weeks and 6 days who were breastfeeding their baby and intended to continue upon discharge, and could be contacted by phone or email after hospital discharge</p> <p>Exclusion criteria: women who did not speak English or French, were unable to present to the clinic (transport not available), with multiple, preterm or adopted babies, with no plan or desire to breastfeed, women who had had breast surgery or a psychological risk that might impede their ability to attend the first appointment at the clinic. Out-of-province women were also excluded given the geographic distance and difference in social services</p>	
Interventions	<p>Intervention (n = 315): within 48 h of discharge, women attended the postpartum clinic. Clinic staff followed up with participants if they failed to keep the mandatory follow-up appointment. The first appointment included maternal assessment and care (e.g. wound care, prescriptions), neonatal care (e.g. weight gain assessment, jaundice screening), blood work including total serum bilirubin (TSB), and breastfeeding assessment and support. Family physicians were available for on-site consultations in the mornings, and LCs and registered nurses were at the clinic throughout the day. Additional follow-up visits were offered to participants as clinically indicated and as many times as they desired up to a maximum of 6 weeks following the birth of their baby</p> <p>Control (n= 157): after hospital discharge, participants were entitled to receive follow-up care and seek breastfeeding support currently available in the community (e.g. through their family doctor, Public Health Unit or private services), but could not attend the postpartum clinic</p>	
Outcomes	<p>Primary: exclusive breastfeeding at 12 weeks postbirth (additional breastfeeding information regarding partial breastfeeding, expressed breast milk and formula feeding was also collected)</p> <p>Secondary:</p> <ul style="list-style-type: none"> <li>Mother Satisfaction Survey</li> <li>Breastfeeding self-efficacy</li> <li>Postpartum depression</li> <li>Use of healthcare resources</li> </ul>	
Notes	All phases of this study were supported by the Ontario Ministry of Health and Long-Term Care	

*Risk of bias*

*Risk of bias*

**Laliberte 2016** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Group designation was given from a randomisation list, generated using a permuted randomized block design, with permutation block sizes of 3, 6, and 9 units, prior to study initiation by an external statistician
Allocation concealment (selection bias)	Low risk	Study researchers, recruiters, and participants were blinded to the randomisation allocations prior to patient randomisation and enrolment into the trial
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women were informed of their randomisation group. Clinicians were also aware of group allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	Study staff were not blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition to 6 months was 14% in the intervention group and 12% in control group
Selective reporting (reporting bias)	High risk	Breastfeeding at 24 weeks is not identified as an outcome in the paper or the protocol, but was reported in table 4
Other bias	Low risk	

**Leite 2005**

Methods	2-arm RCT, with individual randomisation, n = 1003. Participants recruited from 8 public health maternity units, duration of recruitment 6 months
Participants	Urban Brazil Background rates of breastfeeding initiation: high Inclusion criteria: healthy babies, weighing < 3000 g Exclusion criteria: twins, important health problems in mother or child
Interventions	Peer counsellor home visits lasting 30-40 min at 5, 15, 30, 60, 90 and 120 days. Counsellors were from same social group as women they supported, had personal experience of breastfeeding and had been associated with maternity unit milk bank for a minimum of 5 years. Trained with adapted WHO breastfeeding counselling course (20 h). Paid BRL4 per visit. Each counsellor supported 25 mothers
Outcomes	Rates of exclusive, predominant, partial and artificial feeding at 4 months

**Leite 2005** (Continued)

Notes	This is the only study in this review that targeted babies with birthweight below 3000 g. We considered excluding it from this review as the paper did not state the babies had to be born at term and did not specify a lower limit for birthweight. However as the babies had to be 'free of important health problems' we considered them to be healthy and therefore included this study
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<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Computer-generated random number table
Allocation concealment (selection bias)	Low risk	Study secretary opened a sealed envelope that contained the study code
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Did not describe whether mothers, lay workers or health professionals were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Authors state that the "interviewers had not had any prior contact with the mothers and were also unaware as to the objectives of the research (blinding)"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	1003 women randomized. 14% lost to follow-up by the end of 4 months. Reasons for loss to follow-up were not described but the loss appeared balanced across the 2 groups
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Low risk	No baseline imbalance apparent.

**Lucchini 2013**

Methods	Parallel 2-arm RCT, single site, n = 770
Participants	<p>Maternity ward at the Sotero del Rio Hospital, Santiago, Chile. Programme delivered by South East Metropolitan Health Service in conjunction with the Catholic University of Chile</p> <p>Background breastfeeding initiation rates: on this ward 79.4% of the live births were fed with exclusive breastfeeding (EBF) up to 1 month of age and 67.3% were fed in this manner until 3 months of age. This was similar to national figures</p> <p>Inclusion criteria: pregnancy without illness or risk factors which required more intensive maternal and/or perinatal monitoring during the process of labour and delivery, spon-</p>

	<p>taneous initiation of labour , gestational age between 37 + 0 and 41 + 0 weeks, single pregnancy, live fetus and cephalic presentation</p> <p>Exclusion criteria: women with illnesses or risk factors that required more intensive maternal and/or perinatal monitoring</p>
Interventions	<p>Intervention (n = 384): 'comprehensive care' consisting of family member who accompanied the woman from admission to discharge, 24 h/day, and who participated actively throughout the period. Labour took place in a comprehensive room with constant care, with early skin-to-skin contact of at least 1 h and encouragement of early initiation of breastfeeding (positive covariates for EBF). During the immediate postpartum period personalised educational support was delivered by the healthcare team. Early discharge with comprehensive intervention (after 24 h) was complemented by a home visit (after 48 h) where the mother's and baby's care was reinforced, as well as the breastfeeding technique in a family setting</p> <p>Control (n = 386): 'traditional care', i.e. standard care from the public health system. This involved labour management interventions (negative covariates for EBF) with intermittent and passive family participation. Early skin-to-skin contact was performed without any standardised guidelines and mother and child room-sharing began once the newborn had received immediate care. During the postpartum period, professional and technical support was given for the start of breastfeeding in the postnatal unit</p>
Outcomes	Prevalence of exclusive breastfeeding at 8, 16 and 24 weeks
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The pregnant women were assigned randomly to both forms of intervention, using a randomized block design of 6-8 women, so that in each block an equal number of women were assigned to each group but not clear how sequence was generated
Allocation concealment (selection bias)	Unclear risk	No details provided to enable us to judge this.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Did not state whether women or staff providing intervention were blinded, but unlikely
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not stated whether the data collectors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up was 85.9% in the intervention group and 82.6% in the control group. There were no significant differences between the

Lucchini 2013 (Continued)

		women lost to follow-up and those who remained in the study. The number of cases lost to follow-up (15.7%) was mainly due to a change of telephone number and address (Figure 1) For this reason it was expected that those lost to follow-up were 'missing at random'
Selective reporting (reporting bias)	Unclear risk	No protocol or document with predefined outcomes available. This paper focused on data collected at 8 weeks. Data collected at 16 and 24 weeks were not reported and no explanation was given
Other bias	High risk	Intervention contained other components which may influence breastfeeding, including 24-h family participation during hospital stay and these different birth experiences are also important

Lynch 1986

Methods	2-arm RCT, with individual randomisation, single-site study, duration of recruitment not stated, n = 270
Participants	Urban Canada - maternity unit of regional general hospital Background rates of breastfeeding initiation: intermediate. Baseline prevalence (1984) = 69% breastfeeding initiation (75% stopping by 6 months) Inclusion criteria: intending to breastfeed; English-speaking Exclusion criteria: multiple births; birthweight < 2500 g; birth before 37 weeks Participant characteristics: 41% were primiparous; ethnic composition not described; socioeconomic status defined by Blishen scale for husband's occupation (62% groups 2-3)
Interventions	Intervention: combination of home visit by breastfeeding consultant within 5 days of hospital discharge (duration 2 h) and weekly telephone calls by the consultant for 1 month, then monthly from 2-6 months Control: postpartum home visit by public health nurse who gave breastfeeding advice determined largely by the questions and concerns of the mother
Outcomes	Duration of breastfeeding
Notes	

*Risk of bias*

*Risk of bias*

Bias	Authors' judgement	Support for judgement
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**Lynch 1986** (Continued)

Random sequence generation (selection bias)	Unclear risk	Not described "we randomly allocated 270 new mothers".
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It was not stated whether the women, public health nurses or LCs were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The interviewer conducting the questionnaire was not aware of the study group status
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appeared to be little loss to follow-up; 270 women were randomized and questionnaire data were acquired from 256 (5% attrition); 3 women were lost from the intervention group vs 11 from the control group
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Little information about the methods. Possible confounders included: significant differences in baseline characteristics for parity ( $P = 0.02$ ) and intention to return to work ( $P = 0.05$ )

**McDonald 2010**

Methods	2-arm RCT, recruitment March 2000-October 2001 n=849
Participants	Large university teaching hospital in Victoria, Australia Background rates of breastfeeding initiation: high. Baseline prevalence of breastfeeding in Australia = 83% at hospital discharge Participants were women intending to breastfeed their term infants, and were stratified by tertiary education and parity
Interventions	Intervention (n = 425): Extended Midwifery Support (EMS); women received an in-hospital postnatal education session. Postdischarge, they were offered home support visits with a research midwife once a week and telephone contact at least twice a week for 6 weeks Control (n = 424): Standard Midwifery Support (SMS); women received routine midwifery support and information according to the hospital protocol. The study hospital was working towards Baby-Friendly accreditation during data collection (achieved in 2004)

McDonald 2010 (Continued)

Outcomes	Any breastfeeding and exclusive breastfeeding at 6 months	
Notes		
<b>Risk of bias</b>		<b>Risk of bias</b>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Sample stratified by educational level and parity. Methods not clear
Allocation concealment (selection bias)	Unclear risk	Paper stated "Women were asked to select an envelope from a group of at least 6 sealed, opaque envelopes, replenished in blocks of 12. The envelopes contained the allocation to either the intervention or control group"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No detail provided on blinding of participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No detail provided on data collection so judgement not possible
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	849 women randomized. Loss to follow-up was reported by group at 2 months (intervention 83/425, 19.5% vs control 124/424, 29.2%) and at 6 months (intervention 8/425, 1.9% vs. control 4/424, 0.9%)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Abstract did not include details of allocation concealment, outcome assessment or loss to follow-up. Outcomes included in the abstract were reported by ITT

McKeever 2002

Methods	2-arm RCT, individual randomisation, n = 101
Participants	Setting: study carried out in Canada Inclusion criteria: live, singleton, term or near term infant delivered in 12 h before recruitment; women ≥ 21 years residing in defined study area, intending to breastfeed and with satisfactory home circumstances (assessed by postpartum nurses)

McKeever 2002 (Continued)

	Exclusions: non-English-speaking women, caesarean delivery, postpartum complications, infants with congenital abnormalities or morbidity
Interventions	Intervention: planned early discharge from hospital (24 h-36 h postpartum) and up to 3 home visits by community nurse LCs. Content of support unclear. The study aimed to compare of breastfeeding support in home and hospital settings Control: planned hospital discharge 48 h-60 h postpartum (usual care) with hospital based support for breastfeeding
Outcomes	Exclusive breastfeeding at 5-10 days postpartum and satisfaction with care
Notes	We have not included data from this study in the review. Outcomes were not assessed at the same time in the intervention and control groups (mean day of follow-up was 8.4 days in the intervention group vs 7.8 days for controls) and there was high attrition (26% overall, with 33% loss to follow-up in the control group)

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Central randomisation
Allocation concealment (selection bias)	Low risk	Central randomisation by staff not concerned with the study.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Blinding was not possible for the mothers or nurses as the experimental treatment (i.e. discharge to the home-based lactation support) was known."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Interviewers were originally blinded to group status. However, in the course of answering questions about postpartum care and satisfaction, mothers inadvertently revealed their group status."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Outcomes were not assessed at the same time in both groups and there was high attrition (26% overall, with 33% loss to follow-up in the control group)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Quote: "At baseline, no differences in maternal age, parity or gestational age were found in the two groups."

**McLachlan 2016**

Methods	3-arm cluster-controlled trial, single site, n = 9675
Participants	<p>Local government authorities (LGA) in Victoria, Australia - community-based maternal and child health centres</p> <p>Background rates of breastfeeding initiation: only rates at 6 months detailed. Ranged from 32% to 68% in different LGAs in Victoria</p> <p>Inclusion criteria: LGAs in Victoria with a lower rate of any breastfeeding at discharge from hospital than the Victorian state average; and &gt; 450 births per year. For the postal survey women were recruited on the basis of giving birth during the intervention time-frame in all participating LGAs</p> <p>Exclusion criteria: LGAs with breastfeeding initiatives in place similar to the proposed interventions. Women living in participating LGAs were not sent an invitation to take part in the postal survey if it was known that either they or the infant died, they had moved to another LGA since the birth or they were not enrolled in the Maternal and Child Health Service</p>
Interventions	<p>Intervention 1 (n = 3335): home visiting only (HV) - early home-based visiting by a maternal and child health nurse (MCHN) to women identified at risk of breastfeeding cessation. Aimed to provide proactive breastfeeding assistance as early as possible after birth. The focus of the visits were the normalisation of breastfeeding, building women's confidence to breastfeed, reassurance, development of an infant feeding plan (where needed), and provision of a list of useful web sites and telephone numbers. The topics covered at individual visits were driven by the specific needs of the woman</p> <p>Intervention 2 (n = 2891): HV + access to a drop-in centre - women received home visit service as above and could attend local community breastfeeding drop-in centre staffed by a MCHN, and where possible with a trained peer supporter or community educator or counsellor. Also provided mothers with the opportunity to meet and learn from other mothers. The centre was widely advertised</p> <p>Control (n=3449): Usual care. Midwife visit 1-2 days after discharge and then MCHN visit 10-12 days after discharge (breastfeeding assessment, support and advice a core component of care). Then MCH centre based care thereafter</p>
Outcomes	<p>Primary: any breastfeeding at 4 months</p> <p>Secondary: any breastfeeding at 3 and 6 months</p>
Notes	

***Risk of bias***

***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Envelopes shuffled
Allocation concealment (selection bias)	Low risk	Allocation to trial arms took place using opaque envelopes at a state-wide MCH forum

**McLachlan 2016** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding "was not possible at the LGA (randomisation) or cluster levels; however, individual women in the LGAs were not aware of the intervention allocation-the intention was that any trial arm allocation was 'standard' care within the LGA during the intervention period". However it is not clear if this was successful and whether staff were blinded or not
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessment by participant-completed questionnaire sent by mail, but not stated if those analysing the data were blinded to allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	High loss to follow-up at 4 months in control group (69% of women followed-up) and home visiting group (68% of women followed up), Follow-up was higher in home visiting plus group, with 81% of women followed up
Selective reporting (reporting bias)	Low risk	Not all secondary outcomes listed in protocol were reported, but these were not outcomes of interest in this review so we marked this trial as being at low risk of bias
Other bias	Unclear risk	Significant differences in proportion of Australian-born women in across the groups (69% in comparison LGAs; 58% in home-visiting LGAs; 73% in home-visiting plus drop-in centre LGAs). Unclear whether this could have an impact

**McQueen 2009**

Methods	2-arm RCT, single site, n = 150
Participants	<p>Conducted at a tertiary care centre located in Northwestern Ontario, Canada</p> <p>Background breastfeeding initiation rates: 87.3%</p> <p>Inclusion criteria: English-speaking, primiparous mothers who gave birth to a single, healthy, term infant whom they were planning on breastfeeding</p> <p>Exclusion criteria: any condition that could significantly interfere with breastfeeding, such as a serious illness, an infant with a congenital anomaly, or requiring special care that would not be discharged home with the mother</p>

Interventions	Intervention (n = 69): participants received 3 individualized, self-efficacy enhancing sessions with the researcher: 2 in-hospital and 1 by telephone in the early postpartum period. The first session occurred after randomisation and within 24 h of delivery. The second session also took place in-hospital, ideally within 24 h of the first session. In addition, observation of breastfeeding at 1 of the 2 in-hospital sessions was planned to try to maximize performance accomplishment (successful breastfeeding). The third session occurred via telephone within 1 week of hospital discharge Control (n = 81): standard in-hospital and community care
Outcomes	Primary: feasibility, compliance, and the acceptability of the breastfeeding self-efficacy intervention Secondary: breastfeeding self-efficacy, duration, and exclusivity
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Randomisation was achieved using consecutively numbered, sealed opaque envelopes containing group allocations generated by an experienced researcher not involved in the trial
Allocation concealment (selection bias)	Low risk	Randomisation was achieved using consecutively numbered, sealed opaque envelopes containing group allocations generated by an experienced researcher not involved in the trial
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding was not possible.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Mothers were telephoned by a research assistant who was blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition in intervention group was 11.5% and 13.6% in the control group
Selective reporting (reporting bias)	Unclear risk	No trial registration document with prespecified outcomes.
Other bias	Low risk	None identified

Methods	Pilot RCT (n = 150), March-July 2008
Participants	<p>Recruitment from 1 hospital in Northwestern Ontario, Canada, the sole provider of maternity care for the city and regional referral centre</p> <p>Background rates of breastfeeding initiation for Canada: intermediate, however, baseline prevalence of 'ever breastfed' in Ontario 90.6% (WHO Global Data Bank on Infant and Young Child Feeding accessed 12 Oct 2011)</p> <p>Inclusion criteria: English-speaking, primiparous, planning on breastfeeding, with single, healthy, term infants</p> <p>Exclusion criteria: conditions that could significantly interfere with breastfeeding such as serious illness, infant with congenital anomaly or admitted to special care</p>
Interventions	<p>Intervention: standard in-hospital and community postpartum care plus a 1-to-1 self-efficacy intervention from the researcher (a Registered Nurse with practice, education, and research experience working with breastfeeding mothers). The intervention included assessment of the mother's breastfeeding goals and breastfeeding self-efficacy and her general physiologic and affective state; strategies to increase breastfeeding self-efficacy; evaluation, and planning the next session. There were 3 contacts, 2 face-to-face in hospital on days 1 and 2 after the birth, and 1 phone call up to 7 days after hospital discharge</p> <p>Control: standard in-hospital and community postpartum care, which included a visit by a public health nurse after hospital discharge</p>
Outcomes	Feasibility, compliance, and acceptability of the intervention, breastfeeding confidence (self-efficacy scores), any and exclusive breastfeeding at 4 and 8 weeks
Notes	Paper stated "Observation of breastfeeding at 1 of the 2 in-hospital sessions was planned, to try to maximise performance accomplishment (successful breastfeeding)"

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Group allocations generated by an experienced researcher not involved in the trial
Allocation concealment (selection bias)	Low risk	Consecutively numbered, sealed opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and the caregivers were not blinded due to the nature of the intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes at 4 and 8 weeks postpartum were collected during phone interview by research assistant reported to be blind to group allocation

McQueen 2011 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes measured at 8 weeks in 134/150 (89%). Loss to follow-up was balanced across groups. For breastfeeding outcomes we have carried out an ITT analysis
Selective reporting (reporting bias)	Unclear risk	No baseline differences between groups apparent.
Other bias	Unclear risk	Baseline characteristics were similar.

Mejdoubi 2014

Methods	2-arm parallel RCT, single site study, n = 460	
Participants	<p>20 municipalities in the Netherlands, demographics not described</p> <p>Background rates of breastfeeding initiation: not described</p> <p>Inclusion criteria: ≤ 25 years, low educational level (primary school or prevocational secondary school), maximum 28 weeks of gestation, no previous live birth, understood Dutch, and at least 1 of the following additional risk factors: no social support, previously or currently experiencing domestic violence, psychosocial symptoms, unwanted and/or unplanned pregnancy, financial problems, housing difficulties, no education and/or employment and alcohol and/or drug use</p> <p>Exclusion criteria: previous live births, no additional risk factor as detailed above</p>	
Interventions	<p>Intervention (n = 237): the VoorZorg programme - a home visitation programme translated and culturally adapted from the Nurse Family Partnership (NFP) programme. In addition to usual care, women received approximately 10 home visits during pregnancy, 20 during the first life year of the child and 20 during the second by trained, specialised VoorZorg nurses. 6 domains were discussed during the home visits: 1) the health status of the mother, 2) the child's health and safety, 3) the personal development of the mother, 4) the role of the mother, 5) the mother's relation with her partner, family and friends, and 6) the use of (health) care organizations. During pregnancy, women receiving the VoorZorg intervention were encouraged to initiate and continue breastfeeding after childbirth. The VoorZorg nurse also discussed the problems women encountered when breastfeeding their child and worked together with the mother to seek solutions to continue breastfeeding. The VoorZorg nurses also aimed to reduce smoking with the V-MIS smoking cessation programme</p> <p>Control (n = 223): usual care provided by the Dutch Youth Health Care Organizations. Every pregnant women received care by a midwife including health education, physical examination and monitoring fetal development. The baby was automatically registered at an ambulatory well baby clinic for monitoring after birth and the parents were supported in parenthood</p>	
Outcomes	<p>Primary:</p> <p>Prevalence of cigarette smoking (percentage of smokers and average number of cigarettes smoked a day)</p> <p>Average number of cigarettes smoked a day near the baby</p> <p>Birthweight</p>	

	<p>Weeks of gestation          Adverse pregnancy outcome (LBW, prematurity)          Breastfeeding initiation          Breastfeeding at 6 months          Secondary:          Any breastfeeding at 3 and 6 months</p>
Notes	<p>The Netherlands Organisation for Health Research and Development (ZonMw), Academic Collaborative Centre, Child Health Care-North Holland/VU University Medical Center, participating Youth Health Care organizations and ZonMw Geestkracht, and participating city councils provided funding for the implementation of this study</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Computer generated list of random numbers
Allocation concealment (selection bias)	Unclear risk	Independent randomisation procedure performed by a researcher at VU university
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and staff were not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The interviewers were blinded regarding allocation but this may have been disclosed during interview
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up in control group was 18% and 8.4% in intervention group; authors stated baseline characteristics of women who were lost to follow-up in each measurement were similar to women who remained in the study
Selective reporting (reporting bias)	Low risk	Protocol included domestic violence, child development and child abuse as primary outcomes, but these were not reported in the results section. Breastfeeding was not reported as an outcome in the protocol, but was included as a primary outcome in the results paper. Authors stated that prevalence of babies with low birthweight, being premature or being small for gestational age, was similar in both groups

Mejdoubi 2014 (Continued)

Other bias	Low risk	None identified
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Mongeon 1995

Methods	Quasi-RCT (drawing numbered tickets), single site, duration of recruitment not stated, n = 200, follow-up 97%
Participants	Urban Canada Background rates of breastfeeding initiation: intermediate Inclusion criteria: women who wished to breastfeed and who had not previously breastfed Participant characteristics: 97% primiparous, ethnic composition not stated, 57% had received education to college or university level, no specific socioeconomic classification used
Interventions	Intervention: home visit by volunteer during last month of pregnancy followed by telephone contacts weekly for 6 weeks and then 2 weekly to 5 months or until weaning. Volunteers were women who had breastfed themselves and had received 3 training sessions of 3 h duration followed by on-going monthly supervision sessions. Average caseload was 1-3 cases at any 1 time Control: received home visit from public health nurse during the first month after birth followed by other contacts (face-to-face or by telephone) as determined by the mother
Outcomes	Breastfeeding rates at 1, 2, 3, 4 and 6 months
Notes	

**Risk of bias**

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation by "drawing numbered papers"
Allocation concealment (selection bias)	Unclear risk	Not clear
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Article in French, unable to judge blinding of participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was an attempt to blind outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reasons for drop-out recorded; 200 randomized, 3 babies died and 3 other women lost to follow-up

**Mongeon 1995** (Continued)

Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Not clear over what time period women were recruited or whether controls and intervention women were recruited at the same time. Quote: "Subjects were recruited during various periods of time, depending on the availability of volunteers"

**Morrell 2000**

Methods	2-arm RCT, individual randomisation, single-site study recruiting over 14 months, n = 632	
Participants	Urban UK Background rates of breastfeeding initiation: intermediate. National baseline prevalence 66% breastfeeding at birth and 42% at 4 months. Exclusive breastfeeding 21% at 4 months Inclusion criteria: English-speaking women, ≥ 17 years, who gave birth at the study hospital Exclusion criteria: baby spent > 48 h on the SCBU	
Interventions	Intervention: community postnatal support worker with 8 weeks' training provided home-based support of up to 10 visits in the first 28 days (maximum of 3 h/visit) Control: standard UK care (includes postnatal home visits from midwives and health visitors)	
Outcomes	Exclusive or any breastfeeding at 6 weeks and 6 months	
Notes	Study population not limited to those intending to breastfeed Women consenting to participation more likely to be white and have had a CS	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Random number tables
Allocation concealment (selection bias)	Low risk	Sequentially numbered sealed opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details provided about blinding of participants and personnel

**Morrell 2000** (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details provided about blinding of outcome assessment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	623 women randomized; stated that analysis was by ITT; 30 women who declined visits were included in the analysis; 78% follow-up
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	There was some baseline imbalance between groups. Women in the intervention group were more likely to have twins (9 vs 1), to have another adult resident in their household and to have used TENS in labour

**Morrow 1999**

Methods	Community-based cluster-randomised study; recruitment over 18 months, n = 130
Participants	Peri-urban Mexican community Background rates of breastfeeding initiation: high All pregnant or postnatal women were in 39 geographical clusters. Perinatal death only clinical exclusion criterion. Baseline breastfeeding prevalence: 92% initiation; 4% exclusivity at 2 weeks and 3 months; 50% cessation by 6 months
Interventions	Home visits were conducted by peer-counsellors trained by La Leche League (7 days theoretical teaching/2 months in lactation clinics and with mother-to-mother support groups), personal breastfeeding experience was not essential Intervention 1: 6 visits (mid and late pregnancy and at 1, 2, 4 and 8 weeks) Intervention 2: 3 visits (late pregnancy and 1 and 2 weeks) Control: not specified
Outcomes	Breastfeeding at 3 and 6 months Incidence of diarrhoea in infants 0-3 months
Notes	Subgroup analysis: antenatal and postpartum support; proactive intervention with scheduled contacts at home; initial face-to-face contact; intervention delivered by trained counsellors

*Risk of bias*

*Risk of bias*

Bias	Authors' judgement	Support for judgement
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**Morrow 1999** (Continued)

Random sequence generation (selection bias)	Low risk	Cluster-randomisation, clusters stratified by area, randomisation schedule generated by computer
Allocation concealment (selection bias)	Low risk	Clusters randomized by computer.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Clusters randomized to avoid contamination, but women and counsellors would have been aware of intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome measurement was by staff who were aware of group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	130 women from 31 cluster areas randomized; 125 followed up at 3 months and 104 at 6 months (20% attrition at 6 months)
Selective reporting (reporting bias)	Unclear risk	How cluster design was taken into account was not clear. It was stated that ICC values were 'negligible' and the authors stated "these results show that the cluster-randomisation design achieved the equivalent of individual randomisation"
Other bias	Unclear risk	No baseline imbalance apparent, although group size was uneven (this may have been due to chance)

**Muirhead 2006**

Methods	2-arm RCT, with individual randomisation, n = 225
Participants	Setting: general practice in Ayrshire, Scotland Background rates of breastfeeding initiation: low Inclusion criteria: women at 28 weeks' gestation attending for antenatal care at a GP practice Exclusion criteria: not described Participant characteristics: Mean age of intervention group: 28.5 years; SD 5.2; range 17-43. Mean age of control group: 27.8 years; SD 5.5; range 16-40 Parity: 53% primiparous
Interventions	Intervention (n = 112): women were assigned 2 peer supporters (women with previous breastfeeding experience) who contacted them at least once in the antenatal period and provided further antenatal support on request. In the postnatal period after hospital discharge peer supporters contacted women who were still breastfeeding at least every 2 days by phone or by home visit up until 28 days, and further support was available up

Muirhead 2006 (Continued)

	to 16 weeks postpartum Control (n = 113): standard care that included visits from community midwife for the first 10 days, health visitor after 10 days; breastfeeding support groups and breastfeeding workshops were available
Outcomes	Initiation of breastfeeding, any and exclusive breastfeeding at 6 weeks and 6 months, median breastfeeding duration and reasons for giving up breastfeeding
Notes	The researchers noted that “health professionals varied in their commitment to breastfeeding and also in their acceptance of lay assistance, such as peer support”

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation sequences for each stratum (primagravidae, previous formula feeding, previously breastfed < 6 weeks, previously breastfed > 6 weeks) were generated at the start of the trial by computer in blocks of 10 (that is, 5 random allocations to each of the peer support and control groups in each different block of 10) to give approximate numerical balance between groups
Allocation concealment (selection bias)	Low risk	Allocation to control or peer support group was by post-recruitment concealed allocation, with a telephone call for the next allocation on the list
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: “There was no post-allocation concealment as once a woman was allocated to the peer support or control group this was known to the peer supporters and others associated with the trial.”
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The questionnaire were completed in the presence of a GP or practice nurse. It is also stated that trial team were not involved in the questionnaire completion. Unclear if the GP or practice nurse would have been aware of group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low loss to follow-up. Peer support group (intervention group) (n = 112): at 16 week follow-up, n = 110; control group (n = 113): at 16 week follow-up, n = 110

**Muirhead 2006** (Continued)

Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Planned recruitment was for 320 women but ended after 225 women recruited, therefore the study had reduced power to detect differences between groups Few demographic data were reported so it was not clear whether or not there was baseline imbalance, although recruitment was balanced for parity by stratification

**Ochola 2013**

Methods	3-arm cluster-controlled trial, single-site study, n = 360 (note only 2 arms included in analysis)
Participants	Kibera slum, Nairobi, Kenya - a densely populated area that was not well served with basic services such as health facilities, adequate safe water and sanitation services Background rates of breastfeeding initiation: no data on initiation, but for Kenya the exclusive breastfeeding rate for infants under 6 months was 32.0% Inclusion criteria: in the third trimester of pregnancy (34-36 weeks' gestation), HIV-negative, intention to stay in Kibera for at least 6 months after delivery, willing to be visited at home, willing to be included in the study Exclusion criteria: documented chronic diseases such as diabetes mellitus, renal disease, heart disease or any other chronic disease, and eclampsia in a previous pregnancy
Interventions	Intervention 1 (n = 120): home-based intensive counselling group (HBICG); mothers received 7 counselling sessions: prenatally, the first week after delivery and then monthly up to 5 months postpartum. The content was similar to the facility-based semi-intensive counselling group (FBSICG; see Intervention 2) but was more tailored to the mother's needs and more detailed. Women also had more practical exposure with regard to supporting breastfeeding (e.g. positioning, attachment, expression of milk). Counsellor training was the same as for FBSICG Intervention 2 (n = 120): FBSICG; note this intervention was an antenatal one only, so not included in this review). Consisted of 1 session of 1-to-1 counselling at the health centre conducted by the investigator and breastfeeding counsellors. The breastfeeding counsellors were 3 local women trained in accordance with the WHO/UNICEF counselling course (40 h). The counselling content was structured around the benefits of exclusive breastfeeding; preparation for breastfeeding initiation and sustainability of breastfeeding; positioning and attachment of baby to the breast during feeding; and prevention and management of breastfeeding challenges. The single session took place after enrolment into the study. Control (n = 120): usual standard health and nutrition education offered at the health centre. This was a group-based education programme which covered breastfeeding and a range of other topics

Ochola 2013 (Continued)

Outcomes	Primary: exclusive breastfeeding at 1, 3 and 6 months Secondary: cumulative (since birth exclusive breastfeeding at 6 months)
Notes	Funded by Nestle.

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Computer generated using Excel for randomisation of the clusters
Allocation concealment (selection bias)	Low risk	Method of concealment not described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Paper stated that only the investigator and peer counsellors were aware of the treatment given and knew the hypothesis. The nurse in charge was blinded to the intervention allocation. It was not clear if the women were aware of the allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The enumerators conducting the interviews to determine breastfeeding practices were blinded to the study hypotheses to avoid any likelihood of bias in the way they asked questions, even though they were trained to ask questions in a standard way. There was no contact between the enumerators and the breastfeeding counsellors
Incomplete outcome data (attrition bias) All outcomes	High risk	Follow-up in both intervention and control groups was 74.2%. The analysis was as-treated and not ITT. Younger women were significantly more likely to be lost to follow-up
Selective reporting (reporting bias)	Unclear risk	No evidence of a study protocol to judge whether all predefined outcomes were assessed
Other bias	Unclear risk	Funded by Nestle.

Methods	2-arm RCT, n = 1154
Participants	<p>Pennsylvania, USA</p> <p>Background rates of breastfeeding initiation: no details provided</p> <p>Inclusion criteria: singletons and twins born after at least 34 weeks' gestation to English-speaking mothers attempting to breastfeed during the maternity stay and with intent to continue breastfeeding after discharge</p> <p>Exclusion criteria: atypical stays characterised by: 1) a 2-night or longer stay after a vaginal delivery; 2) a 4-night stay or longer after a cesarean section; 3) a hospital course with atypical complications (e.g. ambiguous genitalia, endometritis); or 4) newborn hyperbilirubinemia requiring phototherapy during the nursery stay. Mothers were also excluded for major morbidities and/or pre-existing conditions that would affect postpartum care, lack of a telephone number, previous study participation, residence outside the coverage region of the Visiting Nurse Association of Central Pennsylvania (VNA), or if a home nursing visit was specifically requested by a hospital social worker or child protective services owing to social concerns</p>
Interventions	<p>Intervention (n = 576): 1 home nursing visit within 48 h of hospital discharge (typically 3-5 days post birth). All nurses received continuing education related to breastfeeding support and cultural competency prior to study initiation. All newborns in intervention group were scheduled for an office-based visit 1 week after the visit to assess weight and recovery</p> <p>Control (n = 578): office-base care; postdischarge visit timing for newborns was determined by the newborn nursery physician</p>
Outcomes	<p>Primary: maternal and infant use of unplanned health care services in the 14 days after delivery</p> <p>Secondary:</p> <p>Breastfeeding duration and exclusivity</p> <p>Maternal postpartum depression</p> <p>State of anxiety</p> <p>Perceived social support</p> <p>Parenting self-efficacy</p>
Notes	

**Risk of bias****Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence
Allocation concealment (selection bias)	Unclear risk	No information provided about allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not detailed whether mothers and/or home visiting nurses were blinded

**Paul 2012** (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Telephone interviews with mothers conducted by study coordinators blinded to study group
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	8% attrition by 2-week telephone interview; 13% attrition at 2-month telephone interview. However, at 6 months attrition was 31% in the home nursing visit group and 38% in the office-based care group
Selective reporting (reporting bias)	Unclear risk	Outcomes not stated in Clinicaltrials.gov record. Unclear whether 'any breastfeeding' or 'exclusive breastfeeding' were reported, but both should have been, however, additional information received from author included both
Other bias	Low risk	

**Petrova 2009**

Methods	2-arm RCT, with individual randomisation, n = 104
Participants	Setting: maternal and paediatric clinic for low-income inner-city population (New Jersey, USA) Background rates of breastfeeding initiation in this population: high Inclusion criteria: WIC program-qualified pregnant women in the third trimester of a singleton pregnancy without HIV, cancer, or illegal drug use Participant characteristics: 87.5% of the women were of Hispanic origin, 89% spoke Spanish at home, 30% were single, approximately 70% were educated to less than high school level. 37% of the intervention group, compared with 42% of controls, were expecting their first child
Interventions	Intervention (n = 52): in addition to routine care, allocated to 2 individual educational/support sessions with a LC in the third trimester of pregnancy lasting 15-20 min. After birth the LC provided support at the hospital or by phone soon after discharge, with further phone support after the first or second week then after 1 and 2 months. The participants were asked to contact the LC if they experienced any breastfeeding problems Control (n = 52): routine breastfeeding education and support during the pregnancy and postpartum. LC services were available for all postpartum women if any breastfeeding problems arose during the hospital stay
Outcomes	Exclusive and any breastfeeding at 7 days and 1, 2 and 3 months postpartum
Notes	Among multiparous participants, 27/29 (93%) in the intervention group had previously breastfed, compared with 17/25 (68%) in the control group

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>

Petrova 2009 (Continued)

Random sequence generation (selection bias)	Low risk	Quote: “We used computer generated random numbers to assign women to the control and intervention groups. Each random number was related to an ordinal number that was assigned to the woman once she assigned the informed consent.”
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details provided to enable a judgement.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details provided to enable a judgement.
Incomplete outcome data (attrition bias) All outcomes	High risk	104 women randomized. 82% available to follow-up at 1 month (data included in the review) 70% of women followed up for 3 months (35/52 in intervention group completed the 3-month follow-up (loss of 17); 38/52 in the control group completed the 3-month follow-up (loss of 14)) High attrition, but reasons for loss were given and balanced across groups (e.g. phone disconnected; women did not answer phone; some women did not notify the research team about their delivery)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	There was some baseline imbalance between groups that meant that differences between groups were difficult to interpret. Of the multiparous women 93% in the intervention group had previous breastfeeding experience compared with 68% in the control group. More women in the control group had a CS (40% vs 14%). Both of these differences possibly relate to breastfeeding outcomes

**Porteous 2000**

Methods	2-arm RCT with individual randomisation, single-site study, recruiting over 3 months, n = 52
Participants	Urban Canada Background rates of breastfeeding initiation: intermediate Baseline breastfeeding prevalence at 4 months: approximately 33% Inclusion criteria: singleton pregnancy, healthy mother and child, vaginal delivery, self-identified on breastfeeding questionnaire as unsupported
Interventions	Intervention: breastfeeding support from the researcher, a community midwife, consisting of daily visits in hospital, telephone call within 72 h of discharge and weekly through the fourth week postpartum, and at least 1 home visit (in the first week), with further home visits as required. Home visits lasted 60-90 min Control: hospital care from any member of the mother-child nursing team
Outcomes	Exclusive and partial breastfeeding at 4 weeks
Notes	

***Risk of bias***

***Risk of bias***

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Computerised block randomisation procedure (stratified by planned length of breastfeeding, parity and education)
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	52 randomized, 51 appeared to complete the study, follow-up was 98%
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Recruitment limited by availability of investigator. No baseline imbalance apparent

**Pugh 1998**

Methods	2-arm RCT, with individual randomisation n=60
Participants	Women were recruited at a community hospital in the USA and had diverse socioeconomic status Background rates of breastfeeding initiation: intermediate Inclusion criteria: women who experienced vaginal deliveries after full-term pregnancies Exclusion criteria: not stated Participant characteristics: mean age: 24.4 years; married n = 47 (78%); white n = 55 (93%); completed high school n = 58 (97%); income of USD ≤ 20,000 n = 13 (22%)
Interventions	Standard care included routine breastfeeding support in hospital following delivery Intervention: 2 home visits by a professional community health nurse and phone call from a qualified LC. The nurse provided a structured teaching and support protocol. The focus of the first visit was to enhance breastfeeding. For the second visit, of up to 2 h duration, mothers could choose the content from options including help with dishes or laundry. Most chose education or infant assessment; 2 asked for child care help so they could rest and/or spend time with a partner Control: home visit on day 3 or 4 by a hospital nurse (not specifically about breastfeeding)
Outcomes	Primary: duration of breastfeeding Secondary: fatigue, symptoms of anxiety and depression
Notes	

**Risk of bias**

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomly assigned to the treatment (n = 30) or control group (n = 30)
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and caregivers were not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome data were collected by a research assistant (by telephone). It was not clear whether blinding was achieved
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear. Loss to follow-up was not mentioned and denominators were not provided for the results
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this

**Pugh 1998** (Continued)

Other bias	Unclear risk	Little information was provided on study methods. No information provided about how many women were followed up, blinding, or how randomisation occurred
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**Pugh 2002**

Methods	2-arm RCT, single-site study, recruitment April 1999-February 2000, n = 41; 21 assigned to intervention and 20 to control group	
Participants	Community intervention in urban USA Background rates of breastfeeding initiation: low Inclusion criteria: low-income women receiving financial medical assistance Exclusion criteria: not stated Ethnic composition: 95.2% African American	
Interventions	Intervention: breastfeeding support visits by community health nurse/peer counsellor team. Support offered daily when in hospital, and at home during weeks 1, 2 and 4 and at the team's discretion. Telephone support from peer counsellor twice weekly through to week 8 and monthly through to month 6 Control: usual breastfeeding support consisted of support from hospital nurses, assistance by means of a telephone 'warm line' and if mothers gave birth on a weekday, 1 hospital visit from a LC	
Outcomes	Duration of breastfeeding to 6 months; healthcare services use by infants; costs	
Notes		

<i>Risk of bias</i>			<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>	
Random sequence generation (selection bias)	Unclear risk	Described as "assigned randomly".	
Allocation concealment (selection bias)	Low risk	Described as "a sealed envelope technique".	
Blinding of participants and personnel (performance bias) All outcomes	High risk	Peer supporters would have been aware of intervention. Not clear if women were blinded	
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessment by person or by phone; not blinded.	
Incomplete outcome data (attrition bias) All outcomes	Low risk	41 women randomized, all appeared to have been followed up.	

**Pugh 2002** (Continued)

Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Low risk	Groups similar at baseline.

**Pugh 2010**

Methods	2-arm RCT, with individual randomisation, n = 328
Participants	<p>Setting: 2 hospitals (1 university and 1 community hospital) serving urban areas in Baltimore, Maryland, USA</p> <p>Background rates of breastfeeding initiation: intermediate</p> <p>Inclusion criteria: mother English-speaking, with phone access and living within 25 miles of the hospital, intending to breastfeed, family eligible for WIC program, singleton term infant (&gt; 37 weeks' gestation)</p> <p>Exclusion criteria: infants or mothers with positive drug screen, infants with craniofacial abnormalities, infants admitted to NICU</p> <p>Participant characteristics: all enrolled in WIC program; mean age 23.1 years; 87% African Americans; 26.5% with less than high school education; 79.6% single; 17.4% not employed or in school; 26.6% caesarean births; 50.6% first time mothers; 32.3% with previous breastfeeding experience</p>
Interventions	<p>Intervention (n = 168): in addition to usual care, a structured programme of education and support comprising postnatal visits by a breastfeeding team (community nurse and peer counsellor) daily in hospital, 2 home visits in the first week after discharge, a third visit at approximately 4 weeks, then scheduled phone calls by the peer counsellor at least fortnightly until 24 weeks and phone access to the community nurse (24 h) for 24 weeks. Home visits lasted approximately 45-60 min and the average length of phone calls was approximately 20 min</p> <p>Control (n = 160): usual care included access to a LC in hospital and phone access after discharge home</p>
Outcomes	Any breastfeeding (breastfed at least once during the previous 24 h) at 6, 12, and 24 weeks postpartum
Notes	Baseline variables were measured using established valid instruments and were used as covariates to adjust for differences between randomisation groups in some of the analyses in the paper. In our analyses we have reported unadjusted figures

***Risk of bias***

***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence. Block randomisation (block size 10)

Allocation concealment (selection bias)	Low risk	“sealed envelope technique” ... not entirely clear, not described in detail but probably adequate
Blinding of participants and personnel (performance bias) All outcomes	High risk	Baseline data were collected before randomisation therefore this was collected in a blind fashion, however following randomisation women and staff would be aware of group assignment
Blinding of outcome assessment (detection bias) All outcomes	High risk	There was a serious risk of bias associated with the lack of blinding of outcome assessors. In the intervention group outcome data were collected by the staff carrying out the intervention whereas in the control group outcome data were collected by a research interviewer who the women will not have met
Incomplete outcome data (attrition bias) All outcomes	Low risk	70% of those approached randomized. 328 randomized and followed up, 29% lost to follow-up by 24 weeks but all women included in the analyses. Women who withdrew from the study early in the project were assumed not to be breastfeeding and those who were lost subsequently were assumed not to be breastfeeding since their last contact. Both I and C groups were treated in the same way and loss was similar in the 2 groups. The numbers recorded as still breastfeeding therefore represent a conservative estimate
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol
Other bias	Unclear risk	There was no apparent baseline imbalance although baseline characteristics were used in regression analysis to determine adjusted treatment effect. In our results we have reported the unadjusted data

Quinlivan 2003

Methods	2-arm RCT, single-site study, recruitment July 1998-December 2000, n = 136
Participants	<p>Urban Australia</p> <p>Background rates of breastfeeding initiation: high. Baseline prevalence of breastfeeding in Australia = 83% at hospital discharge</p> <p>Participants were recruited at a teenage pregnancy clinic serving mostly disadvantaged young women. The intervention was offered regardless of feeding intention or practice</p> <p>Inclusion criteria: teenagers aged &lt; 18 years; attending first antenatal appointment at public-care teenage pregnancy clinic for first-time mothers; English-speaking; intending to continue with the pregnancy and not relinquish the infant</p> <p>Exclusion criteria: residence &gt; 150 km from the study hospital; known fetal abnormality</p> <p>Participant characteristics:</p> <p>Ethnic composition of sample: 24% indigenous Australian</p> <p>Socioeconomic status: 86.5% of sample scored low or destitute on score derived from educational level of participant and her parents, and family income</p>
Interventions	<p>Intervention: structured home visits in weeks 1 and 2 by certified nurse-midwives to teach feeding and maternal-infant bonding skills. Further visits at months 1, 2, 3 and 4 to provide advice and support</p> <p>Control: routine postnatal support, counselling and information services provided by the hospital including access to routine hospital domiciliary home-visiting services</p>
Outcomes	Adverse neonatal outcomes (infant death, severe non-accidental injury and non-voluntary foster care); knowledge and practice of contraception, vaccination schedules and breastfeeding
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	By computer-generated randomized allocation schedule
Allocation concealment (selection bias)	Low risk	Concealed in numbered, sealed opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and staff aware of intervention group.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors aware of intervention group.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	65 assigned to the intervention and 71 to the control group. Reasons for drop out recorded, 124 completed trial (91%)

**Quinlivan 2003** (Continued)

Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	It was not clear how the intervention related to some of the outcomes (e.g. early infant death) No baseline imbalance apparent with similar numbers of women in the 2 groups initiating breastfeeding

**Ransjo-Arvidson 1998**

Methods	2-arm quasi-RCT, recruitment 1989-1992 n=408
Participants	Setting: study in a hospital in Zambia 408 women recruited 1 h following delivery at the study hospital Inclusion criteria: normal birth, term, singleton, Apgar score > 7 at 1 min, no visible malformation and mother and baby assessed as healthy
Interventions	Intervention (n = 208): home visits by a midwife at 3, 7, 28 and 42 days. Home visits lasted about 1 h. Midwives examined women and infants and asked about their health; any health problems and related actions; breastfeeding patterns; social support (if any). If indicated, midwives referred women for medical help Control (n = 200): home visit by a midwife at 42 days only
Outcomes	Maternal and infant health problems
Notes	We have not included data from this study in the review as they were not reported in a way that allowed us to enter them into <a href="#">RevMan 2014</a> for meta-analysis. Numbers of breastfeeding women were not reported by randomisation group

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	2-stage randomisation process with recruitment on certain days, when women were randomly selected to be randomized to treatment groups
Allocation concealment (selection bias)	Unclear risk	It was not clear whether the person carrying out the randomisation had any control over the sample selection and the randomisation process

**Ransjo-Arvidson 1998** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Hospital staff were unaware of group allocation. Unclear if midwife delivering intervention and women were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data were collected by research midwives but unclear if they were blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participants seen at follow-up for the intervention group- 98.5% at day 3, 97.5% at day 7, 87% at day 28 and 89% at day 42 Participants seen at follow-up for the control group - 87% at day 42 Loss to follow-up < 20% at each follow-up visit.
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Baseline characteristics were similar.

**Redman 1995**

Methods	2-arm RCT n=235
Participants	Setting: 235 eligible and consenting women booked for delivery at an Australian hospital in 1989 Inclusion criteria: primiparous women who expressed a wish to breastfeed, who booked for delivery before 20 weeks' gestation, aged between 18-35 years and lived within 20 km of the hospital Exclusion criteria: women who received additional care from independent midwives
Interventions	Intervention: programme of care based on health belief model and cognitive-behavioural principles, including a 3-h group teaching session in the antenatal period and a visit by a LC shortly after hospital birth, phone support 2-3 weeks later and at 3 months, with a home visit if needed. The LC was available to provide telephone support at other times Control: usual breastfeeding care and advice along with routine antenatal classes
Outcomes	Breastfeeding at 6 weeks and 4 months postdelivery, reasons for stopping breastfeeding, satisfaction with the intervention
Notes	We have not included data from this study in the review due to very high attrition rates which meant results were difficult to interpret. In this study women were recruited in the antenatal period. 235 women were randomized; 30% were lost to follow-up by 6 weeks postpartum (and full interview data were available for only 56% of the sample).

*Risk of bias*

*Risk of bias*

Redman 1995 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Alternate, by odd or even numbered consent forms. It was stated that forms were given out sequentially
Allocation concealment (selection bias)	Unclear risk	Odd or evenly numbered consent forms. It was stated that those carrying out recruitment and the women were not aware of the code for allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and personnel were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data were collected using a self-completed questionnaire. it is not detailed if the questionnaire contained any information that could identify allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High loss to follow-up with interview data at 6 weeks for only 56% of the sample randomized
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Baseline characteristics similar - no significant differences between control and intervention groups on any of these variables

Santiago 2003

Methods	3-arm RCT, with individual randomisation, single-site study, recruitment August 2000-July 2002, n = 101
Participants	Urban setting in Minas Gerais, Brazil Background rates of breastfeeding initiation: high. Baseline prevalence of breastfeeding in Brazil in the first 30 days = 88% Inclusion criteria: mother breastfeeding her well, term baby when appointment for paediatric clinic made; first clinic consultation took place at $\leq 30$ days Exclusion criteria: mothers who expressed a preference to see a particular paediatrician; babies no longer breastfed at the first appointment Ethnic composition: 62% of babies white
Interventions	Intervention 1: babies were monitored by a paediatrician working with a multidisciplinary breastfeeding team. The paediatrician and team had all received training to promote exclusive breastfeeding (PNIAM: Programa de Incentivo ao Aleitamento Materno, Brazil) Intervention 2: babies were monitored by the same paediatrician, in individual consultations Control: babies were monitored by a paediatrician who did not have formal training to promote exclusive breastfeeding

**Santiago 2003** (Continued)

Outcomes	Exclusive breastfeeding to 4 months	
Notes		
<b>Risk of bias</b>		
		<b>Risk of bias</b>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	(Risk of bias assessment from translation notes.) Random assignment by drawing lots
Allocation concealment (selection bias)	Unclear risk	Random assignment by drawing lots. Described as simple randomisation in translation notes
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was stated that staff were aware of group assignment. It is unclear if women were aware of allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is stated that "information was collected by the author of each child's medical record. it is unclear if it was 1 of the paediatricians that completed or if it was someone who was blinded to allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	It was not clear at what time randomisation took place or the number randomized to each group "the exclusion percentages were similar in the three groups". 190 were eligible and 101 completed the study
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	No baseline imbalance apparent. It was not clear how many women were randomized

**Serafino-Cross 1992**

Methods	2-arm RCT, with individual randomisation, recruitment 1986-1987, n = 52
Participants	Volunteers attending prenatal clinics in Massachusetts USA who intended to breastfeed their babies for 2 months or longer Background rates of breastfeeding initiation: low Inclusion criteria: breastfeeding for the first time, or unsuccessful previous attempts; English-speaking

Interventions	All women received prenatal breastfeeding information. Intervention (n = 26): home visits and telephone contacts up to 2 months postpartum from an experienced breastfeeding counsellor (who also recruited women to the study). Women received 5-8 visits lasting 30-60 min Control (n = 26): usual care; women were given contact details for the clinic nutritionist to use if problems arose
Outcomes	Breastfeeding at 2 months postpartum and 6 months postpartum
Notes	We were only able to include 1 reported result in the review: numbers breastfeeding (any) at 8 weeks postpartum. The remaining data were in a graph and were not easy to interpret or data were not reported by randomisation group

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Method not described as "randomized the clients".
Blinding of participants and personnel (performance bias) All outcomes	High risk	The researcher provided the intervention and would have been aware of group allocation. Women would have been aware if they were to receive the intervention or not
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Women were contacted by phone or mail to complete questionnaires. Not stated who did the data collection and whether they were blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	52 women were recruited. It appeared that all women were followed up at 8 weeks postpartum, but that approximately half of the comparison group were lost to follow-up by 6 months. We have not included any data in the review relating to the outcomes measured at 6 months
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Very low recruitment rate "it took 14 months to enrol just 52 participants from 4 clinics serving in total approximately 1000 pregnant women per year". Results may not

	be generalisable
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**Sikander 2015**

Methods	2-arm cluster-RCT, n = 452
Participants	<p>Union Councils in a rural, resource-poor district in the northwest province of Pakistan with high infant mortality</p> <p>Background rates of breastfeeding initiation: Pakistan has 8% exclusive breastfeeding before 6 months</p> <p>inclusion criteria: women aged 17-40 years, married, in their third trimester of pregnancy, and intending to reside in the study area for the duration of the study</p> <p>Exclusion criteria: women with diagnosed serious medical/psychiatric condition requiring treatment, pregnancy-related illness (except for common conditions, such as anaemia) , and substantial physical/learning disability</p>
Interventions	<p>Intervention (n = 224): 7 psycho-educational sessions integrated into the routine work of lady health workers (LHWs) and delivered to all women in their Union Council catchment areas. First session delivered before birth, second session immediately after birth, and the remaining 5 sessions monthly thereafter. The intervention had 6 components: developing an empathic relationship: a trusting, safe, alliance with the mother and other family members; collaborating with the family in an equal partnership; using guided discovery: a style of engagement to gently probe for the individual and family's health beliefs, and also to stimulate alternative ideas; putting knowledge into practice and behavioural activation; and problem solving. LHWs underwent 2-day (12 h) training in simplified cognitive behavioural therapy principles using participatory approaches</p> <p>Control (n = 228): women received an equal number of visits in exactly the same way as those in the intervention arm, but by routinely trained LHWs</p>
Outcomes	<p>Primary: rate and duration of exclusive breastfeeding in the first 6 months</p> <p>Secondary: impact on traditional practices impeding exclusive breastfeeding</p>
Notes	

**Risk of bias**

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Simple unmatched randomization"
Allocation concealment (selection bias)	Low risk	Randomisation by an independent researcher
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and LHWs were not blinded

**Sikander 2015** (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	The assessors were blind to the allocation status of the mother
Incomplete outcome data (attrition bias) All outcomes	Low risk	19% attrition in intervention group and 22% attrition in control group in 6 months after birth
Selective reporting (reporting bias)	Low risk	All outcomes in protocol were reported on.
Other bias	Low risk	None identified

**Simonetti 2012**

Methods	2-arm RCT, n = 114
Participants	Public maternity hospital in Italy Background rates of breastfeeding initiation: not stated Inclusion criteria: healthy primiparous women without breastfeeding problems, with a healthy baby born at full term (37-41 weeks, birthweight > 2500 g) and who agreed to be enrolled Exclusion criteria: multiparous women, premature baby (born before the 37th week), low birth weight baby (< 2500 g), admission to neonatal intensive care unit or transfer to another hospital, medical condition which could permanently or temporarily counter-indicate breastfeeding (e.g. acute tuberculosis, psychosis, acute phase hepatitis A or B, hepatitis C, HIV), women who did not speak Italian, and women who could not be contacted by telephone)
Interventions	Intervention (n = 55): structured telephonic counselling (STC); each mother received telephone calls during the first 6 weeks after delivery. The phone call timing was planned by both the mother and the licensed midwife (LM) with at least one a week; in addition, mothers were invited to call the LM when necessary to solve any breastfeeding problem. During every phone call, the LM gave support and all information on fully breastfeeding. No weekly calls were missed Control (n = 59): conventional counselling - consisting of programmed periodical visits with the physician at 1, 3 and 5 months after delivery. Participants were also invited to call the LM in case of breastfeeding problems
Outcomes	Primary: breastfeeding at 1,3 and 5 months after delivery Secondary: influence of mother's educational level and employment status on exclusive breastfeeding
Notes	None identified

**Risk of bias**

**Risk of bias**

Bias	Authors' judgement	Support for judgement
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**Simonetti 2012** (Continued)

Random sequence generation (selection bias)	Unclear risk	Quote: "Women who consented to participate were randomly assigned to 1 of the 2 groups, 55 women were enrolled in the experimental group (receiving STC) and 59 were enrolled in the control group (receiving conventional counselling)". Sequence generation not described
Allocation concealment (selection bias)	Unclear risk	No detail provided to enable judgement of this.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not possible due to nature of intervention.
Blinding of outcome assessment (detection bias) All outcomes	High risk	The data were collected by a specialist nurse who monitored all subjects
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not clear if all women who were randomized completed study as numbers not provided
Selective reporting (reporting bias)	Unclear risk	No evidence that outcomes were prespecified
Other bias	Low risk	

**Sjolin 1979**

Methods	Quasi-RCT, single site, duration 12 months, n = 146
Participants	Urban Sweden - maternity ward of University Hospital Background rates of breastfeeding initiation: high. Baseline prevalence (1972): 4% breastfeeding at 24 weeks Inclusion criteria: resident in Uppsala; normal birth; healthy babies weighing > 3 kg Exclusion criteria: none specified Ethnic composition not stated. 28% of mothers had completed college or university education
Interventions	Intervention: 'Interview' with paediatrician in hospital on days 1 and 4, and at home at 2 and 6 weeks and 3 months; telephone contact weekly while breastfeeding followed by home visit if problem noted Control. Usual care,
Outcomes	Partial and exclusive breastfeeding at 2, 4, 8, 12, 16, 20 and 24 weeks
Notes	Primarily designed as a study of the reasons for breastfeeding difficulties and the cessation of breastfeeding. Recruitment halted during holidays

*Risk of bias*

*Risk of bias*

**Sjolin 1979** (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quasi-randomisation depending on time of day of birth
Allocation concealment (selection bias)	High risk	Quasi-randomisation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Women in the control group were not told about the study until the 6 months follow-up interview. Not stated if women in the intervention group were aware of study
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	All interviews were carried out by the same investigator who was aware of group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Interviews took place while women continued to breastfeed and it was not clear how many women remained to follow-up at different points although no drop-out was reported for the final data collection interview at 6 months
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Women in the intervention group reported outcomes at scheduled interviews, whereas the control group were interviewed at 6 months postpartum only. Recall and response bias may have been different in the 2 groups

**Srinivas 2015**

Methods	2-arm RCT, n = 120
Participants	Westown Physician Center (WPC), a hospital-affiliated urban clinic, USA, where most patients received public insurance or charity care Background rates of breastfeeding initiation: data from an inner-city Cleveland clinic with a similar population reported lower rates with any and exclusive breastfeeding at 5 days at 40.8% and 22.0%, respectively Inclusion criteria: aged 18 years or older, with no contraindications to breastfeeding, $\geq$ 28 weeks' gestation at recruitment stage Exclusion criteria: women < 18 years old, non-English speakers, and those with a diagnosis that was an absolute contraindication to breastfeeding (HIV/AIDS, herpes simplex on the breast, tuberculous lesions of the breast)

Interventions	<p>Intervention (n = 50): peer counselling WIC support programme; WIC definition of a breastfeeding peer counsellor: a woman who breastfed her own infant(s) to 1 year with exclusive breastfeeding for 6 months or was currently breastfeeding an infant following recommended practice, who received 20 h training. Counsellor was resident in the local area and received care herself from WPC. Antenatal: peer counsellor initiated contact once during third trimester of pregnancy with additional contacts at mother's request (mostly by telephone). Postnatal: peer counsellor contact within 3-5 days of birth weekly to 1 month, every 2 weeks up to 3 months, and once at 4 months, in person during clinic visits or via telephone. No home visits for safety reasons</p> <p>Control (n = 53): standard care (available to both intervention and control group), included access in hospital to International Board Certified LCs and outpatient lactation support from the clinic paediatricians and the WIC nutritionist. The in-office WIC site had a peer helper available less than once a month</p>
Outcomes	<p>Breastfeeding initiation</p> <p>Any breastfeeding at 1 month and 6 months</p> <p>Exclusive breastfeeding at hospital discharge, 1 month, 6 months</p> <p>Breastfeeding attitude and self-efficacy</p> <p>Perception of breastfeeding support</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Quote: "participants were randomized within these strata in blocks of 4 participants in a 1:1 ratio to intervention (PC) or control (usual care) group". Method of sequence generation not described
Allocation concealment (selection bias)	Unclear risk	No detail provided to enable judgement of this.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The peer counsellor was blinded to self-efficacy and attitude towards breastfeeding, but due to the nature of the intervention would have been aware of the allocation of the women. It was not stated whether the women were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Study co-ordinator administered exit interview and it was not stated whether the co-ordinator was blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number initially randomized not provided, so unable to calculate attrition rate
Selective reporting (reporting bias)	Unclear risk	No evidence of a record of predefined outcomes to judge this
Other bias	Low risk	None identified

**Stockdale 2008**

Methods	2-arm RCT, n = 182
Participants	Suburban hospital and community health and social services trust that served both urban and rural areas in Northern Ireland Background rates of breastfeeding initiation: not detailed Inclusion criteria: primigravid women who intended to have their baby within the trust and who attended the routine 20-week antenatal appointment during the recruitment phase Exclusion criteria: women who did not speak English (or had interpretation services available), women who experienced infant-maternal separation and incidences of newborn abnormalities that required additional infant feeding support, or teenagers who had already attended a breastfeeding workshop
Interventions	Intervention (n = 93): motivationally-enhanced version of midwife instruction as a means of increasing women's expectancy for successful breastfeeding, compared to best practice. The intervention had 4 components: antenatal feeding class (32-36 weeks' gestation), a breastfeeding information book (provided in the antenatal phase), a breastfeeding CD-ROM, postnatal instructional support provided by midwives (up to 3 weeks postnatal) and additional lactation consultancy on request. The postnatal midwives who supported the intervention attended an additional 1-day training session that focused on the role of human motivation and the use of effective strategies to increase participants' expectancy for success Control (n = 89): local best practice
Outcomes	Primary: women's motivation towards breastfeeding Secondary: breastfeeding on discharge from hospital and at 3 weeks
Notes	

***Risk of bias***

***Risk of bias***

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Participants were assigned using computer-generated random numbers to the intervention or control groups
Allocation concealment (selection bias)	Unclear risk	No details provided to enable judgement of this.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded to group membership but unclear if this was successful. Midwives were informed of the allocation through a colour-coded sticker on the women-held records
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated whether researcher or parent education co-ordinator who collected the data were blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition in intervention group was 26% and in control group was 16%. The withdrawal rate was higher in the intervention group (n = 13) compared to the control group (n = 2)

Stockdale 2008 (Continued)

Selective reporting (reporting bias)	Unclear risk	No evidence of prespecified outcomes to judge this.
Other bias	Low risk	None identified

Su 2007

Methods	3-arm RCT, with individual randomisation, n = 450
Participants	National University Hospital, Singapore Background rates of breastfeeding initiation: high Inclusion criteria: healthy pregnant women attending antenatal clinics at the study hospital, with no illness that would contraindicate breastfeeding or severely compromise its success; intending to breastfeed; birth at 34 weeks' gestation or later Exclusion criteria: women with high risk and multiple pregnancies Participant characteristics: 40% primiparous, mixed ethnicity (Chinese 31%-44%, Malay 46%-54%, Indian and other), approximately a third educated beyond secondary school, approximately half employed outside the home, 56% had previously breastfed
Interventions	Intervention 1: antenatal education: in addition to routine care, women received 1 session of antenatal breastfeeding education and printed guides on breastfeeding Intervention 2: postnatal lactation support: in addition to routine care, women received 2 postnatal sessions with a LC, 1 in hospital within the first 3 postnatal days (when they received the same printed guides on breastfeeding as the antenatal education group) and 1 during the first routine postnatal visit 1 to 2 weeks after the birth. Each session lasted about 30 min and covered latching on, proper positioning and other techniques to avoid common breastfeeding complications Control: women received routine antenatal, intrapartum and postnatal care, including optional antenatal classes and postnatal visits by a LC should any problems with breastfeeding arise
Outcomes	Exclusive and any breastfeeding at hospital discharge and 2 weeks, 6 weeks, 3 and 6 months after the birth. Exclusive breastfeeding was defined as giving breast milk as the only food source, with no other foods or liquids, other than vitamins and minerals being given
Notes	Intervention group 1, who received the antenatal intervention, are not included in the analysis in this review

*Risk of bias*

*Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence by external clinical trials unit

**Su 2007** (Continued)

Allocation concealment (selection bias)	Low risk	Telephone allocation by external trials unit (with envelope back up used only on 4 occasions)
Blinding of participants and personnel (performance bias) All outcomes	High risk	For participants, blinding was not mentioned, but women would be aware of allocation. The caregivers who delivered the intervention would be aware of allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data collection was on standard forms and was entered by remote unit, therefore outcome assessment may have been partially blinded. Not clear who conducted the actual interviews
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Low attrition in all arms. In total 450 randomized 347 completed follow-up at 6 months (82%). In the data and analyses, 2 arms included 299 randomized, 245 followed up at 6 months (82%)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	There was an imbalance in the groups due to 4 women being randomized by using back up envelopes because of dysfunction in web randomisation, but groups appeared similar at baseline Some of the data were based on assumptions. Sensitivity analyses were based on the assumption that none of the women lost to follow-up were exclusively breastfeeding at any time point

**Tahir 2013**

Methods	2-arm RCT, n = 357
Participants	Public maternity hospital in Kuala Lumpur Background rates of breastfeeding initiation: 92.2% of mothers were exclusively breastfeeding at the study site before discharge Inclusion criteria: 18 years of age or older; of Malaysian nationality; delivered a single infant at $\geq 37$ weeks' gestation; an intention to breastfeed and the ability to understand and communicate in spoken Malay or English; had received a prenatal breastfeeding education programme at least once; had telephone access; and gave informed consent Exclusion criteria: women with multiple pregnancies or medical problems that might

	hinder breastfeeding; women that delivered via caesarean section; or women whose baby subsequently required prolonged care in a Special Care Nursery
Interventions	<p>Intervention (n = 179): lactation counselling given by certified LCs via telephone twice monthly to each lactating mother, in addition to the current conventional care (as described below). Each mother was expected to receive 12 lactation counselling sessions by the end of the study. Contact was discontinued any time that a mother decided to stop breastfeeding completely. Contact was also discontinued if the mother had given the baby up for foster care and/or had no physical contact to enable her to breastfeed. LCs in this study were registered nurses from the Maternity Hospital Kuala Lumpur who had post-basic training in midwifery and were certified as LCs. All 12 LCs had undergone a 40-h lactation management and counselling course based on the WHO module</p> <p>Control (n = 178): mothers received current conventional care for postnatal breastfeeding promotion or support from their own public healthcare provider. This conventional care included breastfeeding talks during immunisation follow ups, a mothers' communication with the LCs through information or pamphlets received during antenatal or postnatal follow-ups, and advice regarding breastfeeding received at any time from any healthcare workers, the media, peer counsellors, family members or friends</p>
Outcomes	<p>Exclusive breastfeeding at 1, 4 and 6 months</p> <p>Stopped any breastfeeding at 1, 4 and 6 months</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "Generation of the group assignments was conducted using a blocked randomisation method with a block size of four by a random allocation software program"
Allocation concealment (selection bias)	Unclear risk	No details provided to enable judgement of this.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The women and LCs were not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Only the Research Enumerator who collected the breastfeeding outcome data was blinded with respect to the treatment group"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition in intervention and control group was 89.4% and 88.8% respectively
Selective reporting (reporting bias)	Unclear risk	No evidence of predefined outcomes to judge this.
Other bias	Low risk	None identified

**Tylleskar 2011a**

Methods	One of the 3 country sites that completed this cluster-randomised trial - Burkino Faso in French-speaking West Africa (24 clusters: 12 intervention, 12 control). Mother-infant pairs enrolled: 392 intervention and 402 control (794 total). Followed up at 24 weeks: 359/392 (92%) intervention and 372/402 (93%) control
Participants	Rural area where main source of income was farming, 60 primary care facilities and a regional hospital Baseline prevalence of breastfeeding initiation: high (98.4%). Exclusive breastfeeding for babies under 6 months estimated at 16% Inclusion criteria: women living in trial area at least 7 months pregnant and intending to breastfeed, singleton live birth, no serious congenital malformations Exclusion criteria: mothers or infants who died were not included in the analysis Participant characteristics: Mean age of women 25 years. None of the women had any formal education and more than half had had a previous child death. 99% of women had no toilet or an open toilet and < 1% had piped water in yard or home. Monthly income was approximately EUR 3
Interventions	Intervention: peer counselling by supporters who received a modified version of WHO/ UNICEF training (1 week training). Women were given information about breastfeeding and peers provided support and addressed problems or referred women for specialist help. The intervention involved a minimum of 5 home visits, 1 in the third trimester and at least 4 in the postnatal period up to 6 months postpartum. The supporters were local residents, literate, able to travel to visit women in their homes and had a good reputation in the community. Peer counsellors visited the same women each time to achieve continuity of care. The intervention varied in the 3 study areas and was adapted to local circumstances Control: mothers and infants in control clusters in Burkina Faso were given standard healthcare only
Outcomes	Prevalence of exclusive breastfeeding and prevalence of diarrhoea, reported by mothers for infants aged 12 weeks and 24 weeks
Notes	The paper reported that current breastfeeding was assessed at all scheduled postpartum visits using past 24-h and 7-day recalls. Babies who were reported to have received no other food or liquids than breast milk (they may have been administered drugs) were classified as exclusively breastfed. This may have been during the last 24 h or 7 days rather than since birth. Prevalence of diarrhoea was based on the mothers' reports of the past 2 weeks

***Risk of bias***

***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Unclear (different procedures in different areas and the procedure in 1 of the 4 areas was not clear)

Tylleskar 2011a (Continued)

Allocation concealment (selection bias)	Unclear risk	There was no allocation concealment within clusters and participants would be aware of assignment
Blinding of participants and personnel (performance bias) All outcomes	High risk	There was no participant or staff blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was an attempt to mask/blind outcome assessors to randomisation group, although it is possible women would have revealed whether or not they received support. The success of attempted blinding was not formally evaluated
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was flooding in 1 of the 4 original study area and no results were reported for this area. For the remaining 82 clusters in 3 countries for primary outcomes the authors carried out an ITT analysis (i.e. those that were missing were recorded as non-events, i.e. NOT exclusive breastfeeding and no diarrhoea). 2579 women enrolled. Missing data and missed visits at various data collection points
Selective reporting (reporting bias)	Unclear risk	Not apparent
Other bias	Unclear risk	Recruitment procedures and intervention delivery was slightly different in each of the study countries which meant that results were difficult to interpret. It was reported that the ICC in each country for primary outcomes varied considerably and therefore results were reported separately for each country Authors stated, "The community-based approach could possibly have resulted in socially desirable answers, and the results were based on self-reports. A bias towards desirable answers and thereby an increased effect size cannot be ruled out. We also noted some questionnaire fatigue in the Ugandan site-i.e. reluctance to fully engage in answering similar questions after a few interviews"

## Tylleskar 2011b

Methods	Second of 3 country sites that completed the cluster-randomised trial - Mbale district in Eastern Uganda (24 clusters: 12 intervention, 12 control). Mother-infant pairs enrolled: 396 intervention and 369 control (765 total). Followed up at 24 weeks: 368/396 (93%) intervention and 329/369 (89%) control
Participants	Urban and rural areas: urban area included "large slum migrant settlements" Background rates of breastfeeding initiation: high (> 95%) Inclusion criteria: women living in trial area at least 7 months pregnant and intending to breastfeed, singleton live birth, no serious congenital malformations Exclusion criteria: mothers or infants who died were not included in the analysis Participant characteristics: HIV prevalence for fertile women was 6.2%. 26% of women had no toilet or an open toilet and 5% had piped water in yard or home. Mean age 25 years. Women had approximately 6 years of formal education and approximately a third had had a previous child death. Monthly income was approximately EUR 12
Interventions	Intervention: peer counselling as in Burkina Faso (Tylleskar 2011a). Paper stated the intervention varied in the 3 study areas and was adapted to local circumstances Control: mothers and infants in control clusters in Uganda were given standard healthcare only
Outcomes	Prevalence of exclusive breastfeeding and prevalence of diarrhoea, reported by mothers for infants aged 12 weeks and 24 weeks
Notes	The paper stated that current breastfeeding was assessed at all scheduled postpartum visits using past 24-h and 7-day recalls. Babies reported to have received no other food or liquids than breast milk (they may have been administered drugs) were classified as exclusively breastfed. This may have been during the last 24 h or 7 days rather than since birth. Prevalence of diarrhoea was based on the mothers' reports of the past 2 weeks

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Unclear (different procedures in different areas and procedure in 1 of the 4 areas was not clear)
Allocation concealment (selection bias)	Unclear risk	There was no allocation concealment within clusters and participants would be aware of assignment
Blinding of participants and personnel (performance bias) All outcomes	High risk	There was no participant or staff blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was an attempt to mask/blind outcome assessors to randomisation group, although it was possible women would have

**Tylleskar 2011b** (Continued)

		revealed whether or not they received support. The success of attempted blinding was not formally evaluated
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was flooding in 1 of the 4 original study area and no results were reported for this area. For the remaining 82 clusters in 3 countries for primary outcomes the authors carried out an ITT analysis (i.e. those that were missing were recorded as non-events, i.e. NOT exclusive breastfeeding and no diarrhoea). 2579 women enrolled. Missing data and missed visits at various data collection points
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Recruitment procedures and intervention delivery was slightly different in each of the study countries which meant that results were difficult to interpret. It was reported that the ICC in each country for primary outcomes varied considerably and therefore results were reported separately for each country Authors stated, "The community-based approach could possibly have resulted in socially desirable answers, and the results were based on self-reports. A bias towards desirable answers and thereby an increased effect size cannot be ruled out. We also noted some questionnaire fatigue in the Ugandan site-i.e. reluctance to fully engage in answering similar questions after a few interviews"

**Tylleskar 2011c**

Methods	Third of 3 country sites that completed this cluster-randomised trial - 3 geographically separate sites in South Africa (Paarl, a town at the centre of a farming district near Cape Town; Umlazi, a large periurban township near Durban; and Rietvlei, 1 of the country's poorest rural districts: 34 clusters: 17 intervention, 17 control). Mother-infant pairs enrolled: 535 intervention and 485 control (1020 total). Followed up at 24 weeks: 461/535 (86%) intervention and 410/485 (85%) control
Participants	South Africa (3 areas including 1 of the poorest rural area in South Africa) Under 5 mortality rate in South Africa was 67/1000 and infant mortality rate was 48/1000

Tylleskar 2011c (Continued)

	<p>Background rates of breastfeeding initiation: high (&gt; 95%). Exclusive breastfeeding at 6 months was estimated at 8% in 2005-2009</p> <p>Inclusion criteria: women living in trial area at least 7 months pregnant and intending to breastfeed, singleton live birth, no serious congenital malformations</p> <p>Exclusion criteria: mothers or infants who died were not included in the analysis</p> <p>Participant characteristics:</p> <p>16% of women had no toilet or open toilets and 66% had piped water in yard or home. Mean age 23 years. Women had approximately 10 years of formal education and approximately 7% had had a previous child death. Monthly income was approximately EUR 103</p>
Interventions	<p>Intervention: peer counselling as in Burkina Faso and Uganda (Tylleskar 2011a; Tylleskar 2011b). Paper stated the intervention varied in the 3 study areas and was adapted to local circumstances</p> <p>Control: control clusters were visited by peer counsellors, with the same schedule as the intervention clusters, but they assisted families in obtaining birth certificates and social welfare grants. The peer counsellors for the intervention and control clusters in South Africa were kept separate during the study</p>
Outcomes	Prevalence of exclusive breastfeeding and prevalence of diarrhoea, reported by mothers for infants aged 12 weeks and 24 weeks
Notes	The paper stated that current breastfeeding was assessed at all scheduled postpartum visits using past 24-h and 7-day recalls. Babies reported to have received no other food or liquids than breast milk (they may have been administered drugs) were classified as exclusively breastfed. This may have been during the last 24 h or 7 days rather than since birth. Prevalence of diarrhoea was based on the mothers' reports of the past 2 weeks

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Unclear (different procedures in different areas and procedure in 1 of the 4 areas was not clear)
Allocation concealment (selection bias)	Unclear risk	There was no allocation concealment within clusters and participants would be aware of assignment
Blinding of participants and personnel (performance bias) All outcomes	High risk	There was no participant or staff blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was an attempt to mask/blind outcome assessors to randomisation group although it is possible women would have revealed whether or not they received support. The success of attempted blinding

Tylleskar 2011c (Continued)

		was not formally evaluated
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was flooding in 1 of the 4 original study area and no results were reported for this area. For the remaining 82 clusters in 3 countries for primary outcomes the authors carried out an ITT analysis (i.e. those that were missing were recorded as non-events, i.e. NOT exclusive breastfeeding and no diarrhoea). 2579 women enrolled. Missing data and missed visits at various data collection points
Selective reporting (reporting bias)	Unclear risk	Not apparent
Other bias	Unclear risk	Recruitment procedures and intervention delivery was slightly different in each of the study countries which meant that results were difficult to interpret. It was reported that the ICC in each country for primary outcomes varied considerably and therefore results were reported separately for each country Authors stated, "The community-based approach could possibly have resulted in socially desirable answers, and the results were based on self-reports. A bias towards desirable answers and thereby an increased effect size cannot be ruled out. We also noted some questionnaire fatigue in the Ugandan site-i.e. reluctance to fully engage in answering similar questions after a few interviews"

Vidas 2011

Methods	2-arm RCT, n = 100
Participants	Setting not clear. "Our research was conducted by the Association for a healthy and happy childhood-Counseling center for mother and child in Bjelovar, Croatia"- not obvious what type of setting this is, but we infer it is a community-based setting of some sort Background rates of breastfeeding initiation: 50% of women give-up breastfeeding after 6 months in Croatia Inclusion criteria: "the criterion for inclusion in the study was that the mother was nursing her child and the child had up to two months" Exclusion criteria: none stated

Interventions	<p>Intervention (n = 50): "six basic exercises of autogenic training". Not clear what this is but article states "every two weeks mothers were practicing a new exercise. The 6 basic exercises of autogenic training were taught for 12 weeks in small groups to 10 members". "After mothers have learned all the exercises of autogenic training, they have continued to practice until their child reached six months of life". The exercises seem to be delivered in a group setting and promoted breastfeeding</p> <p>Control (n = 50): unclear; Quote "mothers of both groups were advised to successful breastfeeding up to 6 months of age"</p>
Outcomes	<p>Attitude, decision and duration of breastfeeding</p> <p>Mother's level of confidence</p> <p>Motivation for successful breastfeeding</p> <p>Motivation for autogenic training</p> <p>Possible factors influencing breastfeeding</p> <p>Risk factors for postpartum mental disorders, anxiety and postpartal depression</p> <p>Degree of satisfaction with practising autogenic training and its possible role in promoting successful breastfeeding in the examined group</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No information given on sequence generation. Only information about randomisation process was "Mothers were randomly divided into two groups-examined and control"
Allocation concealment (selection bias)	Unclear risk	No information given on allocation concealment. Only information about randomisation process was "Mothers were randomly divided into two groups-examined and control"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Nature of trial meant that participants and personnel would have been aware of group assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information given about blinding of outcome assessment for any outcome
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information given in paper on the numbers assessed for outcomes, other than for breastfeeding at 6 months where the authors reported numbers for each arm and the data. Fig 4 implied they had complete outcome data for this - for all other outcomes it was unclear what number of participants in each arm were assessed for each outcome

Vidas 2011 (Continued)

Selective reporting (reporting bias)	High risk	No statement of the original prespecified primary and secondary outcomes for the trial. No link to trial registry or protocol information which would enable discernment of any selective outcome reporting (or the lack of it)
Other bias	Low risk	None identified

Vitolo 2005

Methods	2-arm RCT, with individual randomisation, n = 500
Participants	Setting: urban, a low-income area of the city of São Leopoldo, Rio Grande do Sul, Brazil. Recruitment from maternity wards of the city's only publicly funded hospital, which mainly serves the low-income population Background rates of breastfeeding initiation: high Inclusion criteria: low-income mothers with healthy, singleton, full-term (> 37 week) babies with birthweight > 2500 g Exclusion criteria: impediments to breastfeeding, HIV/AIDS, or congenital malformation Demographics: 57% male children; 60% of intervention and 52% of control mothers had less than 8 years schooling; 73% of intervention and 67% of controls had low annual incomes (< USD 3000); 34% of mothers were not in paid work; 70% of children were living with mother and father; almost half of the mothers were overweight
Interventions	Both groups received routine assistance from paediatricians in the health service Intervention (n = 200): dietary advice about breastfeeding and the adequate introduction of complementary foods, given monthly for 6 months in home visits starting within 10 days of the child's birth then at 8, 10, and 12 months by 12 trained field-workers (undergraduate students in groups of 2) who counselled mothers on the Ten Steps for Healthy Feeding Children from Birth to Two Years of Age (Brazilian Ministry of Health) Control (n = 300): standard care (not described)
Outcomes	Exclusive breastfeeding at 4 and 6 months; any breastfeeding at 12 months; also diarrhoea, respiratory problems, dental caries, anaemia, hospitalisation and nutritional status at 12-16 months
Notes	Although the paper called this intervention 'dietary counselling', we have included it as a breastfeeding support intervention because its main purpose was to promote exclusive breastfeeding for 6 months followed by healthy complementary foods, and it involved regular visits during the first year of life

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Block randomisation in groups of 5.

**Vitolo 2005** (Continued)

Allocation concealment (selection bias)	Low risk	Randomisation was conducted by an investigator not involved in the eligibility and entry of participants into the study. Fieldworkers were informed of this allocation and then proceeded with the study
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and care staff would be aware of group assignment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers were blinded to the group status to the mother-infant pair
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	500 women were randomized (200 to the intervention and 300 to the control group). By 12 months 163 intervention group (81%) and 234 control group (78%) remained available to follow-up. Reasons for loss to follow-up were give by group with reasons. However there were some discrepancies between publications and information provided by the author in the numbers followed up
Selective reporting (reporting bias)	Low risk	Not apparent
Other bias	Unclear risk	Method of randomisation led to imbalanced groups. Mothers and children appeared similar at baseline. There were some discrepancies between publications and information provided by the author in the numbers followed up and in the results. We have used information provided by the author

**Wambach 2009**

Methods	3-arm RCT 3-arm, with individual randomisation, n = 390
Participants	The study was carried out in 7 prenatal clinics in the American Midwest. Clinics provided services to low-income adolescent mothers Baseline prevalence of breastfeeding initiation in country/setting: low Inclusion criteria: age 15-18 years, in second trimester of pregnancy, expecting first birth, planning to keep baby, able to read and speak English, with access to phone; at birth, only mothers of singleton, term healthy babies were included Exclusion criteria: women who had birth complications that prohibited or delayed breastfeeding beyond 48 h

	Sample characteristics: mean age 17 years (SD 0.9); 61% African American; 75% low-income; 74% single and living with their families, and 71% were in school
Interventions	Intervention (n = 128): 2 antenatal classes (1.5-2 h) on benefits of breastfeeding and practical issues run by the LC and the peer counsellor, followed up by phone calls. After the birth, phone calls made to those who had initiated breastfeeding, at 4, 7, 11, 18 days and 4 weeks to provide support Control 1 (n = 128): the same contact schedule of classes and phone calls as the intervention group, with content concentrating on more general pregnancy and health issues Control 2 (n = 134): usual care with no special intervention
Outcomes	Data on breastfeeding were available for women who initiated breastfeeding - this meant results were difficult to interpret
Notes	We have not included outcome data from this study in the review due to very high levels of attrition. This was a study where women were recruited in the second trimester and interventions took place both prenatally and postnatally. For postnatal outcomes only those women who initiated breastfeeding were followed up. There was considerable loss to follow-up. 390 were randomly assigned. Women who did not attend at least 1 of the study classes were dropped from the study. Follow-up data on duration of breastfeeding were available for 201 women who initiated breastfeeding (51%)

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "list of random codes generated by the study bio-statistician."
Allocation concealment (selection bias)	Unclear risk	It was not clear how allocation was concealed at the point of randomisation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Study described as being unblinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Study described as being unblinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	390 women were randomized and those who did not attend at least 1 of the study classes were excluded. Follow-up data on duration of breastfeeding was available for 201 who initiated breastfeeding (51%)
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this

Wambach 2009 (Continued)

Other bias	Unclear risk	Unclear - data limited - only reported in the form of an abstract
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Wen 2011

Methods	2-arm RCT, n = 667
Participants	The trial was conducted in socially and economically disadvantaged areas of Sydney, Australia, during 2007-2010 Background rates of breastfeeding initiation: no information provided Inclusion criteria: ≥ 16 years old, expecting first child, between weeks 24-34 of pregnancy, able to communicate in English, and lived in the local area Exclusion criteria: women were excluded from the study if they had severe medical conditions as evaluated by their physicians
Interventions	Intervention (n = 337): 5 or 6 home visits from a specifically trained research nurse delivering a staged home-based intervention in the antenatal period and at 1, 3, 5, 9 and 12 months. At each visit the research nurse spent 1 h-2 h with the mother and infant. (The nurse addressed 4 key areas: infant feeding practices, infant nutrition and active play, family physical activity and nutrition, as well as social support). The was delivered by trained research nurses in accordance with a protocol ( <a href="http://www.healthybeginnings.net.au/">www.healthybeginnings.net.au/</a> ) . Each visit involved standard information with key discussion points. and appropriate resources to reinforce the information Control (n = 330): received the usual childhood nursing service, comprising 1 home visit within a month of birth if needed. Additional visits at baseline and 12 months were conducted by a research assistant for the purpose of data collection only
Outcomes	Exclusive breastfeeding at 6 months Prevalence of any breastfeeding at 6 months and 12 months Median breastfeeding duration Time at introduction of solids
Notes	

*Risk of bias*

*Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "group allocation, which was determined by a computer-generated random number"
Allocation concealment (selection bias)	Low risk	Random allocation was concealed by sequentially numbered, sealed, opaque envelopes containing the group allocation. A research assistant who had no direct contact with participating mothers was responsible for generating the random numbers and preparing the envelopes

Wen 2011 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and those delivering the intervention were not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome data were collected by telephone at 6 months and by face-to-face interview in the home at 12 months. The data collectors and the research staff who dealt with data entry and analysis were masked to treatment allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up in intervention group was 82.5% at 6 months and 85.8% in the control group. "Those lost to follow-up were significantly younger and less educated and were more likely to be unemployed or have low income (Table 1). The main reasons for loss to follow-up were as follows: could not be contacted (67.8%), moved out of the area (14.2%), no longer interested (8.9%), too busy (4.0%), and illness or death (5.0%). This was similar across both groups"
Selective reporting (reporting bias)	Low risk	The breastfeeding outcomes were prespecified in the trial registry record
Other bias	Unclear risk	Authors noted that they were unable to complete the baseline assessment and randomisation before birth, as planned, for 190 women (93 in the intervention group and 97 in the control group). There was no significant difference between these 190 and the 337 who were assessed and randomized before birth (175 in the intervention group and 162 in the control group) for any of the characteristics. Of the 268 participating mothers remaining in the intervention group at 12 months, 34.7% received 5 home visits after giving birth and 35.3% received 6 home visits, including an antenatal visit

Wilhelm 2015

Methods	2-arm RCT, n = 53
Participants	Mexican-American women (American women of Mexican ethnicity/ancestry) residing in rural western Nebraska in the central USA Background rates of breastfeeding initiation: initiation 80% in Hispanic/Latino women. Duration and exclusivity of breastfeeding at 6 months was 45.2% and 14% respectively Inclusion criteria: self-identified Mexican-American mothers between the ages of 15-50 years who were breastfeeding at the time of recruitment/consent Exclusion criteria: admission of the mother to the ICU, multiple births, congenital abnormalities in the infant, or infant admitted to NICU
Interventions	Intervention (n = 26): motivational interviewing (MI); MI was operationalised by asking the participant to rank the importance of breastfeeding for 6 months (1-10 scale) and her confidence in her ability to continue breastfeeding (1-10 scale). The researcher focused

	<p>on the lower score and asked the woman why she did not choose a higher number and what she thought it would take to increase the number. Initial intervention delivered at day 3 visit, MI booster sessions delivered at week 2 and week 6 visits to promote behavioural change</p> <p>Control (n = 27): attention control (AC); mothers in the AC group were given educational information about infant safety including information on fall prevention, poisoning, fires, and burns during the first visit, about choking/aspiration, suffocation, drowning, and smoking during the second visit, and about car seat safety during the final visit. The principle investigator conducted all AC sessions</p>
Outcomes	<p>Intention to breastfeed for 6 months</p> <p>Breastfeeding self-efficacy</p> <p>Duration of breastfeeding</p>
Notes	Feasibility study

<i>Risk of bias</i>		<i>Risk of bias</i>
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	The process was unclear (e.g. was a random number table or computerised randomisation used? However, because the authors stated that a randomisation schedule was prepared by the statistician, we can probably be confident there was true randomisation here)
Allocation concealment (selection bias)	Unclear risk	No information provided about what happened with the sequence, e.g. sealed numbered envelopes or not - unclear if randomisation could have been subverted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants aware of group assignment given nature of the interventions. The principal investigator conducted the intervention and was aware of the group assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear - report did not state who collected outcomes data and whether they were masked to intervention/control
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Authors stated, "High levels of attrition (69%, n = 18, in the MI group and 63%, n = 17, in the AC group) by week 6 impaired our ability to evaluate the potential of our MI intervention. 7 (27%) of the MI mothers and 13 (48%) of the AC mothers were no longer participating because they discontinued breastfeeding prior to week 6. We were unable to reach the remaining mothers (11 in the MI group [42%] and 4 in the AC group [15%]) in person or by phone to conduct the remaining assessments and interventions/control sessions. Subsequently, we reestablished contact with all but 3 mothers (all in the MI group) and determined their duration of breastfeeding through 6 months"

Wilhelm 2015 (Continued)

Selective reporting (reporting bias)	High risk	No trial registry information given or protocol available; paper did not state if the outcomes were prespecified, so not possible to compare outcomes reported in this paper vs those pre-planned, and thus evaluate the possibility of selective outcome reporting. Authors did say however, "Our primary goal was to evaluate the effectiveness of MI by comparing intent to breast-feed, breastfeeding self efficacy, and duration of breastfeeding between mothers receiving the MI intervention and those receiving attention alone"
Other bias	Unclear risk	None noted

Winterburn 2003

Methods	Single-site study, duration of recruitment not reported, n = 72; 30 allocated to the intervention and 42 to the control group
Participants	Community study in North Trent, England, UK Background rates of breastfeeding initiation: intermediate. National baseline prevalence 66% breastfeeding at birth Inclusion criteria: mothers attending for antenatal care on 1 area. Other details not reported
Interventions	Intervention: the midwife asked mothers during their pregnancy to identify a close female confidante who could support them to breastfeed, and visited the mother and confidante together during the third trimester to discuss breastfeeding
Outcomes	Duration of breastfeeding to 3 months; women's satisfaction with the intervention; midwives' assessments of the intervention
Notes	Numerical outcome data were provided by the researcher.

*Risk of bias*

*Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomly allocated"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and the health visitors and community midwives would have been aware of the group allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	Data (including details of the intervention) were collected by the health visitor

Winterburn 2003 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	72 randomized; it was not clear whether full data were available for all women at 3 months
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	No baseline characteristics reported.

Wolfberg 2004

Methods	2-arm RCT, with individual randomisation; few details of study methods reported	
Participants	Partners of women attending for antenatal care at Baltimore Hospital USA 2001-2002 (567 pregnant women were approached)	
Interventions	Intervention: 1 group session for fathers, lasting 2 h, to encourage them to support their partners to breastfeed Control: usual care; fathers received classes on child safety and baby care	
Outcomes	Breastfeeding at 4, 6 and 8 weeks and breastfeeding duration	
Notes	We have not included data from this study in the review due to very high levels of attrition. 567 pregnant women were approached, of the 431 that agreed to participate only 59 fathers completed the study (14%). It was not clear at what point randomisation occurred	

*Risk of bias* *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not clear if women or fathers were aware of allocation/study hypotheses. The person delivering the class would have been aware of the intervention, but unclear if health professionals providing care would be aware of allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data were collected through phone calls or questionnaires. It was not stated who collected data and whether or not they were blinded

**Wolfberg 2004** (Continued)

Incomplete outcome data (attrition bias) All outcomes	High risk	431 women agreed to participate, but only 14% were followed up
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Quote: "The expectant mothers and fathers who were assigned randomly to the 2 study groups were demographically similar." Baseline characteristics tables were presented.

**Wrenn 1997**

Methods	2-arm quasi-RCT (even numbers to intervention and odd numbers to control group), single-site, recruitment April 1999-February 2000, n = 186, with 79 assigned to the intervention and 107 to the control group	
Participants	<p>Urban USA - military hospital in Texas</p> <p>Background rates of breastfeeding initiation: intermediate. Baseline breastfeeding rate in Texas at hospital discharge = 67% in 1999</p> <p>Inclusion criteria: mothers on postpartum ward of study hospital; aged &gt; 18 years, primiparous, uncomplicated delivery and postpartum, healthy baby, mother planned to breastfeed for at least 6 weeks</p> <p>Exclusion criteria: hospitalisation of mother or baby for &gt; 4 days; mothers who did not speak English</p> <p>Ethnic composition of sample: 63% white, 11% black, 20% Hispanic, 2% Asian, 3% other</p> <p>All participants were members of the armed forces or their dependents</p>	
Interventions	<p>Intervention: breastfeeding support in hospital visit lasting approximately 30 min, home visit 2-4 days after discharge lasting 45-60 min, and phone call 10-14 days after the home visit</p> <p>Control: standard care (not described)</p>	
Outcomes	Breastfeeding attrition to 6 weeks	
Notes		

**Risk of bias**

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Allocation by odd and even numbers in groups of 10
Allocation concealment (selection bias)	High risk	Could be anticipated

Wrenn 1997 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The person delivering the intervention would have been aware of allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	The person delivering the intervention seems to have collected outcome data
Incomplete outcome data (attrition bias) All outcomes	High risk	Information on drop-outs incomplete and loss to follow-up not balanced across groups. 79 in intervention group, 5 were lost to follow-up, data at 6 weeks from 68. Outcome data were not obtained from 32 women in the control group at 6 weeks so more women were enrolled (107 enrolled to this group). Some breastfeeding duration data were obtained from drop-outs by phone
Selective reporting (reporting bias)	Unclear risk	We did not have access to the trial registration or protocol, so could not assess this
Other bias	Unclear risk	Replacing women lost to follow-up in the control group means that this study is at high risk of bias

Wu 2014

Methods	2-arm quasi-RCT, n = 74
Participants	<p>Participants were recruited from the maternity department of a tertiary hospital in a major city of central China, Wuhan</p> <p>Background rates of breastfeeding initiation: not reported for Wuhan but 95.6% in Shanghai. In Whuhan 67% of mothers have stopped breastfeeding by 4-6 months</p> <p>Inclusion criteria: <math>\geq 18</math> years of age, able to read and understand Mandarin, new mother with a single, healthy term infant, and intending to breastfeed</p> <p>Exclusion criteria: any condition that would interfere with breastfeeding, such as a serious illness, mental illness, or an infant requiring special care that could not be discharged with the mother</p>
Interventions	<p>Intervention (n = 37): self-efficacy intervention. Women received three sessions post-partum: one within 1 day of delivery, 1 the next day and third 1 week after discharge. The sessions involved assessment of breastfeeding goals and self-efficacy, self-efficacy-enhancing strategies, and evaluation. Assessment enabled individualization of the intervention to meet the woman's needs. The self-efficacy strategies were informed by the WHO breastfeeding counselling course. At the end of each session women completed an evaluation form which was used to identify any changes needed and plan the following session</p>

Wu 2014 (Continued)

	Control (n = 37): standard care that included in-hospital care and follow-up by a community nurse after discharge
Outcomes	Breastfeeding self-efficacy Breastfeeding duration and exclusivity at 4 and 8 weeks postpartum
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient detail provided "a quasi-random, point-of-reference sample of participants"
Allocation concealment (selection bias)	Unclear risk	No details provided to enable judgement of this.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details provided to enable judgement of this.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details provided to enable judgement of this.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up in intervention group was 89% and 92% in the control group
Selective reporting (reporting bias)	Unclear risk	No evidence of documentation of prespecified outcomes available to enable judgement of this
Other bias	Unclear risk	Authors noted a potential risk of social desirability bias, as the intervention was delivered by the first author

Yotebieng 2015

Methods	3-arm cluster-controlled trial, n = 975
Participants	Health-care clinics in Kinshasa, DR Congo Background rates of breastfeeding initiation: near-universal initiation of breastfeeding 90% breastfeeding at age 1 year; 69% of babies aged 0-1 month and 35% of those aged 2-3 months (about 10-14 weeks) were exclusively breastfed Inclusion criteria: all mothers who gave birth to 1 healthy child in 1 of the participating facilities between 24 May-25 August 2012 and who intended to attend well-baby clinic visits in the same facility Exclusion criteria: intended to attend well-baby clinic visits in a different health facility, or to travel before the child was aged at least 6 months

Interventions	<p>Intervention 1 (n = 363): Baby Friendly Hospital Initiative (BFHI) steps 1-9; healthcare staff from antenatal and maternity care (i.e. delivery rooms and postpartum wards) in the intervention facilities were trained using the WHO/UNICEF course. Session 14 of the training on 'Ongoing support for mothers' was limited only to 'Describe how to prepare a mother for discharge'. Session 15 on 'Making your hospital baby friendly' was not covered. Additional material in French developed as part of a different project was distributed to staff in clinics. Implementation of steps 1-9 was assessed at the end of the study using the hospital self-appraisal questionnaire and each of the clinics randomized to intervention groups met at least 80% of the global criteria for each step</p> <p>Intervention 2 (n = 308): BFHI steps 1-10; staff training as for Intervention 1 and staff from well-child clinics also received the same training. Flyers distributed to mothers before discharge from the postpartum ward and during well-child clinic visits. These were developed locally and contained culturally appropriate messages addressing behaviours that had been identified as the main contributors to suboptimum breastfeeding practices (such as giving the baby water in the first 6 months of life) in a pretrial survey. These were published in 2 languages (French and local language). Additional material in French that had been developed as part of a different project was distributed to staff in clinics</p> <p>Implementation of steps 1-10 was assessed at the end of the study using the hospital self-appraisal questionnaire and each of the clinics randomized to intervention groups met at least 80% of the global criteria for each step</p> <p>Control (n = 304): standard care</p>
Outcomes	<p>Primary:</p> <p>Breastfeeding initiation within 1 h</p> <p>Exclusive breastfeeding at 14 and 24 weeks</p> <p>Secondary:</p> <p>Prevalence of infants with reported diarrhoea between 10-14 weeks postpartum and 18-24 weeks postpartum</p> <p>Prevalence of infants with respiratory illness between 10-14 weeks postpartum and 18-24 weeks postpartum</p>
Notes	

<i>Risk of bias</i>		<i>Risk of bias</i>
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The 3 pairs of facilities were ranked alphabetically and a computer was used to generate 3 random numbers
Allocation concealment (selection bias)	Low risk	The randomisation was done by the study statisticians who had no involvement in enrolment or follow-up of participants
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Staff in participating clinics could not be masked to the interventions to group assignments because of the nature of the interventions". Mothers were masked to group as-

		signment and this worked "quite well"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Attempts were made to blind interviewers but this "did not work so well"
Incomplete outcome data (attrition bias) All outcomes	Low risk	12% of total participants randomized lost to follow-up by 24 weeks postpartum
Selective reporting (reporting bias)	Low risk	Breastfeeding outcomes were prespecified in study protocol.
Other bias	Low risk	None identified

### Abbreviations

AIDS: acquired immunodeficiency syndrome  
 BFI: Baby Friendly Initiative (UNICEF)  
 BFHI: Baby Friendly Hospital Initiative  
 BINGO: Best Infant Nutrition for Good Outcomes  
 BMI: body mass index  
 CS: caesarean section  
 d: day(s)  
 EP: electronic prompt  
 FAB: Food, physical activity and breastfeeding  
 FBSICG: Facility-based semi-intensive counselling group  
 GP: general practitioner  
 h: hour(s)  
 HBICG: Home-based semi-intensive counselling group  
 HIV: human immunodeficiency virus  
 HV: Health Visitor  
 ICC: intra-cluster correlation coefficient  
 ICU: intensive care unit  
 ITT: intention-to-treat analysis  
 LBW: low birth weight  
 LC: lactation consultant  
 LHW: lady health worker  
 MB training: maternal breastfeeding training  
 MCH: Maternal and Child Health  
 MCHN: Maternal and Child Health Nurse  
 min: minute(s)  
 NICU: neonatal intensive care unit  
 PAIRINGS: Provider Approaches to Improved Rates of Infant Nutrition & Growth Study  
 PC: Primary Care  
 PCT: primary care trust  
 RCT: randomized controlled trial  
 RG: Registrar General  
 SCBU: special care baby unit  
 SD: standard deviation  
 SPSS: Statistical Package for the Social Sciences  
 TENS: transcutaneous electrical nerve stimulation

vs: versus

WHO: World Health Organization

WIC: Special Supplemental Nutrition Programme for Women, Infants and Children (US Department of Agriculture, Food and Nutrition Service)

UNICEF: the United Nations Children's Fund

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

Study	Reason for exclusion
<a href="#">ACTRN12614000605695</a>	Intervention targeted at fathers only.
<a href="#">ACTRN12615000063516</a>	Study of breastfeeding promotion not breastfeeding support.
<a href="#">Agrasada 2005</a>	Low birthweight infants. Under consideration for review of support for mothers breastfeeding infants who are not term and healthy
<a href="#">Ahmed 2008</a>	Premature infants. Under consideration for review of support for mothers breastfeeding infants who are not term and healthy
<a href="#">Ahmed 2016</a>	Web-based intervention
<a href="#">Ball 2011</a>	The intervention examined in this trial was not a breastfeeding support intervention. The trial examined the use of a baby cot that was clamped onto the side of the mother's bed so that the baby was within easy reach of the mother at all times
<a href="#">Baqui 2008</a>	Intervention was given antenatally and postnatally by community health workers giving home visits to promote newborn health and. Comparison was group sessions with same aim. This study was assessing general health and clinical outcomes, not breastfeeding support
<a href="#">Barlow 2006</a>	Educational intervention not intended to facilitate continued breastfeeding
<a href="#">Barnet 2002</a>	Intervention did not have the purpose of facilitating continued breastfeeding
<a href="#">Beiler 2011</a>	Not a breastfeeding support intervention.
<a href="#">Benitez 1992</a>	Intervention was educational, not support.
<a href="#">Bica 2014</a>	Study comparing mothers who live with their mothers and mothers who do not
<a href="#">Black 2001</a>	Intervention did not have the purpose of facilitating continued breastfeeding
<a href="#">Blixt 2014</a>	Not a trial.
<a href="#">Bolam 1998</a>	Evaluated an educational intervention.
<a href="#">Brown 2008</a>	Low birthweight infants. Under consideration for review of support for mothers breastfeeding infants who are not term and healthy

(Continued)

Byas 2011	Intervention targeted at fathers.
Carlsen 2013	Specifically focused on overweight or obese women so does not meet healthy women inclusion criteria
Cattaneo 2001	Intervention was staff training, and participants were hospitals
Caulfield 1998	Not a randomized controlled trial (see Dyson et al).
Chapman 2011	This study specifically focused on women with obesity. The study will be considered for inclusion in a proposed review on breastfeeding support for women at high risk of health problems that affect breastfeeding
Christie 2011	Not a breastfeeding support intervention.
Davies-Adetugbo 1996	Controlled study of breastfeeding counselling intervention without randomisation
Davies-Adetugbo 1997	Infants with diarrhoea. Under consideration for review of support for mothers breastfeeding infants who are not term and healthy
Davis 2014	Participants were students nurses. Outcomes were their knowledge and attitudes
Ebbeling 2007	Not a randomized controlled trial.
Edwards 2013a	Delivered by a computer agent (not health professional or lay worker) and appeared to give educational advice, not support
Ehrlich 2014	Not a breastfeeding support intervention.
Eneroth 2007	Not a study of a breastfeeding support intervention.
Ferrara 2008	Participants were women with gestational diabetes. Under consideration for review of support for mothers with conditions affecting/affected by breastfeeding
Finch 2002	Evaluated an antenatal educational and marketing intervention. Both groups received postnatal breastfeeding support. Under consideration for the review Interventions for promoting the initiation of breastfeeding (Dyson et al)
Finch 2015	Not focused on breastfeeding support.
Flax 2014	Educational intervention.
Forster 2004	Evaluated an educational intervention.
Forster 2006	Antenatal intervention with no postnatal component.
Gagnon 1997	Intervention not relevant for this review. The intervention was an alternative to standard care. The intervention was not aimed at facilitating breastfeeding, rather the trial compared women who were

(Continued)

	randomized to early hospital discharge with telephone follow-up (with home visits by nurses only for those women who left hospital within 36 h of the birth “to encourage them to leave the hospital early”) versus usual care with later discharge from hospital. It was not clear that the intervention included any breastfeeding support. Although outcomes included breastfeeding the main focus was on “maternal competence” and infant outcomes. 44% post-randomisation exclusions
Garcia-Montrone 1996	Educational intervention. Controls were matched, but not randomized
Giglia 2015	Web-based programme. Not over the phone or face-to-face.
Gijsbers 2006	This study focused on families with a history of asthma.
Girish 2013	Not breastfeeding support.
Guise 2003	A review
Haider 1996	Infants with diarrhoea. Under consideration for review of support for mothers breastfeeding infants who are not term and healthy
Haider 2014	Non-randomised selected study participants.
Hall 2007	Not an RCT (groups not concurrent). Substudy asking open-ended questions
Hanafi 2014	Intervention was education rather than support, and only measured breastfeeding initiation and attitudes towards and knowledge of breastfeeding. No measures of sustained breastfeeding
Harari 2014	Texting intervention. Not face-to-face or over the phone.
Hauck 1994	Intervention was a booklet and did not involve contact with an individual
Henderson 2001	Evaluated an educational intervention.
Hives-Wood 2013	News article
Hoddinott 2012a	This was a secondary report on feasibility, acceptability and fidelity of the intervention within the RCT. No breastfeeding data reported
Ijumba 2015	Study participants included HIV-positive women.
Israel-Ballard 2014	Study participants were breastfeeding women.
Isselmann 2006	Educational intervention which did not have the purpose of facilitating continued breastfeeding
Jahan 2014	Antenatal educational intervention only with no postnatal component
Jakobsen 2008	Educational intervention
Jang 2008	Not an RCT (groups not concurrent).

(Continued)

Johnston 2001	This study examined an intervention carried out in the antenatal period
Jones 2004	Evaluated an education intervention. In this study women were offered specialist lactation advice by the researcher regarding returning to work and milk expression. This was a 1-h evidence-based session and was reinforced with a written leaflet. Results were reported for those women still breastfeeding on their return to work
Junior 2007	Very low birthweight infants. Under consideration for review of support for mothers breastfeeding infants who are not term and healthy
Katepa-Bwalya 2011	Trial about using materials (counselling cards) as part of an antenatal counselling session. HIV-positive women
Kistin 1994	Non-randomised observational study.
Kronborg 2012	Antenatal education programme with no postnatal component.
Labarere 2003	Evaluated an educational intervention.
Labarere 2011	Educational intervention delivered via CD-ROM.
Lavender 2004	Evaluated an educational intervention.
Lewin 2005	A review
Lieu 2000	Support was not supplementary to standard care.
Louzada 2012	Not a breastfeeding support intervention.
MacArthur 2002	Intervention was not breastfeeding support. No breastfeeding outcomes reported
MacArthur 2009	Antenatal intervention with no postnatal component.
Mannan 2008	All the women in this study received the breastfeeding intervention and were analysed on the basis of intervention intensity and not on the basis of comparator versus intervention
Martin 2015	Study with overweight and obese mothers (thus not healthy).
Martin-Iglesias 2011	Study was of a healthcare professional education intervention
Mattar 2003	Evaluated an educational intervention.
Maycock 2013	Intervention aimed at fathers.
Maycock 2015	Ongoing trial of an educational intervention.
McInnes 2000	Geographical controls

(Continued)

McLeod 2003	This study specifically focused on smoking and the aim of the support intervention was to encourage women to quit or reduce smoking in pregnancy, although breastfeeding outcomes were reported. The study will be considered for inclusion in a proposed review on breastfeeding support for women at high risk of health problems that affect breastfeeding
Merewood 2006	Infants in neonatal intensive care. Under consideration for review of support for mothers breastfeeding infants who are not term and healthy
Mesters 2013	Participants had a family history of asthma so may not meet inclusion criteria as 'healthy'
Moore 1985	Participants in this study may not have been healthy mothers. We excluded this study as it focused on parents with eczema or asthma and was examining the impact of a breastfeeding intervention on the occurrence of these diseases in babies
Moreno-Manzanares 1997	Correspondence with author established study was controlled, but not randomized
Nasehi 2012	Early breastfeeding initiation was the intervention rather than an outcome. This study aimed to assess the effect of early breastfeeding initiation on exclusive breastfeeding duration
Nekavand 2014	Trial of an educational intervention.
Neyzi 1991	It was not clear whether this was a randomized trial. Only 66% follow-up in intervention group
Nguyen 2014	Did not report a trial
Nkonki 2014	Economic evaluation - part of PROMISE-EBF trial.
Noel-Weiss 2006	Antenatal intervention with no postnatal component.
Nor 2009	Not an RCT. Qualitative study looking at women's views of peer counselling
Nor 2012	Qualitative study (mothers' experiences) embedded within cluster-RCT (Nkonki 2014).
Ochola 2013a	Abstract only - qualitative aspects of cluster-RCT above in (Nkonki 2014).
Olenick 2011	The intervention took place before the birth; there was no postnatal component
Otsuka 2012	The intervention took place before the birth; there was no postnatal component
Otsuka 2014	Intervention was primarily educational.
Pascali-Bonaro 2004	Paper was not about a trial.
Paul 2011	Not breastfeeding support.
Penfold 2014	The follow-up was only 3 days, so the outcomes did not meet the inclusion criteria

(Continued)

Perez-Blasco 2013	Not breastfeeding support.
Perez-Escamilla 1992	Study controlled, but not randomized.
Peterson 2002	Both groups received WIC breastfeeding education. The intervention group received social support for maternal diet, activity and weight loss outcomes
Phillips 2010	This study only recruited women whose babies were admitted to neonatal intensive care. Breastfeeding support for mothers of poorly babies will be considered in a separate review
Phillips 2011	Intervention about smoking cessation and both groups got breastfeeding support
Phillips 2012	Babies in neonatal intensive care unit.
Pinelli 2001	Very low birthweight infants. Under consideration for review of support for mothers breastfeeding infants who are not term and healthy
Pollard 1998	Self monitoring, not support.
Pollard 2011	This study did not examine a breastfeeding support intervention by professionals or peers. The intervention group completed daily feeding logs recording breastfeeding practices
Pound 2015	Hospitalised jaundiced infants.
Rasmussen 2010	Did not report a study.
Rasmussen 2011	This study specifically focused on women with obesity. The study will be considered for inclusion in a proposed review on breastfeeding support for women at high risk of health problems that affect breastfeeding
Ratner 1999	Intervention did not have the purpose of facilitating continued breastfeeding
Rea 1999	Training intervention with no data on breastfeeding women.
Reeve 2004	Evaluated an antenatal education intervention.
Rojjanasrirat 1987	Study changed methodology part way through.
Rossiter 1994	Educational intervention
Rowe 1990	Abstract only available. No information on intervention used
Rush 1991	Trial of hospital telephone help-line. The intervention was an invitation to call a general telephone support line in the postnatal period; the help-line was available to women in the control group, but this new service development was not promoted with this group. The aim of the study was to examine the uptake of this service (i.e. reasons for and number of calls to the help-line and to other hospital departments from control and intervention women). The intervention was general and was not specifically

(Continued)

	to encourage breastfeeding; breastfeeding and breastfeeding duration were not measured
<a href="#">Sakha 2008</a>	All the participants had given birth by caesarean section. Both groups received an educational intervention. 1 group received a drug to promote lactation
<a href="#">Sakkaki 2013</a>	Study participants were all women who had received caesarean section
<a href="#">Schlomer 1999</a>	Assessing effectiveness of breastfeeding assessment tools (LATCH or Infant Breastfeeding Assessment Tool (IBFAT)), and their correlation with scales of breastfeeding problems (Maternal Breastfeeding Evaluation Scale (MBFES) and Potential Early Breastfeeding Problem Tool (PEBPT)) not supporting breastfeeding
<a href="#">Schy 1996</a>	Evaluated a purely educational intervention.
<a href="#">Sciacca 1995</a>	Support intervention available to all women in the trial.
<a href="#">Segura-Millan 1994</a>	Study controlled, but not randomized.
<a href="#">Serrano 2010</a>	The intervention examined in this study was baby massage and not breastfeeding support. Breastfeeding was reported as a secondary outcome
<a href="#">Sisk 2006</a>	Not an RCT.
<a href="#">Steel O'Connor 2003</a>	Support was not supplementary to standard care.
<a href="#">Stuebe 2016</a>	Women had gestational diabetes.
<a href="#">Susin 2008</a>	Participants were not randomized.
<a href="#">Svensson 2013</a>	The intervention was focused on skin-to-skin positioning for babies with latch problems. Breastfeeding counselling was given to both randomized groups
<a href="#">Szucs 2015</a>	Monitoring system, breastfeeding outcomes
<a href="#">Talukder 2012</a>	After 6 months of intervention, an endline survey was conducted on a different sample of mothers from those assessed at baseline
<a href="#">Talukder 2016</a>	Trial of an educational intervention.
<a href="#">Thakur 2012</a>	Based on low birthweight babies - recruited postnatally.
<a href="#">Thomson 2009</a>	Both groups received support as part of standard care. The intervention was not breastfeeding support
<a href="#">Thussanasupap 2006</a>	Educational intervention. Not an RCT (assignment was 30 then another 30)
<a href="#">Tohotoa 2012</a>	The intervention targeted fathers' anxieties. Though breastfeeding was an aim of the trial, the recruitment and eligibility was based solely on fathers' characteristics, so there is no way of knowing whether women and babies were healthy

(Continued)

Tully 2012	Intervention was a side cot attached to bed, not directly a breastfeeding intervention
Valdes 2000	Study was controlled, but not randomized.
Vianna 2011	The intervention consisted of music therapy rather than breastfeeding support; women and their premature babies (< 1750 g) were included in the trial
Vitolo 2012	A study of dietary counselling in reducing the intake of energy-dense foods by infants
Vitolo 2014	The intervention involved training health professionals about healthy feeding practices, including breastfeeding. Women were approached directly for outcome measurement only - what support if any they received from health staff was unclear, but we only have the abstract
Wallace 2006	This study was excluded as it examined a brief educational intervention by midwives advising mothers on the correct positioning of the baby for breastfeeding
Wan 2011	This study was excluded as it compared two models of nursing care (continuous versus task orientated) and was not a study of breastfeeding support interventions.
Wasser 2015	Proposal for a trial.
Westphal 1995	Intervention was training, and participants were hospitals.
Wiggins 2005	Evaluated a social support intervention.
Williams 2014	Not breastfeeding support intervention.
Wockel 2009	This study examined an intervention aimed at fathers which was offered as part of antenatal childbirth preparation classes. There was no postnatal component to the intervention

### Abbreviations

h: hour(s)

RCT: randomised controlled trial

WIC: Special Supplemental Nutrition Programme for Women, Infants and Children (US Department of Agriculture, Food and Nutrition Service)

### Characteristics of studies awaiting assessment *[ordered by study ID]*

### Babakazo 2015

Methods	2-arm cluster-RCT, n = 422
Participants	Kinshasa, Democratic Republic of the Congo Background rates of breastfeeding initiation: 52.4% No details about inclusion and exclusion criteria available in English abstract
Interventions	Intervention: training of healthcare providers through the Baby Friendly Hospital Initiative using the "20 hour course for Maternity Staff" Total number randomised: details not provided in English abstract Control: details not provided in English abstract
Outcomes	Exclusive breastfeeding at 6 months Median duration of breastfeeding
Notes	Needs to be translated from French

### Bahri 2013

Methods	3-arm, parallel RCT, n = 90
Participants	Health centres in Gonbad, Iran Background rates of breastfeeding initiation: > 90% Inclusion criteria: pregnant women. No further details provided in English abstract Exclusion criteria: no details provided in English abstract.
Interventions	Intervention 1 (n = 30): 3-h workshop on breastfeeding training Intervention 2 (n = 30): booklet about breastfeeding provided Control (n = 30): no special training on breastfeeding
Outcomes	Knowledge about breastfeeding Health beliefs about postpartum breastfeeding Breastfeeding behaviour in first 24 h after delivery
Notes	Needs to be translated from Arabic

### Cabezas 2014

Methods	2-arm, parallel RCT, n = 220
Participants	Women receiving care from the Sexual and Reproductive Health Centre in Barcelona, Spain Background rates of breastfeeding initiation: 77% Inclusion criteria: low-risk pregnancy and being cared for in the Sexual and Reproductive Health Centre Exclusion criteria: not specified
Interventions	Intervention: usual care plus telephone support from a community midwife Control: usual care Total number randomised: not specified for either group.

**Cabezas 2014** (Continued)

Outcomes	Frequency of difficulties that women experienced breastfeeding Satisfaction with telephone support
Notes	Conference abstract. Unable to locate authors.

**Kamau-Mbuthia 2013**

Methods	3-arm, parallel RCT, n = 505
Participants	Low income women attending for antenatal care at a large hospital in Kenya Background rates of breastfeeding imitation: 56.1% No details about inclusion and exclusion criteria provided.
Interventions	Intervention 1: continuous cell phone-based peer support (CPS); support was provided by trained peer support leaders from late pregnancy (32-36 weeks) until 3 months postpartum Intervention 2: monthly peer support group (PSG). Support was provided by trained peer support leaders from late pregnancy (32-36 weeks) until 3 months postpartum Control: standard care by existing facility-based support No details provided about the total number randomised in each group
Outcomes	Exclusive breastfeeding at 3 months
Notes	Conference abstract only. SM contacted authors for more information 20 July 2016

**Li 2014**

Methods	2-arm, cluster randomised trial, n = 308
Participants	Women attending community health clinics in Shanghai at 11-22 weeks gestation Background rates of breastfeeding imitation: 41.0% No details provided in abstract about inclusion/exclusion criteria
Interventions	Intervention: weekly SMS messages from 28 weeks gestation until the children were 1 year old. 'Message bank' development was based on literature review and in-depth interviews/focus group discussion with pregnant women, new mothers and healthcare providers Control: no details provided in abstract No details provided about the total number randomised in each group
Outcomes	Exclusive breastfeeding at 4 months
Notes	Conference abstract only. SM contacted authors for more information 21 July 2016

### Mortazavi 2014

Methods	2-arm RCT, n = 186
Participants	Women attending health centres in Sabzevar, Iran Background rates of exclusive breastfeeding at 6 months: 53.1% Inclusion criteria: wanted pregnancy and primigravidity Exclusion criteria: no details provided in English abstract
Interventions	Intervention: husbands attended prenatal care Control: women attended prenatal care alone No details provided about total number randomised in each group
Outcomes	Satisfaction of husband involvement Husband taking care of baby in absence of mother Husband's support of breastfeeding
Notes	Needs to be translated from Arabic.

### Raisi 2012

Methods	2-arm., parallel RCT, n = 140
Participants	Primiparous women attending the selected health centres of Tehran University of Medical Sciences, Iran Background rates of breastfeeding imitation: > 90% Details of inclusion/exclusion criteria not provided in English abstract
Interventions	Intervention (n = 70): telephone counselling on breastfeeding provided by one of the researchers Control (n = 70): routine care
Outcomes	Exclusive breastfeeding at 1 and 3 months Duration of continuity and exclusivity of breastfeeding
Notes	Needs to be translated from Arabic

### Reeder 2014

Methods	3-arm, parallel RCT, n = 1948
Participants	English- or Spanish-speaking recipients of the Supplemental Nutrition Program for Women, Infants, and Children (WIC) in Oregon, USA Background breastfeeding imitation rates: 90% Inclusion criteria: English- and Spanish-speaking women attending a new pregnancy appointment for the Supplemental Nutrition Program for Women, Infants, and Children (WIC) programme between July 2005 and July 2007; intending to breastfeed or undecided about breastfeeding Exclusion criteria: no exclusions on the basis of age, multiple gestations, known risk factors or previous birth history
Interventions	Intervention 1 (n = 646): low frequency peer counselling; women received 4 planned, peer-initiated contacts: the first after initial prenatal assignment, the second 2 weeks before the expected due date, and the third and fourth at 1 and 2 weeks postpartum

**Reeder 2014** (Continued)

	Intervention 2: (n = 645): high frequency peer counselling; women received 8 scheduled calls. The first 4 calls were the same as those in the low-frequency treatment group and the last 4 calls were scheduled at months 1, 2, 3, and 4
Outcomes	Breastfeeding imitation Exclusive breastfeeding at 1, 3 and 6 months Any breastfeeding at 1, 3 and 6 months
Notes	SM contacted authors for data 21 July 2016.

**Taylor 2014**

Methods	4-arm RCT, n = 802
Participants	Multiparous and primiparous women recruited during pregnancy. No other details provided about participants or study setting
Interventions	Intervention 1: 'Sleep'; education sessions antenatally and at 3 weeks targeting the prevention of sleep problems, followed by an intervention from 6 months postpartum targeting the treatment of sleep problems Intervention 2: 'FAB'; provision of a LC to promote breastfeeding to 6 months, and education sessions at 3, 5, 7, 9, 12 and 18 months targeting healthy eating, sedentary time and active play for families Intervention 3: 'Combo'; Sleep and FAB interventions Control: standard Well Child Care (note all groups received this) No details provided in abstract about numbers randomised to each group
Outcomes	BMI (at 2 years) Levels of physical activity Infant feeding Sleep Dietary intake
Notes	Conference abstract only. SM contacted authors for more information 21 July 2016

**Whalen 2011**

Methods	2-arm RCT, n = 206
Participants	Mother-baby dyads attending a 2-week well-baby visit. Study mothers were mainly white, non-Hispanic, highly educated, married, of higher socioeconomic status, planned to return to work or school after their baby's birth, and reported good to excellent baseline confidence in breastfeeding No details provided about inclusion/exclusion criteria.
Interventions	Intervention (n = 100): online breastfeeding tutorial and maternal needs assessment administered at 2-week, 2-, 4-, and 6-month well-baby visits with provider counselling targeted to the mother's needs Control (n = 106): usual care
Outcomes	Exclusive breastfeeding at 2 months Exclusive breastfeeding at 2 months

**Whalen 2011** (Continued)

	Any breastfeeding at 2 months
Notes	Conference abstract only. SM contacted authors for further details 21 July 2016

**Abbreviations**

BMI: body mass index

FAB: Food, physical activity and breastfeeding

LC: lactation consultant

RCT: randomised controlled trial

WIC: Special Supplemental Nutrition Programme for Women, Infants and Children (US Department of Agriculture, Food and Nutrition Service)

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

**Forster 2014**

Trial name or title	Ringling Up about Breastfeeding: a randomised controlled trial exploring early telephone peer support for breastfeeding (RUBY) - trial protocol
Methods	2-arm RCT
Participants	All eligible women having a baby at the Women's, Monash Medical Centre and Sunshine Hospital during the recruitment period will be offered participation. Women attending these hospitals, although from a wide range of backgrounds, tend to be relatively disadvantaged, with low income and of culturally diverse backgrounds (even among those women who do speak English) Inclusion criteria: women admitted to the postnatal wards as public patients who have had a first live birth; are proficient in English; and breastfeeding or intending to breastfeed Exclusion criteria: serious illness (e.g. severe pre-eclampsia/eclampsia, significant postpartum haemorrhage, severe psychiatric disturbance, pulmonary embolus); infant remaining in hospital after the mother's postnatal discharge; multiple birth; mother has chosen to formula feed; or antenatal membership of the Australian Breastfeeding Association (ABA), as this may be associated with a higher breastfeeding intention
Interventions	Intervention: proactive peer support will be provided by telephone Control: usual care; all women recruited to the trial will receive usual hospital postnatal care and infant feeding support. The usual length of hospital stay postpartum is 2 nights following a vaginal birth and 3 for caesarean births. All women are eligible for 1 or more home visits by a hospital midwife in the early postnatal period as well as ongoing support from their local Maternal and Child Health (MCH) nurse
Outcomes	Primary: the proportion of infants who are breastfed for at least 6 months
Starting date	Unclear
Contact information	Australian and New Zealand Clinical Trials Registry ACTRN12612001024831
Notes	

### Karanja 2012

Trial name or title	A community-based intervention to prevent obesity beginning at birth among American Indian children: study design and rationale for the PTOTS study
Methods	A cluster-RCT
Participants	A birth cohort of 577 children (infants and toddlers aged 0-2 years) from 5 American Indian tribes randomised by tribe to either the intervention (3 tribes) or the comparison condition (control; 2 tribes)
Interventions	Intervention: includes nutrition and physical activity goals, and consists of a community-wide component coupled with an individualised family-counselling component to improve nutrition and physical activity in infants and toddlers. The nutrition goals are presented in 4 modules: 1) breastfeeding, 2) curtailment of sugar sweetened beverage consumption, 3) introduction of healthy solid foods, and 4) parental management of feeding behaviours Control: parents and guardians in the control tribes consent to provide study data for their children. Nondiagnostic dental screenings are offered to children aged 1-5 years as a service to these comparison communities
Outcomes	Breastfeeding initiation and duration rates
Starting date	Unclear
Contact information	N Karanja Center for Health Research, Kaiser Permanente-Northwest/Hawaii/Southeast, 3800 N. Interstate Avenue, Portland, OR 97227, USA e-mail: Njeri.Karanja@kpchr.org
Notes	

### Kikuchi 2015

Trial name or title	Ghana's Ensure Mothers and Babies Regular Access to Care (EMBRACE) programme: study protocol for a cluster-randomised controlled trial
Methods	Cluster-RCT using an effectiveness-implementation hybrid design in Dodowa, Kintampo, and Navrongo, Ghana
Participants	The study population is women of reproductive age between the ages of 15 and 49 years
Interventions	The provision of an intervention package to women living in randomly allocated intervention clusters. The package includes: 1) use of a new continuum of care card, 2) continuum of care orientation for health workers, 3) 24-h health facility retention of mothers and newborns after delivery, and 4) postnatal care by home visits
Outcomes	Maternal, newborn, and child health outcomes for both intervention and implementation impacts Intervention outcomes: continuum of care completion rate, rate of postnatal care within 48 h, complication rate requiring mothers' and newborns' hospitalisations, and perinatal and neonatal mortality Implementation outcomes: intervention coverage of the target population, intervention adoption and fidelity, implementation cost, and sustainability

**Kikuchi 2015** (Continued)

Starting date	Unclear
Contact information	Current Controlled Trials ISRCTN90618993. Registered on 3 September 2014
Notes	

**Kimani-Murage 2013**

Trial name or title	Effectiveness of personalised, home-based nutritional counselling on infant feeding practices, morbidity and nutritional outcomes among infants in Nairobi slums: study protocol for a cluster-randomised controlled trial
Methods	A cluster-randomised study design, will be conducted in 2 slums in Nairobi, Korogocho and Viwandani, where 14 community units (defined by the Government's healthcare system) will form the unit of randomisation
Participants	A total of 780 pregnant women and their respective child will be recruited into the study. The mother-child pair will be followed up until the child is 1 year old. Study participants will include all pregnant women aged 12-49 years old, who are residents of CUs in Korogocho and Viwandani slums that fall within the Nairobi Urban Health and Demographic Surveillance System area, and their respective children (when born). These will be recruited during pregnancy on a rolling basis until the desired sample size is achieved
Interventions	The mothers will receive regular, personalised, home-based counselling by trained Community Health Workers on maternal, infant and young child nutrition. Regular assessment of knowledge, attitudes and practices will be done, coupled with assessments of nutritional status of the mother-child pairs and diarrhoea morbidity for the children
Outcomes	Primary: exclusive breastfeeding for 6 months
Starting date	September 2012
Contact information	*Correspondence: ekimani@aphrc.org: African Population and Health Research Center (APHRC), PO 10787, 00100 Nairobi, Kenya
Notes	

**Kimani-Murage 2015**

Trial name or title	Feasibility and effectiveness of the baby friendly community initiative in rural Kenya: study protocol for a randomised controlled trial
Methods	A formative study using participatory action research design will first be conducted, followed by a cluster-randomised trial utilising both qualitative and quantitative data collection methods. 12 CUs will constitute the clusters to be included in the study. CUs are geographically defined units, mostly equal to a village and usually have a population size of approximately 5000 people
Participants	This trial will include women of reproductive age (15-49 years) who are pregnant at the time of recruitment, and their respective children from the pregnancies aged less than 6 months in Koibatek sub-county in Baringo county

**Kimani-Murage 2015** (Continued)

Interventions	The intervention will involve implementation of the BFCI in the intervention clusters. The proposed BFCI in Kenya is a multifaceted program for promotion of optimal breastfeeding and infant and young child nutrition, and other practices including maternal nutrition in the community. The BFCI is based on the principles of the BFHI, but extends them to the community in order to provide women with a comprehensive support system to improve breastfeeding practices and other maternal, infant and young child nutrition practices at the community level. The BFCI package (unpublished) adapted for implementation in Kenya involves an 8-step plan
Outcomes	Primary: proportion of children being exclusively breastfed for the first 6 months
Starting date	January 2015
Contact information	ISRCTN03467700; Date of registration: 24 September 2014
Notes	

**Nabulsi 2014**

Trial name or title	A complex breastfeeding promotion and support intervention in a developing country: study protocol for a randomised clinical trial
Methods	A randomised controlled single-blind parallel-arm clinical trial to investigate whether a complex intervention targeting new mothers' breastfeeding knowledge, skills and social support within a Social Network and Social Support theory framework will increase exclusive breastfeeding duration among women in Lebanon
Participants	Healthy pregnant women who are in their first or second trimester and who intend to breastfeed after delivery will be eligible to participate in this study
Interventions	Intervention: women will receive, in addition to standard clinical care, a complex intervention starting in early pregnancy until 6 months postdelivery. The intervention is composed of the following elements: 1) prenatal breastfeeding education to raise knowledge and awareness, 2) postpartum professional lactation support to improve maternal skills and self-efficacy, 3) postpartum peer (lay) support to build social support, and enhance social capital within women's social networks. These include skill building activities for the provision of effective breastfeeding support Control: women will receive standard prenatal and postnatal care that is usually offered to mothers at both study sites
Outcomes	Primary: percentage difference in 6-month breastfeeding exclusivity rates between the intervention and control groups
Starting date	Unclear
Contact information	Current Controlled Trials ISRCTN17875591
Notes	

### Nair 2015

Trial name or title	Participatory women's groups and counselling through home visits to improve child growth in rural eastern India: protocol for a cluster-randomised controlled trial
Methods	A cluster-RCT in 2 rural districts of Jharkhand and Odisha (Eastern India)
Participants	The unit of randomisation is a purposively selected cluster of approximately 1000 population. A total of 120 geographical clusters covering an estimated population of 121,531 were randomised to 2 trial arms: 60 clusters in the intervention arm and 60 clusters in the control arm. The study participants are pregnant women identified in the third trimester of pregnancy and their children (n = 2520)
Interventions	Intervention: a community-based worker carrying out 2 activities: 1) 1 home visit to all pregnant women in the third trimester, followed by subsequent monthly home visits to all infants aged 0-24 months to support appropriate feeding, infection control, and care-giving; 2) a monthly women's group meeting using participatory learning and action to catalyse individual and community action for maternal and child health and nutrition. Also receive an intervention to strengthen Village Health Sanitation and Nutrition Committees Control: receive an intervention to strengthen Village Health Sanitation and Nutrition Committees only
Outcomes	Mothers and their children are followed up at 7 time points: during pregnancy, within 72 h of delivery, and at 3, 6, 9, 12 and 18 months after birth Primary: children's mean length-for-age Z scores at 18 months Secondary: wasting and underweight at all time points, birthweight, growth velocity, feeding, infection control, and care-giving practices Additional qualitative and quantitative data are collected for process and economic evaluations
Starting date	July 2013
Contact information	ISRCTN register 51505201; Clinical Trials Registry of India number 2014/06/004664
Notes	

### NCT01383070

Trial name or title	Evaluation of the effectiveness of cell phone technology as community based intervention to improve exclusive breastfeeding and reduce infant morbidity rates
Methods	Cluster-randomised trial
Participants	Staff training to promote breastfeeding
Interventions	All the women in the trial will receive hospital maternity care at hospitals using BFHI (WHO/UNICEF Baby Friendly Hospital Initiative) training for staff Intervention clusters: in addition to counselling in the hospitals during the scheduled antenatal visits, women will receive personalised lactation consultation and support via cell phone (handsets provided). Cell phone counselling will continue until 24 weeks after the birth Control clusters: existing staff at the hospitals will be encouraged to set up their own systems to continue counselling of women during the antenatal period, at delivery and during immunisation visits

Outcomes	<p>Primary: exclusive breastfeeding at 24 weeks</p> <p>Secondary:</p> <p>Timely initiation of breastfeeding</p> <p>Timely initiation of complimentary feeding</p> <p>Duration of any breastfeeding</p> <p>Infant growth</p> <p>Hospital admissions/mortality for infants and mothers</p> <p>Maternal satisfaction</p> <p>Cost effectiveness</p>
Starting date	August 2010
Contact information	ceuggmc@yahoo.co.in
Notes	Clinical Trials.gov accessed 14 December 2011 showed "This study is currently recruiting participants" with the verification date June 2011

**Abbreviations**

BFCI: Baby Friendly Community Initiative  
 BFHI: Baby Friendly Hospital Initiative  
 CU: Community Unit  
 h: hour(s)  
 MIYCN: Maternal and Young Child Nutrition  
 RCT: randomised controlled trial  
 UNICEF: the United Nations Children's Fund  
 WHO: World Health Organization

## DATA AND ANALYSES

### Comparison 1. All forms of support versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Stopping breastfeeding (any) before last study assessment up to 6 months	51	21418	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.88, 0.95]
2 Stopping exclusive breastfeeding before last study assessment up to 6 months	46	18591	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.85, 0.92]
3 Stopping breastfeeding (any) at up to 4-6 weeks	33	11264	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.80, 0.95]
4 Stopping exclusive breastfeeding at up to 4-6 weeks	32	10960	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.71, 0.89]
5 Sensitivity analysis by risk of bias allocation concealment: stopping any breastfeeding at up to six months	51		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.1 Studies at low risk of bias	27	13465	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.89, 0.96]
5.2 Unclear or high risk of bias	24	7953	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.83, 0.95]
6 Sensitivity analysis by risk of bias allocation concealment: stopping exclusive breastfeeding at up to six months	46		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
6.1 Studies at low risk of bias	27	11351	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.89, 0.96]
6.2 Unclear or high risk of bias	19	6828	Risk Ratio (M-H, Random, 95% CI)	0.74 [0.65, 0.84]
7 Sensitivity analysis by risk of bias allocation concealment: stopping any breastfeeding at 4-6 weeks	31		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
7.1 Studies at low risk of bias	19	6817	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.81, 0.96]
7.2 Unclear or high risk of bias	12	3528	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.68, 1.03]
8 Sensitivity analysis by risk of bias allocation concealment: stopping exclusive breastfeeding by 4-6 weeks	32		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
8.1 Studies at low risk of bias	20	7107	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.79, 0.96]
8.2 Unclear or high risk of bias	12	3164	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.48, 0.86]

### Comparison 2. All forms of support versus usual care: SUBGROUP ANALYSIS - who delivered the intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Stopping any breastfeeding before last study assessment up to 6 months	51	21418	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.88, 0.95]
1.1 Professional support	37	16835	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.89, 0.96]
1.2 Lay support	9	3109	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.77, 0.93]
1.3 Both professional and lay support	5	1474	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.91, 1.03]
2 Stopping exclusive breastfeeding before last study assessment	46	18424	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.85, 0.92]
2.1 Professional support	30	12760	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.89, 0.96]
2.2 Lay support	13	4590	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.65, 0.87]
2.3 Both professional and lay support	3	1074	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.44, 1.32]
3 Stopping any breastfeeding at up to 4-6 weeks	34	11815	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.78, 0.92]
3.1 Professional support	23	8104	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.72, 0.91]
3.2 Lay support	8	2789	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.78, 1.06]
3.3 Both professional and lay support	3	922	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.68, 1.11]
4 Stopping exclusive breastfeeding at up to 4-6 weeks	32	10934	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.71, 0.89]
4.1 Professional support	22	7435	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.75, 0.95]
4.2 Lay support	8	2354	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.46, 0.89]
4.3 Both professional and lay support	2	1145	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.89, 0.99]

### Comparison 3. All forms of support versus usual care: SUBGROUP ANALYSIS - type of support

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Stopping any breastfeeding before last study assessment up to 6 months	50	20946	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.88, 0.95]
1.1 Predominantly telephone support	3	677	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.65, 1.17]
1.2 Predominantly face-to-face contact	24	13890	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.86, 0.95]
1.3 Balanced telephone and face-to-face support	23	6379	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.87, 0.98]
2 Stopping exclusive breastfeeding by last study assessment up to 6 months	46	19495	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.87, 0.93]

2.1 Predominantly telephone support	2	419	Risk Ratio (M-H, Random, 95% CI)	1.0 [0.99, 1.01]
2.2 Predominantly face-to-face contact	29	13905	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.81, 0.90]
2.3 Balanced telephone and face-to-face	17	5171	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.93, 1.00]
3 Stopping any breastfeeding by 4-6 weeks	32	11076	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.79, 0.93]
3.1 Predominantly telephone support	3	1133	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.54, 1.08]
3.2 Predominantly face-to-face contact	13	5186	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.75, 0.94]
3.3 Balanced telephone and face-to-face	17	4757	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.78, 1.02]
4 Stopping exclusive breastfeeding by 4-6 weeks	31	10311	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.69, 0.89]
4.1 Predominantly telephone support	3	1142	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.54, 1.55]
4.2 Predominantly face-to-face contact	16	5382	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.57, 0.81]
4.3 Balanced telephone and face-to-face	13	3787	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.88, 0.99]

#### Comparison 4. All forms of support versus usual care: SUBGROUP ANALYSIS - timing of support

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Stopping any breastfeeding at last study assessment up to 6 months	51	21418	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.88, 0.95]
1.1 Postnatal support alone	35	15570	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.86, 0.95]
1.2 Antenatal component to support	16	5848	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.88, 0.97]
2 Stopping exclusive breastfeeding by last assessment up to 6 months	45	18374	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.88, 0.94]
2.1 Postnatal support alone	29	11683	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.84, 0.94]
2.2 Antenatal component to support	17	6691	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.89, 0.97]
3 Stopping any breastfeeding at 4-6 weeks	32	11262	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.80, 0.93]
3.1 Postnatal support alone	22	7793	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.75, 0.93]
3.2 Antenatal component to support	10	3469	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.81, 1.00]
4 Stopping exclusive breastfeeding at up to 4-6 weeks	31	10311	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.69, 0.89]
4.1 Postnatal support alone	23	7764	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.61, 0.93]

4.2 Antenatal component to support	8	2547	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.81, 0.96]
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### Comparison 5. All forms of support versus usual care: SUBGROUP ANALYSIS - breastfeeding initiation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Stopping any breastfeeding by last assessment up to 6 months	49	21162	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.89, 0.95]
1.1 Settings with high breastfeeding initiation rates	21	11798	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.86, 0.95]
1.2 Settings with Intermediate initiation rates	18	7238	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.89, 0.98]
1.3 Settings with low initiation rates	10	2126	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.84, 1.00]
2 Stopping exclusive breastfeeding at last assessment up to 6 months	41	16768	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.87, 0.94]
2.1 Settings with high breastfeeding initiation rates	26	11347	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.80, 0.90]
2.2 Settings with Intermediate initiation rates	10	4052	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.93, 1.02]
2.3 Settings with low initiation rates	5	1369	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.99, 1.01]
3 Stopping any breastfeeding at up to 4-6 weeks	31	12929	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.82, 0.93]
3.1 Settings with high breastfeeding initiation rates	11	5295	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.71, 0.92]
3.2 Settings with Intermediate initiation rates	17	6096	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.85, 1.00]
3.3 Settings with low initiation rates	6	1538	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.79, 1.00]
4 Stopping exclusive breastfeeding at up to 4-6 weeks	29	9911	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.69, 0.89]
4.1 Settings with high breastfeeding initiation rates	16	5933	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.62, 0.84]
4.2 Settings with Intermediate initiation rates	8	2609	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.80, 0.95]
4.3 Settings with low initiation rates	5	1369	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.86, 1.08]

**Comparison 6. All forms of support versus usual care: SUBGROUP ANALYSIS - number of postnatal contacts**

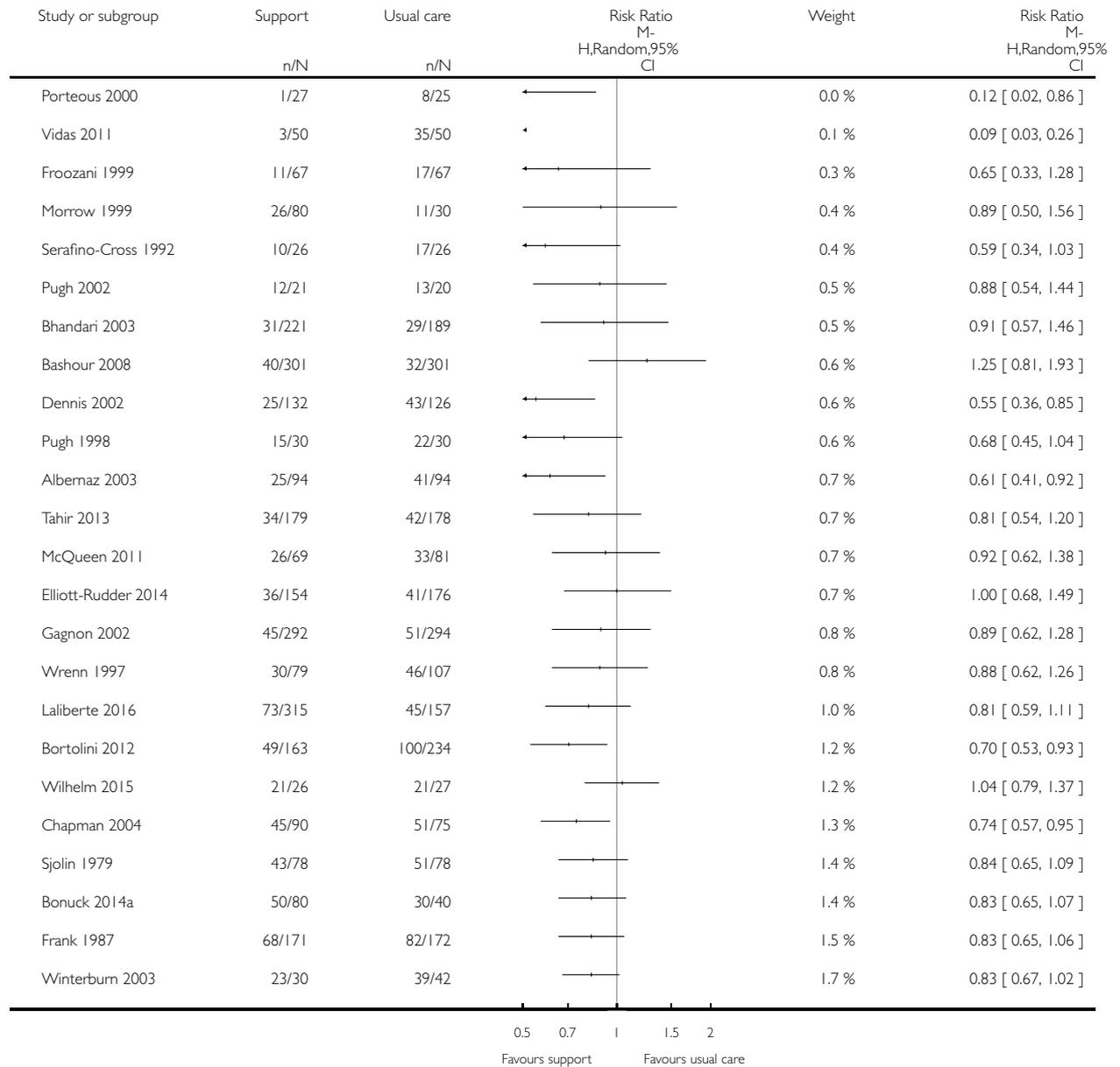
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Stopping any breastfeeding before last study assessment up to 6 months	51	21418	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.88, 0.95]
1.1 Unspecified number of contacts	10	7187	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.85, 0.97]
1.2 Less than 4 postnatal contacts	12	5151	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.86, 1.00]
1.3 Between 4 and 8 postnatal contacts	14	3236	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.77, 0.97]
1.4 9 or more postnatal contacts	15	5844	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.88, 0.98]
2 Stopping exclusive breastfeeding before last study assessment	46	18424	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.85, 0.92]
2.1 Unspecified number of contacts	7	3645	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.84, 1.02]
2.2 Less than 4 postnatal contacts	11	4511	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.91, 1.01]
2.3 Between 4 and 8 postnatal contacts	16	5148	Risk Ratio (M-H, Random, 95% CI)	0.73 [0.63, 0.84]
2.4 9 or more postnatal contacts	12	5120	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.81, 0.98]
3 Stopping any breastfeeding at up to 4-6 weeks	33	11180	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.79, 0.93]
3.1 Unspecified number of contacts	6	2631	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.75, 0.99]
3.2 Less than 4 postnatal contacts	14	4789	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.70, 0.99]
3.3 Between 4 and 8 postnatal contacts	6	1088	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.63, 1.00]
3.4 9 or more postnatal contacts	8	2672	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.80, 1.06]
4 Stopping exclusive breastfeeding at up to 4-6 weeks	32	10960	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.71, 0.89]
4.1 Unspecified number of contacts	5	1972	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.84, 0.99]
4.2 Less than 4 postnatal contacts	12	3768	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.84, 0.96]
4.3 Between 4 and 8 postnatal contacts	7	1519	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.48, 0.82]
4.4 9 or more postnatal contacts	9	3701	Risk Ratio (M-H, Random, 95% CI)	0.74 [0.40, 1.38]

### Analysis 1.1. Comparison 1 All forms of support versus usual care, Outcome 1 Stopping breastfeeding (any) before last study assessment up to 6 months.

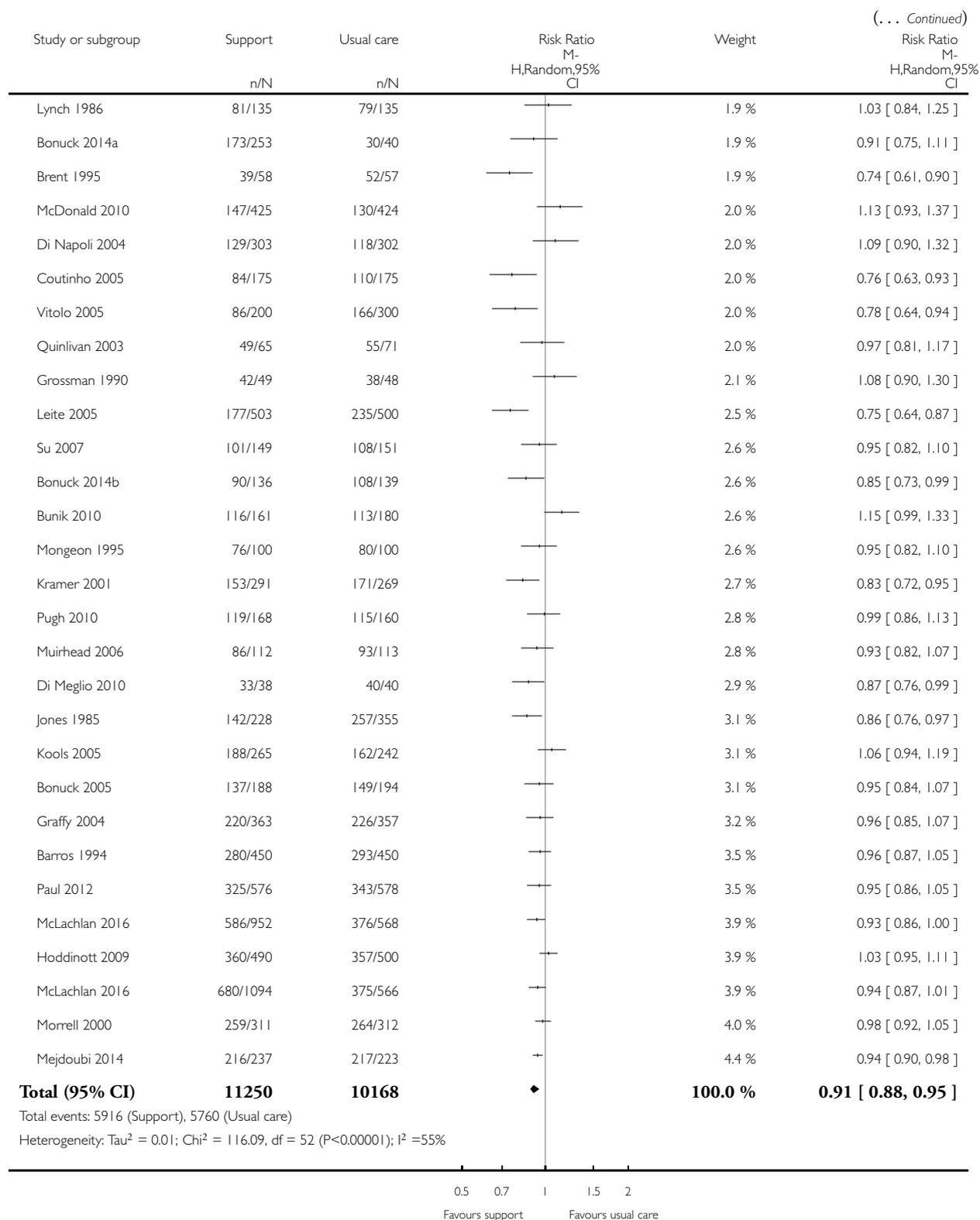
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 1 All forms of support versus usual care

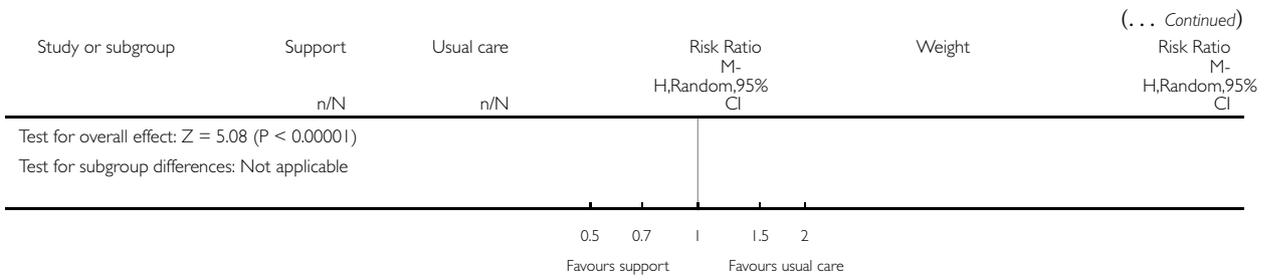
Outcome: 1 Stopping breastfeeding (any) before last study assessment up to 6 months



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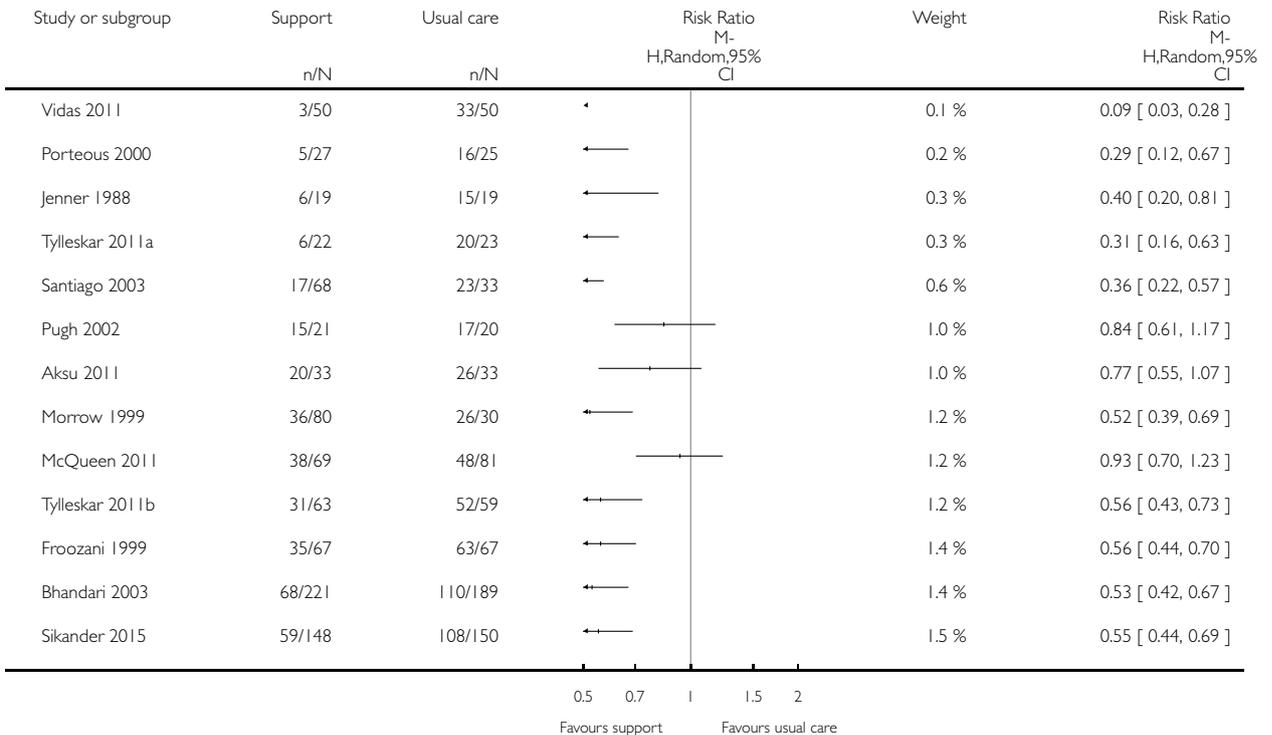


**Analysis 1.2. Comparison 1 All forms of support versus usual care, Outcome 2 Stopping exclusive breastfeeding before last study assessment up to 6 months.**

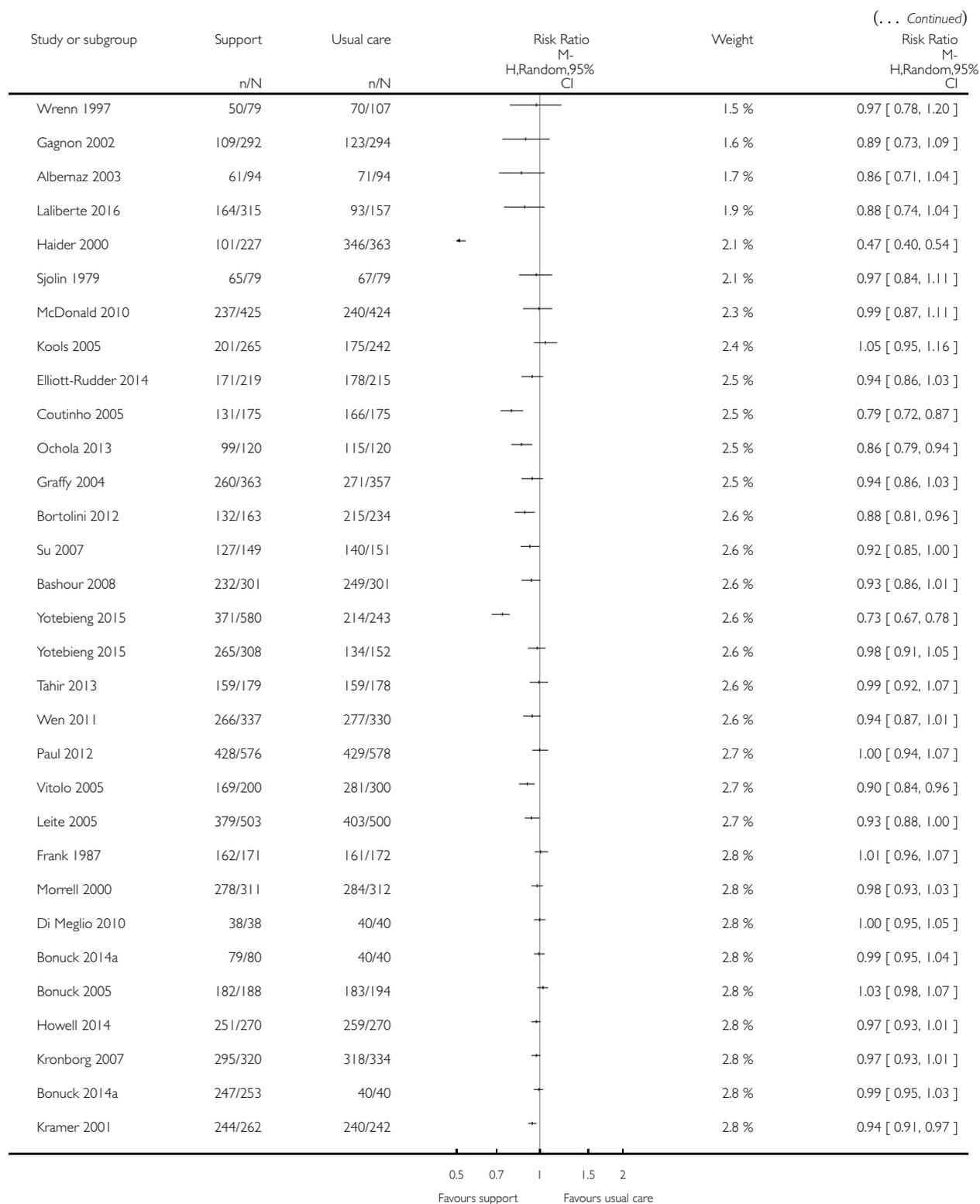
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 1 All forms of support versus usual care

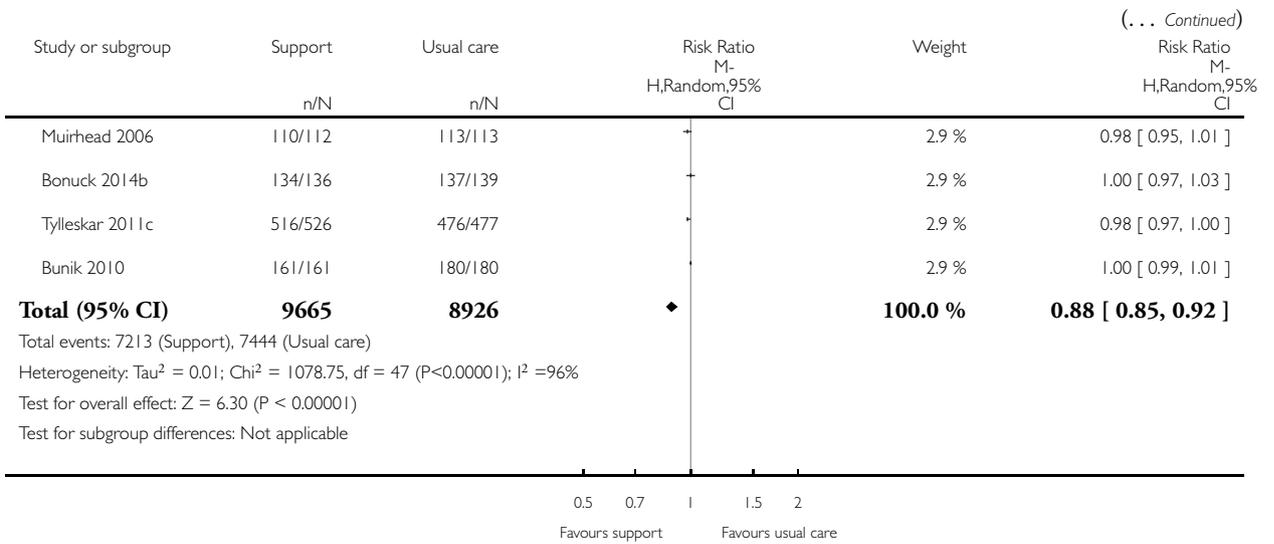
Outcome: 2 Stopping exclusive breastfeeding before last study assessment up to 6 months



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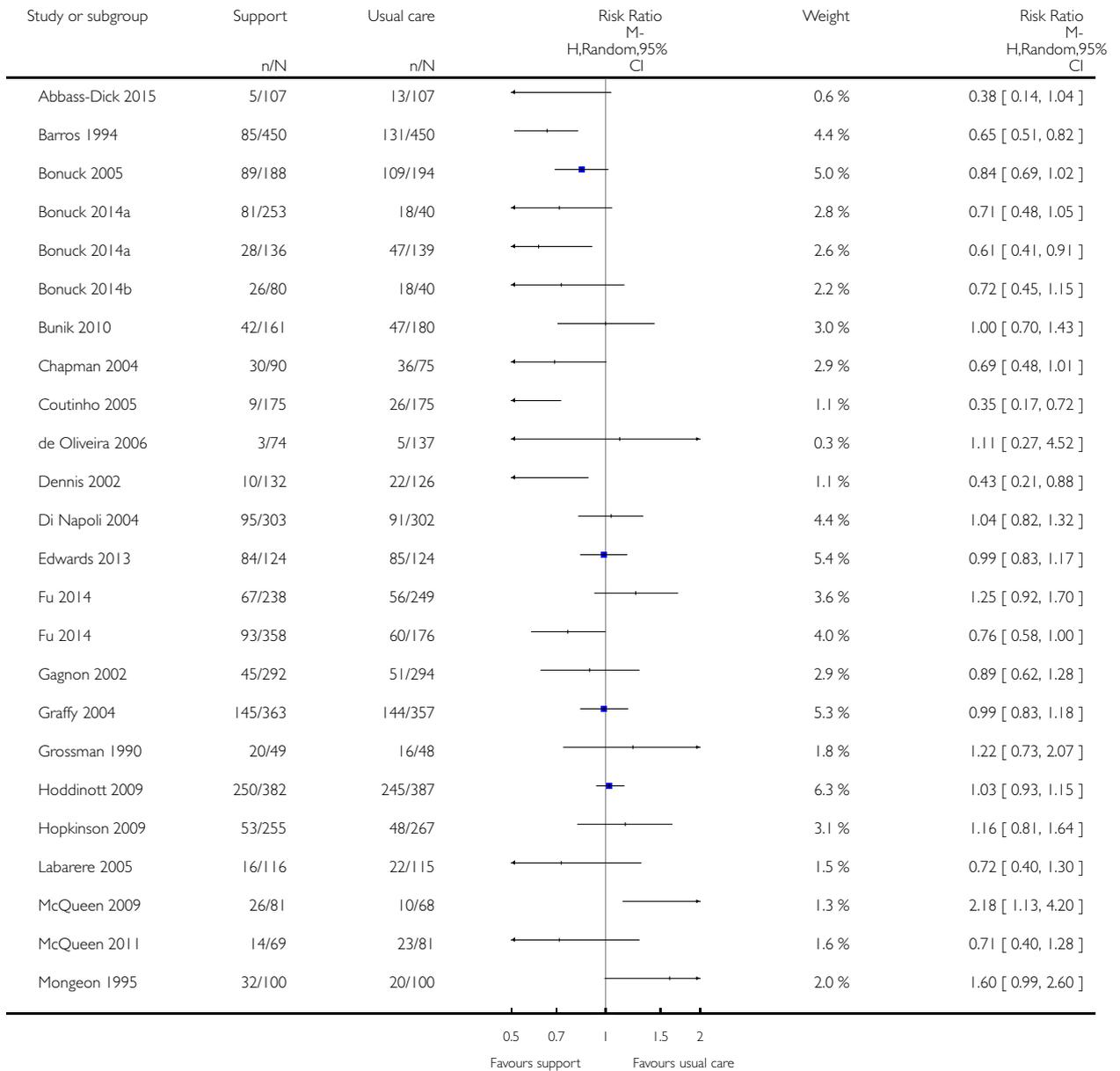


### Analysis 1.3. Comparison 1 All forms of support versus usual care, Outcome 3 Stopping breastfeeding (any) at up to 4-6 weeks.

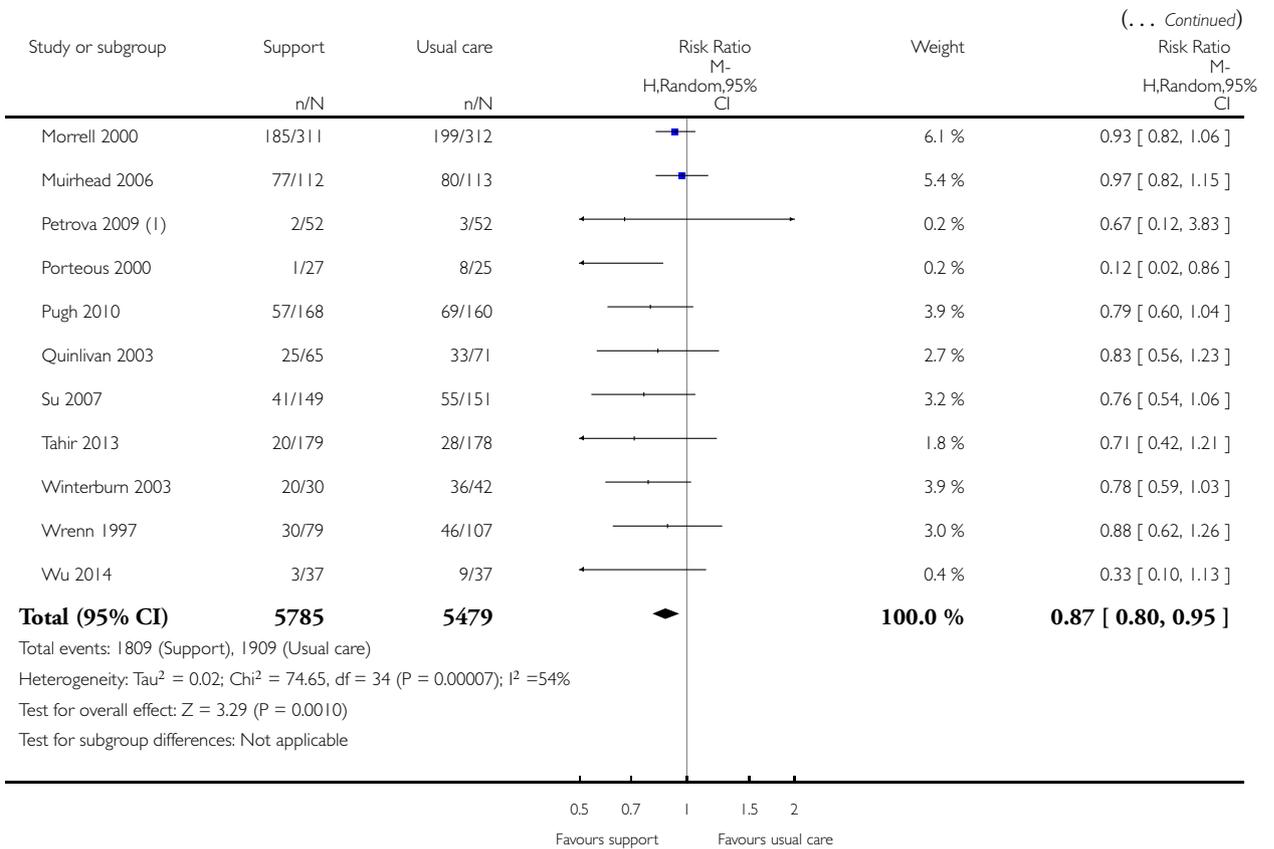
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 1 All forms of support versus usual care

Outcome: 3 Stopping breastfeeding (any) at up to 4-6 weeks



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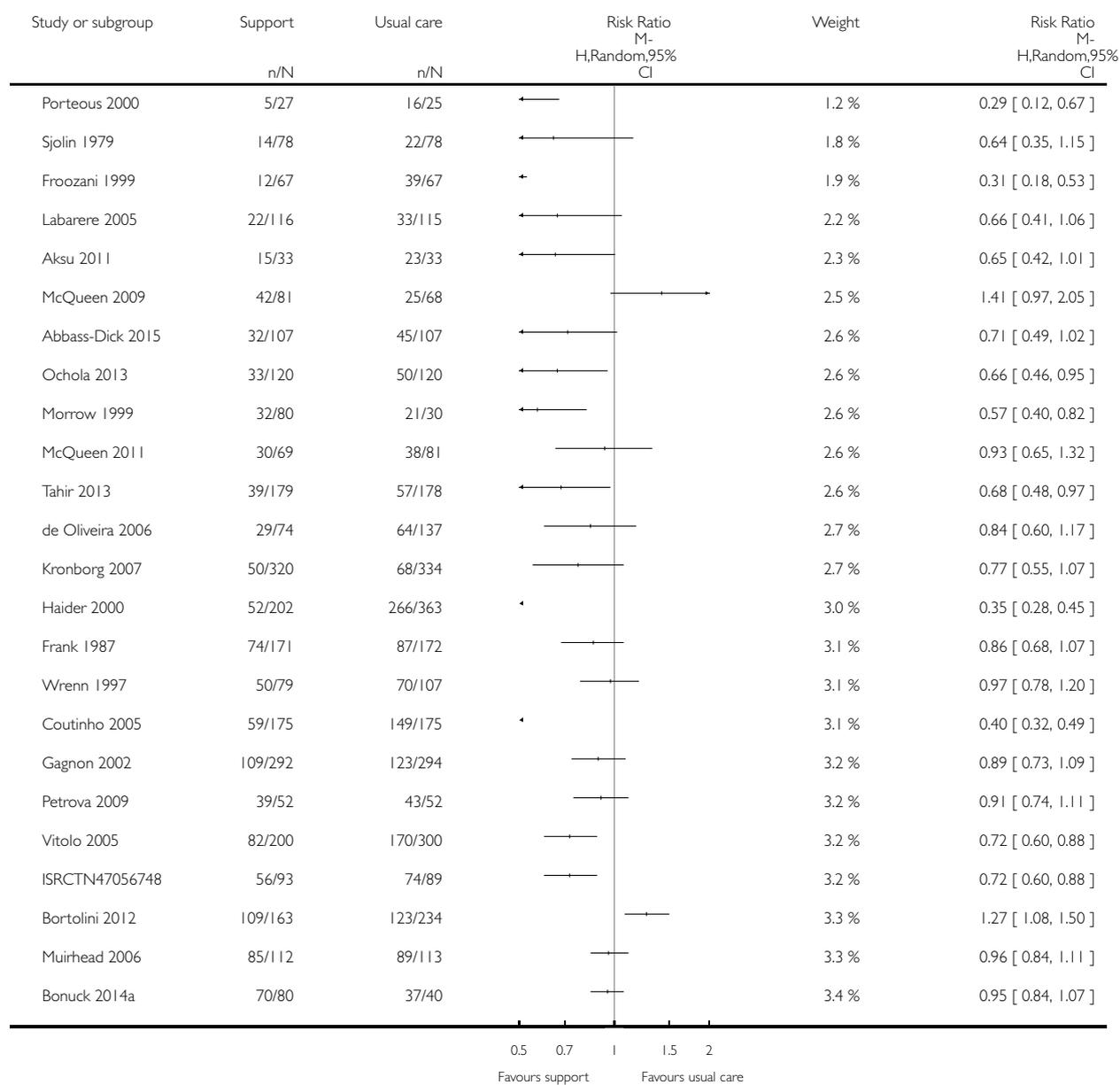
(1) Estimated from graph.

### Analysis 1.4. Comparison 1 All forms of support versus usual care, Outcome 4 Stopping exclusive breastfeeding at up to 4-6 weeks.

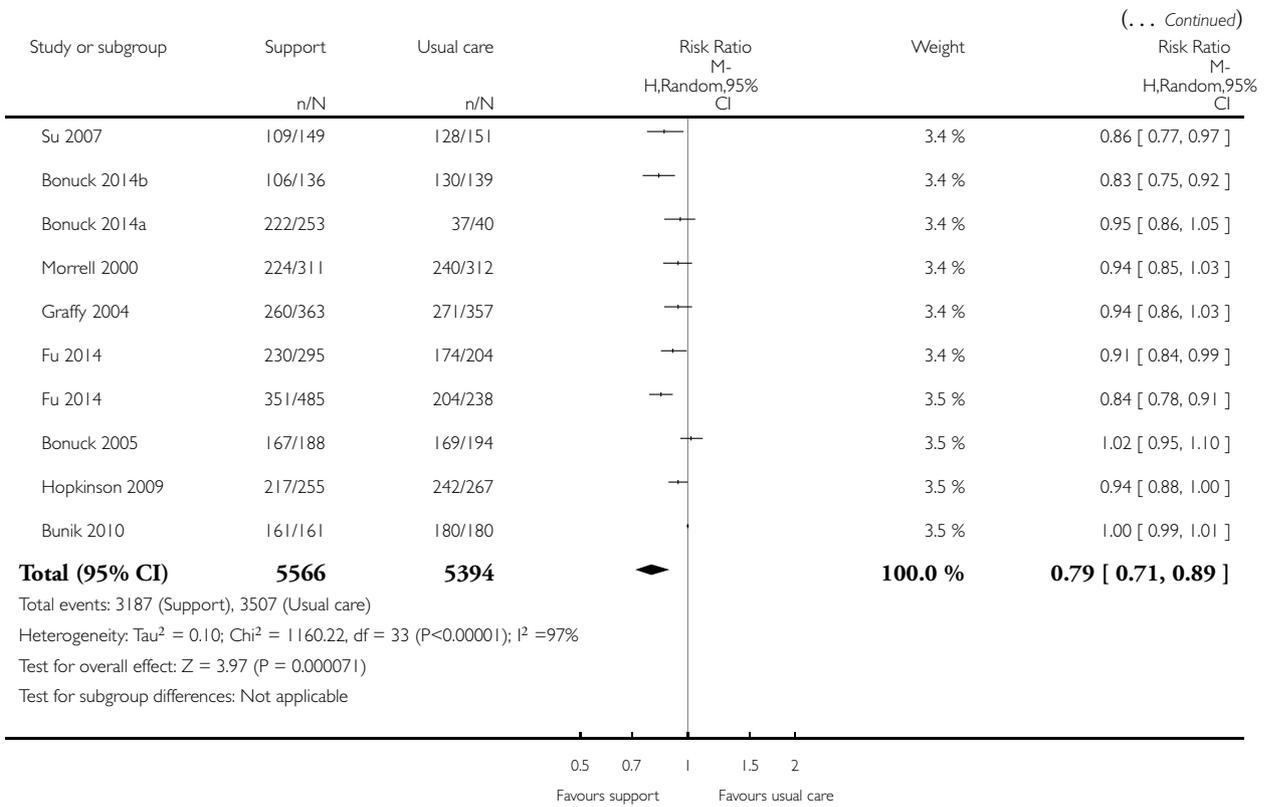
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 1 All forms of support versus usual care

Outcome: 4 Stopping exclusive breastfeeding at up to 4-6 weeks



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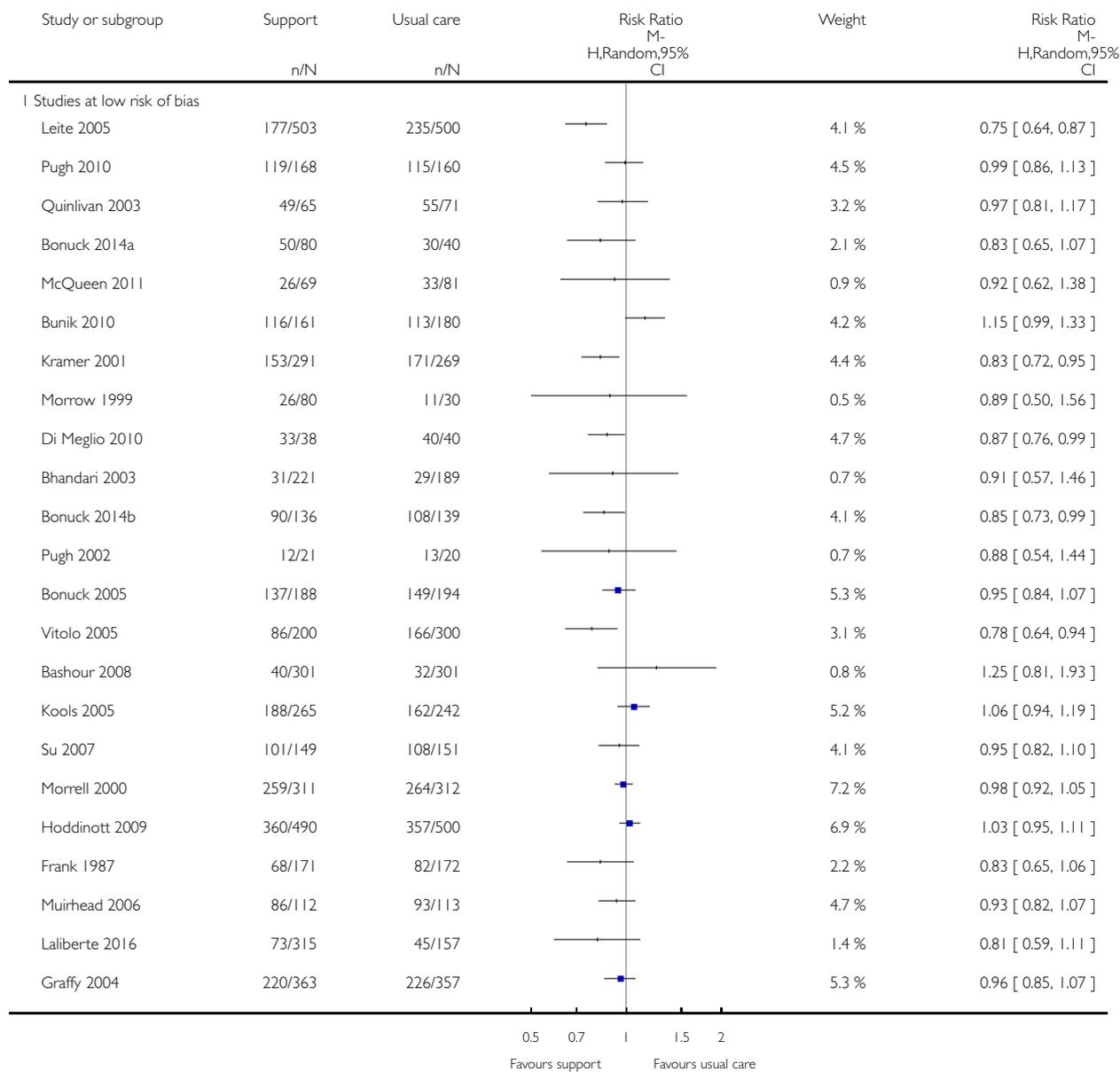


### Analysis 1.5. Comparison 1 All forms of support versus usual care, Outcome 5 Sensitivity analysis by risk of bias allocation concealment: stopping any breastfeeding at up to six months.

Review: Support for healthy breastfeeding mothers with healthy term babies

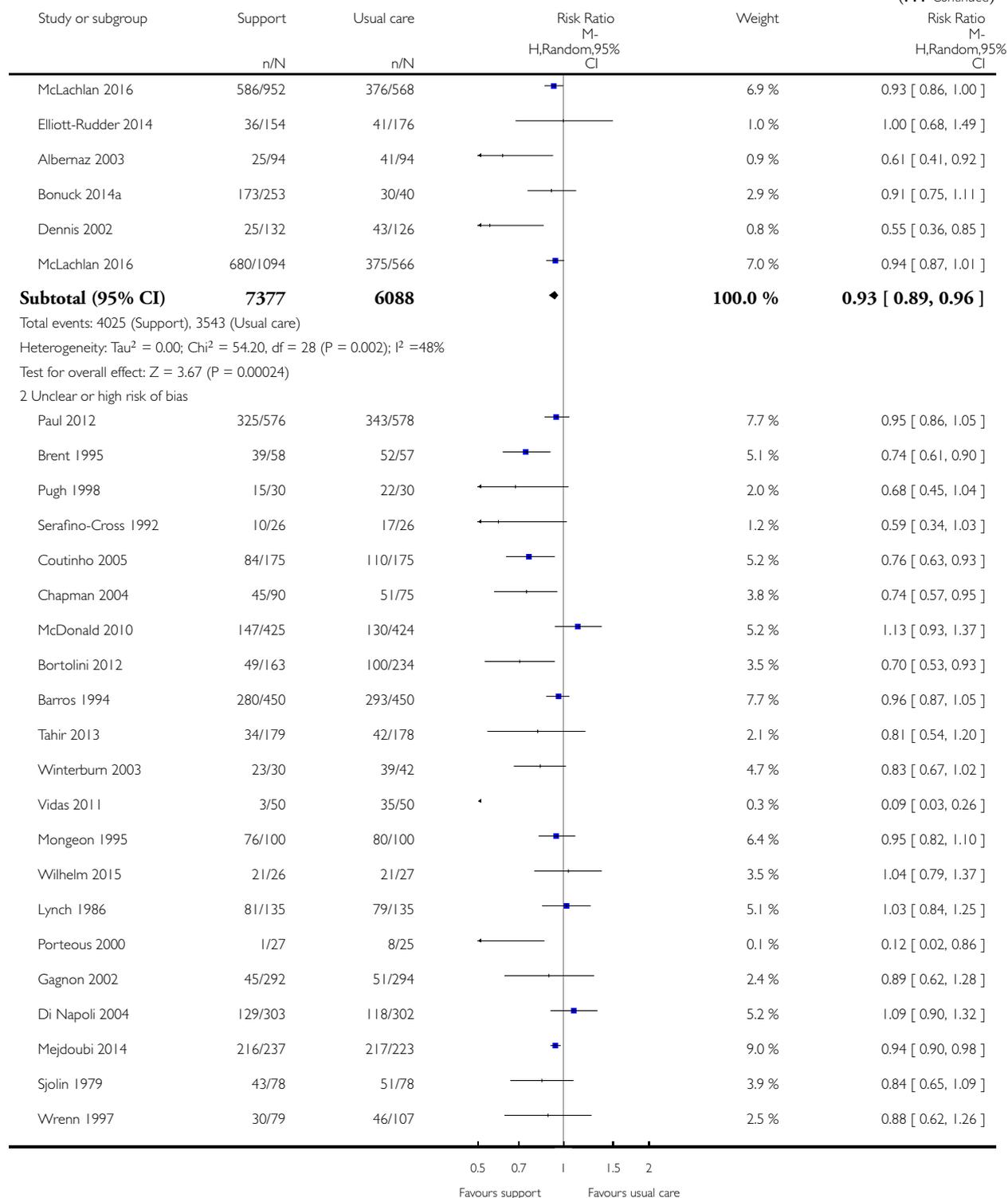
Comparison: 1 All forms of support versus usual care

Outcome: 5 Sensitivity analysis by risk of bias allocation concealment: stopping any breastfeeding at up to six months

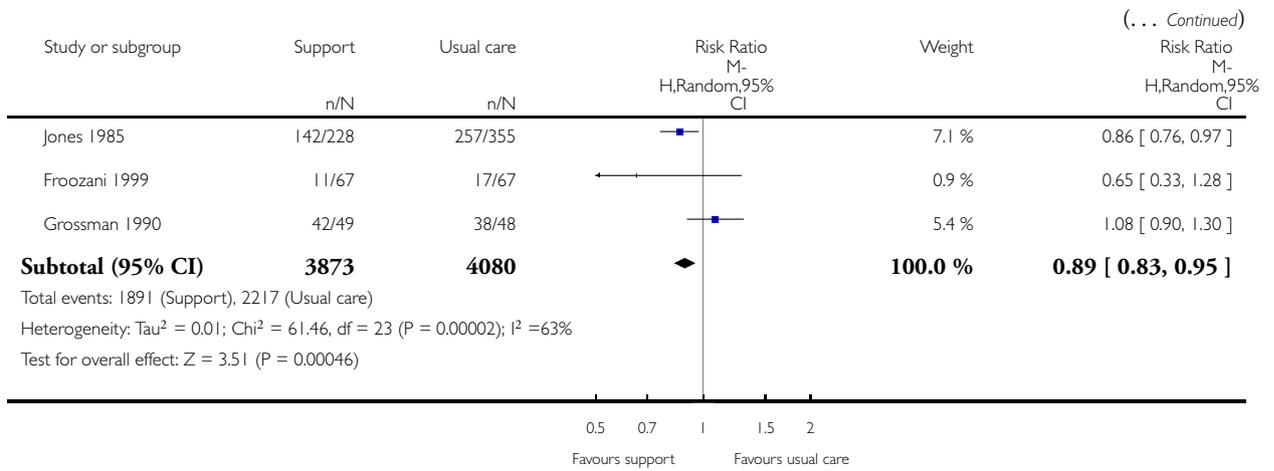


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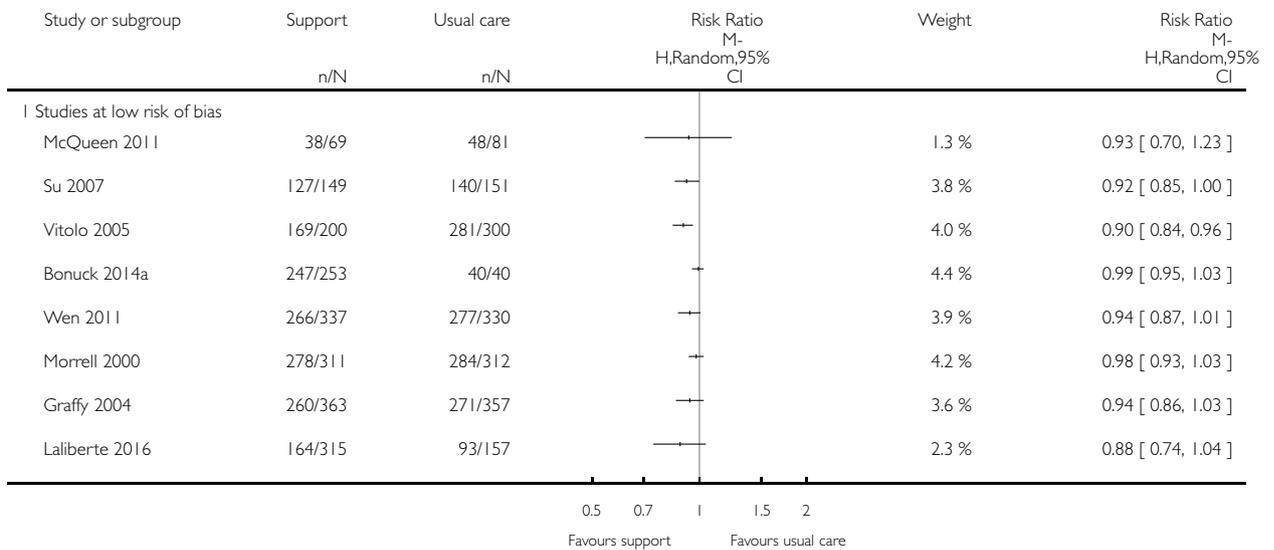


**Analysis 1.6. Comparison 1 All forms of support versus usual care, Outcome 6 Sensitivity analysis by risk of bias allocation concealment: stopping exclusive breastfeeding at up to six months.**

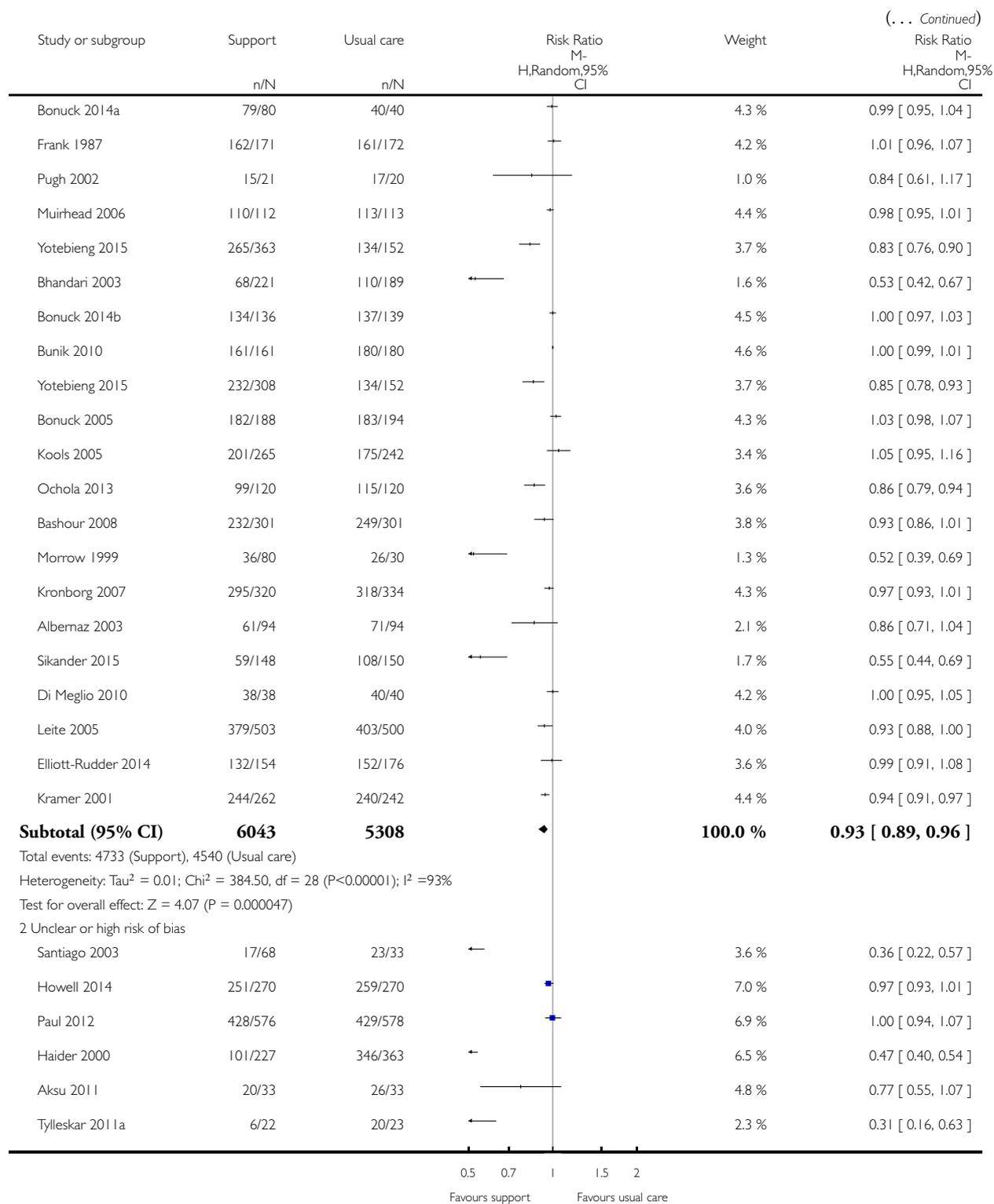
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 1 All forms of support versus usual care

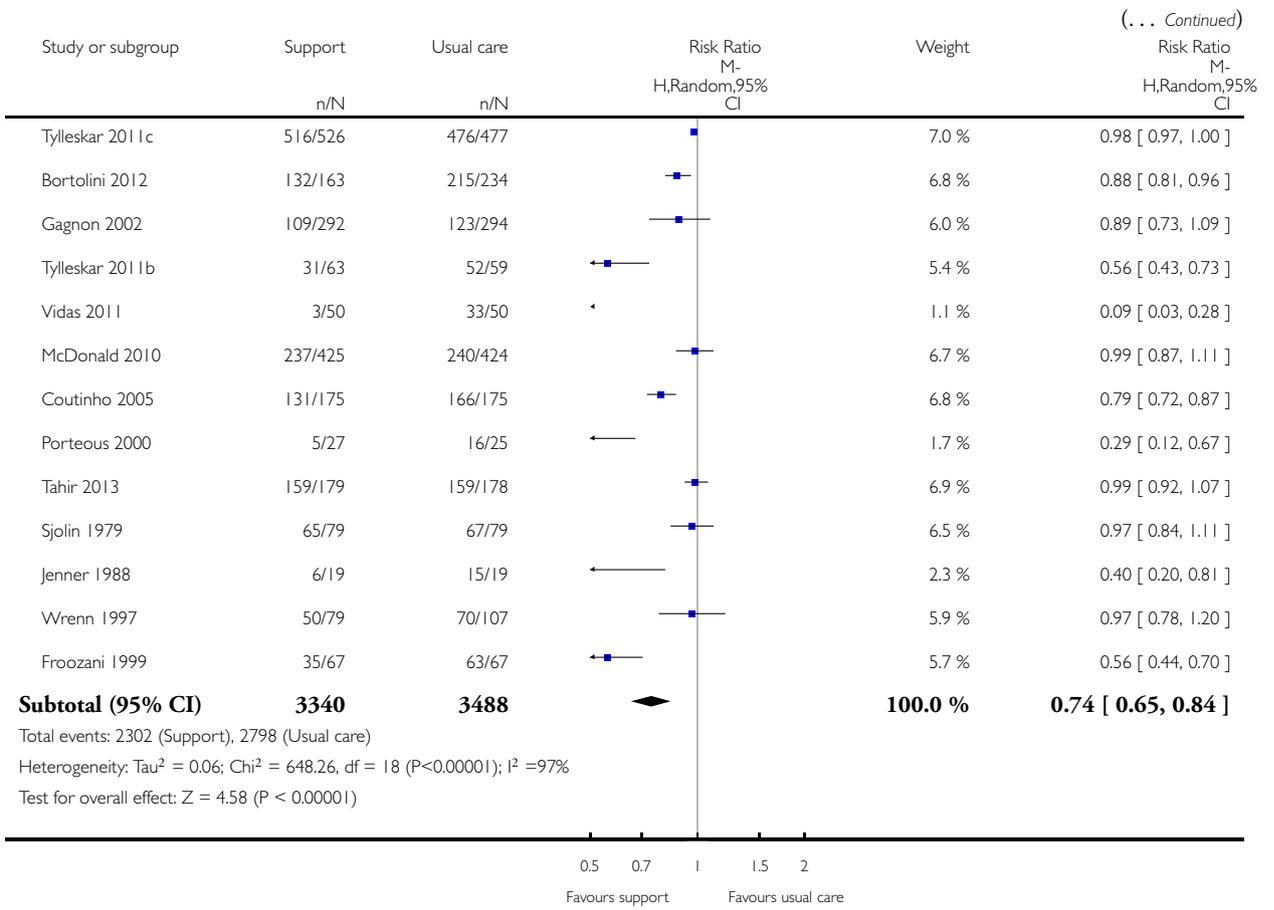
Outcome: 6 Sensitivity analysis by risk of bias allocation concealment: stopping exclusive breastfeeding at up to six months



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(Continued . . .)

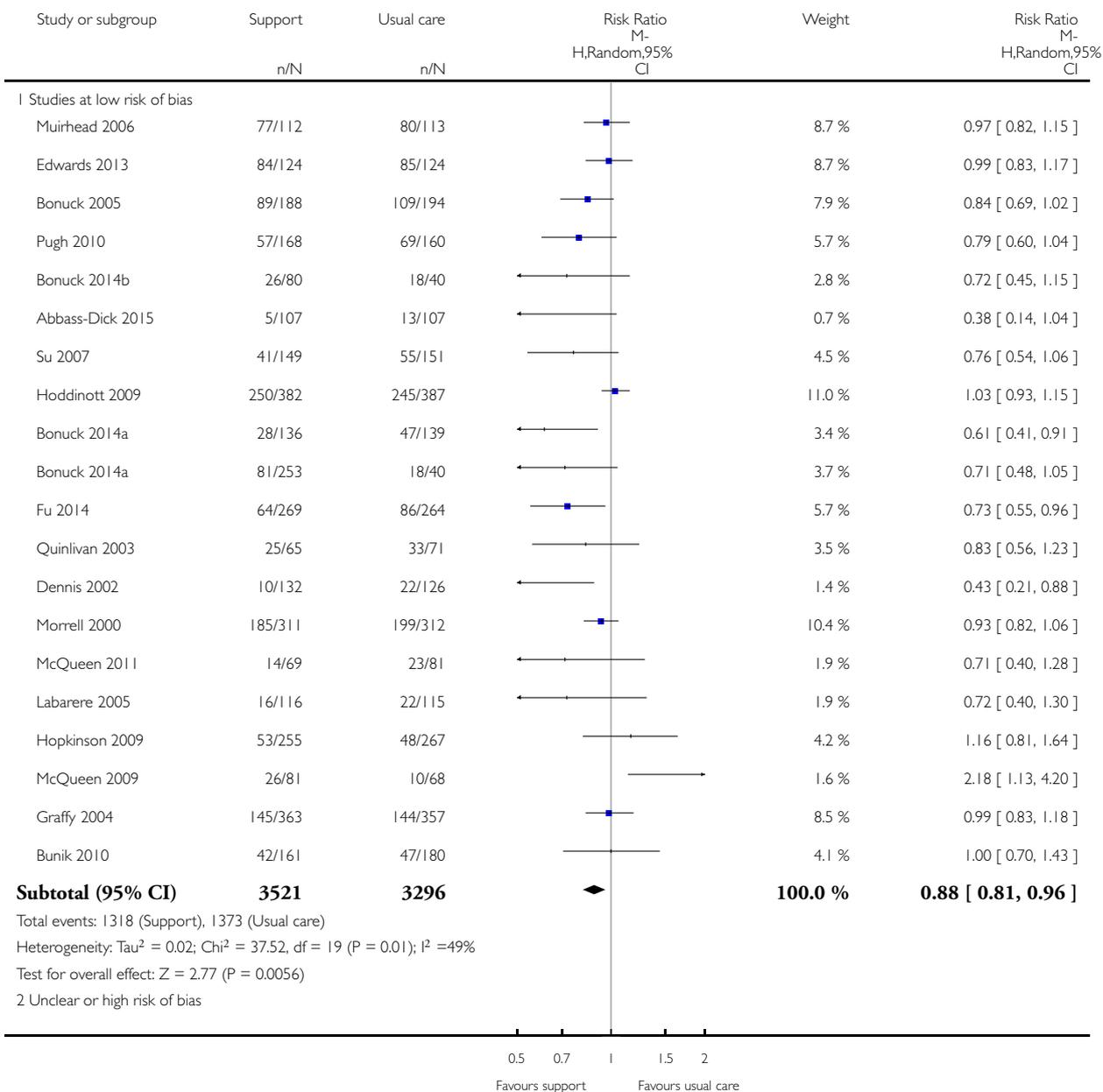


### Analysis 1.7. Comparison 1 All forms of support versus usual care, Outcome 7 Sensitivity analysis by risk of bias allocation concealment: stopping any breastfeeding at 4-6 weeks.

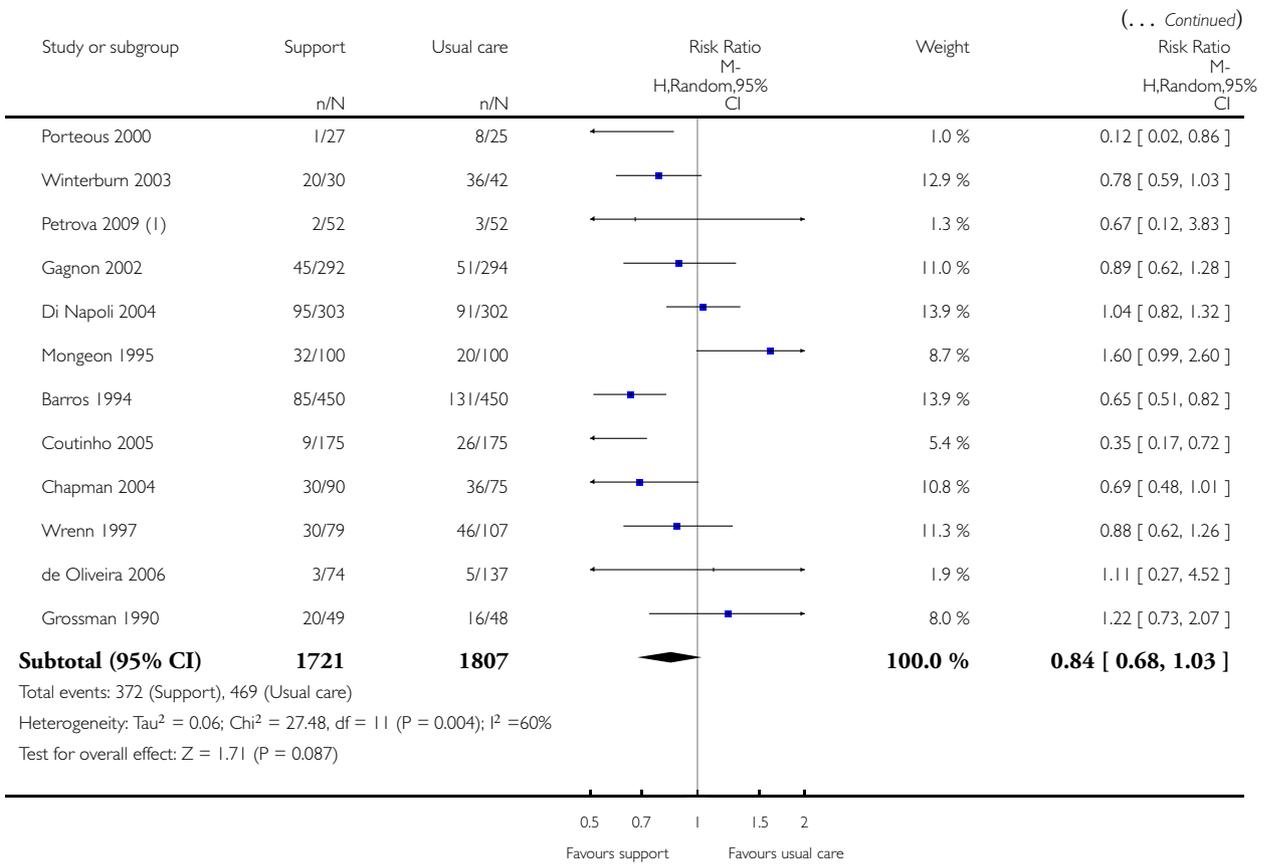
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 1 All forms of support versus usual care

Outcome: 7 Sensitivity analysis by risk of bias allocation concealment: stopping any breastfeeding at 4-6 weeks



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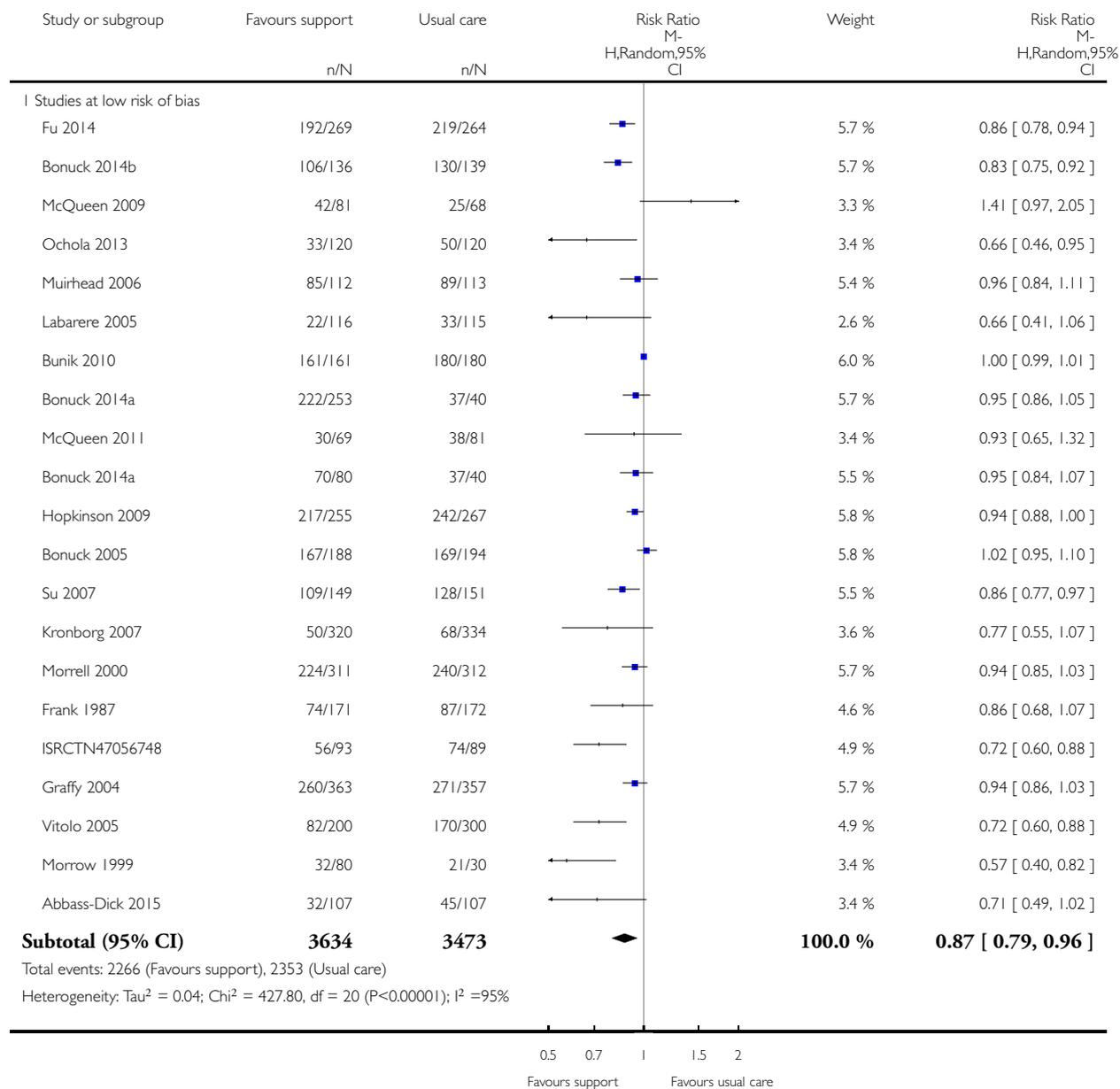
(1) Estimated from graph.

**Analysis 1.8. Comparison 1 All forms of support versus usual care, Outcome 8 Sensitivity analysis by risk of bias allocation concealment: stopping exclusive breastfeeding by 4-6 weeks.**

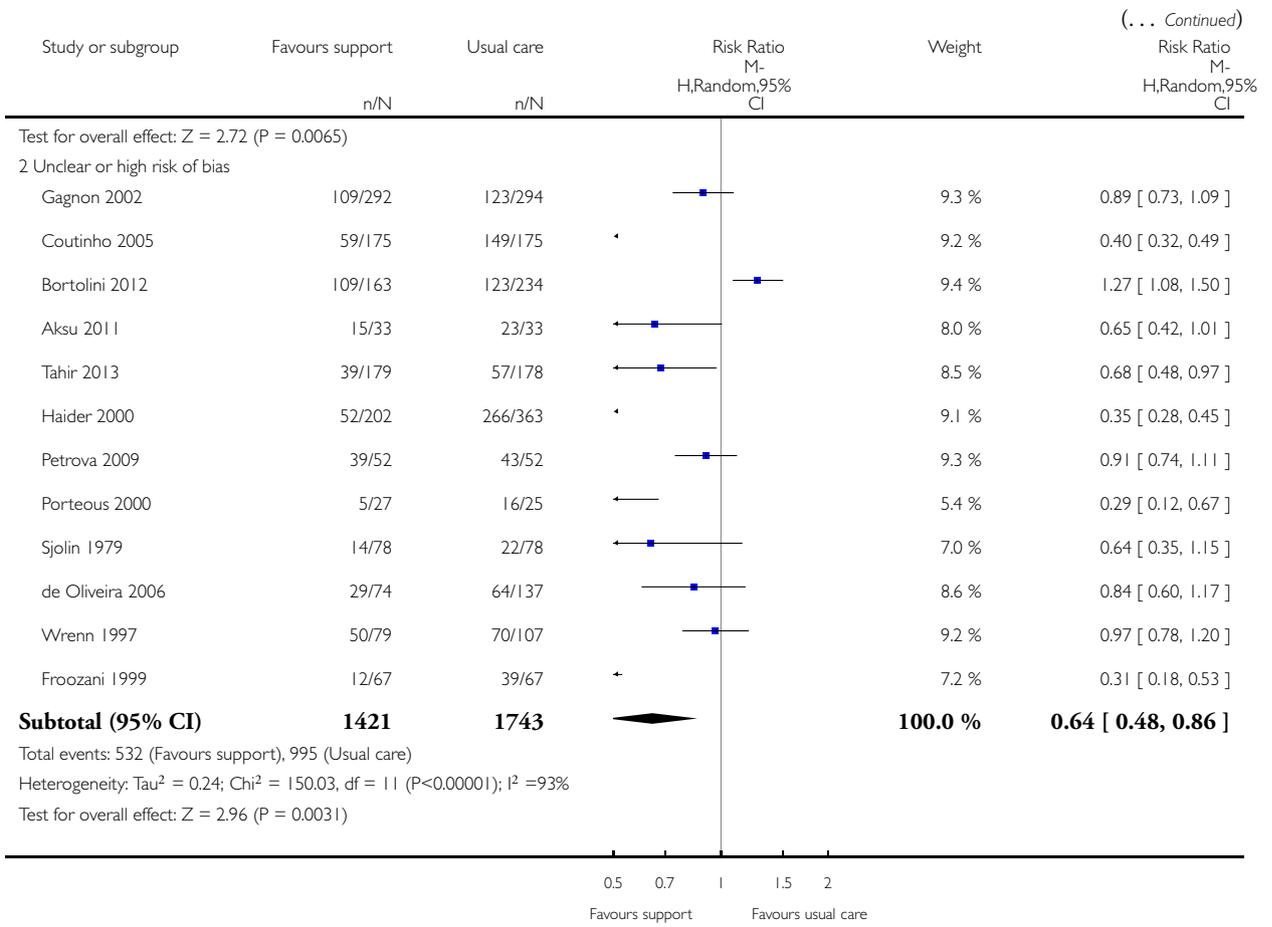
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 1 All forms of support versus usual care

Outcome: 8 Sensitivity analysis by risk of bias allocation concealment: stopping exclusive breastfeeding by 4-6 weeks



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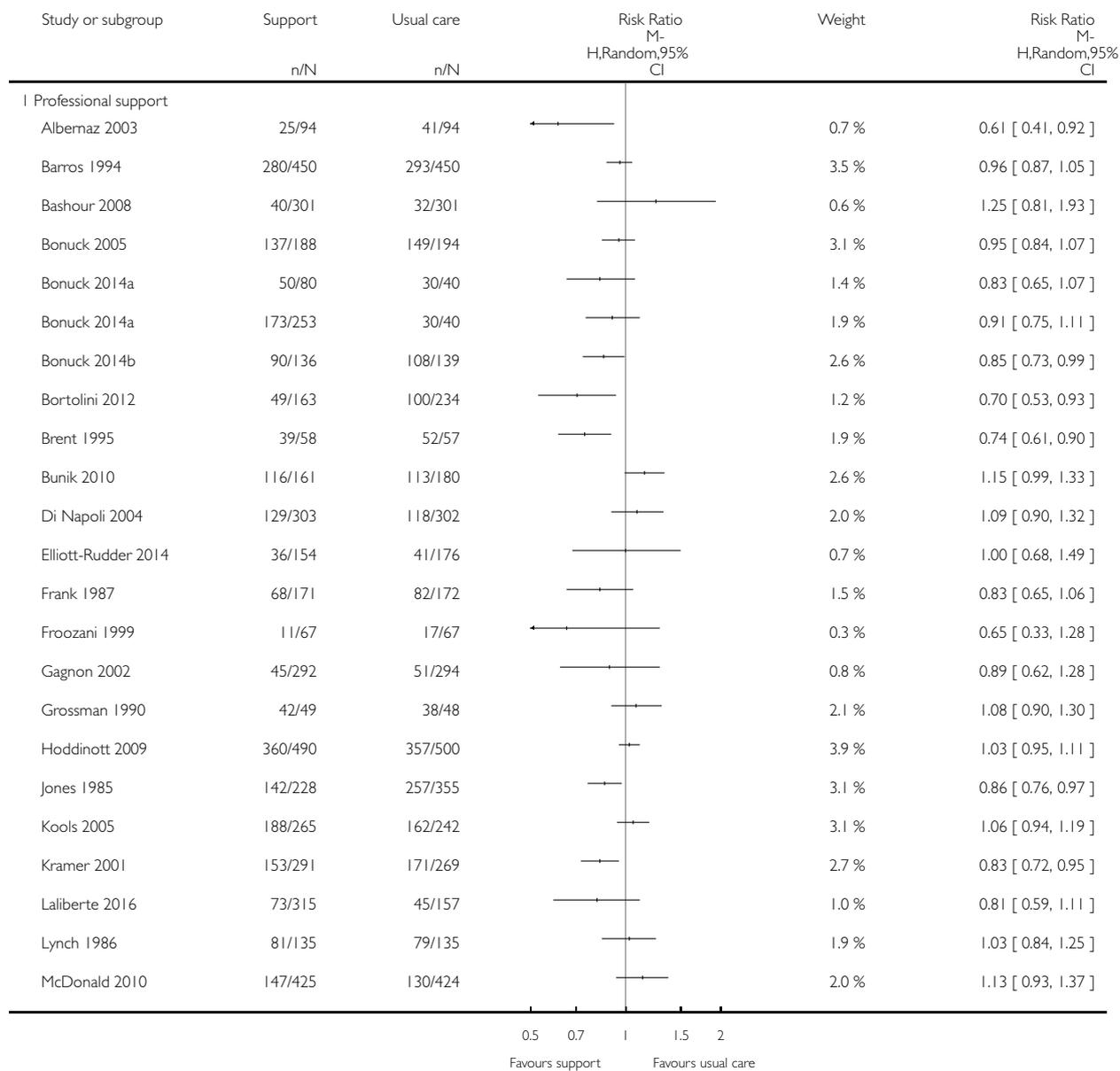


**Analysis 2.1. Comparison 2 All forms of support versus usual care: SUBGROUP ANALYSIS - who delivered the intervention, Outcome 1 Stopping any breastfeeding before last study assessment up to 6 months.**

Review: Support for healthy breastfeeding mothers with healthy term babies

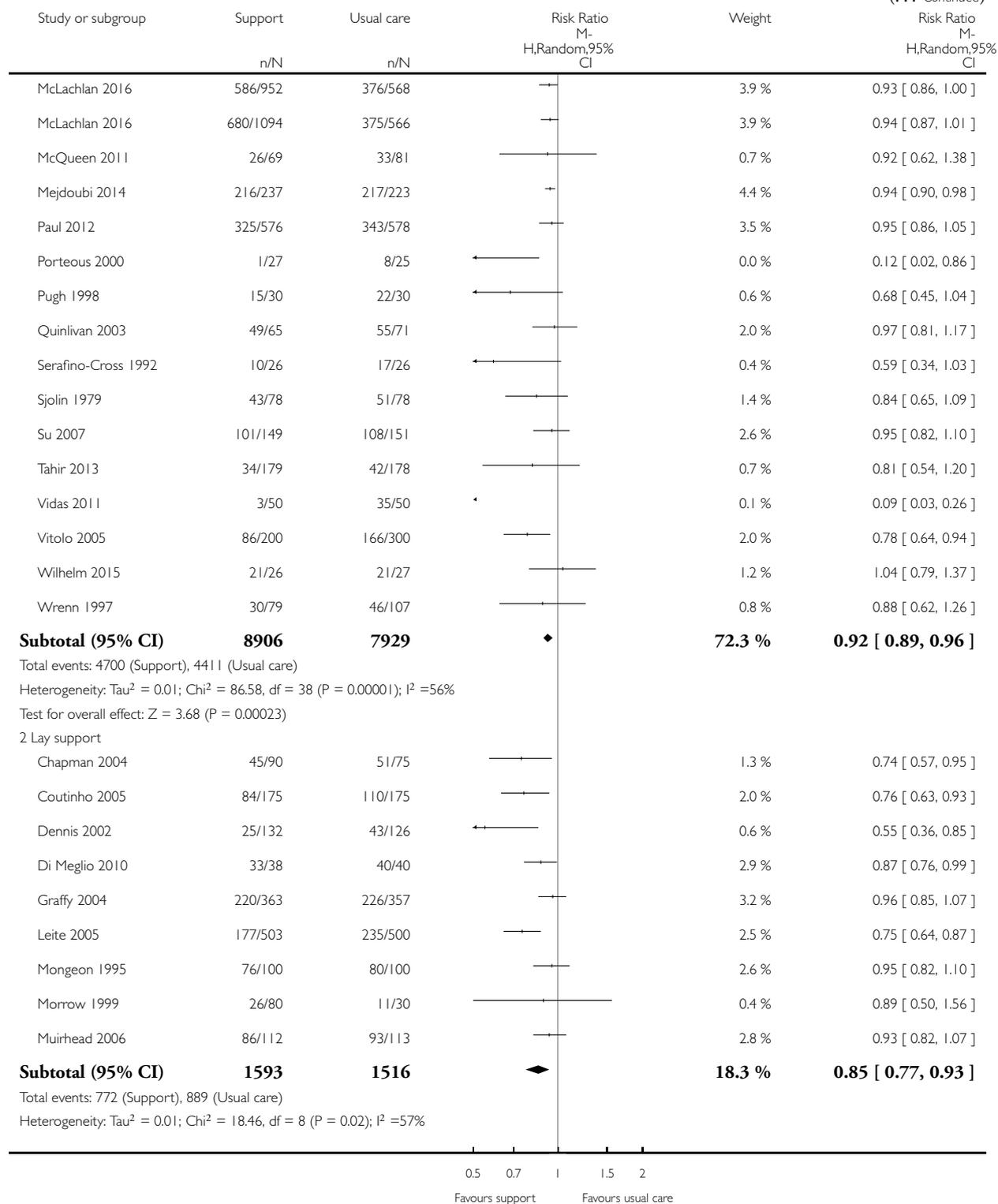
Comparison: 2 All forms of support versus usual care: SUBGROUP ANALYSIS - who delivered the intervention

Outcome: 1 Stopping any breastfeeding before last study assessment up to 6 months

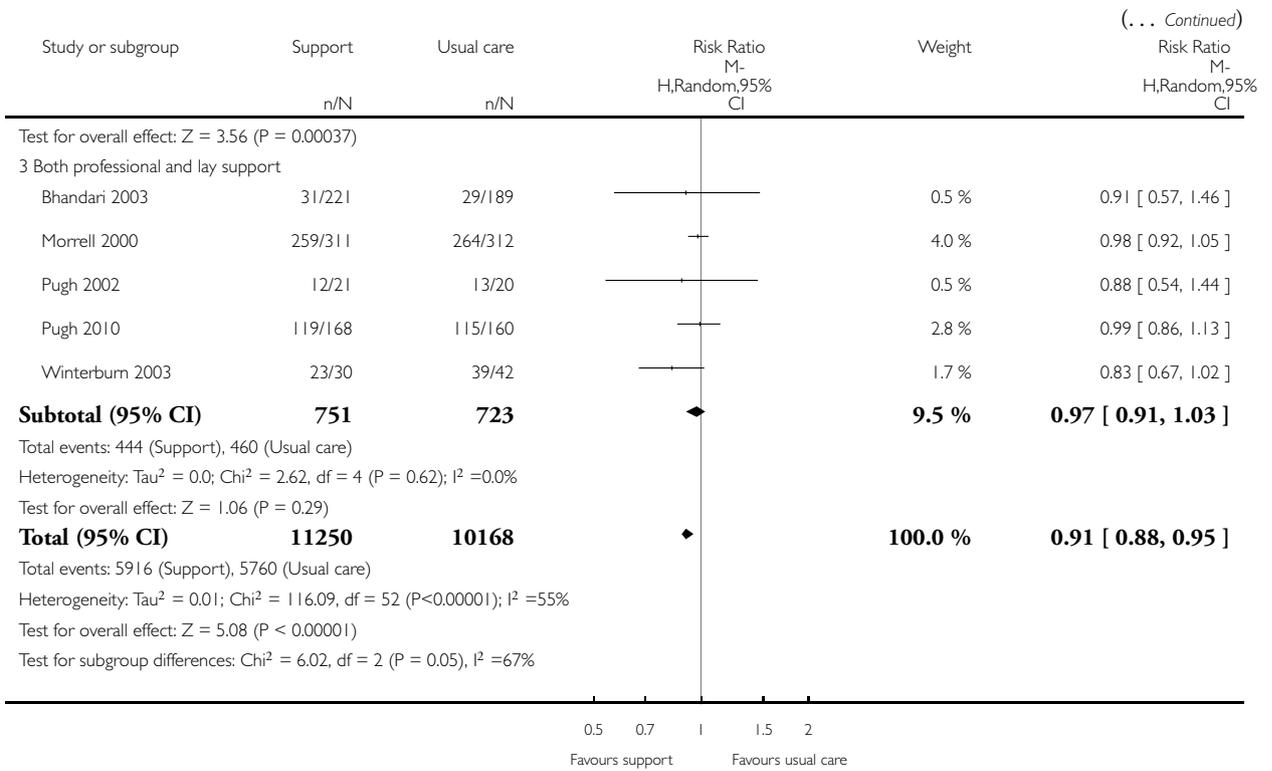


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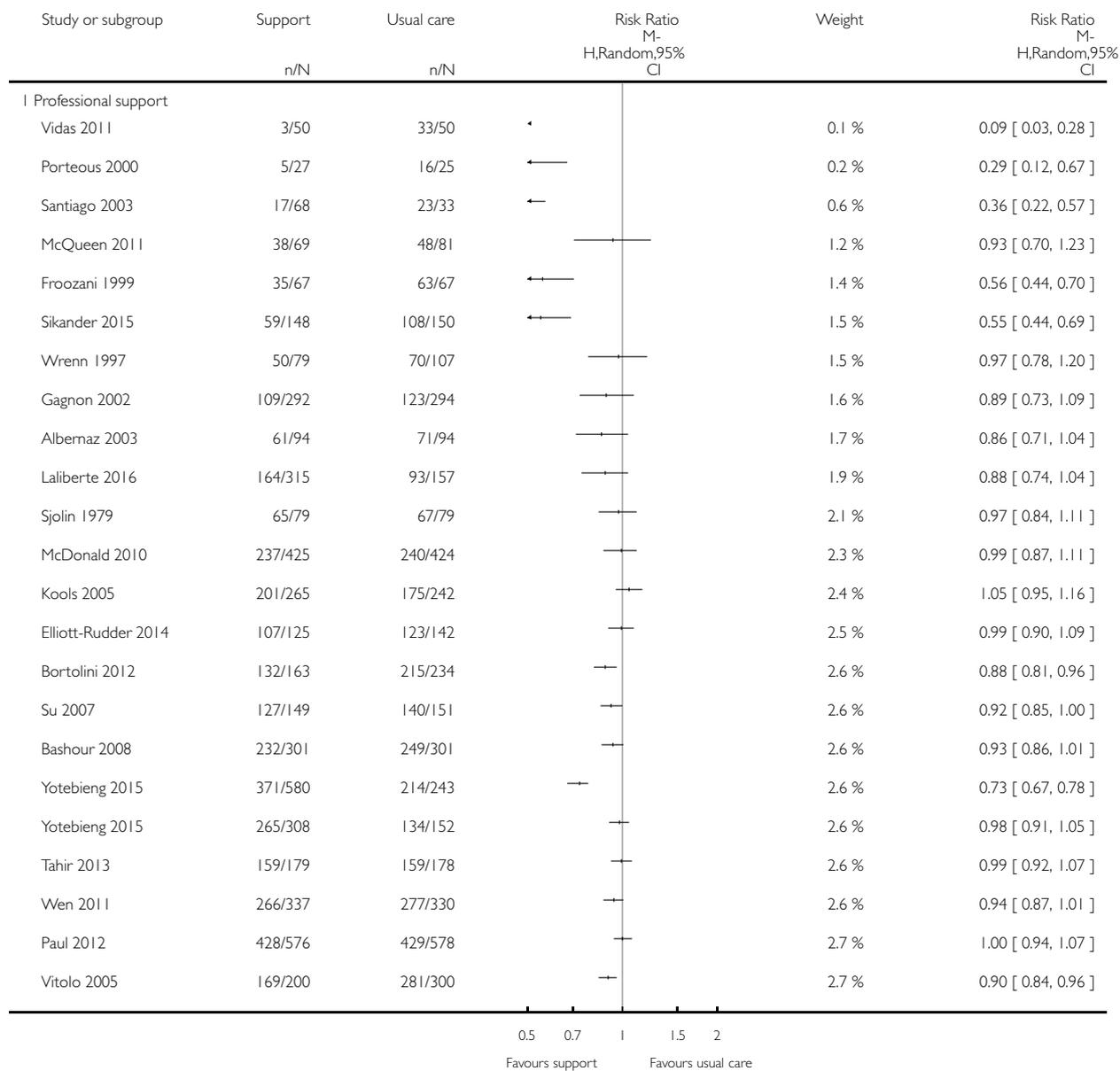


**Analysis 2.2. Comparison 2 All forms of support versus usual care: SUBGROUP ANALYSIS - who delivered the intervention, Outcome 2 Stopping exclusive breastfeeding before last study assessment.**

Review: Support for healthy breastfeeding mothers with healthy term babies

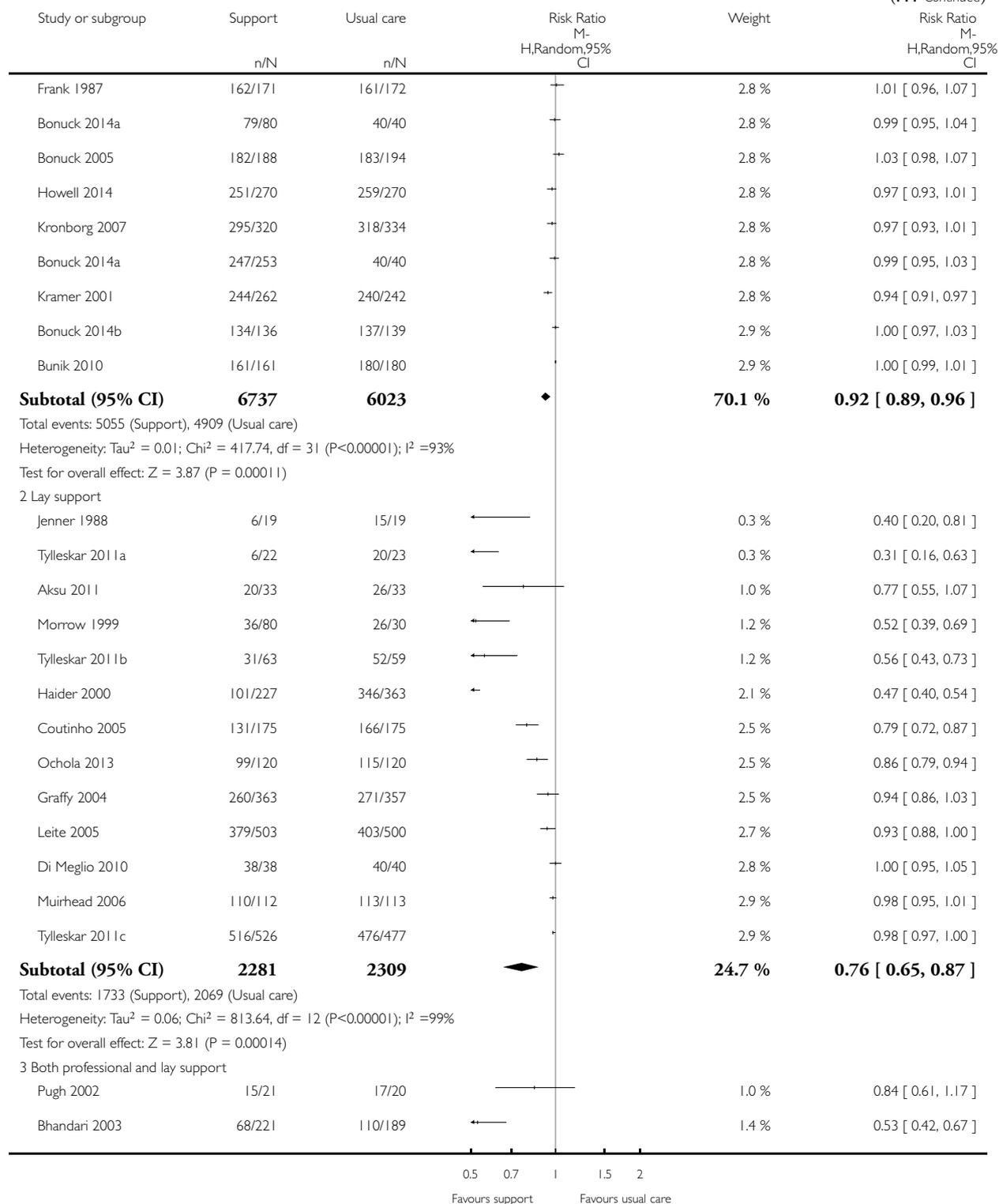
Comparison: 2 All forms of support versus usual care: SUBGROUP ANALYSIS - who delivered the intervention

Outcome: 2 Stopping exclusive breastfeeding before last study assessment

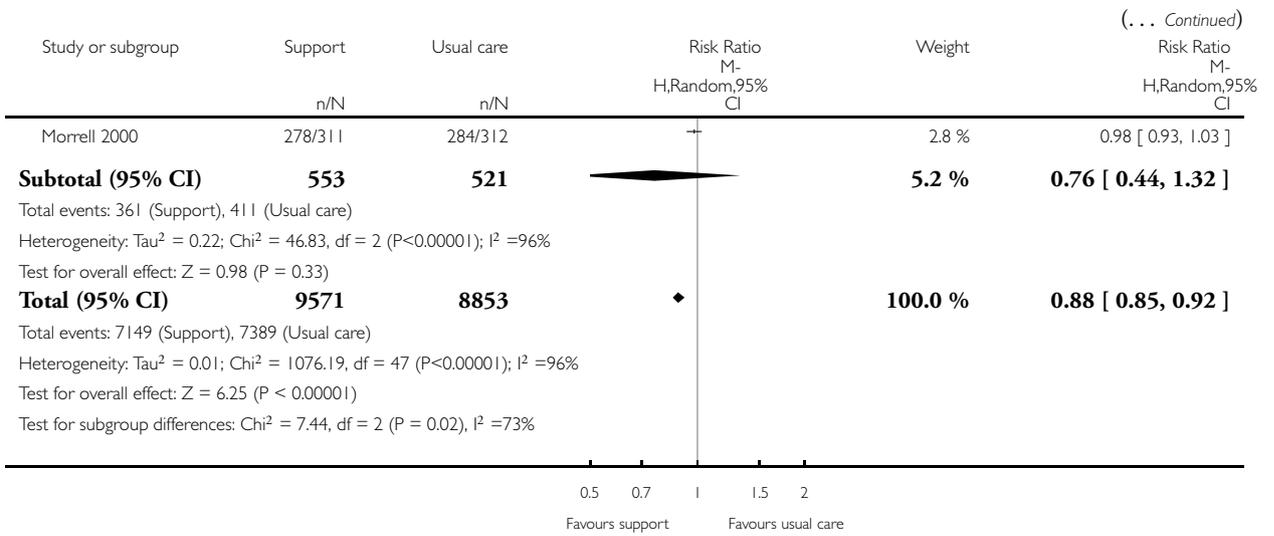


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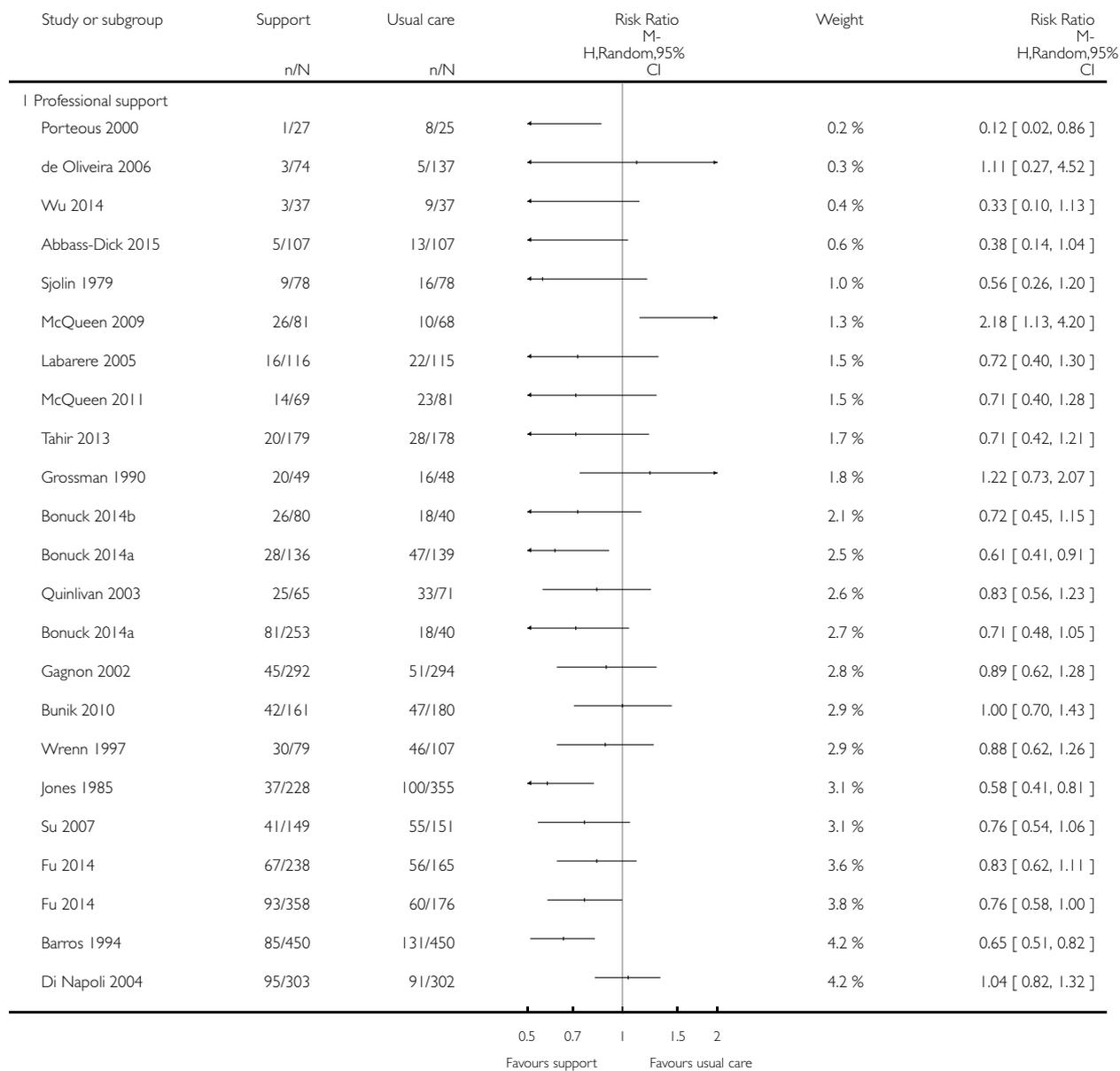


**Analysis 2.3. Comparison 2 All forms of support versus usual care: SUBGROUP ANALYSIS - who delivered the intervention, Outcome 3 Stopping any breastfeeding at up to 4-6 weeks.**

Review: Support for healthy breastfeeding mothers with healthy term babies

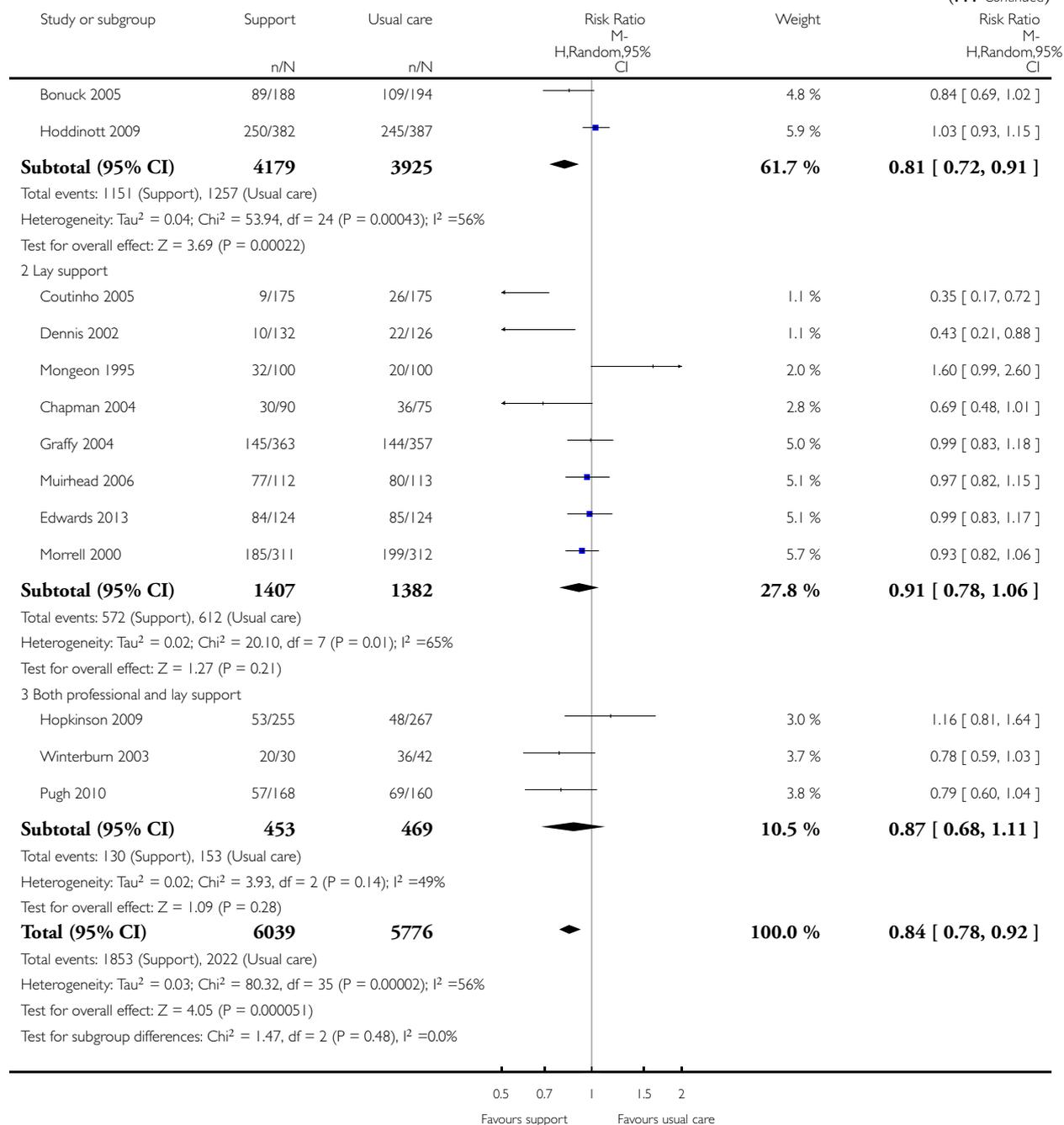
Comparison: 2 All forms of support versus usual care: SUBGROUP ANALYSIS - who delivered the intervention

Outcome: 3 Stopping any breastfeeding at up to 4-6 weeks



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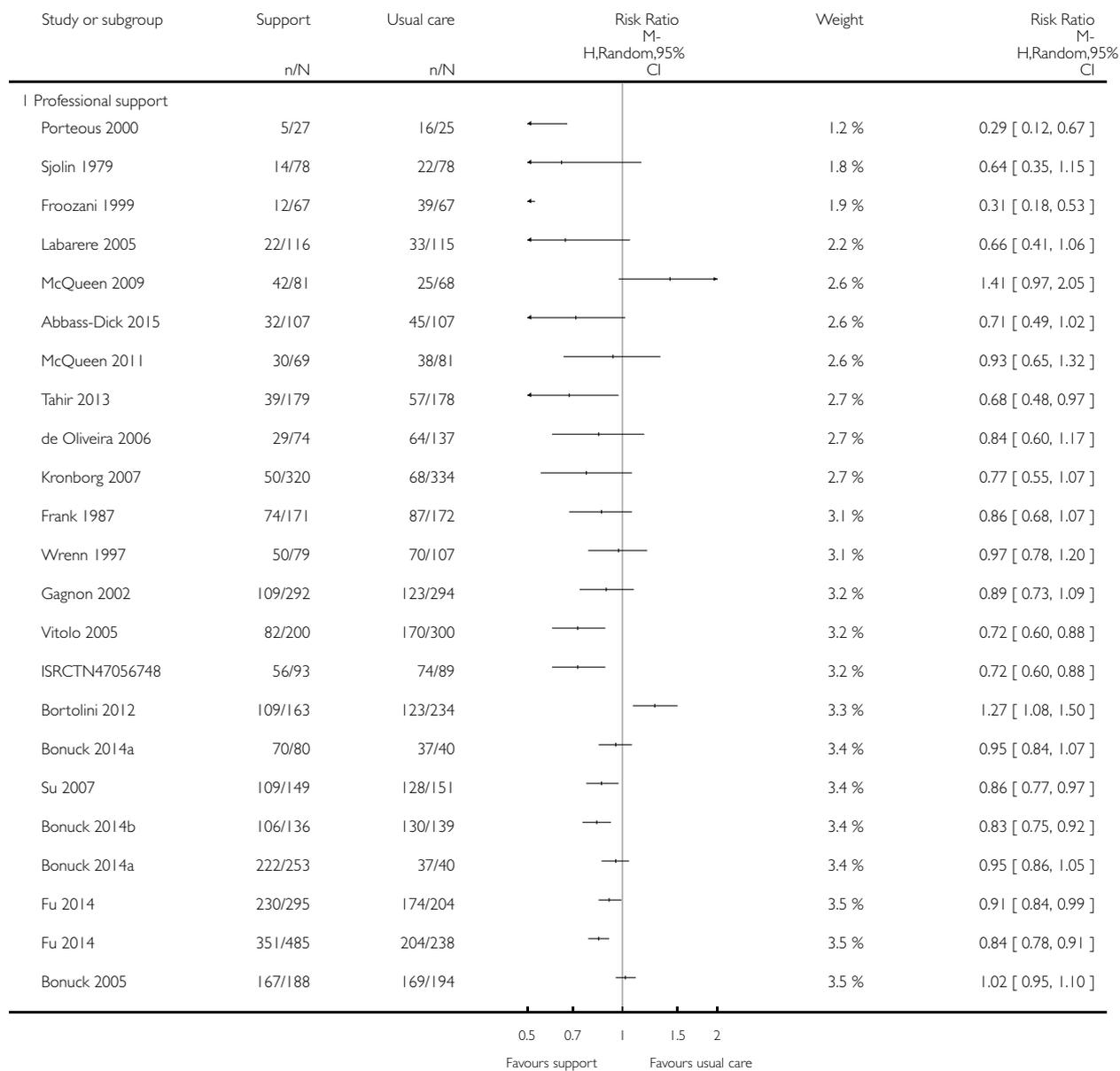


**Analysis 2.4. Comparison 2 All forms of support versus usual care: SUBGROUP ANALYSIS - who delivered the intervention, Outcome 4 Stopping exclusive breastfeeding at up to 4-6 weeks.**

Review: Support for healthy breastfeeding mothers with healthy term babies

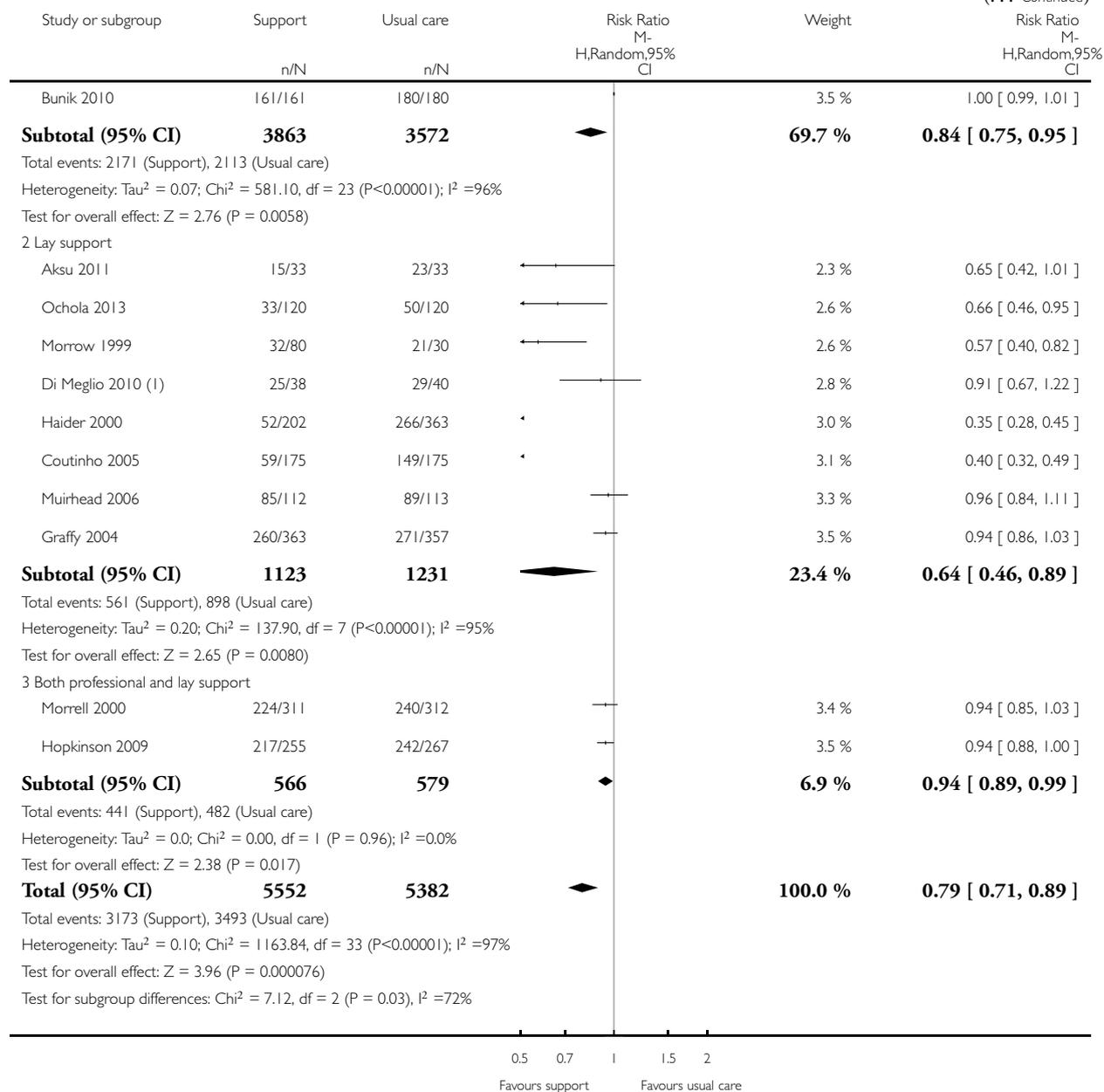
Comparison: 2 All forms of support versus usual care: SUBGROUP ANALYSIS - who delivered the intervention

Outcome: 4 Stopping exclusive breastfeeding at up to 4-6 weeks



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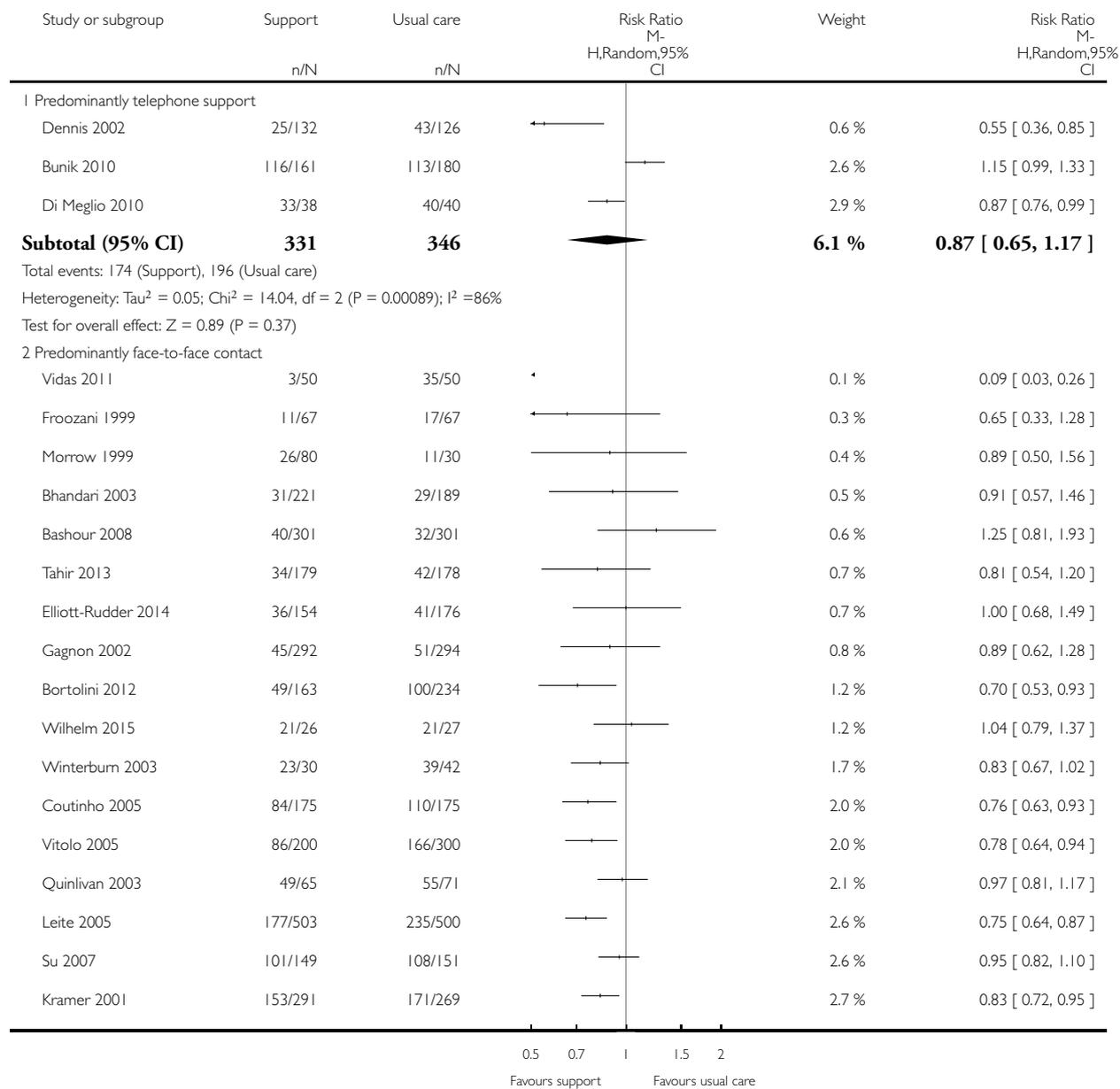
(1) It was not clear when these data were collected.

### Analysis 3.1. Comparison 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support, Outcome 1 Stopping any breastfeeding before last study assessment up to 6 months.

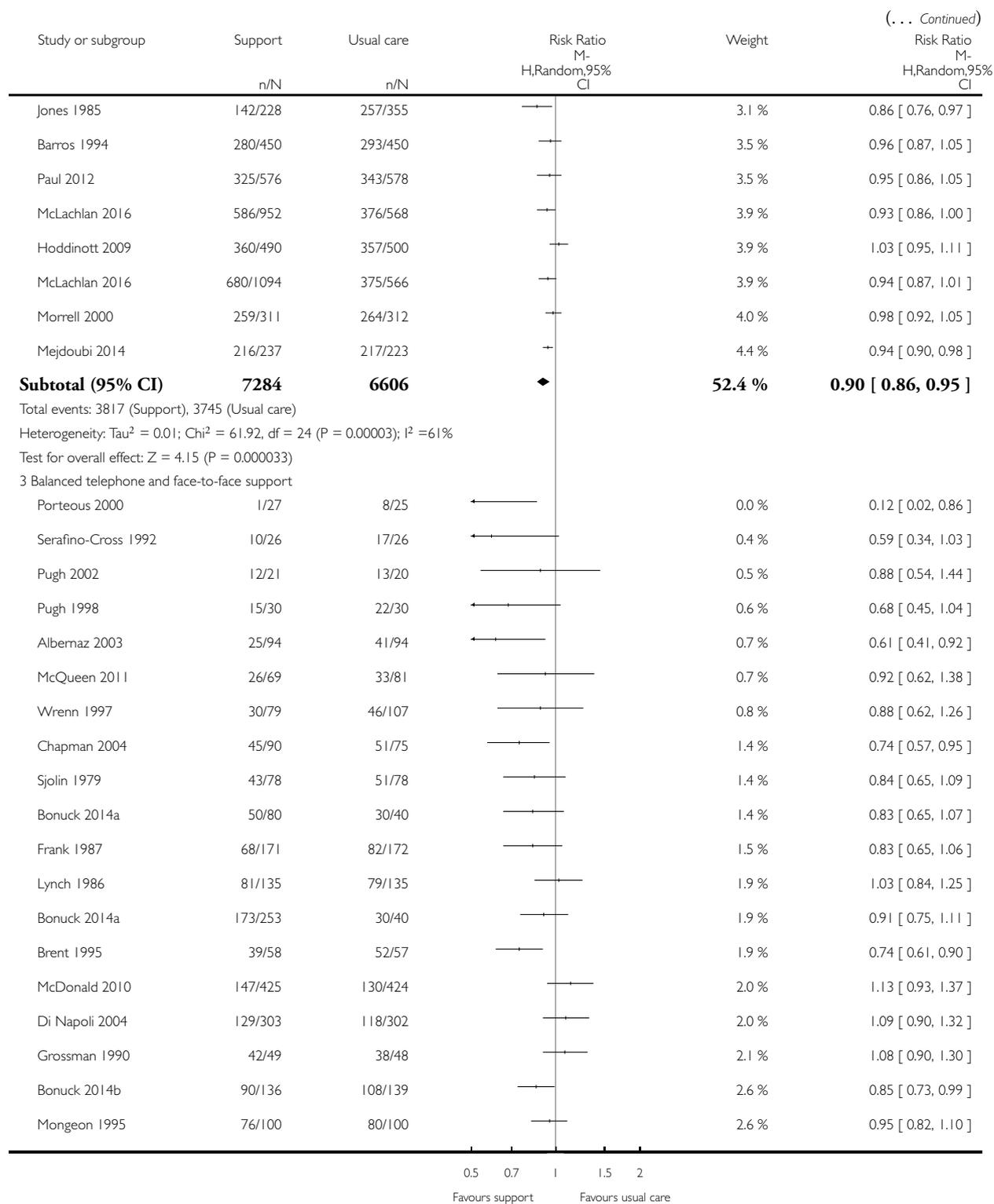
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support

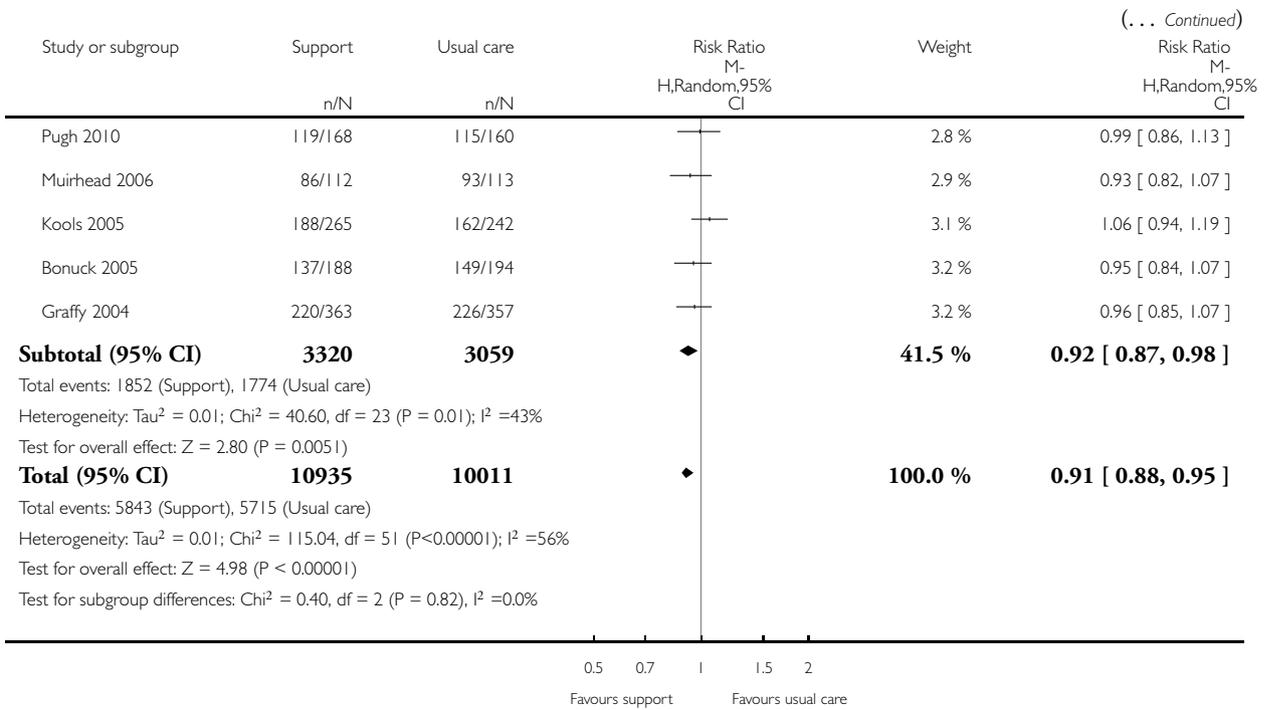
Outcome: 1 Stopping any breastfeeding before last study assessment up to 6 months



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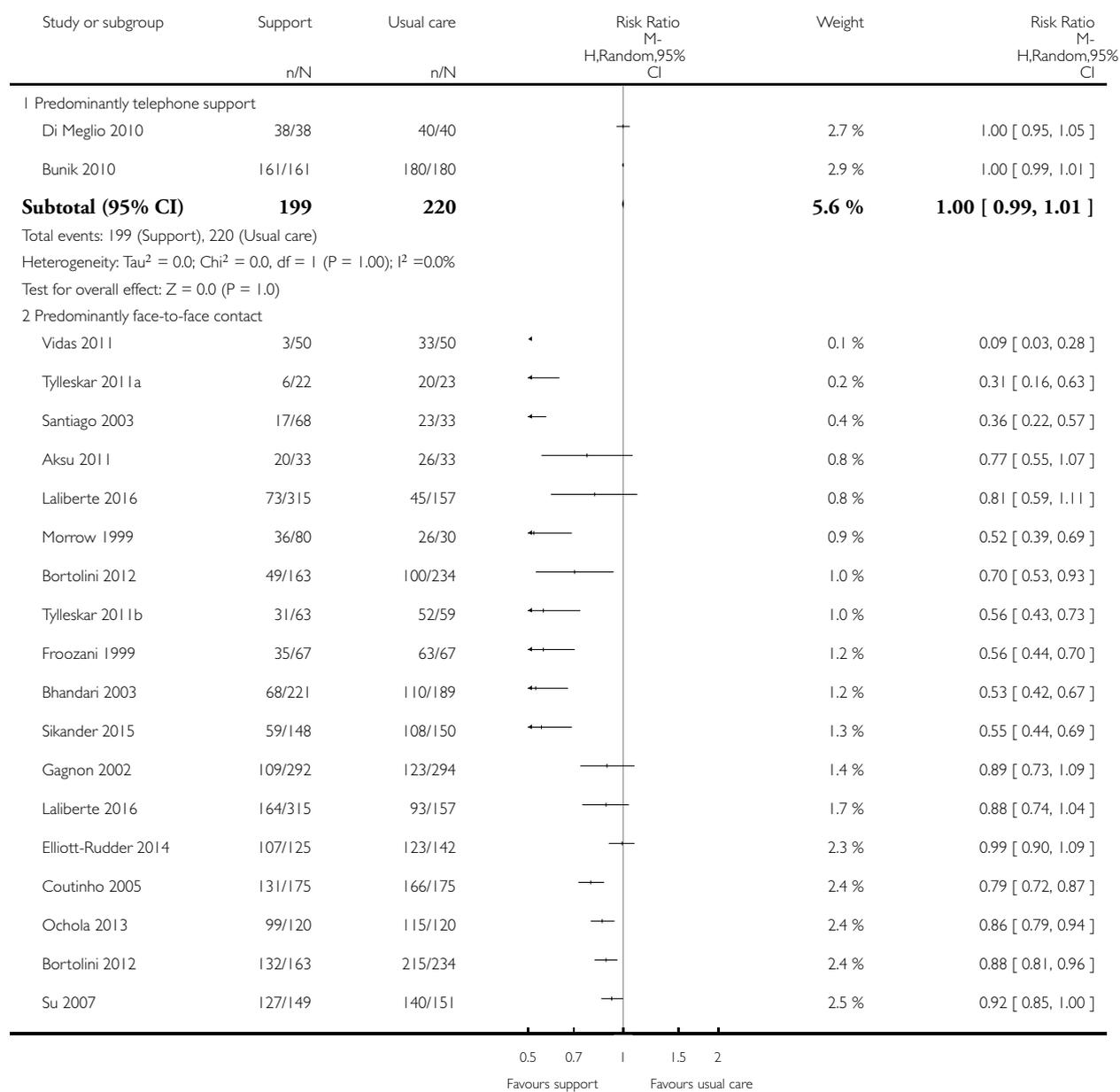


### Analysis 3.2. Comparison 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support, Outcome 2 Stopping exclusive breastfeeding by last study assessment up to 6 months.

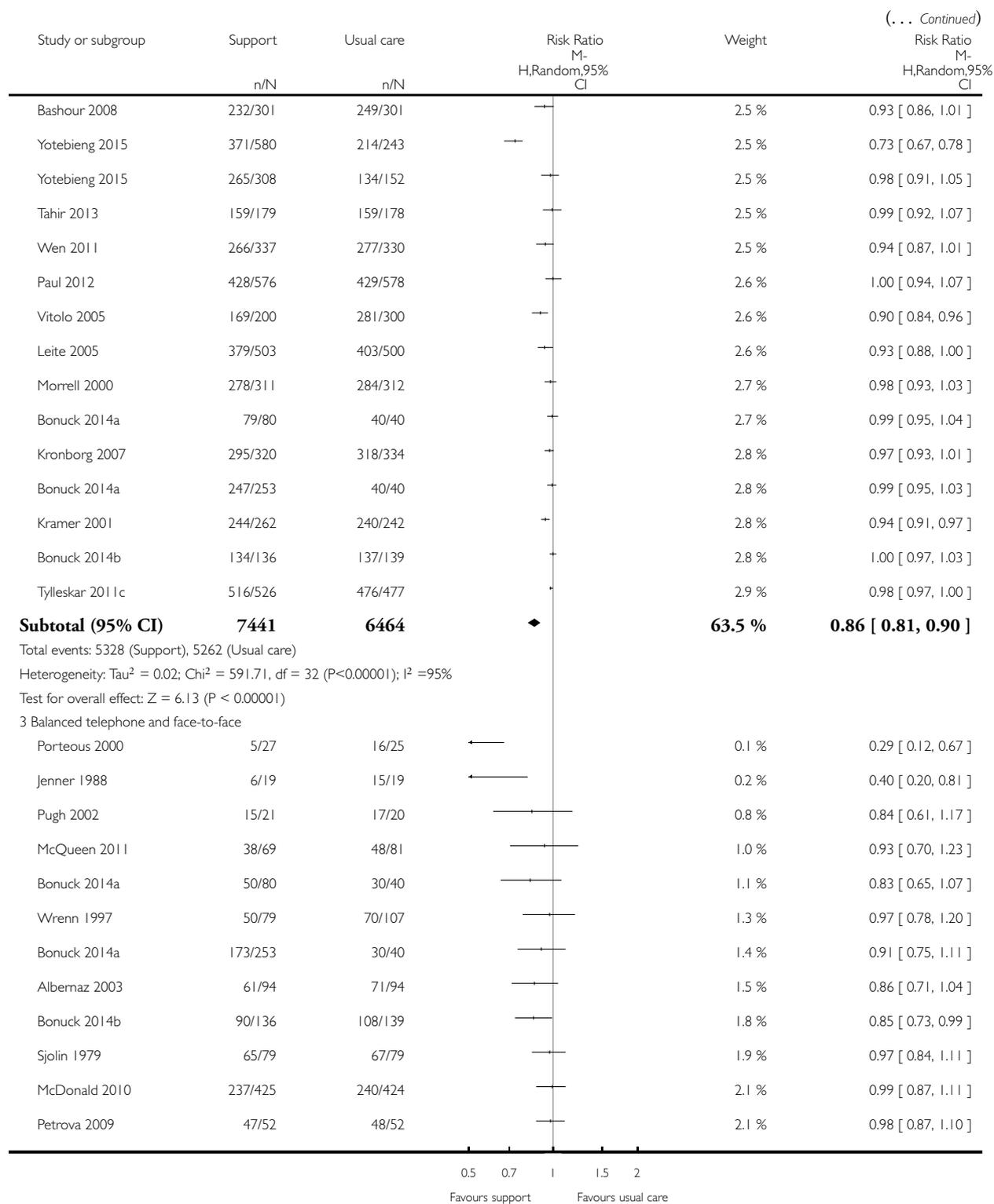
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support

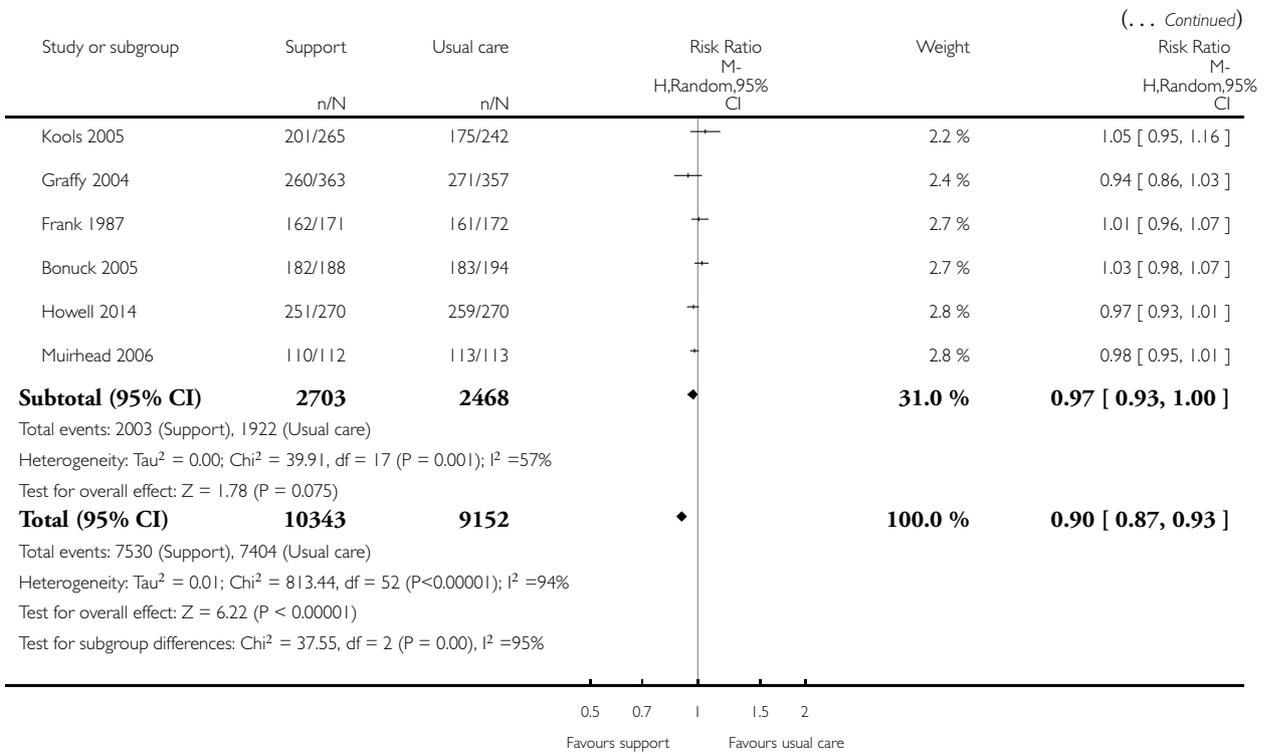
Outcome: 2 Stopping exclusive breastfeeding by last study assessment up to 6 months



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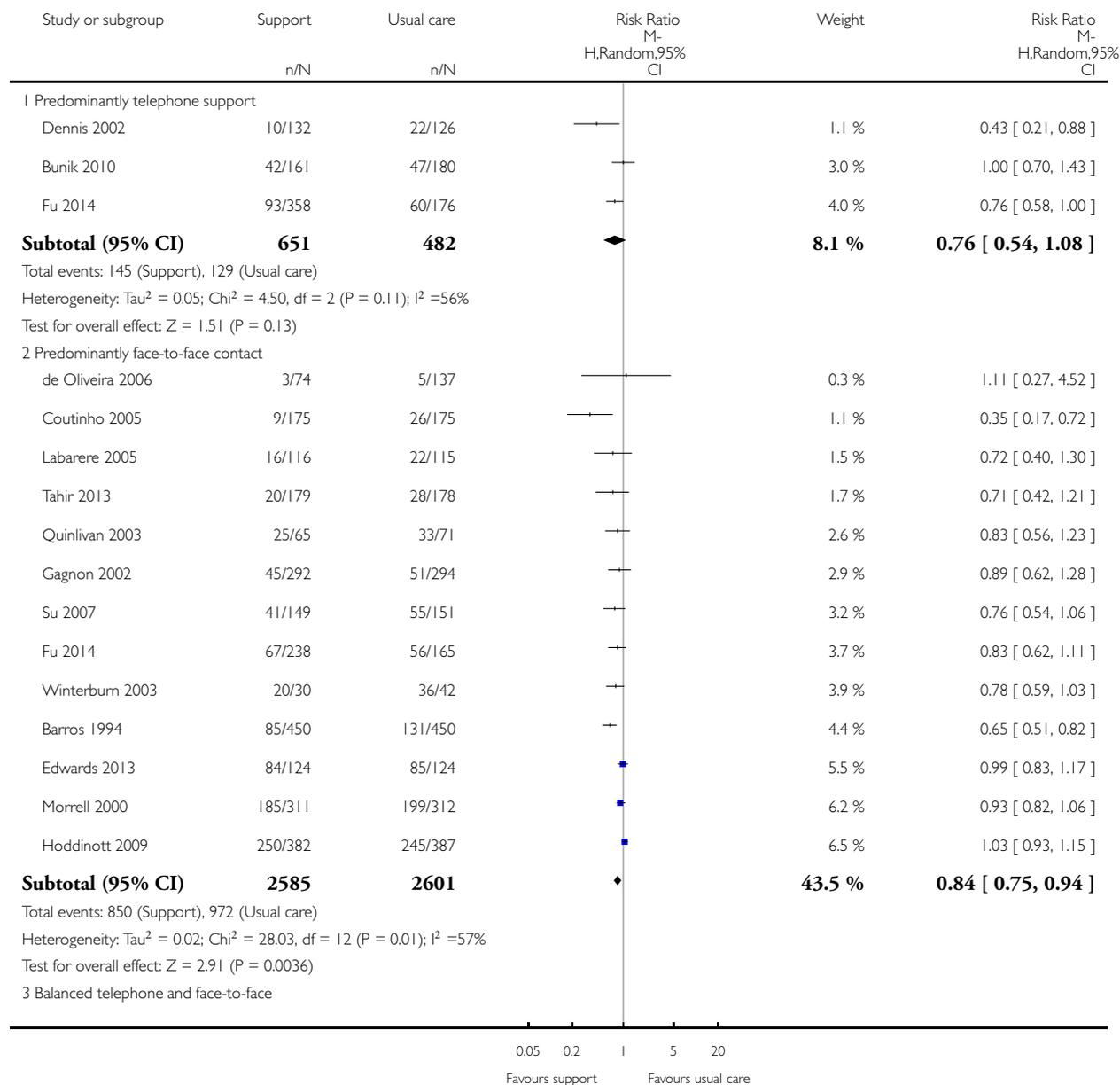


### Analysis 3.3. Comparison 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support, Outcome 3 Stopping any breastfeeding by 4-6 weeks.

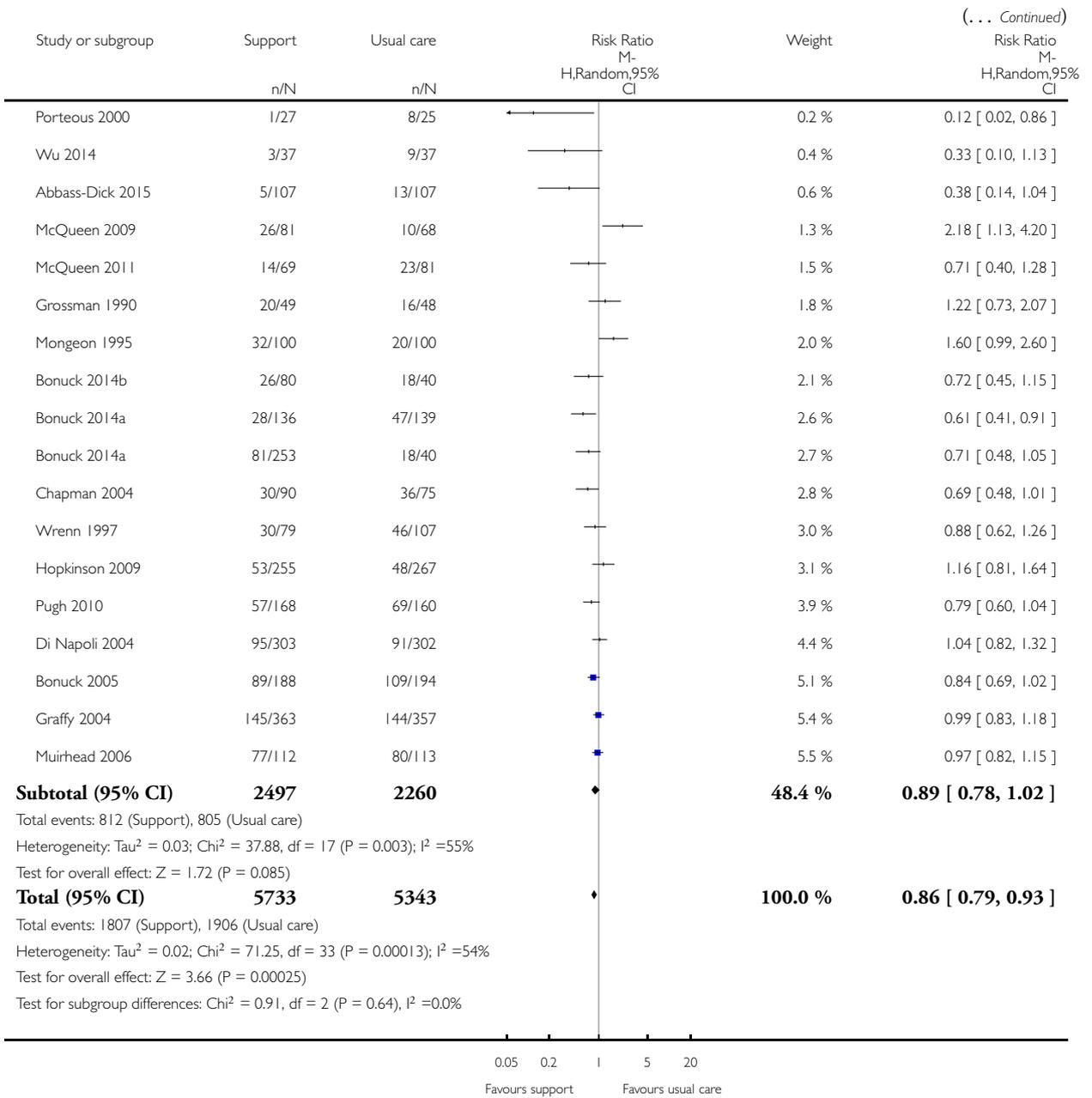
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support

Outcome: 3 Stopping any breastfeeding by 4-6 weeks



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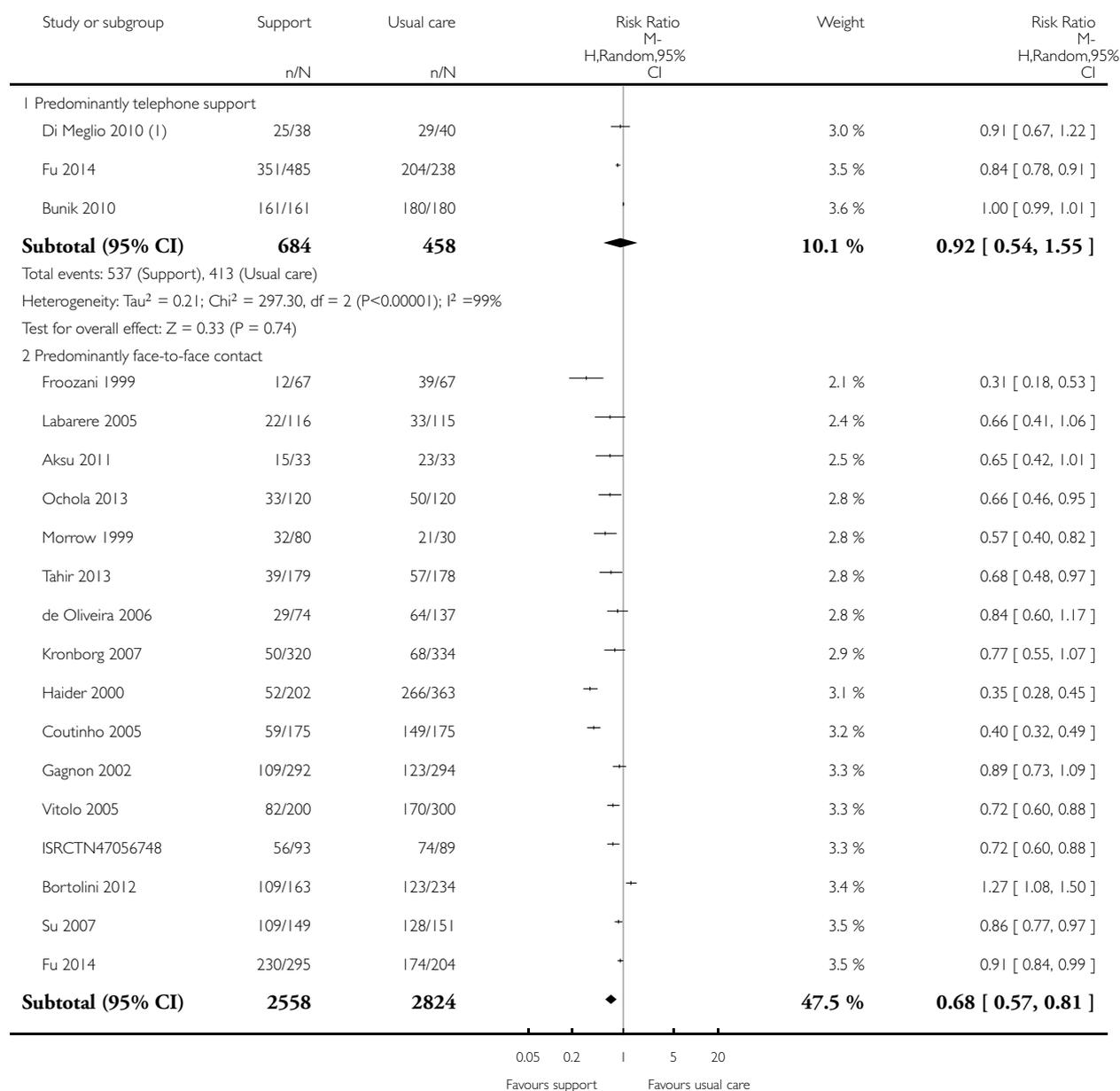


### Analysis 3.4. Comparison 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support, Outcome 4 Stopping exclusive breastfeeding by 4-6 weeks.

Review: Support for healthy breastfeeding mothers with healthy term babies

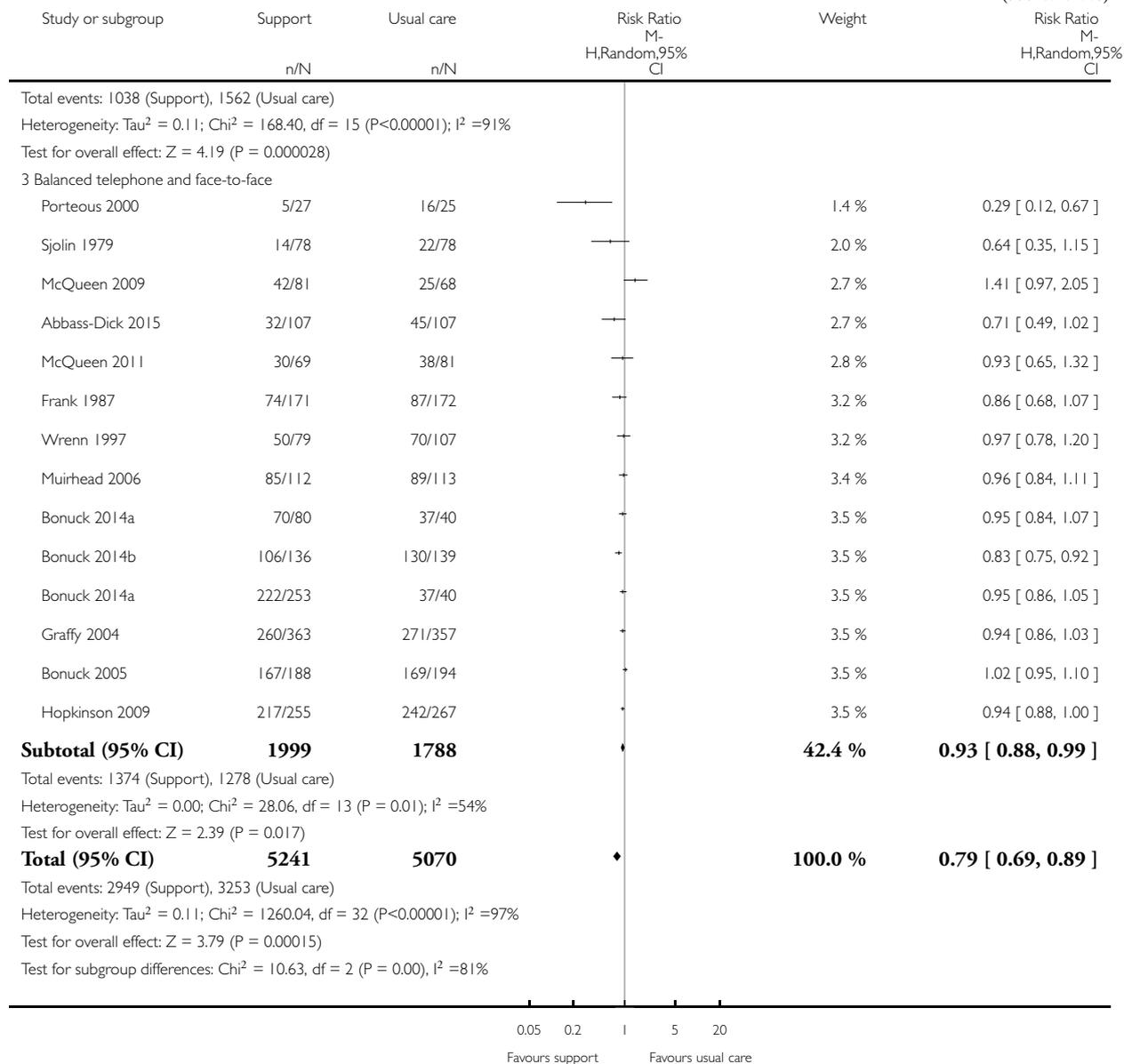
Comparison: 3 All forms of support versus usual care: SUBGROUP ANALYSIS - type of support

Outcome: 4 Stopping exclusive breastfeeding by 4-6 weeks



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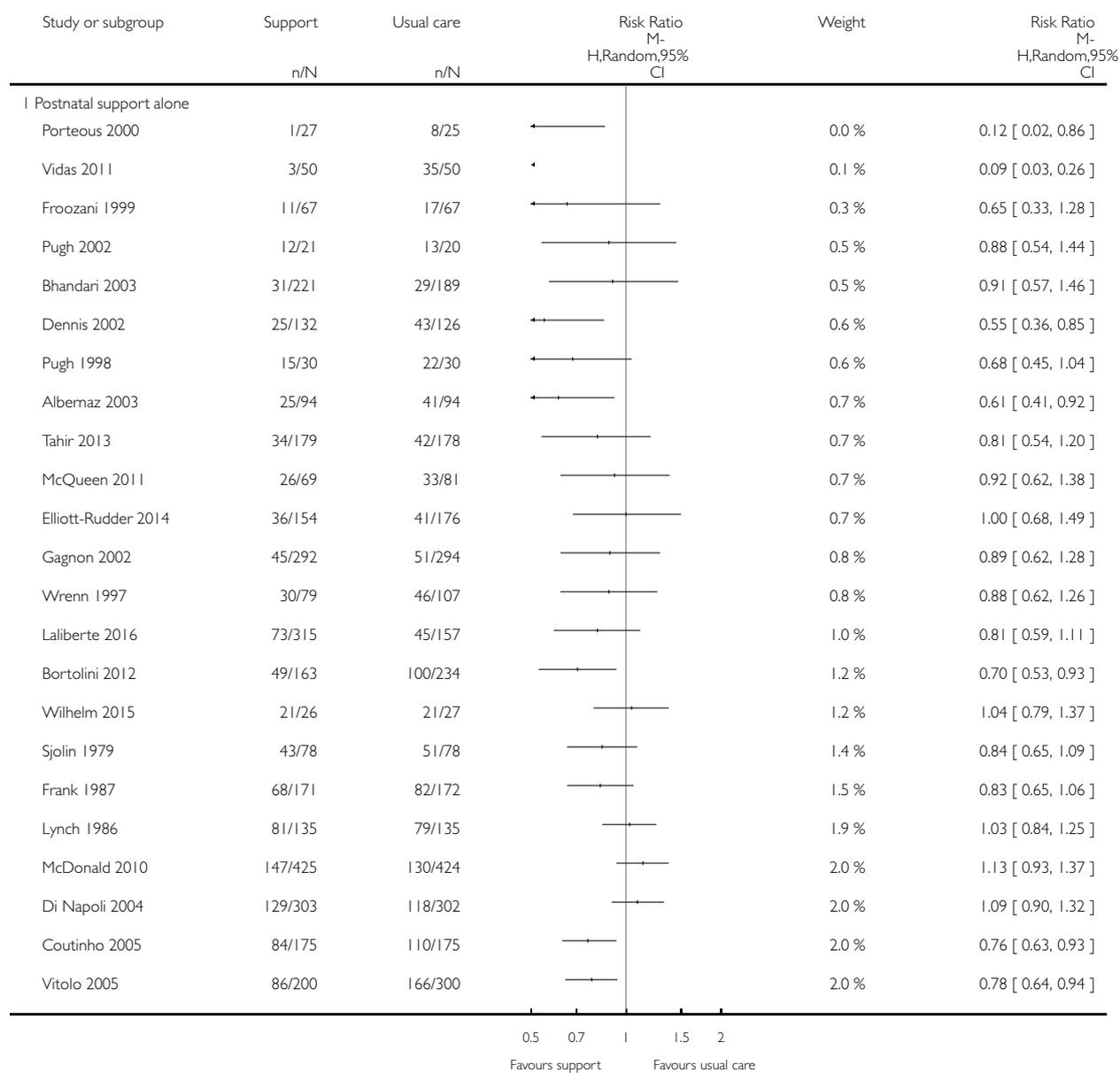
(1) It was not clear when these data were collected.

**Analysis 4.1. Comparison 4 All forms of support versus usual care: SUBGROUP ANALYSIS - timing of support, Outcome 1 Stopping any breastfeeding at last study assessment up to 6 months.**

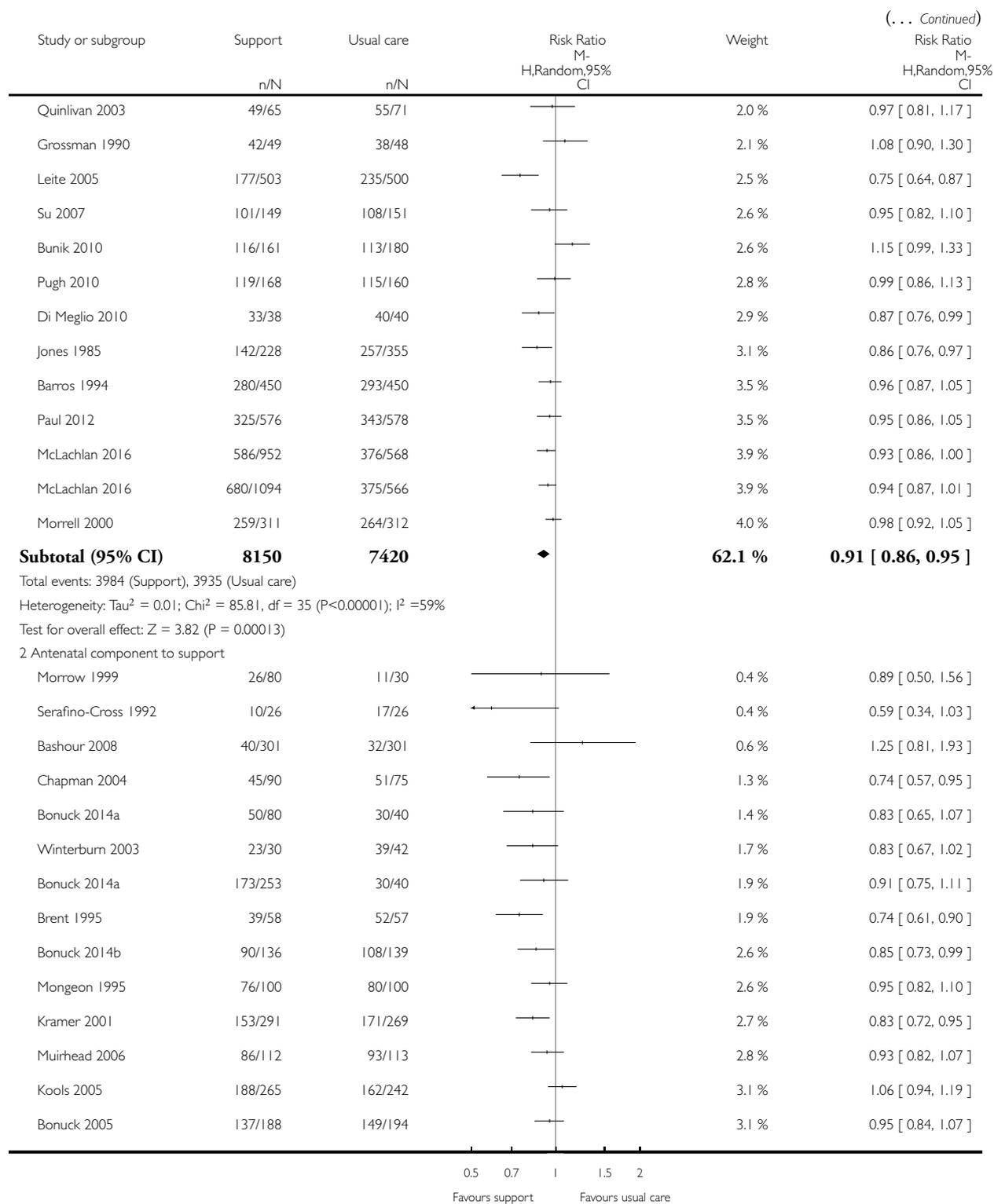
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 4 All forms of support versus usual care: SUBGROUP ANALYSIS - timing of support

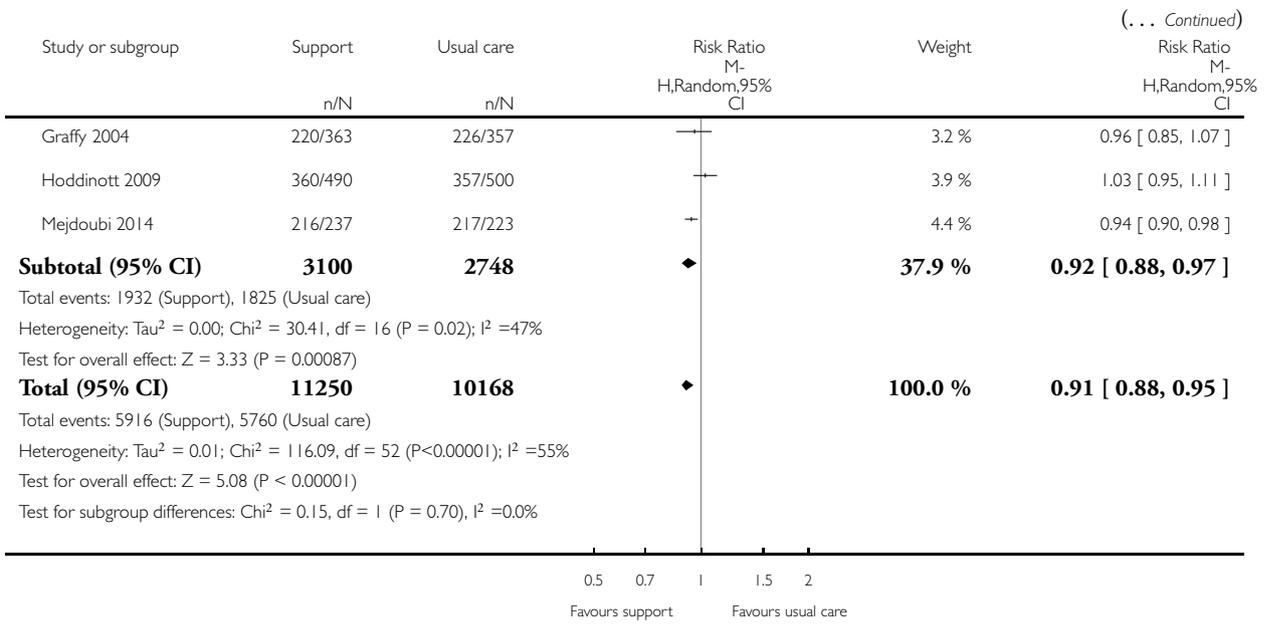
Outcome: 1 Stopping any breastfeeding at last study assessment up to 6 months



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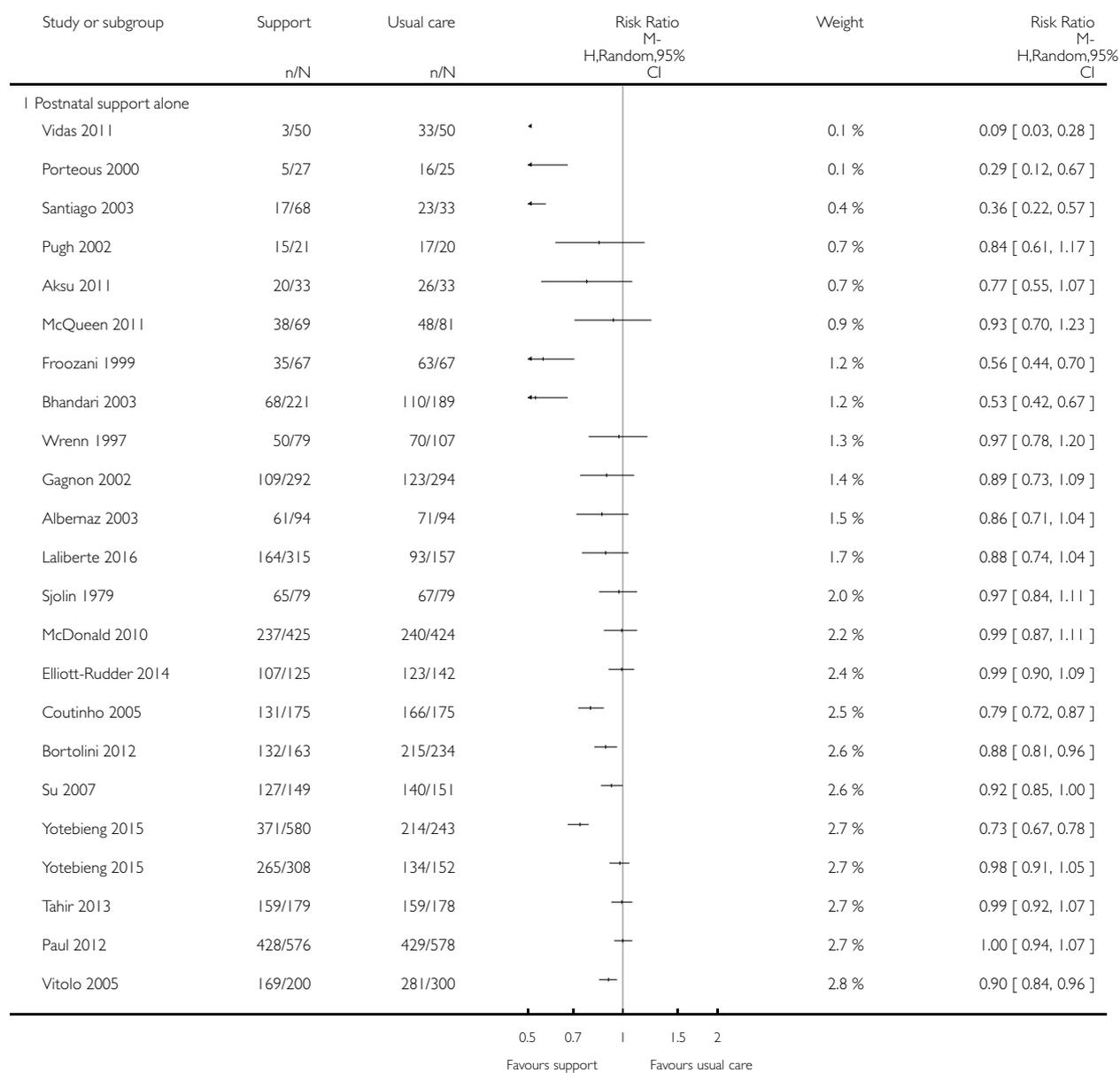


**Analysis 4.2. Comparison 4 All forms of support versus usual care: SUBGROUP ANALYSIS - timing of support, Outcome 2 Stopping exclusive breastfeeding by last assessment up to 6 months.**

Review: Support for healthy breastfeeding mothers with healthy term babies

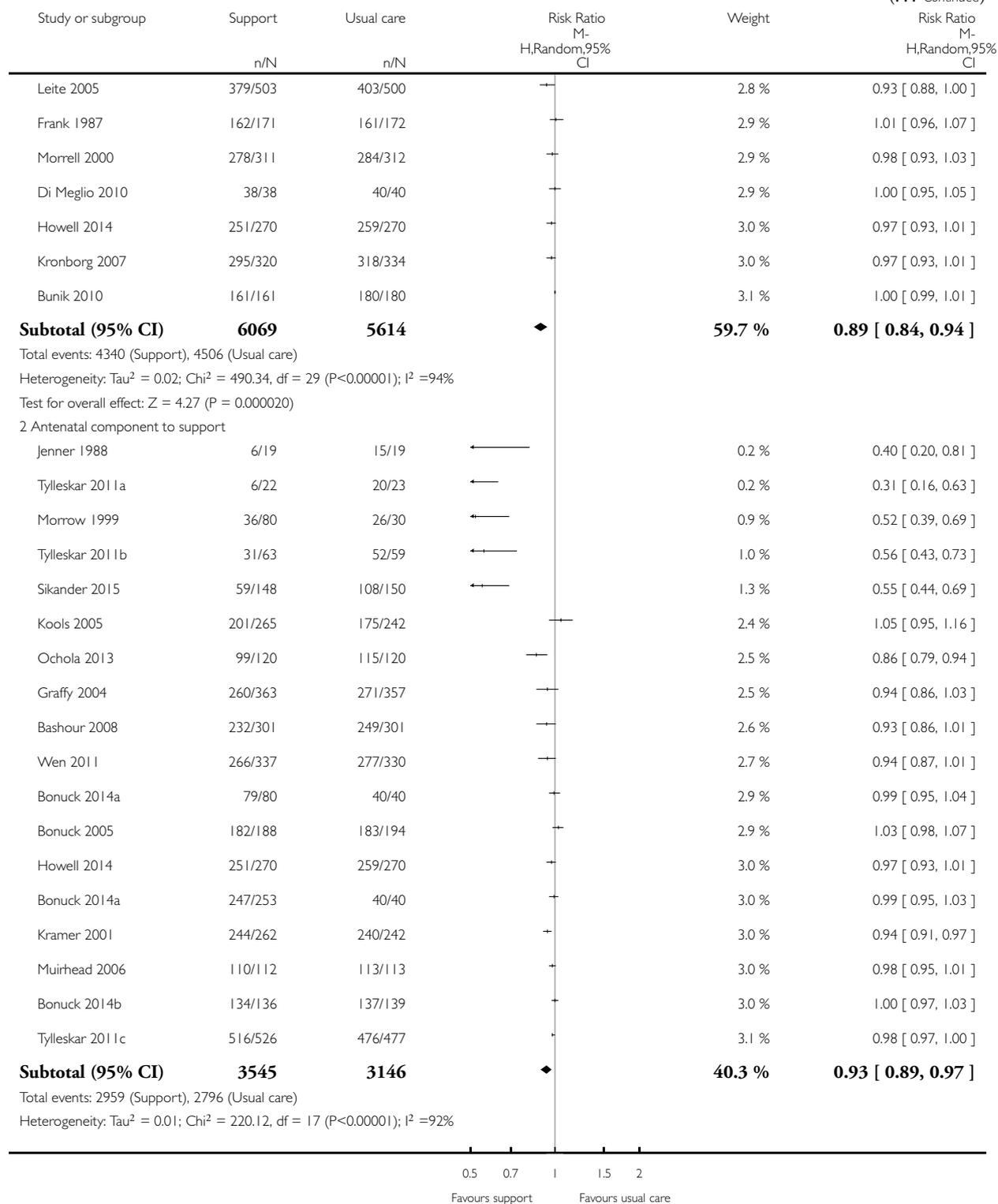
Comparison: 4 All forms of support versus usual care: SUBGROUP ANALYSIS - timing of support

Outcome: 2 Stopping exclusive breastfeeding by last assessment up to 6 months

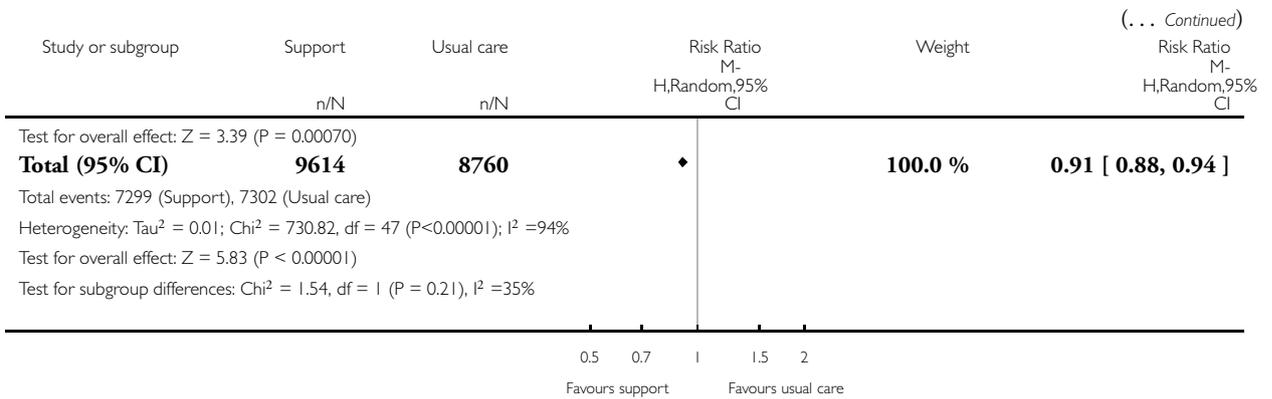


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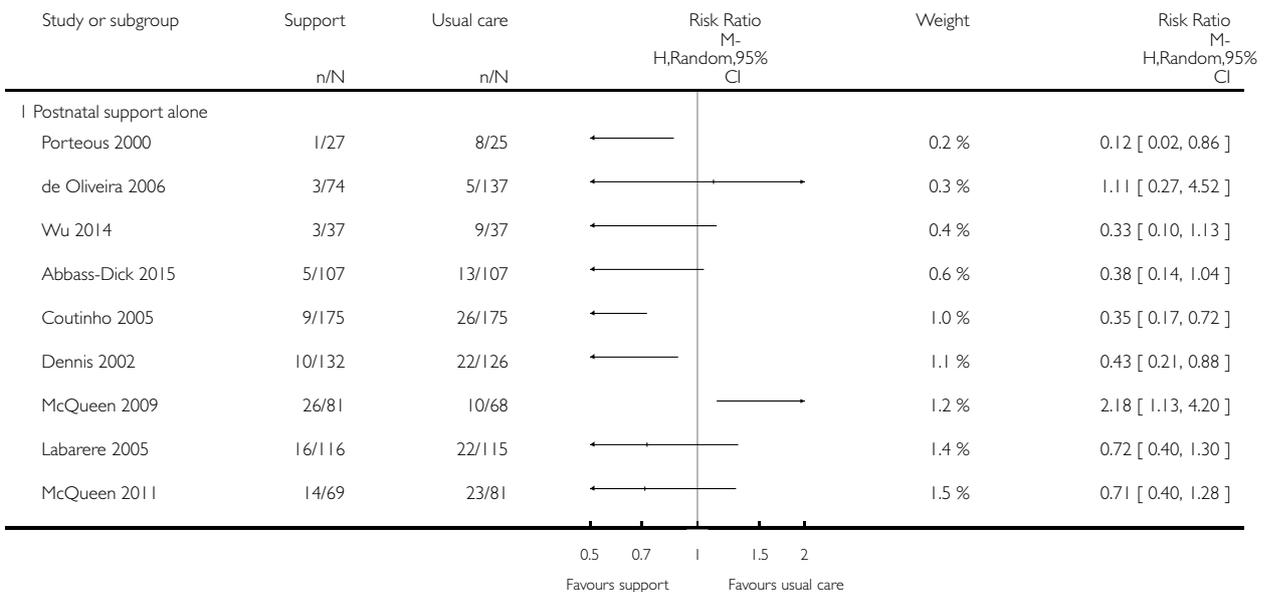


### Analysis 4.3. Comparison 4 All forms of support versus usual care: SUBGROUP ANALYSIS - timing of support, Outcome 3 Stopping any breastfeeding at 4-6 weeks.

Review: Support for healthy breastfeeding mothers with healthy term babies

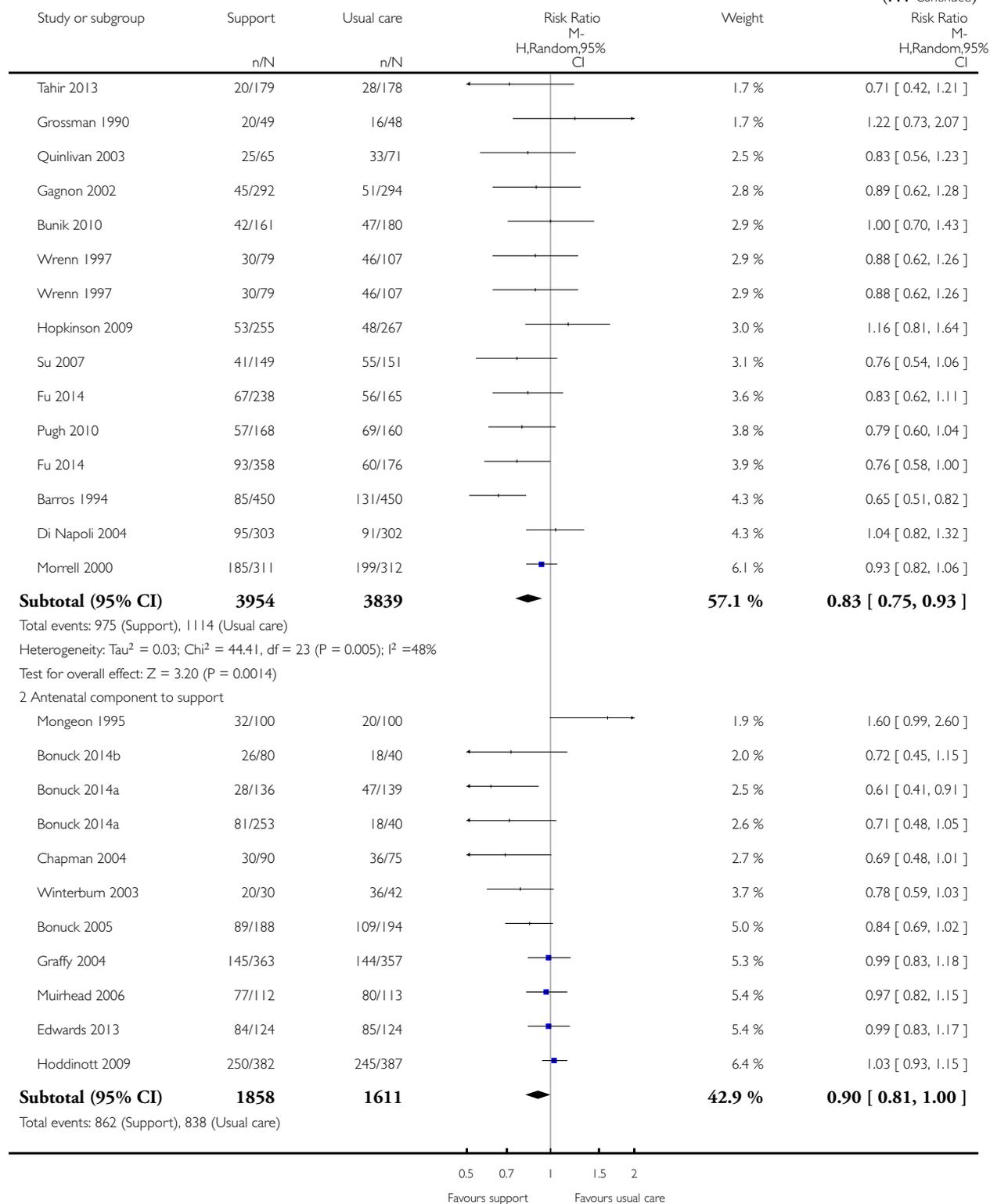
Comparison: 4 All forms of support versus usual care: SUBGROUP ANALYSIS - timing of support

Outcome: 3 Stopping any breastfeeding at 4-6 weeks

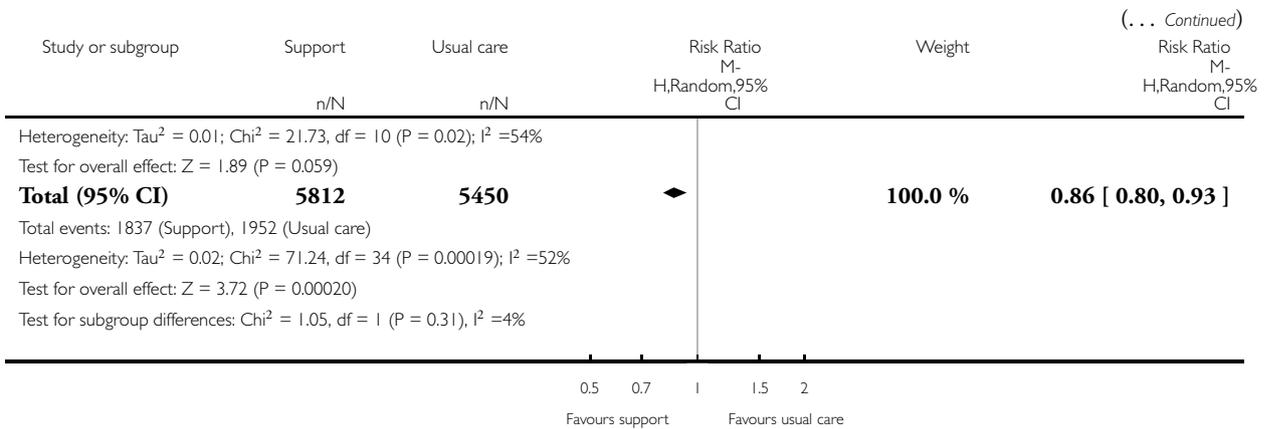


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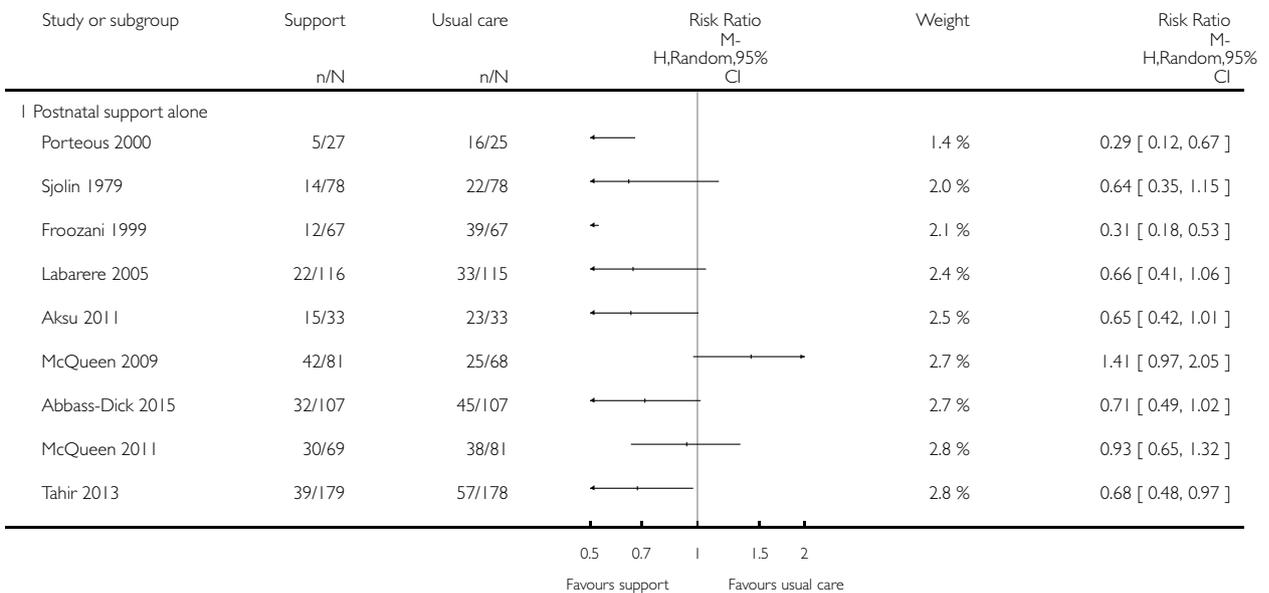


**Analysis 4.4. Comparison 4 All forms of support versus usual care: SUBGROUP ANALYSIS - timing of support, Outcome 4 Stopping exclusive breastfeeding at up to 4-6 weeks.**

Review: Support for healthy breastfeeding mothers with healthy term babies

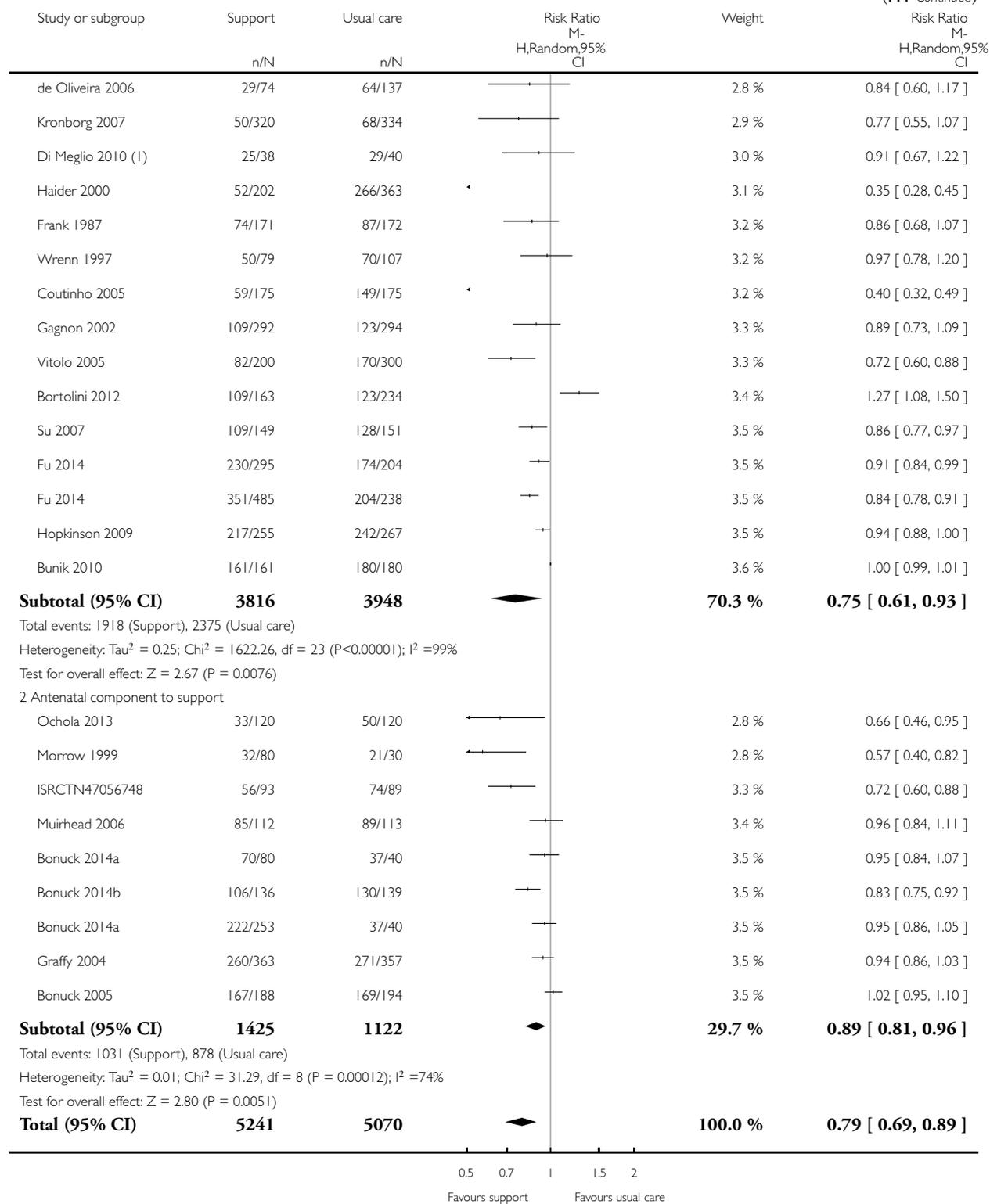
Comparison: 4 All forms of support versus usual care: SUBGROUP ANALYSIS - timing of support

Outcome: 4 Stopping exclusive breastfeeding at up to 4-6 weeks

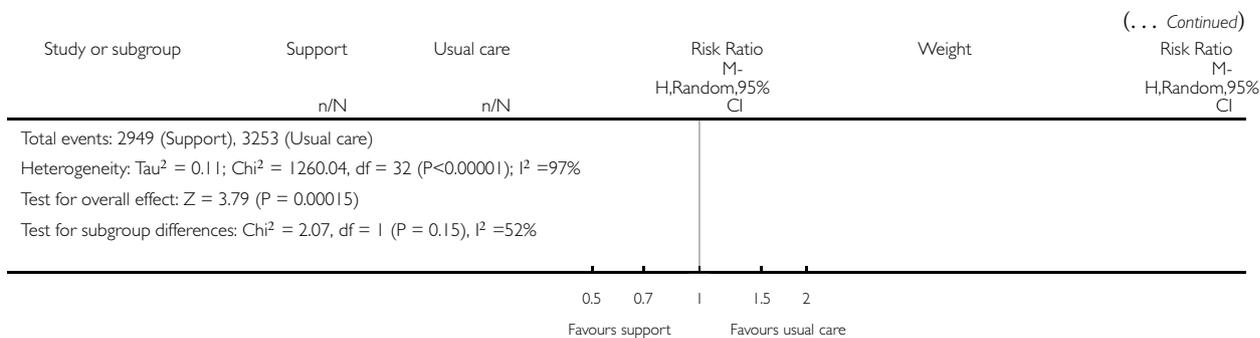


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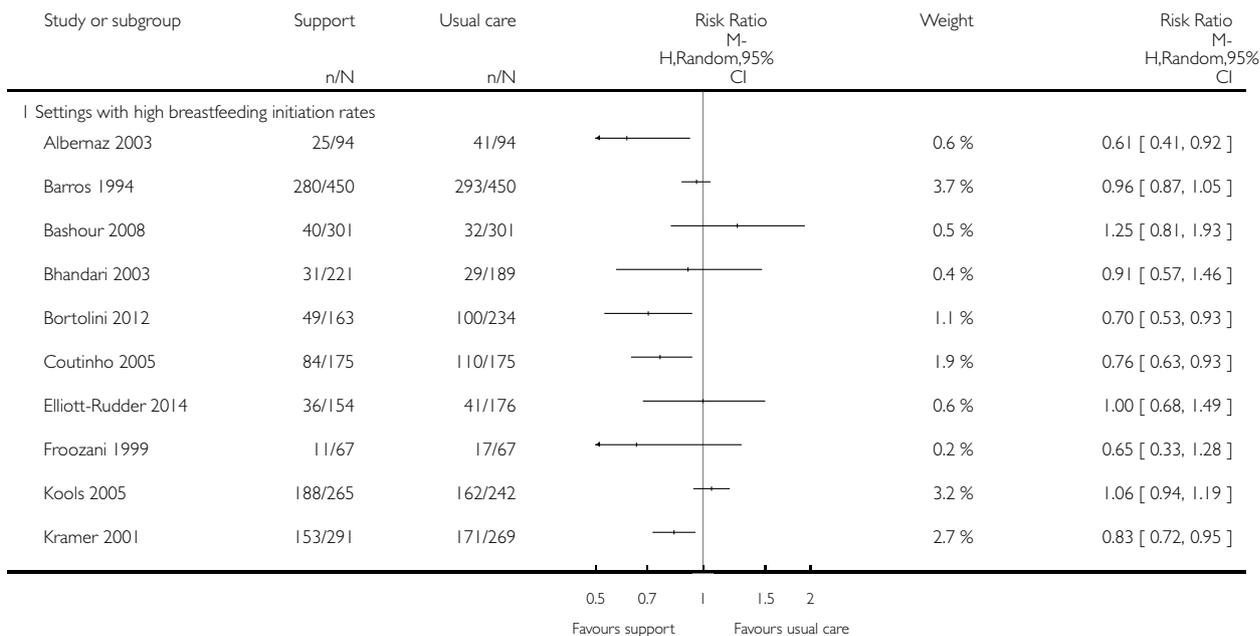
(I) It was not clear when these data were collected.

### Analysis 5.1. Comparison 5 All forms of support versus usual care: SUBGROUP ANALYSIS - breastfeeding initiation, Outcome 1 Stopping any breastfeeding by last assessment up to 6 months.

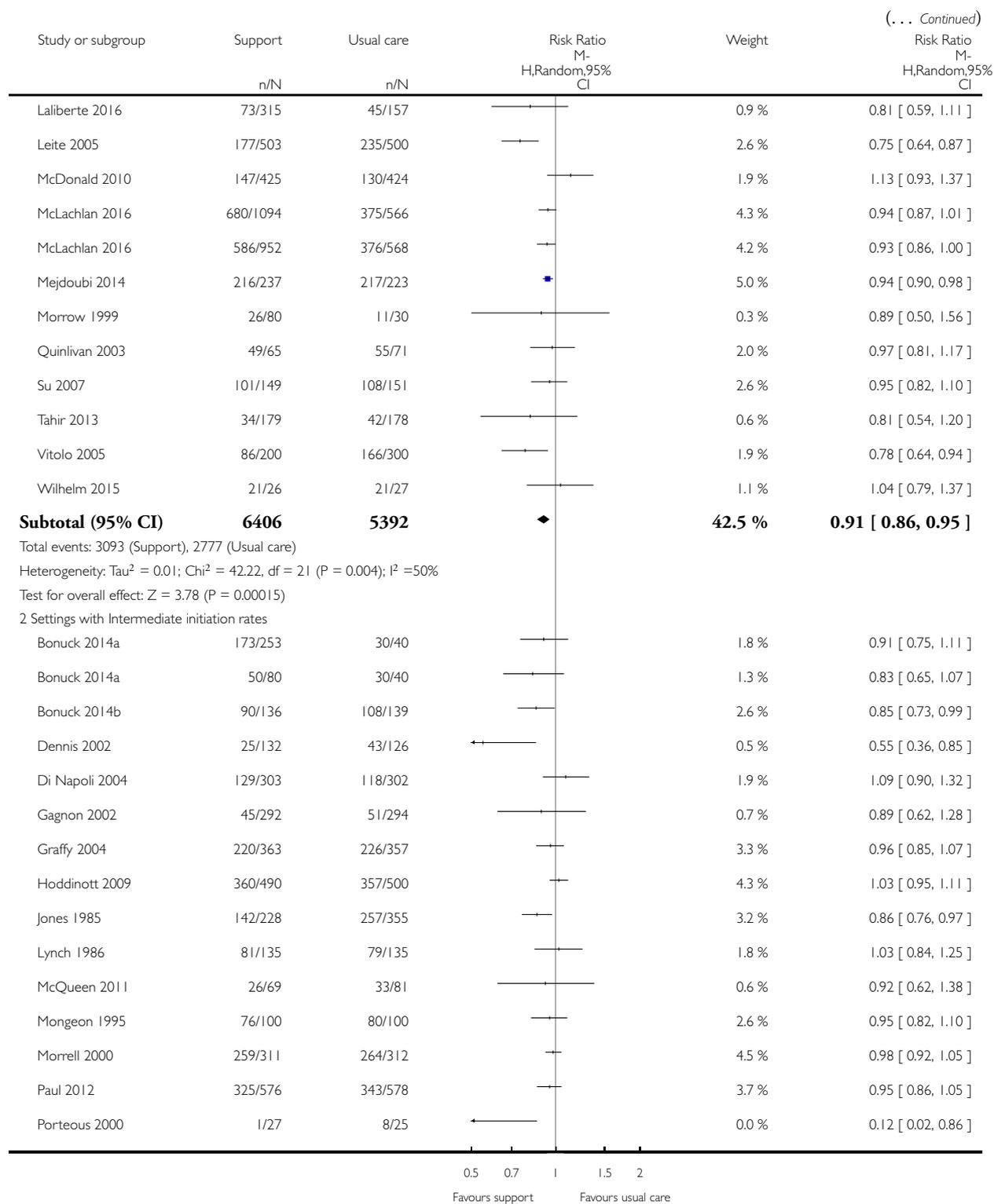
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 5 All forms of support versus usual care: SUBGROUP ANALYSIS - breastfeeding initiation

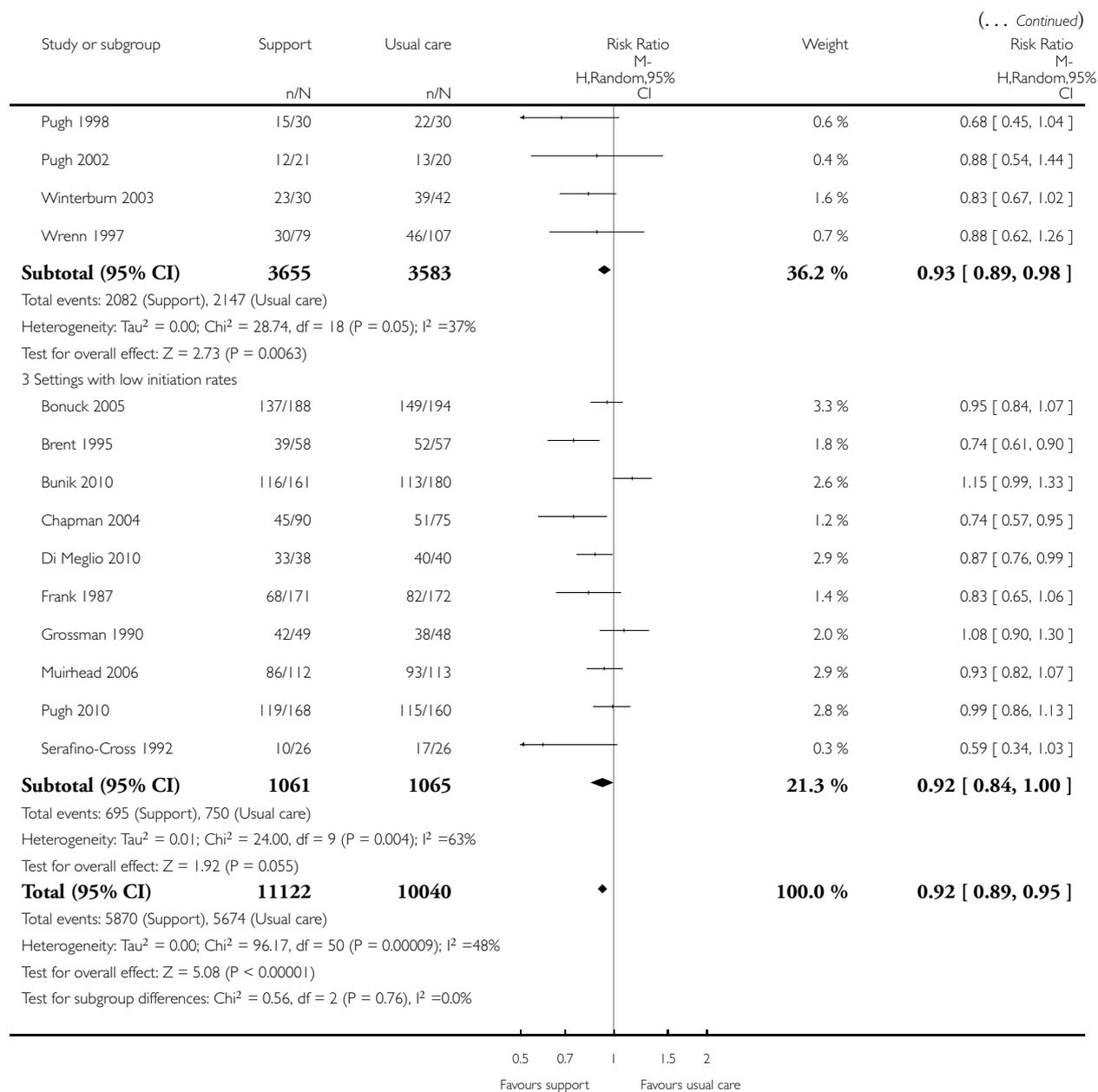
Outcome: 1 Stopping any breastfeeding by last assessment up to 6 months



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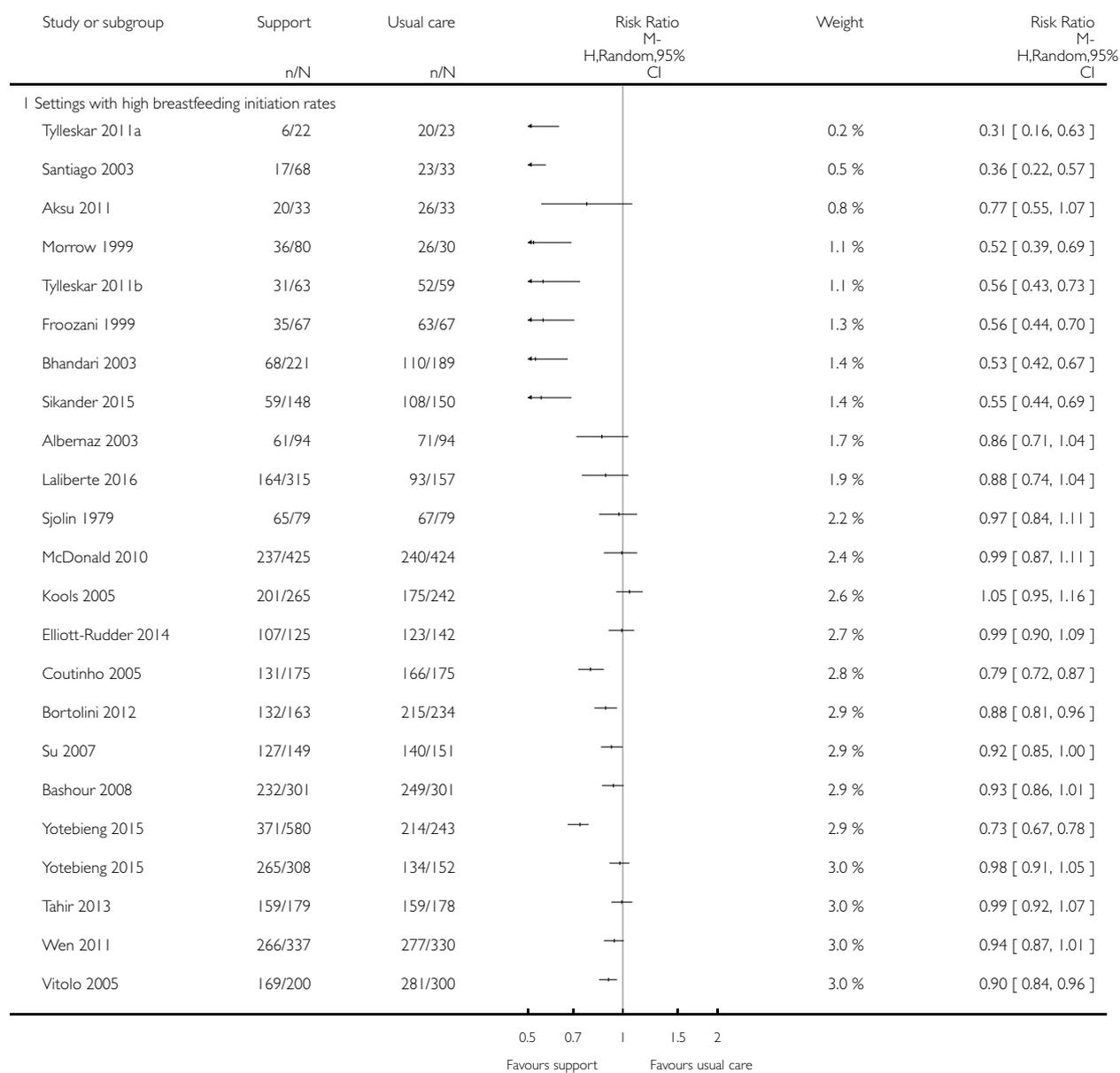


**Analysis 5.2. Comparison 5 All forms of support versus usual care: SUBGROUP ANALYSIS - breastfeeding initiation, Outcome 2 Stopping exclusive breastfeeding at last assessment up to 6 months.**

Review: Support for healthy breastfeeding mothers with healthy term babies

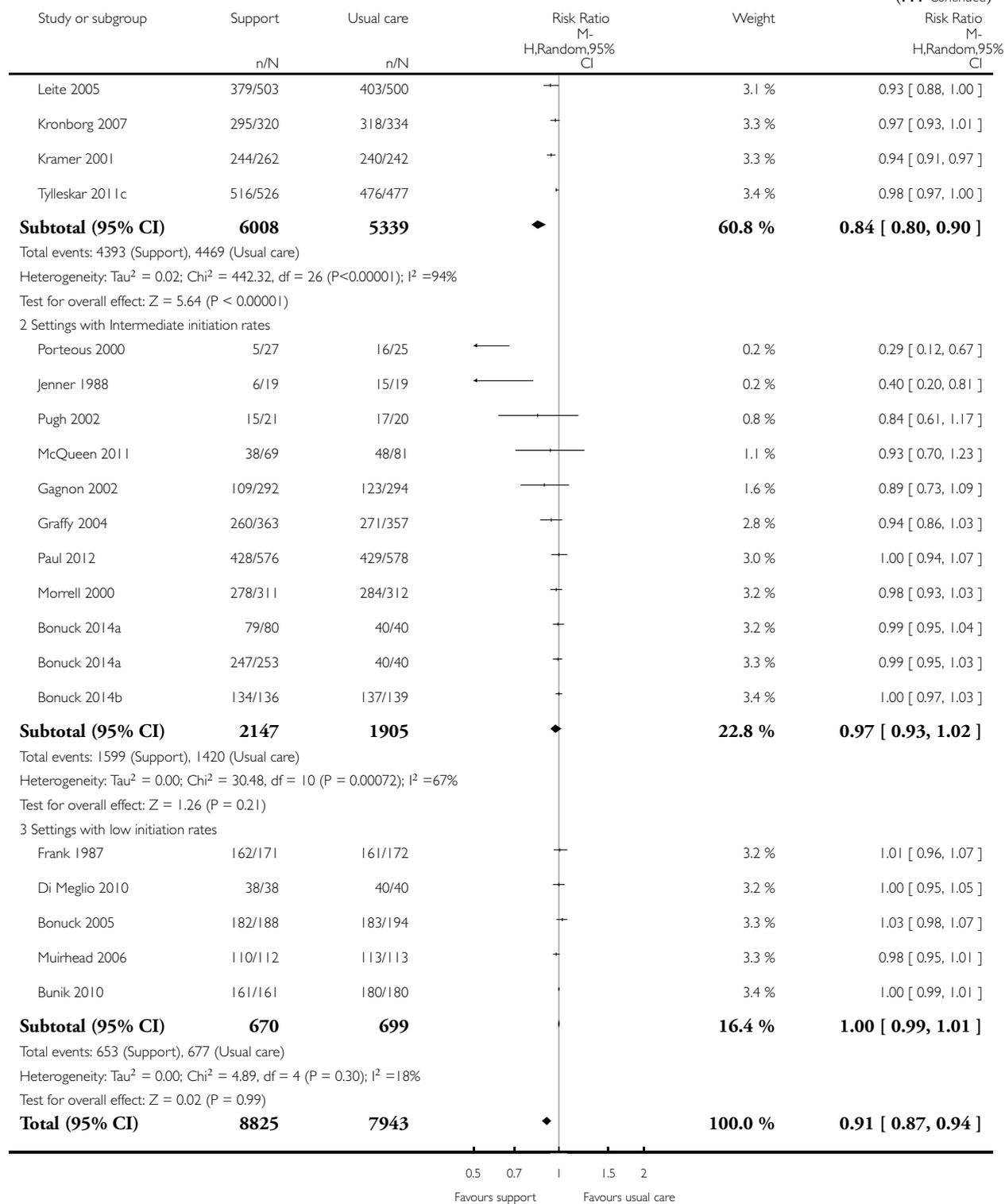
Comparison: 5 All forms of support versus usual care: SUBGROUP ANALYSIS - breastfeeding initiation

Outcome: 2 Stopping exclusive breastfeeding at last assessment up to 6 months



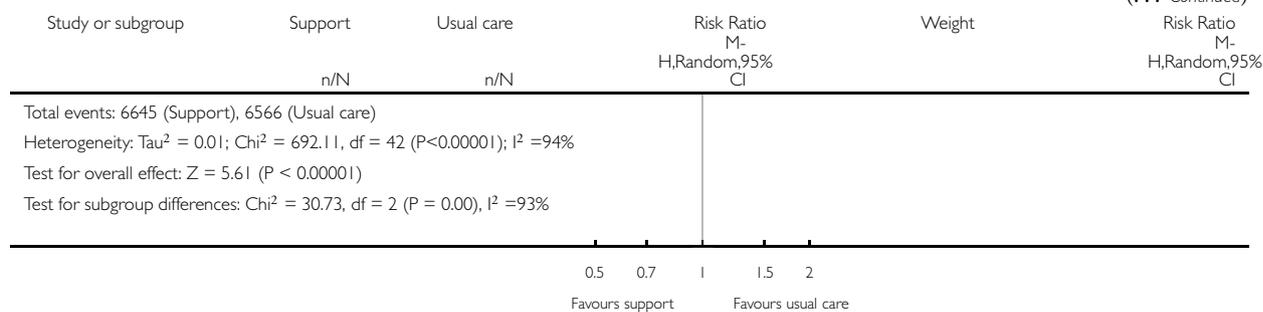
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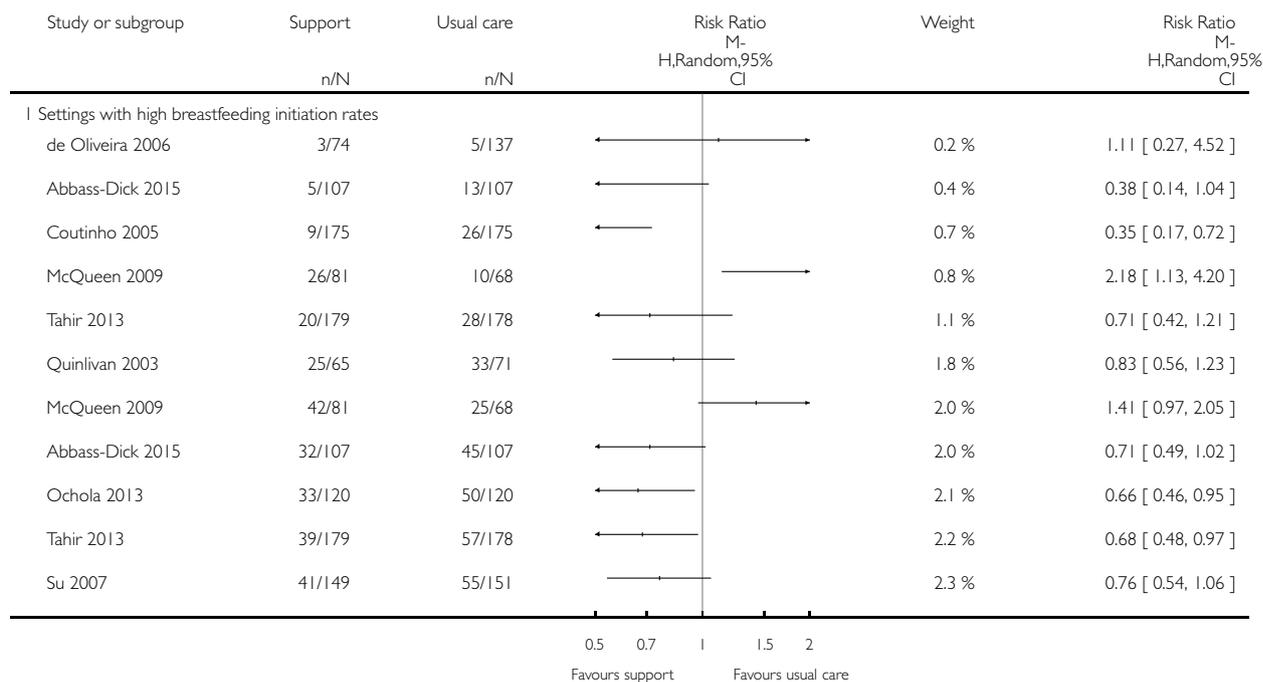


### Analysis 5.3. Comparison 5 All forms of support versus usual care: SUBGROUP ANALYSIS - breastfeeding initiation, Outcome 3 Stopping any breastfeeding at up to 4-6 weeks.

Review: Support for healthy breastfeeding mothers with healthy term babies

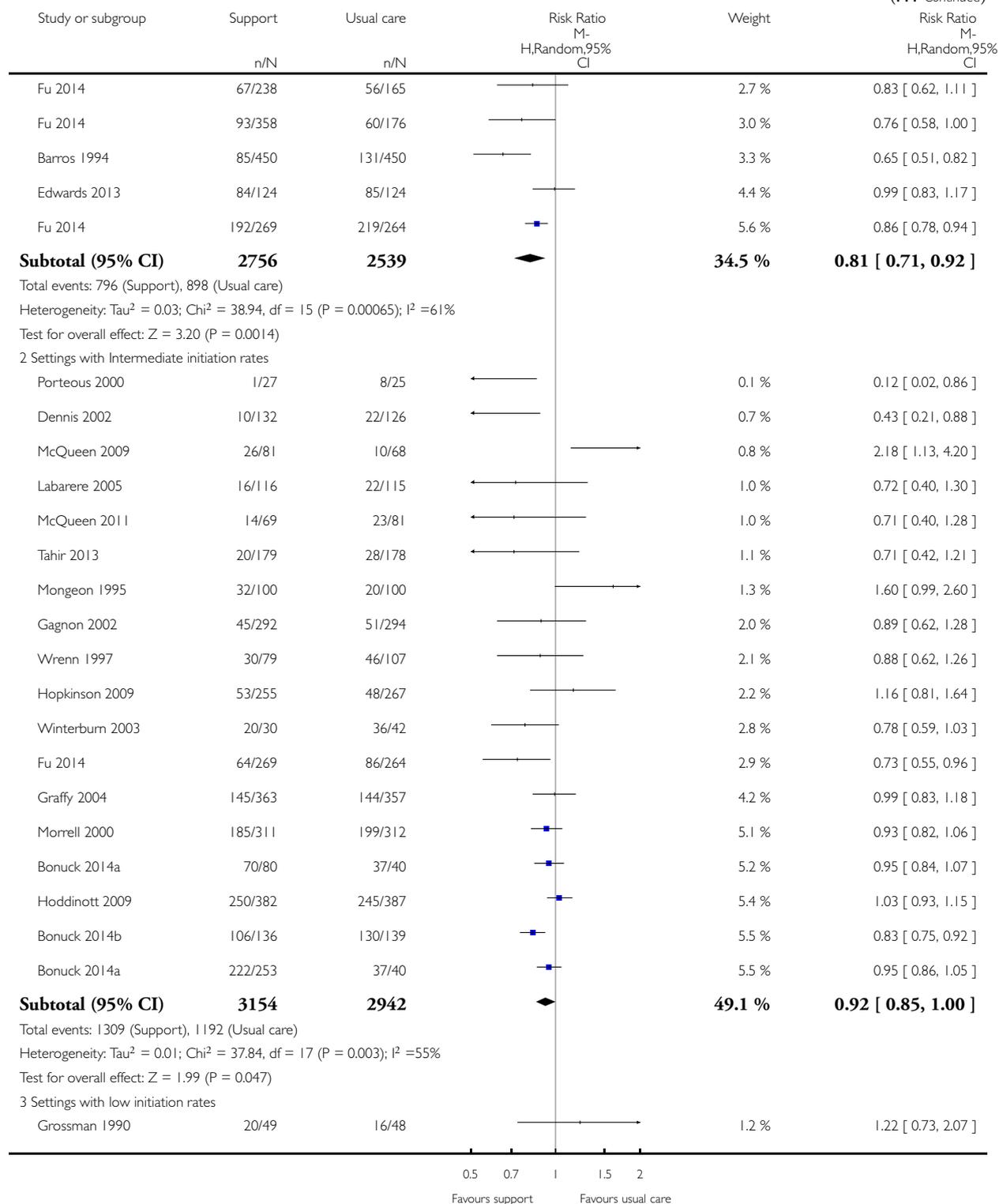
Comparison: 5 All forms of support versus usual care: SUBGROUP ANALYSIS - breastfeeding initiation

Outcome: 3 Stopping any breastfeeding at up to 4-6 weeks

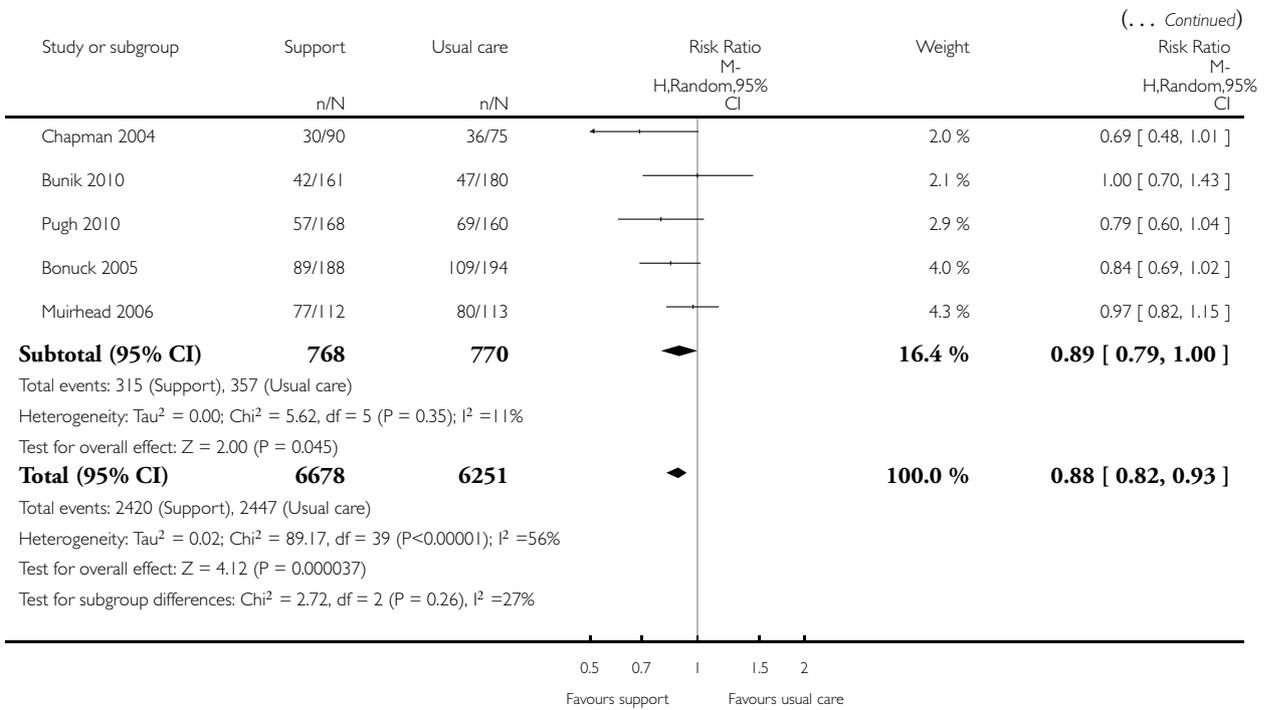


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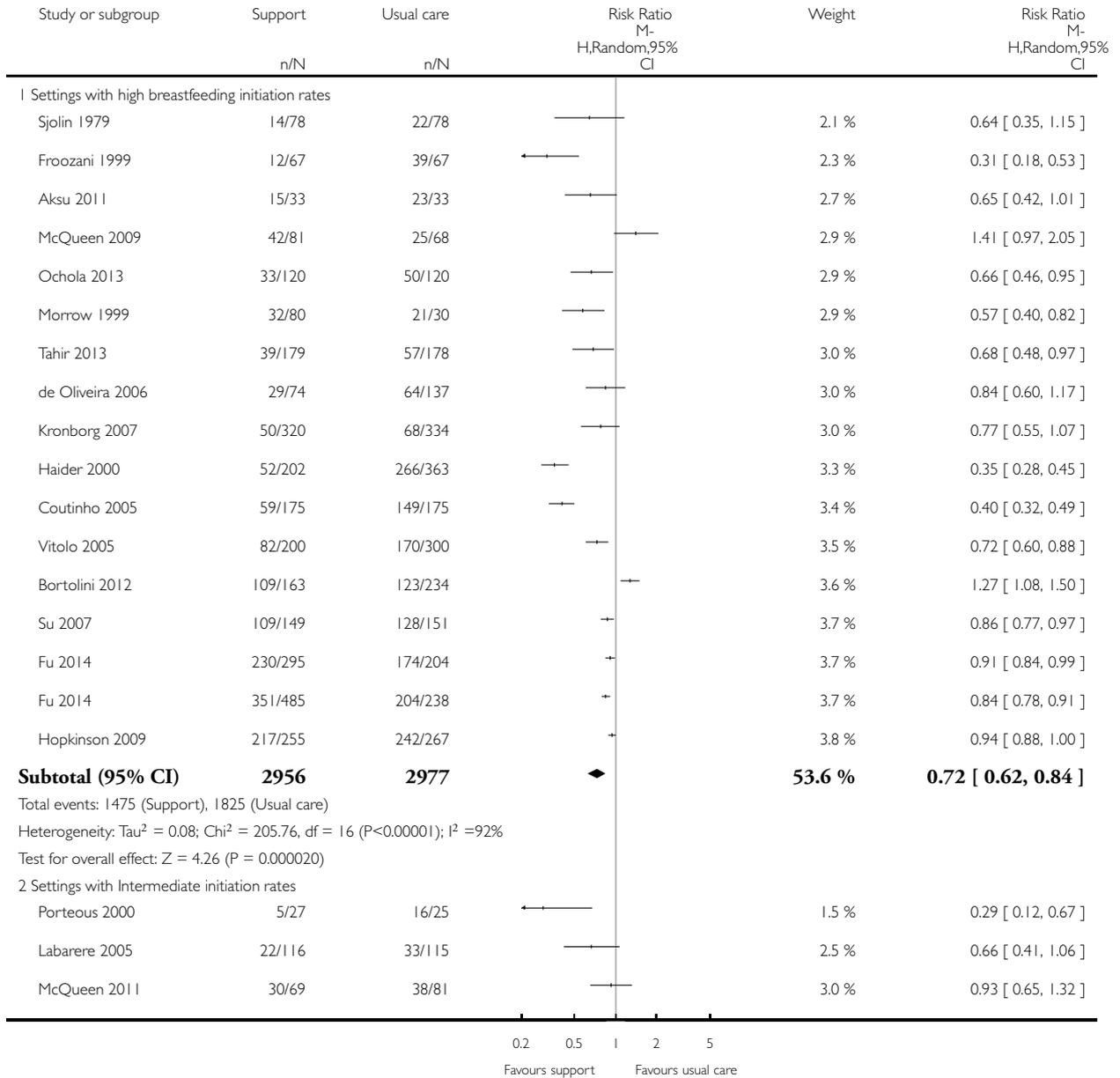


**Analysis 5.4. Comparison 5 All forms of support versus usual care: SUBGROUP ANALYSIS - breastfeeding initiation, Outcome 4 Stopping exclusive breastfeeding at up to 4-6 weeks.**

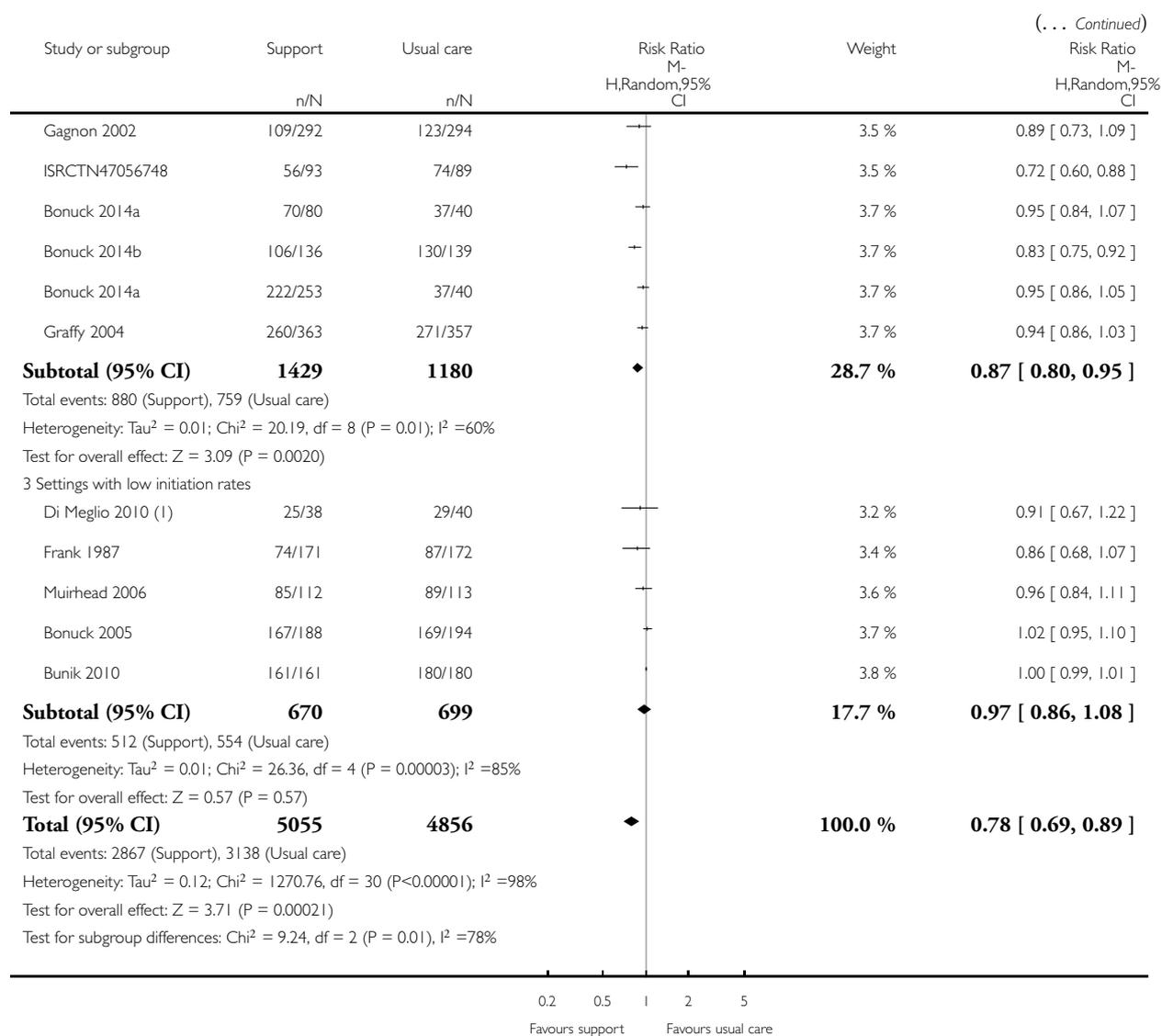
Review: Support for healthy breastfeeding mothers with healthy term babies

Comparison: 5 All forms of support versus usual care: SUBGROUP ANALYSIS - breastfeeding initiation

Outcome: 4 Stopping exclusive breastfeeding at up to 4-6 weeks



(Continued ...)



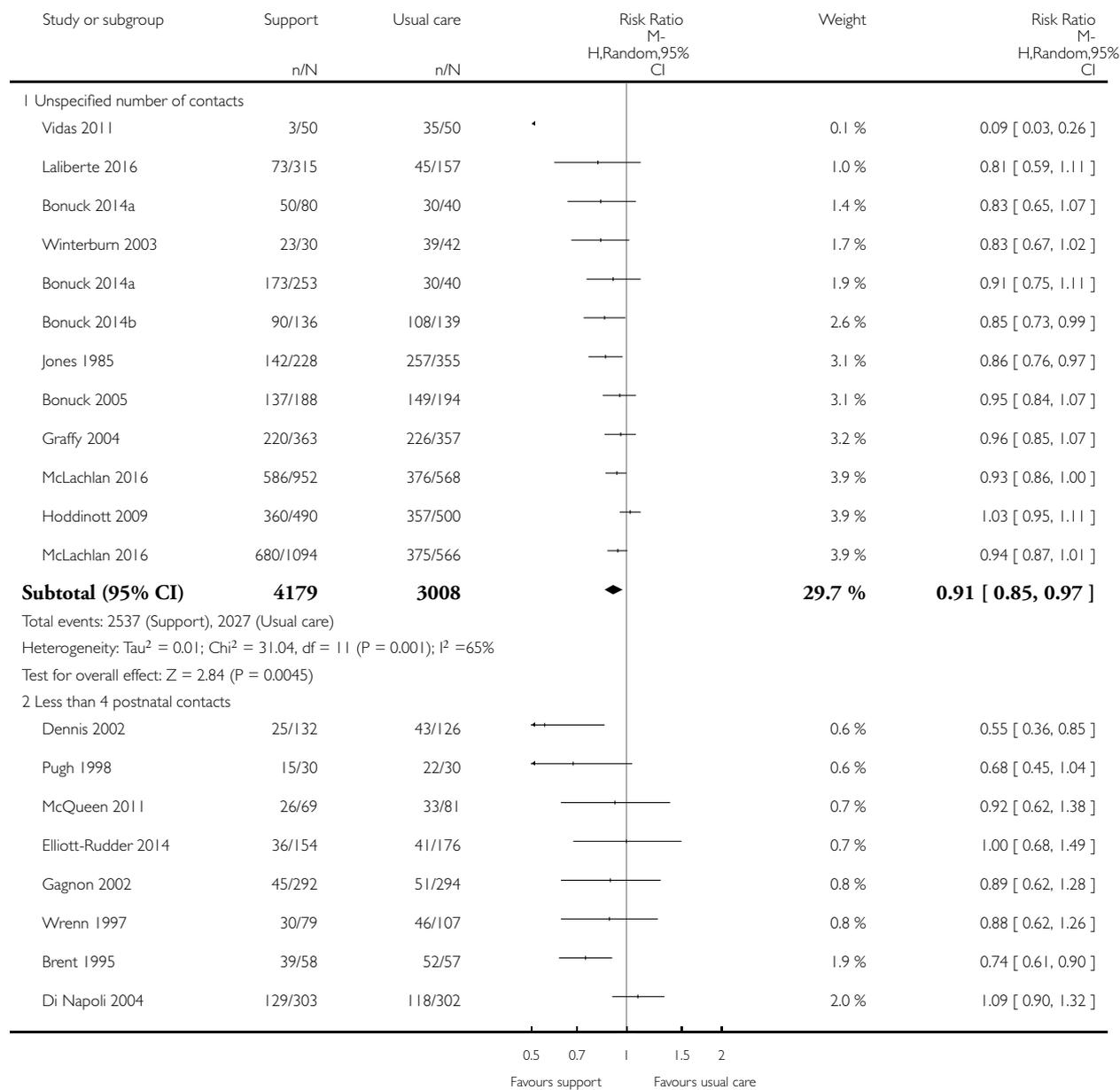
(1) It was not clear when these data were collected.

**Analysis 6.1. Comparison 6 All forms of support versus usual care: SUBGROUP ANALYSIS - number of postnatal contacts, Outcome 1 Stopping any breastfeeding before last study assessment up to 6 months.**

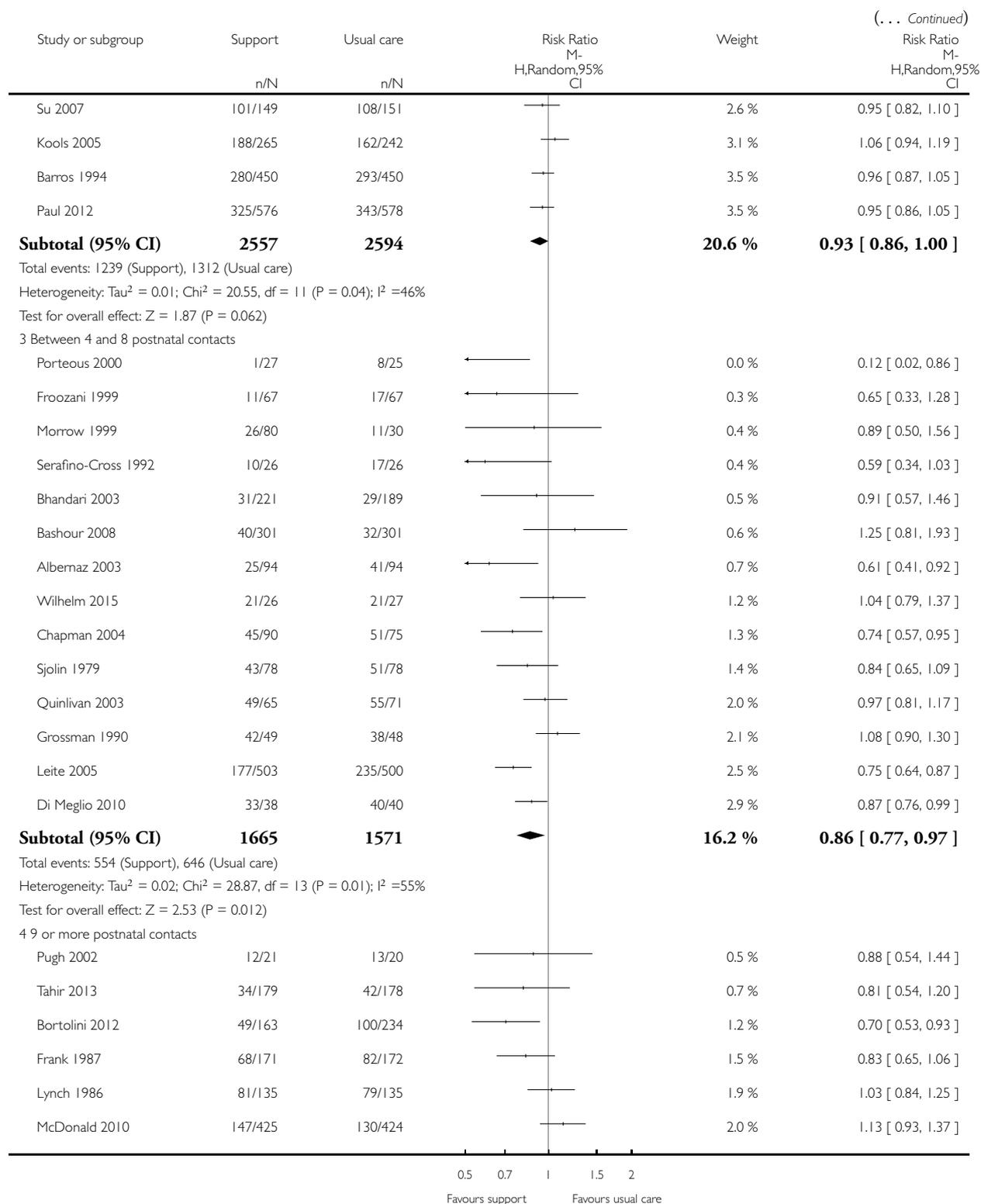
Review: Support for healthy breastfeeding mothers with healthy term babies

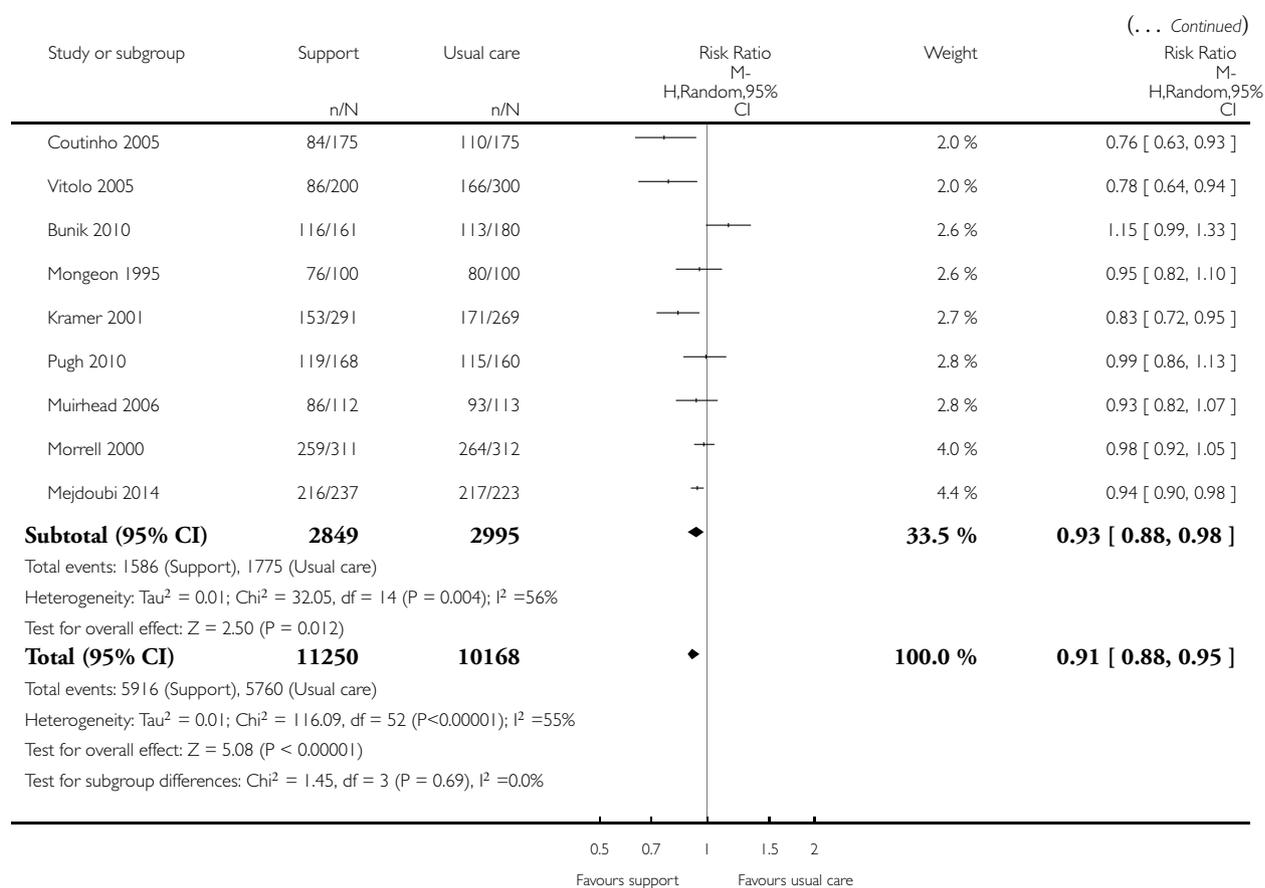
Comparison: 6 All forms of support versus usual care: SUBGROUP ANALYSIS - number of postnatal contacts

Outcome: 1 Stopping any breastfeeding before last study assessment up to 6 months



(Continued ...)



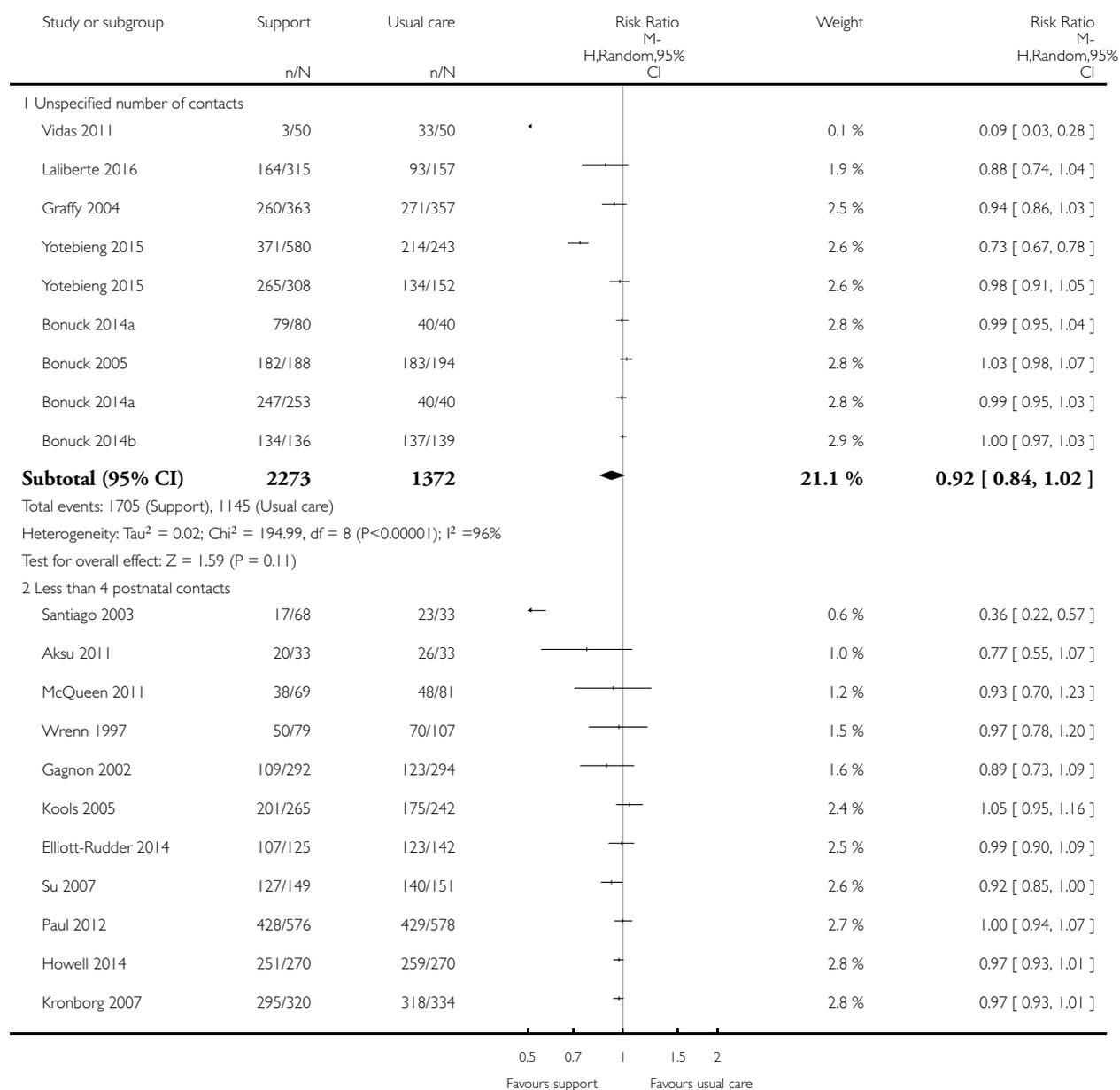


**Analysis 6.2. Comparison 6 All forms of support versus usual care: SUBGROUP ANALYSIS - number of postnatal contacts, Outcome 2 Stopping exclusive breastfeeding before last study assessment.**

Review: Support for healthy breastfeeding mothers with healthy term babies

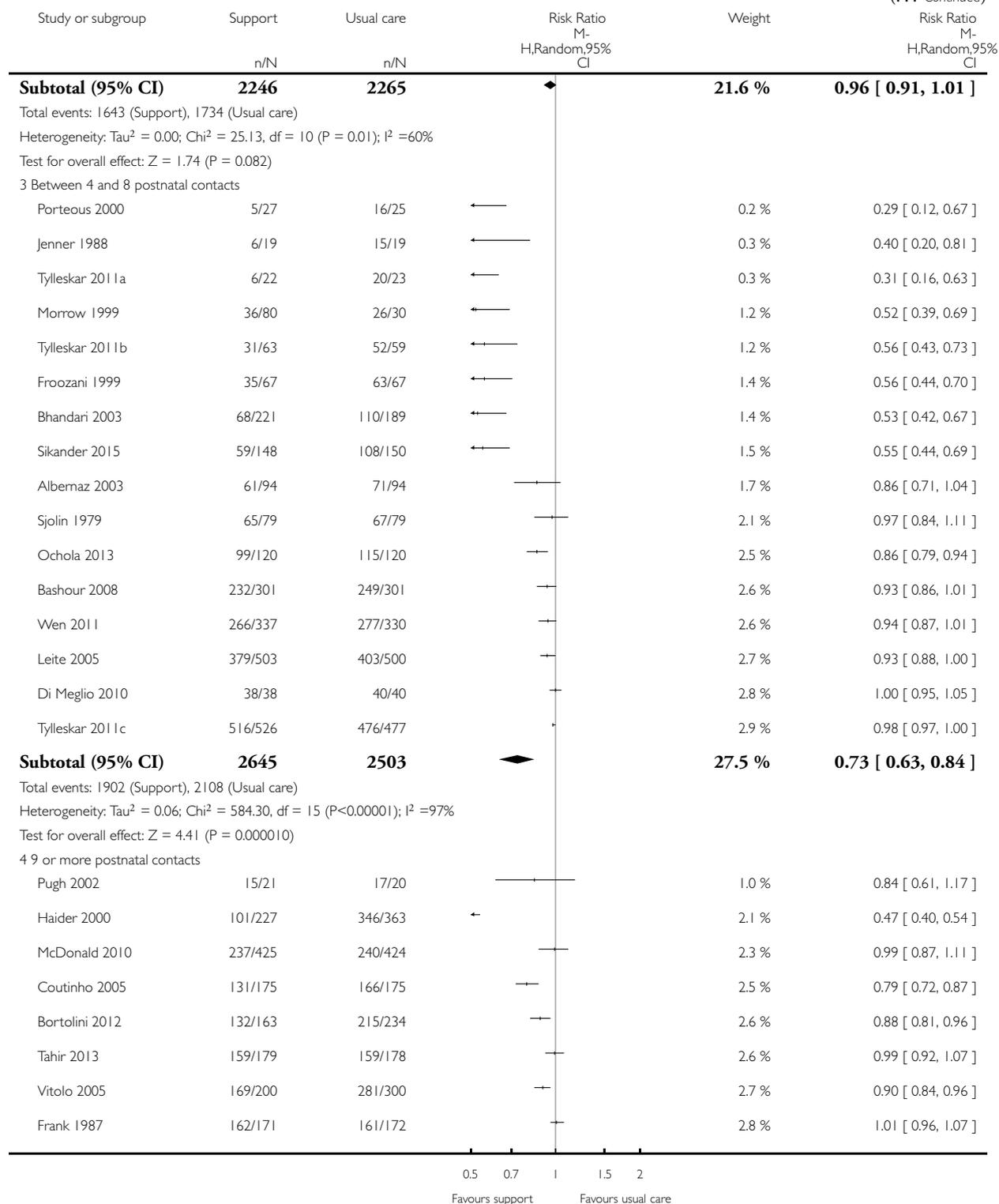
Comparison: 6 All forms of support versus usual care: SUBGROUP ANALYSIS - number of postnatal contacts

Outcome: 2 Stopping exclusive breastfeeding before last study assessment

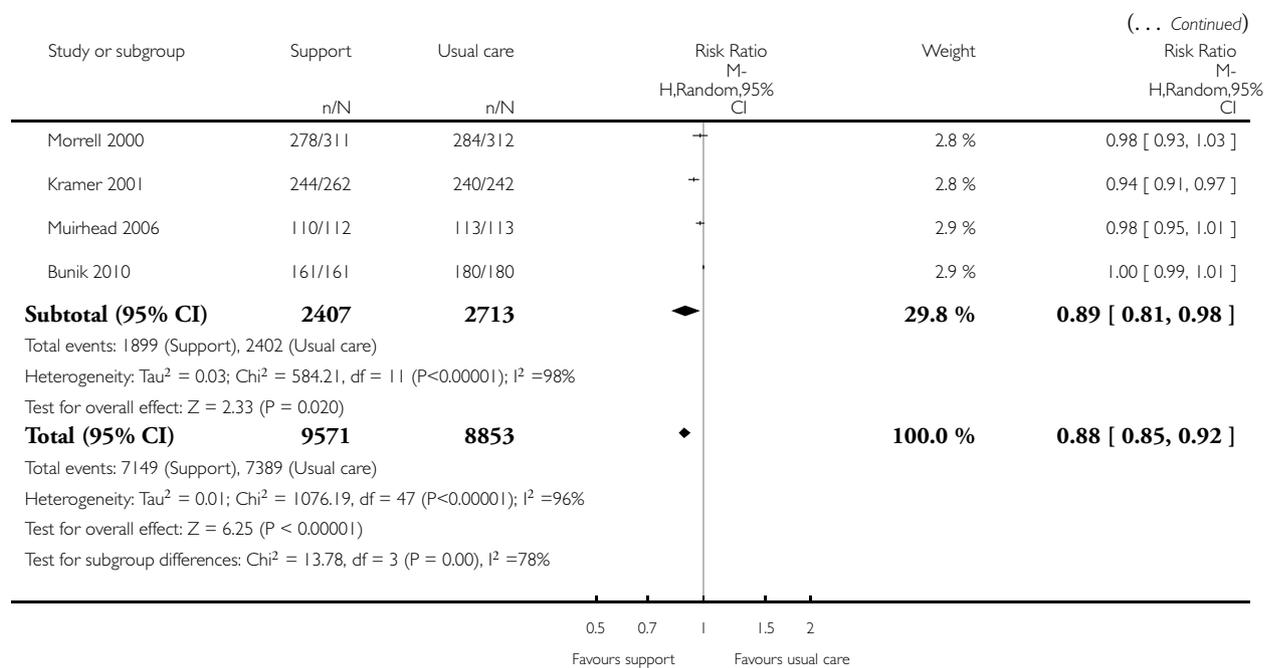


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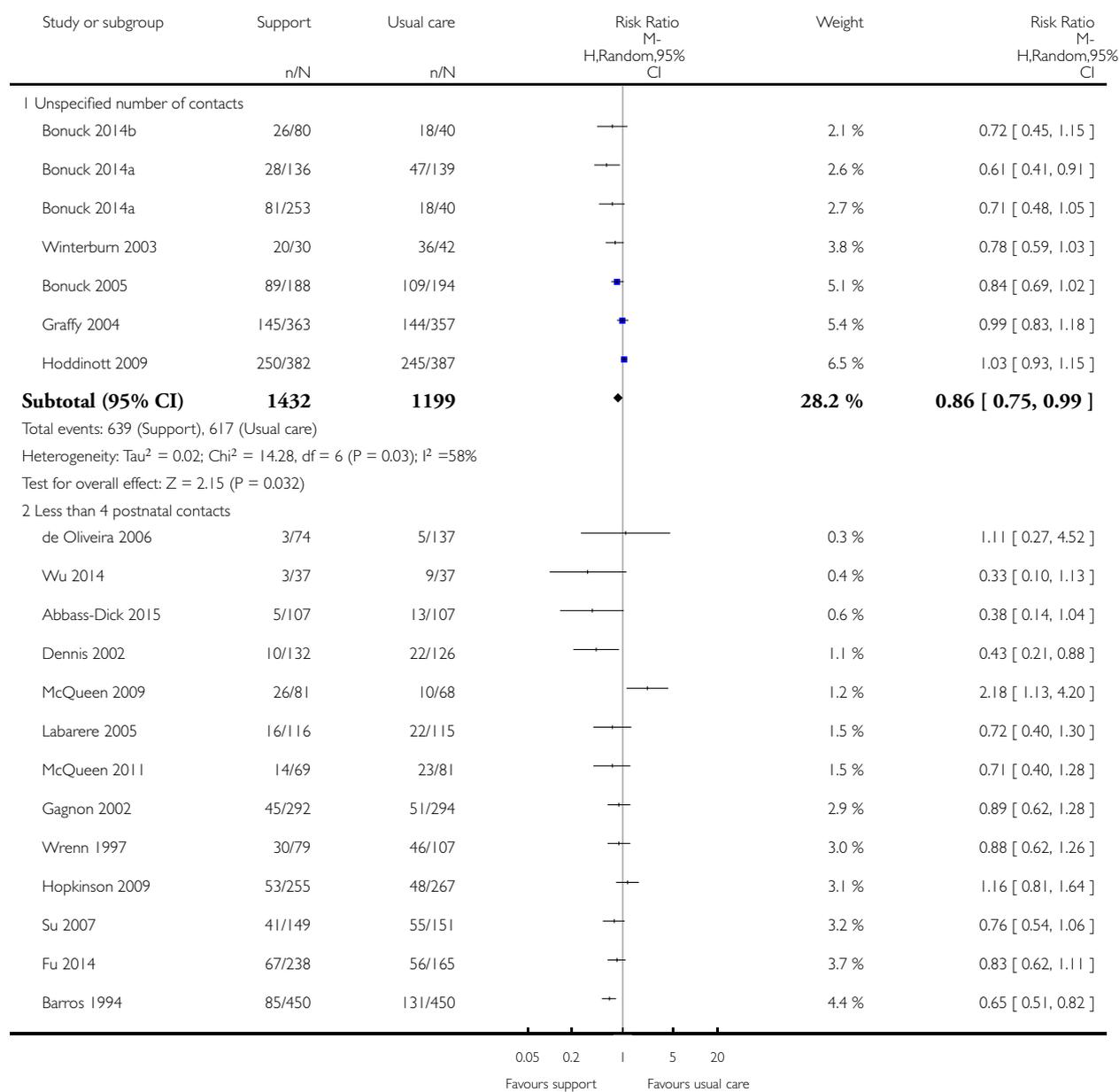


### Analysis 6.3. Comparison 6 All forms of support versus usual care: SUBGROUP ANALYSIS - number of postnatal contacts, Outcome 3 Stopping any breastfeeding at up to 4-6 weeks.

Review: Support for healthy breastfeeding mothers with healthy term babies

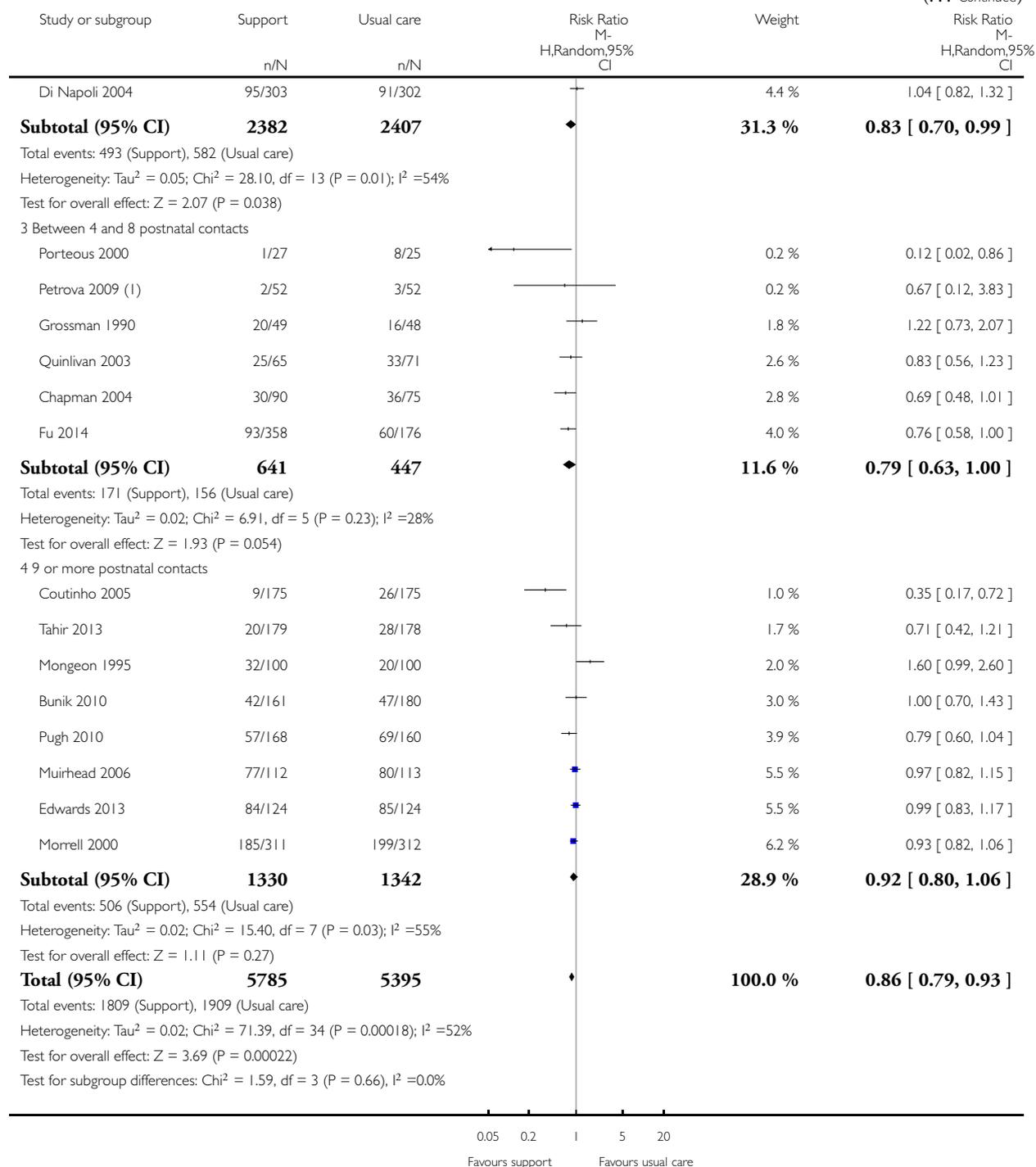
Comparison: 6 All forms of support versus usual care: SUBGROUP ANALYSIS - number of postnatal contacts

Outcome: 3 Stopping any breastfeeding at up to 4-6 weeks



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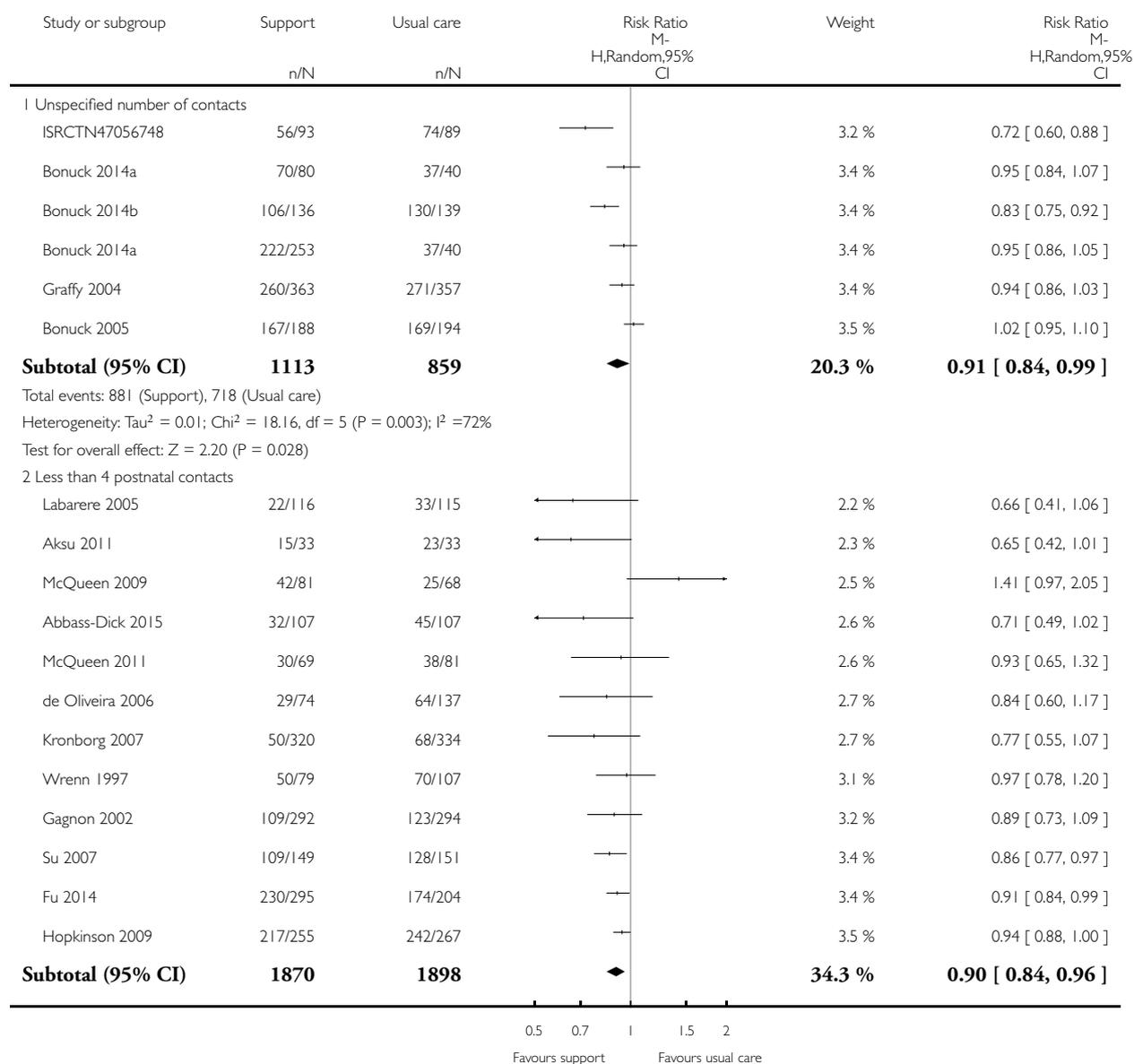
(1) Estimated from graph.

**Analysis 6.4. Comparison 6 All forms of support versus usual care: SUBGROUP ANALYSIS - number of postnatal contacts, Outcome 4 Stopping exclusive breastfeeding at up to 4-6 weeks.**

Review: Support for healthy breastfeeding mothers with healthy term babies

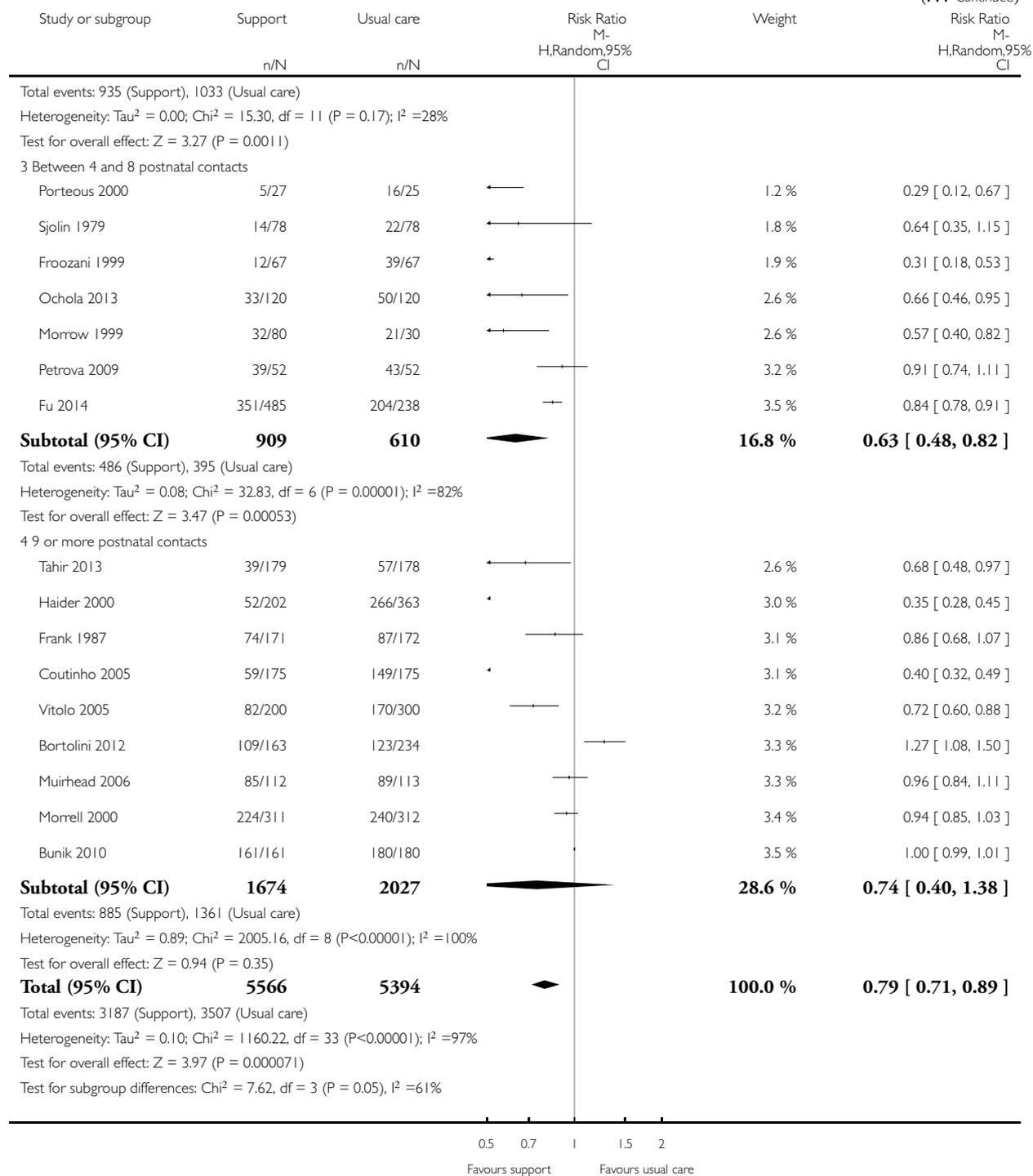
Comparison: 6 All forms of support versus usual care: SUBGROUP ANALYSIS - number of postnatal contacts

Outcome: 4 Stopping exclusive breastfeeding at up to 4-6 weeks



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## ADDITIONAL TABLES

Table 1. Summary of included studies from 2016 update

Study	RCT 2-arm	RCT 3-arm	RCT 4-arm	Cluster	Background breast- feeding rates (low, medium high)	Type of sup- porter (pro- fes- sional, lay per- son, both)	Type of sup- port (face- to- face, tele- phone)	Tim- ing of sup- port (ante- natal (ante + post- natal (post) , or post alone)	Whethe r sup- port was: proac- tive (sched- uled con- tacts) or re- active (women needed to re- quest sup- port)	Num- ber of post- natal con- tacts (< 4, 4-8, 9+)	Data in- cluded in out- come 1	Data in- cluded in out- come 2	Data in- cluded in out- come 3	Data in- cluded in out- come 4
Ab- bas- Dick 2015	x				High	Pro- fes- sional	Face- to- face and tele- phone	Post alone	Proac- tive	< 4	N	N	Y	Y
Bonuck 2014 (BINGC trial)			x		Medium	Pro- fes- sional	Face- to- face and tele- phone	Post alone	Proac- tive	Un- clear	Y	Y	Y	Y
Bonuck 2014a (PAIR- INGS trial)	x				Medium	Pro- fes- sional	Face- to- face and tele- phone	Ante and post	Proac- tive	Un- clear	Y	Y	Y	Y
Bor- tolini 2012	x				High	Pro- fes- sional	Face- to- face	Post alone	Proac- tive	9+	Y	Y	N	Y
Camero 2013			High	Pro- fes-	Face- to-	Ante and	Proac- tive	< 4	N	N	N	N		

**Table 1. Summary of included studies from 2016 update** (Continued)

					sional	face	post							
Chapman 2008	x				Medium	Professional	Face-to-face and telephone	Ante and post	Proactive	9+	N	N	N	N
Edwards 2013	x				High	Lay	Face-to-face	Ante and post	Unclear	9+	N	N	Y	N
Efrat 2015	x				High	Professional	Telephone	Ante and post	Proactive	9+	N	N	N	N
Elliot-Rudder 2014	x			x	High	Professional	Face-to-face	Post alone	Proactive	< 4	Y	Y	N	N
Fu 2014		x		x	High	Professional	Telephone	Post alone	Proactive	4 to 8	N	N	Y	Y
Hanson 2015	x			x	High	Lay	Face-to-face	Ante and post	Proactive	4 to 8	N	N	N	N
Hoddinott 2012	x				Medium	Professional	Telephone	Post	Proactive	9+	N	N	N	N
Howell 2014	x				High/low	Professional	Face-to-face and telephone	Post	Proactive	< 4	N	Y	N	N
Jolly 2012	x			x	Low	Lay	Face-to-face or telephone	Ante and post	Proactive	4 to 8	N	N	N	N

**Table 1. Summary of included studies from 2016 update** (Continued)

Liberte 2016	x				High	Professional	Face-to-face	Post alone	Proactive	Unclear	Y	Y	N	N
Lucchini 2013	x				High	Professional	Face-to-face	Post	Proactive	< 4	N	N	N	N
McLachlan 2016		x		x	High	Professional	Face-to-face	Post alone	Proactive	Unclear	Y	N	N	N
McQueen 2009	x				High	Professional	Face-to-face and telephone	Post alone	Proactive	< 4	N	N	Y	Y
Mejdoubi 2014	x				High	Professional	Face-to-face	Ante and post	Proactive	9+	Y	N	N	N
Ochola 2013		x		x	High	Lay	Face-to-face	Ante and post	Proactive	4 to 8	N	Y	N	Y
Paul 2012	x				Medium	Professional	Face-to-face	Post alone	Proactive	< 4	Y	Y	N	N
Sikander 2015		x		x	High	Professional	Face-to-face	Ante and post	Proactive	4 to 8	N	Y	N	N
Simonetti 2012	x				High	Professional	Telephone	Post alone	Proactive	4 to 8	N	Y	N	N
Srinivas 2015	x				Medium	Lay	Face-to-face and telephone	Ante and post	Proactive	> 9	N	N	N	N

**Table 1. Summary of included studies from 2016 update** (Continued)

Stockdale 2008	x				Medium	Professional	Face-to-face	Ante and post	Unclear	Unclear	N	N	N	N
Tahir 2013	x				High	Professional	Face-to-face	Post alone	Proactive	9+	N	Y	Y	Y
Vidas 2011	x				Unknown	Professional	Face-to-face	Post alone	Unclear	Unclear	N	Y	N	N
Wen 2011	x				High	Professional	Face-to-face	Ante and post	Proactive	4 to 8	N	Y	N	N
Wilhelm 2015	x				High	Professional	Face-to-face	Post alone	Proactive	4 to 8	Y	N	N	N
Wu 2014	x				Unknown	Professional	Face-to-face and telephone	Post alone	Proactive	< 4	N	N	Y	N
Yotebieng 2015		x		x	High	Professional	Face-to-face	Post alone	Proactive	Unclear	N	Y	N	N
	25	5	2	8							11	13	8	8

**Abbreviations**

ante: antenatally

N: no

post: postnatally

Y: yes

## WHAT'S NEW

Last assessed as up-to-date: 29 February 2016.

Date	Event	Description
29 February 2016	New search has been performed	Search updated and 31 new studies included. The review now includes a total of 100 studies, with 73 studies providing data A 'Summary of findings' table has been incorporated in this update. In order to expedite this review rapidly to be ready to inform the World health Organisation recommendations on breastfeeding in maternity facilities, we have restricted the outcomes analysed in this update to the primary outcomes only. Secondary outcomes analysed in the previously published version of this review will be added in the next update of this review in two years time.
29 February 2016	New citation required but conclusions have not changed	Conclusions broadly similar.

## HISTORY

Protocol first published: Issue 3, 1998

Review first published: Issue 1, 1999

Date	Event	Description
12 December 2011	New search has been performed	In the previous version of this review ( <a href="#">Britton 2007</a> ) we included 34 trials in 14 countries. In this updated version, we assessed 218 reports; corresponding to 150 separate studies. We have included 67 studies and excluded 79. Four studies are still ongoing or awaiting further assessment. In this updated version we have added further subgroup analysis and discuss the impact of different types of support interventions
12 December 2011	New citation required but conclusions have not changed	The update was prepared by a new author team. Studies were carried out in 21 countries. Overall conclusions have not changed, but we include more evidence on the effect of interventions in different settings and for different types of interventions; proactive interventions that rely mainly on face-to-face support are more likely to succeed

(Continued)

27 July 2009	Amended	Search updated, 68 reports added to <a href="#">Studies awaiting classification</a> .
6 November 2008	Amended	Converted to new review format.
30 January 2006	New citation required and conclusions have changed	New review team prepared this update. Previous versions of this review categorised support as 'professional' or 'lay'. This edition introduces a new category: combined lay and professional support. Studies in this category demonstrated a significant effect on duration of any breastfeeding, especially in the first two months
30 January 2006	New search has been performed	Searches updated. We have included fourteen new studies and excluded an additional 30 studies

## CONTRIBUTIONS OF AUTHORS

This update is based on the previous Cochrane Review, [Renfrew 2012b](#), and has involved new authors.

Alison McFadden contributed to planning its restructure, assessment of study eligibility, data extraction and analysis and drafting text for the Background, Discussion and Conclusions, and commented on review drafts.

Anna Gavine contributed to planning its restructure, assessment of study eligibility, data extraction and analysis, drafting text for the Description of included studies, and commented on review drafts.

Mary Renfrew was co-author of earlier versions of this review and lead author of the previous version. In this update of the review she contributed to planning its restructure, and drafting text for the Background, Discussion and Conclusions, and commented on review drafts.

Angela Wade provided statistical advice for this and all the earlier versions of this review. She advised about including cluster-randomised trials in the analyses and commented on review drafts.

Phyll Buchanan contributed to assessment of study eligibility, data extraction, and commented on drafts.

Jane Taylor contributed to assessment of study eligibility, data extraction, and commented on drafts.

Emma Veitch contributed to assessment of study eligibility, data extraction, and commented on drafts.

Anne-Marie Rennie contributed to assessment of study eligibility, data extraction, and commented on drafts.

Susan Crowther contributed to assessment of study eligibility, data extraction, and commented on drafts.

Sara Neiman contributed to assessment of study eligibility, data extraction, and commented on drafts.

Steve MacGillivray co-ordinated this update and contributed to planning its restructure, assessment of study eligibility and data extraction. He set up conducted and reported the analyses, drafted text for the Methods and Results sections and commented on review drafts.

## DECLARATIONS OF INTEREST

Alison McFadden: nothing to declare.

Anna Gavine: my institution (University of Dundee) has received two small grants from WHO to support my contribution to this review.

Mary Renfrew: my institution (University of Dundee) received two small grants from WHO to help with completion of this review. This paid for some research support for data extraction and analysis.

Angela Wade: nothing to declare.

Phyll Buchanan: I am a trustee of the Breastfeeding Network and therefore interested in the effectiveness of support for breastfeeding mothers, especially peer support.

Jane Taylor: I am a volunteer in the Breastfeeding Network and therefore interested in the effectiveness of support for breastfeeding mothers.

Emma Veitch: I am a volunteer in the Breastfeeding Network and therefore interested in the effectiveness of support for breastfeeding mothers.

Sara Neiman: I am a volunteer in the Breastfeeding Network and therefore interested in the effectiveness of support for breastfeeding mothers. I work for the NHS as a Registered Midwife and therefore the evidence base is very important to me in my work.

Anne-Marie Rennie: as a midwife I have an interest in support for breastfeeding mothers, and my role as Infant Feeding Co-ordinator is also interested in support for breastfeeding mothers.

Susan Crowther: nothing to declare.

Steve MacGillivray: my institution (University of Dundee) has received two small grants from WHO to support my contribution to this review.

## SOURCES OF SUPPORT

### Internal sources

- University of York, UK.

### External sources

- Cochrane Pregnancy and Childbirth received a grant from the Evidence and Programme Guidance Unit, Department of Nutrition for Health and Development, World Health Organization, Switzerland.
- National Institute for Health Research Health Technology Assessment programme, grant number 10/106/01, UK.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the original protocol, (1998), Odds ratios (ORs) with 95% confidence intervals (CIs) were specified as being the measure of treatment effect. However, in the first published version of the review, [Sikorski 1999](#), and in all subsequent versions of the review, Risk Ratios (RRs) with 95% CIs have been presented. In the original protocol, the subgroups specified for investigation of heterogeneity were reported as being income group and both ante- and post-natal time periods. Income group was removed from subsequent versions and with the addition of many more studies, the following subgroups have been incorporated:

1. By type of supporter (professional versus lay person, or both).
2. By type of support (face-to-face versus telephone support).
3. By timing of support (antenatal and postnatal versus postnatal alone) - in original protocol.

4. By whether the support was proactive (scheduled contacts) or reactive (women needed to request support).
5. By background breastfeeding initiation rates (low, medium or high background rates).
6. By intensity of support (number of scheduled contacts).

No sensitivity analyses were specified in the original protocol, 1998. In subsequent versions of the review and in the current update, sensitivity analyses looking at the effect of allocation concealment by comparing results from studies at low risk of bias as opposed to unclear or high risk of bias were incorporated.

The methods section has been updated to the current standard methods for Cochrane Pregnancy and Childbirth reviews and the review now focuses on healthy mothers with healthy term infants. A 'Summary of findings' table has been incorporated for this 2016 update.

In this update, 2016, we have not included data for the following secondary outcomes. Primary outcomes were recorded for stopping any or exclusive breastfeeding before four to six weeks and before six months postpartum. Other outcomes of interest in previous versions of this review were stopping any or exclusive breastfeeding at other time points (two, three, four, nine and 12 months), measures of neonatal and infant morbidity (where available) and measures of maternal satisfaction with care or feeding method. Secondary outcomes were not considered in this update so that the review could be completed in time to inform the World Health Organisation's review of the evidence and update of the WHO recommendations on breastfeeding in maternity facilities. A new set of core outcomes for Cochrane pregnancy and childbirth breastfeeding reviews is currently being developed and the outcomes from this core set may influence future outcomes chosen for this review.

Secondary outcomes included in last update, 2012:

1. Stopping breastfeeding before two, three, nine and 12 months postpartum.
2. Stopping exclusive breastfeeding before two, three, nine and 12 months postpartum.
3. Maternal satisfaction with care.
4. Maternal satisfaction with feeding method.
5. All-cause infant or neonatal morbidity.

In this update, 2016, "healthy" in terms of types of participants has been more clearly defined: "Participants were healthy pregnant women considering or intending to breastfeed or healthy women who were breastfeeding healthy babies. Healthy women and babies were considered those who did not require additional medical care (e.g. women with diabetes, women with HIV/AIDS, overweight or obese women) or surgical care (e.g. women who required a Caesarean Section). Studies which focused specifically on women with additional care needs were excluded."

## **INDEX TERMS**

### **Medical Subject Headings (MeSH)**

\*Breast Feeding; \*Social Support; Health Education [\*methods]; Randomized Controlled Trials as Topic; Term Birth

### **MeSH check words**

Female; Humans; Infant