Interventions for supporting the initiation and continuation of breastfeeding among women who are overweight or obese

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Interventions for supporting the initiation and continuation of breastfeeding among women who are overweight or obese (Protocol)

Soltani H, Fair FJ

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[Intervention Protocol]

Interventions for supporting the initiation and continuation of breastfeeding among women who are overweight or obese

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The main objective of this review is to evaluate the effectiveness of interventions to improve breastfeeding rates in women who are overweight or obese.

We will also examine the effectiveness of different types of interventions based on the intervention delivery format (individual or group and face-to-face or mobile technology); style (proactive or reactive); intensity; provider (peer or professional workers); setting (community or hospital, Baby Friendly Initiative accredited; background breastfeeding initiation rate); timing (antenatal, postnatal or both); and co-morbidities (without complications or with gestational diabetes mellitus or pre-existing diabetes, caesarean section, preterm birth).

BACKGROUND

Description of the condition

The World Health Organization (WHO) recommends that infants are exclusively breastfed until six months of age with continued breastfeeding thereafter alongside appropriate complementary foods, due to the many health benefits of breastfeeding for both the mother and infant (WHO 2001). Infants fed with human milk substitutes are at increased risk of infections, asthma (Eidelman 2012; Salone 2013; Lessen 2015), atopic dermatitis (Eidelman 2012), some childhood leukaemias (Eidelman 2012; Salone 2013), coeliac disease (Eidelman 2012; Lessen 2015), and sudden infant death syndrome (Eidelman 2012; Salone 2013; Lessen 2015). Long-term risks to the infant of not receiving breast milk have also been demonstrated such as increased obesity, ischaemic heart disease, and type 1 and type 2 diabetes in later life (Eidelman 2012; Salone 2013; Lessen 2015). For preterm infants breastfeeding reduces the risk of developing necrotising enterocolitis (Eidelman 2012; Salone 2013; Lessen 2015). Mothers who do not breastfeed their infant are at increased risk of breast cancer, ovarian cancer (Eidelman 2012; Salone 2013; Lessen 2015), type 2 diabetes, postnatal depression (Eidelman 2012; Lessen 2015), and osteoporosis (Lessen 2015). Mother-infant bonding is also believed to be reduced if the mother does not breastfeed (Lessen 2015). There is much debate around the association between breastfeeding and postnatal weight changes, with some finding no association between breastfeeding and postpartum weight loss

(Neville 2014) and others showing less weight loss when not breastfeeding (Lessen 2015).

The internationally recognised definition of being overweight is having a body mass index (BMI) between 25.0 and 29.9 kg/m², and the definition of obesity is a BMI of 30.0 kg/m² or over (WHO 2000). Other definitions also exist for different populations, most notably the WHO definition for Asian populations (WHO 2004). The rate of overweight and obesity across the globe continues to rise, with 34.9% of women currently having a BMI ≥ 25 kg/m² and 13.9% a BMI ≥ 30 kg/m² (Stevens 2012).

It is well-established within the literature that women who are overweight or obese have poorer breastfeeding outcomes. It has been shown that women with a raised BMI are less likely to intend to breastfeed (Krause 2011) and a systematic review of maternal obesity and breastfeeding has found that obese women plan to breastfeed for a shorter time period than women with a BMI in the normal range (Amir 2007). Numerous studies and reviews have also found that compared to women with a BMI in the normal range, women who are overweight or obese are less likely to initiate breastfeeding, initiate breastfeeding later on average, are less likely to breastfeed exclusively and breastfeed for a shorter duration, even when confounders such as age, parity, method of delivery, smoking, delayed lactogenesis and feeding intention are adjusted for (Amir 2007; Mok 2008; Lepe 2011; Wojcicki 2011; Thompson 2013; Hauff 2014). The most recent review suggests that women who have a BMI > 30 kg/m² have a 13% decreased rate of breastfeeding initiation and a 20% decreased likelihood of any breastfeeding at six months (Babendure 2015). The risk of early discontinuation of any or full breastfeeding has been shown to increase progressively with increasing BMI (Baker 2007). The link between a high BMI and decreased initiation of breastfeeding has also been shown regardless of gestational weight gain (Li 2003).

Several reasons have been proposed for why women who are overweight or obese are less likely to breastfeed. Factors believed to impact on early breastfeeding success for women who are overweight or obese are mechanical factors and delayed lactogenesis (Babendure 2015). Some women who are obese have larger breasts than women with a BMI in the normal range, which can make traditional breastfeeding positions more difficult (Babendure 2015). Women who are obese have also been shown to experience increased postpartum oedema which flattens the nipples, again making it more difficult to latch an infant. Women who are obese having more mechanical difficulties with breastfeeding is supported by a study that has shown that prior to discharge from hospital and also at one and three months post-delivery, more women who are obese than women with a BMI in the normal range report breastfeeding problems such as cracked nipples, which are associated with poor attachment (Mok 2008). Lactogenesis, the production of copious milk, is triggered following the removal of the placenta (Babendure 2015). For most women this occurs within 72 hours of birth; however more women with a high BMI have an onset of lactogenesis after 72 hours than women with a BMI in the normal range (Hilson 2004). Even when other confounders are adjusted for, women who were overweight or obese prior to pregnancy have been found to have a reduced prolactin response to suckling at both 48 hours and seven days post-delivery (Rasmussen 2004). Potential reasons for this delay in lactogenesis in women who are obese are: i) the increased oedema experienced by these women, which is linked to delayed lactogenesis; ii) an increased likelihood of a prolonged labour and caesarean section. This could be as the result of the release of leptin from adipose tissue which inhibits oxytocin, which is the hormone needed both for labour and the milk ejection reflex; iii) a less steep decline in insulin concentrations from the end of pregnancy to initiation of lactation in obese women. It is suggested that insulin is needed for lactogenesis, so an insulin imbalance can influence the timing of lactogenesis (Babendure 2015). The delay in lactogenesis decreases the mother's confidence that her milk is sufficient for her child, leading to early substitution and early cessation of breastfeeding. Women with a raised BMI are more likely to have medical complications such as gestational diabetes, a caesarean section or a preterm birth (Marchi 2015), which have been linked with delayed lactogenesis (Amir 2007), reduced initiation of breastfeeding (Thompson 2013), and increased risk of early termination of full or any breastfeeding (Baker 2007). This may be in part due to pregnancy complications making early separation of the mother and infant more likely. However, even among those with medical conditions that are known to decrease the breastfeeding rate, an association between obesity and reduced breastfeeding continues to exist (Babendure 2015).

Factors suggested to impact upon the duration of exclusive or any breastfeeding for women who are obese include physiological, anatomical and psychosocial (Babendure 2015). Free androgens increase with increasing BMI and are particularly linked to polycystic ovaries, which occurs more often in women who are overweight or obese (Babendure 2015). Mid-pregnancy androgen levels have been negatively correlated with breastfeeding duration at both three and six months (Carlsen 2010). It is also postulated that women who are overweight or obese may be so, due to subclinical hypothyroidism. Thyroid hormones especially levothyroxine (T4) and liothyronine (T3) are needed for the initiation and maintenance of breastfeeding (Babendure 2015). Animal studies have suggested that obesity in childhood negatively affects the development of breast glandular tissue. Anatomically, women who are overweight or obese may therefore have mammary hypoplasia/insufficient glandular tissue (Babendure 2015). Many of the characteristics experienced by women who are overweight or obese are consistent with this, including their reporting of insufficient supply (Mok 2008), describing stopping breastfeeding due to perceived insufficient supply (Guelinckx 2012), and being more likely to try to express in the first two months postpartum but less likely to have successfully expressed than women with a normal BMI (Leonard 2011). Furthermore, no association between BMI and early cessation of breastfeeding has been shown

for multiparous women who have successfully breastfed a child previously (Kronborg 2012). This may suggest that the biological factors associated with early cessation of breastfeeding had been overcome in these women.

Psychosocial factors include confidence to reach breastfeeding goals, feeding practices of friends and family, maternal self-efficacy and body image (Babendure 2015). Women who are obese have greater body dissatisfaction and lower self-esteem than women with a BMI in the normal range, both of which could impact upon breastfeeding intentions (Amir 2007). Women who are overweight or obese also usually belong to social classes that traditionally breastfeed less, which may lead these women to feel more uncomfortable about breastfeeding in public (Amir 2007). Indeed one French study found mothers who were obese more often felt uncomfortable about feeding in public or in front of others than normal weight women and were less likely to seek breastfeeding support in the first three months post-delivery (Mok 2008). However, psychosocial factors are not the sole contributor to lower breastfeeding rates in women who are overweight or obese, as differences in breastfeeding rates continue to exist after adjusting for socio-cultural factors (Hauff 2014). Furthermore, research has shown that while socio-economic status significantly influences long-term breastfeeding, maternal BMI is consistently a significant predictor of breastfeeding prior to six months (Soltani 2009). Given that women who are overweight or obese have a lower incidence of breastfeeding initiation and breastfeed for a shorter time period, many clinicians and researchers have recognised the need for additional encouragement and support for women with a raised BMI both during pregnancy and in the first year after delivery to initiate and maintain breastfeeding (Mok 2008; Hesch Anstey 2011; Krause 2011; Babendure 2015). Establishing effective ways to support women who are overweight or obese is of particular importance, considering that the proportion of women who are overweight and obese across the globe, including in developing countries, continues to increase (Hossain 2007; Heslehurst 2010; Stevens 2012).

Description of the intervention

This review evaluates interventions that could potentially increase initiation or duration of breastfeeding in women who are overweight or obese. Various types of interventions exist which can be delivered in combination or alone and in different settings (in hospital or in the community and in services that are Baby Friendly Initiative accredited or not). This review will include the following intervention types.

1. Education. This provides women with information about breastfeeding, including physiology, common concerns and their management and an in depth description of the benefits of breastfeeding for mothers and their babies. Education can be in a variety of forms including - verbal and written and can be delivered through different formats face-to-face in an individual or group setting, online or through mobile applications. It is usually provided in the antenatal period, but can also be provided in the postnatal period or both in the antenatal and postnatal periods.
2. Social support. This includes emotional, material or financial, physical, reassurance, praise, networking and meeting with others or the opportunity to discus and respond to a woman's questions. Support is usually provided in the postnatal period, however initial contact with the woman can be in the antenatal period. Support can be delivered by peer or professional workers. This can include face-to-face support or more remote forms of support such as telephone, Internet or mobile technologies. It can be provided to women individually or as part of a group and can be reactive responding to women's requests or proactive with scheduled visits. The level of support can vary from one off support to ongoing support.
3. Physical interventions can include antenatal or postnatal breast expression, and hospital practices such as encouragement of skin-to-skin contact between mother and infant at delivery.

How the intervention might work

The support a mother receives influences initiation and duration of feeding, as does prenatal education and hospital practices (Lessen 2015).

A comprehensive taxonomy for the reporting of specific behaviour change techniques incorporated within interventions has been devised by Michie 2013. Within this taxonomy, educational interventions would use behaviour change techniques within the 'shape knowledge' cluster, through providing instructions on how to perform the behaviour such as providing advice on positioning and attachment. Techniques within the 'natural consequences' cluster would also be utilised if information was provided on the health consequences of breastfeeding. Social support falls within the 'social support' cluster of behaviour change techniques and could also contain behaviour change techniques within the 'reward and treat' cluster if financial incentives or rewards are used. Physical interventions such as antenatal or postnatal breast expression aim to improve lactogenesis by an early stimulation and hormonal release, addressing concerns that women who are overweight or obese have insufficient glandular tissue growth in the breasts.

Several reviews have been undertaken on interventions to support breastfeeding. These have shown that any form of extra support is effective at increasing any breastfeeding at six months postpartum and on increasing exclusive breastfeeding at four to six weeks (Renfrew 2012). In particular face-to-face and proactive support were more likely to be successful, as were interventions in settings with high breastfeeding initiation rates. A further review has found educational- and support-based interventions are effective at increasing exclusive breastfeeding at birth, one month and up to five months of age and at decreasing the rate of no breastfeeding (Haroon 2013). Interventions that included both individual and

group counselling were more effective than either an individual or group intervention in isolation. Neither of these reviews have however looked at what interventions are effective for women who are overweight or obese. Due to the fact that women with a raised BMI have different breastfeeding expectations and practices to women with a BMI in the normal range (Mok 2008), and due to the many possible factors noted above that can specifically influence the breastfeeding practices of women who are overweight or obese (Babendure 2015), it is important to establish what interventions are most effective within this group of women.

Why it is important to do this review

The benefits to both the mother and the infant of breastfeeding are well known (Eidelman 2012; Salone 2013; Lessen 2015). It is also well-established within the literature that women who are overweight or obese have different breastfeeding expectations, practices and poorer breastfeeding outcomes than women with a BMI in the normal range, including decreased breastfeeding initiation and reduced breastfeeding length for both exclusive and any breastfeeding (Hauff 2014; Babendure 2015). Physical, psychological, socio-cultural, medical and health services reasons have been proposed for this disparity (Babendure 2015; Lessen 2015), all of which mean that this group of women are in need of extra support both in the antenatal period and post-delivery to initiate and maintain breastfeeding. It is therefore essential to determine the most beneficial methods of breastfeeding support for women who are overweight or obese. The continuing global trend of increased obesity both in the general and the obstetric populations (Hossain 2007; Heslehurst 2010; Stevens 2012) make this issue particularly important.

OBJECTIVES

The main objective of this review is to evaluate the effectiveness of interventions to improve breastfeeding rates in women who are overweight or obese.

We will also examine the effectiveness of different types of interventions based on the intervention delivery format (individual or group and face-to-face or mobile technology); style (proactive or reactive); intensity; provider (peer or professional workers); setting (community or hospital, Baby Friendly Initiative accredited; background breastfeeding initiation rate); timing (antenatal, postnatal or both); and co-morbidities (without complications or with gestational diabetes mellitus or pre-existing diabetes, caesarean section, preterm birth).

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials, cluster-randomised trials and quasi-randomised controlled studies will be included in this review. For studies published in abstract form only, we will contact the authors for further details and the study will be included if sufficient data are available on the study quality, intervention and outcomes of interest. Studies using a crossover design will not be eligible for inclusion in this review.

Types of participants

Participants will be any pregnant or lactating woman who is overweight or obese (as defined by trial authors based on pre-pregnancy or booking pregnancy body mass index (BMI)) and has been recruited into a trial where the intervention is aimed at supporting breastfeeding, either initiation or maintenance. All women who are overweight or obese will be included irrespective of co-existing medical complications, e.g. diabetes, preterm delivery, caesarean section.

Types of interventions

Any intervention specifically aimed at supporting mothers who are overweight or obese to breastfeed which is over and above the care usually provided within that setting.

Interventions may include social, educational, physical or other support, or any combination of these.

Antenatal, postnatal or combined antenatal and postnatal interventions will be included so long as they are designed to improve breastfeeding rates among women who are overweight or obese.

Interventions delivered at the level of the individual, in groups or a combination of these will be included. Interventions may be provided by either peer or professional workers and in hospital or community settings.

Interventions can be compared either with each other or against a control group which receives routine care for that setting.

Types of outcome measures

Primary outcomes

1. Intention to breastfeed.
2. Initiation of breastfeeding - defined as the baby being put to the breast or being given any of the mother's breast milk within 48 hours of delivery (NHS England 2014).
3. Duration of exclusive breastfeeding.
4. Duration of any breastfeeding.

Secondary outcomes

1. Maternal postpartum weight retention.
2. Maternal postpartum BMI.
3. Maternal satisfaction with care.
4. Maternal satisfaction with feeding method.
5. Maternal nipple health.
6. Mode of birth.
7. Infant weight gain.
8. All-cause infant or neonatal morbidity - as reported by trial authors, for example, neonatal hypoglycaemia, low weight gain, infections.
9. All-cause infant or neonatal mortality.
10. Gestational age.
11. Cost-effectiveness of the intervention.

Search methods for identification of studies

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

Electronic searches

We will search the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator.
The Register is a database containing over 20,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate the Pregnancy and Childbirth Group's Trials Register including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link to the editorial information about the Cochrane Pregnancy and Childbirth Group in *The Cochrane Library* and select the '***Specialized Register***' section from the options on the left side of the screen.
Briefly, the Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

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

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth Group review topic (or topics), and is then added to the Register. The Trials Search Co-ordinator searches the Register for each review using this topic number rather than keywords. This results in a more specific search set that will be fully accounted for in the relevant review sections (Included, Excluded, Awaiting Classification or Ongoing).
In addition, we will search ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned and ongoing trial reports using the terms given in Appendix 1.

Searching other resources

We will search the reference lists of retrieved studies for further eligible studies.
We will not apply any language or date restrictions.

Data collection and analysis

Selection of studies

Both review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion or, if required, we will consult a third person.
We will create a study flow diagram to map out the number of records identified, included and excluded.

Data extraction and management

We will design a form to extract data. For eligible studies, both review authors will extract the data using the agreed form. We will resolve discrepancies through discussion. We will enter data into Review Manager software (RevMan 2014) and check for accuracy. When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Both review authors will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreement by discussion or by involving a third assessor. In addition, if cluster-randomised trials are included we will assess risk of (i) recruitment bias; (ii) baseline imbalance; (iii) loss of clusters; (iv) incorrect analysis; and (v) comparability with individually-randomised trials as outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* [Section 16.3.2] (Higgins 2011).

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

We will describe for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.
We will assess the method as:

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

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

We will describe for each included study the method used to conceal allocation to interventions prior to assignment and will assess whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.
We will assess the methods as:

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

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

For this type of intervention, blinding women and clinical staff is generally not feasible, although it may be possible to blind outcome assessors.

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

We will describe for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We will assess blinding separately for different outcomes or classes of outcomes.
We will assess methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

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

In studies examining breastfeeding support, women may be followed up over many months. A cut-off of 20% missing data will therefore be used to assess a study as low risk of bias. We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We will state 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 is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake.
We will assess methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups; maximum of 20% missing data);
- 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);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found.
We will assess the methods as:

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

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

We will describe for each included study any important concerns we have about other possible sources of bias.
We will assess whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. For the purpose of

this review, 'high quality' will be defined as a trial having adequate sequence generation, allocation concealment and an attrition rate of less than 20%. We will explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Assessing the quality of the body of evidence using the GRADE approach

The quality of the evidence will be 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 outcomes for the main comparisons.

1. Intention to breastfeed.
2. Initiation of breastfeeding.
3. Duration of exclusive breastfeeding.
4. Duration of any breastfeeding.

We will use the GRADEpro Guideline Development Tool to import data from Review Manager 5.3 (RevMan 2014) in order to create 'Summary of findings' tables. A summary of the intervention effect and a measure of quality for each of the above outcomes will be 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 will present results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We will include cluster-randomised trials in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* [Section 16.3.4] (Higgins 2011) using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

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

Multiple-armed trials

We will include multi-armed trials and attempt to overcome potential unit of analysis errors by combining groups to create a single pair-wise comparison, or select one pair of interventions and exclude the others as described in the *Cochrane Handbook for Systematic Reviews of Interventions* [Section 16.4.] (Higgins 2011).

Dealing with missing data

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and all participants will be analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis using the Tau^2, I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if an I^2 is greater than 30% and either the Tau^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

If there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2014). We anticipate some heterogeneity between studies in terms of the intervention and study populations, we will therefore use random-effects meta-analysis for combining data. The random-effects analyses results will be presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau^2 and I^2. The random-effects summary will be treated as the average of the range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.

If we use random-effects analyses, the results will be 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 identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

We plan to carry out the following subgroup analyses by:

1. BMI category (overweight versus obese);
2. intervention provider (professional versus partner/family member/peer support);
3. type of intervention delivery (face-to-face versus remote support; group versus individual);
4. timing of intervention (antenatal and postnatal versus postnatal alone);
5. whether the intervention was proactive (scheduled contact) versus reactive (contact requested by the woman);
6. setting of the intervention (Baby-Friendly Initiative accredited institution versus non Baby-Friendly Initiative accredited institution);
7. location of the intervention (hospital versus community);
8. intensity of intervention (number of scheduled contacts);
9. mode of delivery (normal vaginal delivery versus assisted/operational birth (instrumental vaginal delivery and caesarean section));
10. socio-economic status of the population (high and medium versus low);
11. background breastfeeding initiation rates (high (≥ 80%) and medium (60% to < 80%) versus low (< 60%));
12. co-morbidities (without complications versus with gestational diabetes mellitus, pre-existing diabetes and preterm birth).

Primary outcomes only will be used in the subgroup analysis.

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

Sensitivity analysis

We will carry out sensitivity analysis based on the quality of the included trials to identify the impact of the methodological quality on the overall results. For the purpose of this review, 'high quality' will be defined as a trial having adequate sequence generation, allocation concealment and an attrition rate of less than 25%. If cluster-randomised trials are included, sensitivity analysis will also be used to investigate the effect of variation in the ICC and to investigate the effect of the unit of randomisation. We will restrict sensitivity analyses to the primary outcomes.

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As part of the pre-publication editorial process, this protocol has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search terms for ICTRP and ClinicalTrials.gov

breastfeeding AND obese
breastfeeding AND overweight

CONTRIBUTIONS OF AUTHORS

Hora Soltani (HS) is the contact person and guarantor for the review.

Both authors participated in conceiving and designing the protocol. Frankie Fair wrote the background section, HS revised and completed the protocol.

DECLARATIONS OF INTEREST

Hora Soltani: none known.

Frankie J Fair: none known.