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Breastfeeding education and support for women with multiple pregnancies

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ABSTRACT

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

1. To describe the forms of breastfeeding education and support for women with multiple pregnancies examined in randomised controlled studies.
2. To examine the effectiveness of different modes of interventions (e.g. face-to-face or over the telephone, or by different sorts of healthcare or lay practitioners), and whether interventions containing both antenatal and postnatal elements are more effective than those taking place in the antenatal or postnatal period alone.
3. To examine the effectiveness of education and support from different care providers and (where information was available) training for care providers.

BACKGROUND

Description of the condition

Description of the condition (breastfeeding multiples)

The incidence of multiple births in developed countries has risen since the 1970s ([Blondel 2002](#); [Collins 2007](#)). In the United States,

rates increased from 19.3 to 30.7 per 1000 live births between 1980 and 1999 ([Russell 2003](#)), while in England and Wales the rate increased from 10 per 1000 in 1980, to 16 per 1000 in 2011 ([NICE 2013](#)). In 2013 in England and Wales this comprised of 10,593 sets of twins, 187 triplets, and “three quads and above” ([ONS 2014](#)). European rates in 2000 varied from 12.2 per 1000 maternities in Italy to 19.4 per 1000 in the Netherlands ([Blondel 2006](#)). In developing countries rates of between nine and 18 per 1000 live births have also been reported ([Smits 2011](#)). This rise and variation in rates is due to the use of reproductive techniques,

and is partly accounted for by more births to older women and more multiple births in women from more affluent backgrounds (Smith 2014). More recently, rates of higher order births have declined as changes in assisted reproductive techniques (ART) to reduce multiple pregnancies have been implemented (Smith 2014; Umstad 2013).

Multiple pregnancy carries greater risks for both mother and babies, with around a 50% risk of preterm birth in multiple pregnancy (Blondel 2006; NICE 2013). Additional fetal risks include fetofetal transfusion syndrome, intrauterine growth restriction and congenital abnormalities (NICE 2013). There is higher risk of operative delivery (Antsaklis 2013; Kyvernitakis 2013; Lee 2011). Infants conceived through ART may be at even higher risk of complications (Murray 2014); consequently, admission to the neonatal unit is more likely. This causes stress and anxiety for parents, separation of the mother from her babies (Flacking 2006), and has a cost implication for the healthcare provider (Chambers 2014). There is strong evidence that not breastfeeding or not being fed breast milk carries greater risks both for the infant and for the mother (Renfrew 2012a). Breastfeeding protects the infant against gastrointestinal disease, respiratory disease, otitis media and necrotising enterocolitis (NEC), and protects the mother against breast cancer (Renfrew 2012a). Breastfeeding is also likely to lead to improvements in IQ, reduce rates of Sudden Infant Death Syndrome (SIDS) and reduce obesity in young children, and there is growing evidence that it confers a number of other health and development benefits on the child and health benefits on the mother (Renfrew 2012a). It has been estimated that even modest increases in the numbers of infants breastfed exclusively could have considerable cost savings for the health service (Renfrew 2012a). For preterm infants, the protection breast milk confers against NEC is particularly important.

All mothers have to make decisions about how to feed their baby, however mothers of multiples face more challenges feeding their infants than mothers of singletons and may need additional advice and support. Mothers of twins have been found to have lower intention to breastfeed (Lustiv 2013), to be less likely to initiate breastfeeding (Yokoyama 2006), and to be less likely to offer any breastfeeding (Multiple Births Foundation 2011) or to breastfeed exclusively (McAndrew 2012; Multiple Births Foundation 2011). A European study found that overall 36.4% of twins were breastfed at discharge, compared to 39.3% of singleton infants, with the rate of breastfeeding at discharge varying widely between countries (Bonet 2011). In Japan at three to six months, 4.1% of twins or triplets were exclusively breastfed compared to 44.7% of singletons (Yokoyama 2006). A UK-wide survey found 69% of twins were breastfed initially, compared to 81% of singletons (McAndrew 2012). This study also reported that twins were more likely to be given donor milk, and have formula introduced by one week old (McAndrew 2012). They found that some mothers reported feeding each baby by differing methods: reasons included one baby being ill or in hospital and needing special formula or drip

or tube feeding (8%), one baby starting solids earlier (8%), or babies taking differing amounts of milk (6%) (McAndrew 2012). Prematurity contributes to a higher percentage of twins starting partial breastfeeding and moving to full breastfeeding later (Flidel-Rimon 2002). In the UK, older women and those living in more affluent circumstances are more likely to breastfeed (McAndrew 2012) and this difference also applies to infants from multiple pregnancies (Ostlund 2010).

Some of the issues faced by mothers of multiples are related to the practicalities of feeding more than one infant at the breast, and this may mean that advice offered to mothers of singletons may not be appropriate (Bennington 2011). Mothers of multiples may have more difficulty offering early and continuous skin-to-skin contact with their infants, there may be delay in initiation of suckling at the breast, the infants may have a disorganised or immature sucking pattern as a result of prematurity and the demands of facilitating frequent suckling are more challenging (Bennington 2011; Cinar 2013). Women who have delivered by caesarean section are less mobile, less able to care for more than one infant at once and may have more difficulty finding a comfortable position to feed (Bennington 2011; Flidel-Rimon 2002). Decisions may have to be made about whether to feed the infants together or feed separately. There may be conflicting needs: accommodating the individual feeding preferences of each infant may be incompatible with the extra time needed to feed separately (Bennington 2011; Gromada 1998). Simultaneous feeding of two babies will stimulate simultaneous let down, and can facilitate feeding if one infant has weak suckling, however the practicalities of this can be hard to manage without help in the early stages of breastfeeding, particularly if two hands are needed to encourage a satisfactory latch (Flidel-Rimon 2002; Gromada 1998; Multiple Births Foundation 2011). Waking a sleeping baby for simultaneous feeding may not be easy and is unlikely to result in a satisfactory feed. Simultaneous feeding of more than two babies is not a practical possibility, however similar issues arise with feeding multiples with formula, and in addition, extra time is required to make up formula feeds (Bennington 2011).

Prematurity adds to the already significant challenges of initiating and maintaining lactation for twins and higher order multiples. Twin infants born prematurely are less likely than twins born at term to be breastfed (Ostlund 2010). Problems can be exacerbated by the degree of prematurity and the severity of any additional illness, and the consequences of an operative delivery (Bennington 2011). Mothers of infants born early may be motivated to express breast milk as a way of providing a unique contribution to the care of their infants. There have been reports that for premature infants, breast milk may be seen by staff as a product, leading to pressure from neonatal intensive care unit (NICU) staff on mothers to express milk (Flacking 2006), with the consequence that breast milk feeding may be favoured over breastfeeding (Niela-Vilén 2014). There is some evidence that counselling women who intend to formula feed about the benefits of expressing milk for very low

birthweight babies increases the incidence of lactation initiation and breast milk feeding without increasing maternal stress and anxiety (Sisk 2006). Expressing breast milk can lead to women who did not plan to breastfeed, eventually feeding their infants directly at the breast (Sisk 2006).

While feeding directly at the breast is optimal for stimulating a good supply of milk, the above practicalities and the additional challenges of prematurity, may mean that feeding at the breast is not possible initially. The mother may express her milk and mother's own or donor expressed breast milk (EBM) can then be given by bottle, tube or cup (Damato 2005; Gromada 1998). The latter two options may increase the chances of a baby subsequently feeding successfully at the breast while in hospital, however cup feeding may increase length of stay and success is likely to be dependent on the experience of the staff (Collins 2008). Within the NICU a lack of privacy can make expression of breast milk, initiation of skin contact and breastfeeding difficult for many mothers (Alves 2013; Flacking 2006; Gromada 1998; Niela-Vilén 2014). Facilities to pump and store EBM in the NICU are essential (Gromada 1998). However, the transition from bottle or alternative feeding methods to breastfeeding may be problematic (and involves decisions about when and how to make the transition), and particularly if discharge is staggered (Bennington 2011; Gromada 1998). Some mothers report that feeding EBM by bottle is a preferable method because there is certainty about the volume of milk being fed (Niela-Vilén 2014) and it is also a way of allowing others to assist with feeding particularly with higher order multiples (Multiple Births Foundation 2011). Milk expression may be by hand or by pump (hand pump or electrical pump, single or double pumping): there is no strong evidence that one method is better than another (Becker 2015). An increase in milk supply can be achieved by early initiation of pumping, increased frequency of pumping, warming of breast, massage of breast and relaxation and therapeutic touch (Becker 2015). If only one baby is able to latch, the mother can simultaneously pump on the other side (Gromada 1998). There are various options for changing sides or for supplementing and if mothers are advised and supported well, they are likely to find a pattern that suits their circumstances (Bennington 2011; Gromada 1998). Various positioning options such as the underarm hold or the use of a special V-shaped pillow to support the babies may be helpful (Flidel-Rimon 2002; Gromada 1998). If a mother is unable to express sufficient milk, or does not wish to express milk, pasteurised donor breast milk can be used. This has been found to protect against NEC (ESPGHAN 2013). NICE guidelines make recommendations about the safe and effective operation of donor milk banks (NICE 2010), however not all areas operate this service.

When infants are premature or ill and admission to the NICU is required, the consequent likely (though not inevitable) separation of mother and babies, and the possibility of long periods of hospitalisation, the mother being discharged home before the babies, her need for rest and recovery, the need to care for older

siblings, long periods of pumping, staggered infant discharge and the involvement of many other caregivers can make establishing a good milk supply and initiating breastfeeding very challenging (Bennington 2011; Gromada 1998; Multiple Births Foundation 2011). Success in breastfeeding a premature infant has been reported to compensate for any perceived sense of 'failure' a mother may experience in regard to the premature birth, and can give her a sense of achievement (Flacking 2006; Flacking 2007; Niela-Vilén 2014).

Kangaroo skin-to-skin mother care is an effective intervention to improve the duration of breastfeeding in all settings (Renfrew 2009). It is an alternative to conventional neonatal care for low birthweight (LBW) infants and has some benefits for breastfeeding outcomes (Conde-Agudelo 2014). Early skin contact with the mother soon after birth improves breastfeeding at one to four months post birth and is associated with other benefits for the mother and baby including improvements in attachment and bonding (Moore 2012). However, achieving sufficient skin contact when there is more than one baby can be more challenging and the evidence for this intervention in multiple pregnancies is lacking.

Although mothers of multiples can produce sufficient breast milk, especially if given appropriate help and support (Multiple Births Foundation 2011), anxiety about adequacy of milk supply is a frequently reported concern for mothers of multiples who are breastfeeding (Cinar 2013; Flidel-Rimon 2002; Multiple Births Foundation 2011). For mothers of preterm infants there may also be anxiety about the sufficiency of breast milk to meet the nutritional needs of their infants (Flacking 2007). This concern may be exacerbated by the often routine use of fortification of breast milk with artificial fortifier while the infant is in the NICU and being fed by nasogastric tube (Roze 2012). Supplementation with formula or donor EBM may be considered by staff if there is insufficient supply of mother's own EBM, however inadequate pumping can lead to reduced stimulation of the breast, a reduced milk supply and earlier cessation or less likelihood of exclusive breastfeeding (Gromada 1998). The use of supplementary artificial formula has been found to lead to a higher rate of short-term growth, but also a higher rate of NEC (Quigley 2014). For very preterm infants (< 32 weeks), although the use of fortifier has been shown to improve weight gain while in NICU and while enteral feeding is used, once the baby commences breastfeeding the use of fortifier is less easy. Roze et al (Roze 2012) found improved long-term neurological outcomes for very preterm infants breastfeeding at discharge, thus providing reassurance for mothers that continued breastfeeding is advantageous regardless of initial concerns about weight gain assessed as sub-optimal.

More widely, just as for singletons, other issues can impact on attitudes and practices towards breastfeeding multiples. These include: cultural beliefs and pressures (e.g. anxiety about breastfeeding in public, beliefs about adequacy of milk supply); lack of availability of trained support; legislation to protect women who are

breastfeeding; and commercial pressures from marketing and advertising of formula by manufacturers (Save the Children 2013). In general studies are lacking in details about the complexities of feeding multiples and do not specify details of the feeding method such as direct breastfeeding, use of tube, cup or bottle, the use of fortifiers, the use of supplementary milks, the use of donor breast milk, or expressed maternal breast milk and the differences in feeding method between different babies (Renfrew 2009).

Description of the intervention

Education and support for breastfeeding multiples

Critical to success with breastfeeding multiples is information and support from staff (Multiple Births Foundation 2011). Support might be given by a trained healthcare professional (such as a nurse, midwife, or lactation consultant), a peer counsellor or a lay advisor. Advice might include early anticipatory advice in pregnancy, multidisciplinary support or advice consistent with mother's goals and pace (Gromada 1998; Szucs 2009). Specific advice might be needed to help mothers distinguish normal infant feeding behaviour from issues related to caring for multiples (Gromada 1998). Staff may be able to advise about patterns of feeding, avoidance of sore nipples, feeding from both breasts equally, expressing after feeds, providing sufficient stimulation (both direct feeding and regular and frequent expression of milk) and the use of a pacifier to satisfy the need to suck (Bennington 2011). Advice may be provided on a one-to-one basis or as part of a group and could take place in hospital or at home. Following discharge from hospital, contact could be face-to-face, over the phone or using teleconferencing facilities. Increasingly mothers are turning to websites or online sources of information and support (Newby 2015). For healthy term infants any form of extra support improves the duration of 'any breastfeeding' and the duration of exclusive breastfeeding (Renfrew 2012b). However, much of this evidence relates to singleton infants: although some studies include multiples, results are not usually reported separately therefore applicability to infants from multiple pregnancies is uncertain (Renfrew 2009). Many staff lack experience or confidence about feeding multiples, and incorrect or discouraging advice can be detrimental (Cinar 2013; Damato 2005). Staff in NICU may view bottle feeding as a way of ensuring faster growth of the preterm baby and therefore quicker discharge home (Niela-Vilén 2014).

At an organisational level, the UNICEF Baby Friendly Initiative (BFI) accreditation of the hospital results in improvement in breastfeeding outcomes for infants including those in NICU (Dall'Oglio 2007; Renfrew 2009). Other organisational interventions in NICU such as Family Centred Care may have an impact on maternal confidence and success with breastfeeding (POPPY Steering Group; Wataker 2012).

Successfully breastfeeding twins and higher order multiples is time consuming for the mother, who is likely to need good support at home to ensure she gets sufficient rest and adequate nutrition (Multiple Births Foundation 2011). As with breastfeeding singletons (Renfrew 2012b), adequate help and support during the weeks after birth is likely to be important for success in breastfeeding. Support can come from non-professional sources such as peer (mother-to-mother) support, community support groups, support groups for multiples (Tamba (Twins & Multiple Births Association), MBF (Multiple Births Foundation)), etc) and support from family. These aspects may be even more important for multiples. Support may take the form of practical support (help with housework, cooking, etc.) or emotional support. Enhancing the mother's trust and confidence in her ability to sustain a sufficient milk supply is crucial (Gromada 1998). As the babies get older, workplace support and facilities may be especially important for mothers of multiples in long-term maintenance of breastfeeding (Gromada 1998), while further advice and support may be needed during weaning to help prevent problems with milk stasis and mastitis (Gromada 1998).

Women may require advice on specific interventions which may facilitate or inhibit successful breastfeeding of multiples. Pacifier use has been found to have no effect on long-term breastfeeding outcomes in term singleton infants when breastfeeding is already established (Jaafar 2012) and while pacifier use may be promoted in preterm infants for the promotion of physiological stability (Pinelli 2005), the effect on the initiation of feeding at the breast is unknown. However, the use of a pacifier has been suggested as an intervention that can facilitate feeding multiples (Cinar 2013).

How the intervention might work

Breastfeeding confers particular benefits on twins and higher order multiples (Renfrew 2012a). Women with multiple pregnancies are known to be less likely to intend to breastfeed, and to be less likely to initiate and sustain breastfeeding compared with those with singleton pregnancies (Lustiv 2013; Yokoyama 2006). Tailored advice on initiating and sustaining breastfeeding or breast milk feeding may be needed for women with multiple pregnancies, particularly in cultures where breastfeeding is not the norm. The practical difficulties of caring for two or more infants may also mean that women require encouragement and emotional support in order to breastfeed their babies (Multiple Births Foundation 2011). It is possible that education and support for women with multiple pregnancies may increase the number of women initiating breastfeeding and reduce the risk of early discontinuation.

Why it is important to do this review

Rates of breastfeeding of twins or higher order multiples are lower than rates of breastfeeding singletons suggesting that further ev-

idence is needed about how to support this group of women. Women have reported that the help and support they received with infant feeding for multiple pregnancies was insufficient: a UK study found that 34% of mothers of twins said further support with feeding would have helped (McAndrew 2012). Similarly, in Turkey, mothers of twins reported they would have liked more support and better advice during pregnancy (Cinar 2013). Although there is good evidence for interventions that are effective in promoting and supporting women to breastfeed healthy term singletons (Renfrew 2012b), and also for the promotion and support of breastfeeding in the neonatal unit (Renfrew 2009), evidence is lacking about interventions that are effective for women with multiple pregnancies. Women who are breastfeeding more than one infant face particular challenges: there is a need for evidence-based recommendations about what works to help women with multiples initiate and continue to breastfeed.

OBJECTIVES

1. To describe the forms of breastfeeding education and support for women with multiple pregnancies examined in randomised controlled studies.
2. To examine the effectiveness of different modes of interventions (e.g. face-to-face or over the telephone, or by different sorts of healthcare or lay practitioners), and whether interventions containing both antenatal and postnatal elements are more effective than those taking place in the antenatal or postnatal period alone.
3. To examine the effectiveness of education and support from different care providers and (where information was available) training for care providers.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised or quasi-randomised trials examining breastfeeding education and support interventions for women with multiple pregnancies. We will include cluster-randomised trials. We will include studies reported in brief abstracts provided sufficient information is provided to allow us to assess risk of bias; if not, such studies will await further assessment pending publication of the full study report. Cross-over studies are not an appropriate research design for this type of intervention and will not be included.

Types of participants

Women with multiple pregnancies, during pregnancy or after birth and regardless of gestation at time of birth.

We will include trials that recruit both women with multiple and singleton pregnancies provided that there are separate data available for women with multiple pregnancies.

Types of interventions

Breastfeeding education and support during pregnancy, the postnatal period (including immediately after delivery), or both for women with multiple pregnancies. This could include 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 it 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 will be included if the intervention occurs in the postnatal period alone or also includes an antenatal component.

We will include studies examining interventions which include education and support as part of a broader package of care provided that these elements are an important part of the package of care. We will include education and training interventions aimed at staff providing care, provided that these interventions are designed to improve the education and support offered to women.

We will include education or support for using any intervention designed to increase breastfeeding or breast milk feeding. This could include education or support interventions to encourage women to express breast milk either in the antenatal or postnatal period, or maternal education and support about other interventions which might increase or interfere with breastfeeding (such as pacifier use or kangaroo skin-to-skin mother care).

Comparisons: we will compare different modes of interventions with each other or with standard care offered in that setting, and we will identify the components of that standard care wherever possible.

Types of outcome measures

The main outcome measure will be the effect of the interventions on stopping breastfeeding or breast milk feeding by specified points in time. Primary outcomes will be recorded for stopping any or exclusive breastfeeding before four to six weeks and

at the last study assessment (up to six months). Other outcomes of interest will be 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.

Primary outcomes

1. Initiation of breastfeeding (baby put to the breast, even if on one occasion only [McAndrew 2012](#)) or breast milk feeding for each baby.
 2. Initiation of breast milk expression by the mother.
 3. Stopping any breastfeeding or any breast milk feeding before four to six weeks postpartum for each baby.
 4. Stopping exclusive breastfeeding or exclusive breast milk feeding (baby has only ever been given breast milk and never given formula, solid foods or any other liquids [McAndrew 2012](#)) before four to six weeks postpartum for each baby.
 5. Stopping breast milk expression before four to six weeks postpartum.
 6. Stopping any breastfeeding or any breast milk feeding before six months postpartum for each baby.
 7. Stopping exclusive breastfeeding or exclusive breast milk feeding before six months postpartum for each baby.
 8. Stopping breast milk expression before six months postpartum.
- Breast milk feeding could include expressed maternal breast milk, or expressed donor breast milk.

Secondary outcomes

1. Stopping any breastfeeding or any breast milk feeding before two, three, nine and 12 months postpartum.
2. Stopping exclusive breastfeeding or exclusive breast milk feeding before two, three, nine and 12 months postpartum.
3. Frequency of milk collection or number of participants expressing milk, or volume of expressed breast milk at any time point.
4. Maternal satisfaction with care.
5. Maternal satisfaction with feeding method.
6. All-cause infant or neonatal morbidity (trialist defined).
7. Maternal morbidity (trialist defined).
8. Duration of NICU stay (days).
9. Psycho-social outcomes including measures of attachment, self-esteem, mental health, etc.

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 (PCG).

Electronic searches

We will search the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator.

For full search methods used to populate the PCG 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. We will not apply any language or date restrictions.

Data collection and analysis

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

Selection of studies

Two review authors (H Whitford (HW) and T Dowswell (TD)) 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 review author (M Renfrew (MR)).

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, two review authors (HW, TD or S Wallis (SW)) will independently extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult another member of the review team (MR). 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

Two review authors (HW, TD or SW) 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 (MR).

(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)

Blinding women and staff to support and education interventions is not straightforward and is usually not attempted. However, we will describe for each included study any methods used to blind or partially blind study participants and personnel from knowledge of which intervention a participant received. We will consider that studies are at low risk of bias if we judge that any attempted blinding was likely to be effective or if we judge that lack of blinding would be unlikely to affect results. We will assess blinding separately for different outcomes or classes of outcomes.

We will assess the methods as:

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

(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)

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);
- 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 such as baseline imbalance between groups.

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. We will explore the impact of the level of bias through undertaking sensitivity analyses - see [Sensitivity analysis](#).

Assessment of the quality of the evidence using the GRADE approach

For our main comparison (any education of support intervention versus standard care/no intervention), we will assess the quality of the evidence 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.

1. Initiation of breastfeeding or breast milk feeding for each baby.
2. Stopping any breastfeeding or any breast milk feeding before four to six weeks postpartum for each baby.
3. Stopping exclusive breastfeeding or exclusive breast milk feeding before four to six weeks postpartum for each baby.
4. Stopping any breastfeeding or any breast milk feeding before six months postpartum for each baby.
5. Stopping exclusive breastfeeding or exclusive breast milk feeding before six months postpartum for each baby.
6. Maternal satisfaction with care.

7. Maternal satisfaction with feeding method.

We have included women's views of feeding methods and care as outcomes to be graded as the focus of the review is on the quality of care for women as well as breastfeeding outcomes for the baby. We will use the [GRADEpro](#) Guideline Development Tool to import data from Review Manager ([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 if such trials are identified and are otherwise eligible. We will adjust their sample sizes using the methods described in the *Handbook* 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 subgroup analysis to investigate the effects of the randomisation unit.

Cross-over trials

We will not include cross-over trials; such trials are not appropriate for this type of intervention.

Trials with more than two arms

If we identify trials with more than two arms we will pool results using the methods set out in the *Handbook* (Higgins 2011) to avoid double-counting.

Other unit of analysis issues

This review focuses on multiple pregnancies. Outcomes for babies from the same pregnancy (twins or higher multiples) are not independent. For some outcomes (e.g. preterm birth) outcomes for babies from the same pregnancy are likely to be the same, or very highly correlated. For other outcomes there will be a lower correlation (e.g. fetal death or infant anomaly). For breastfeeding outcomes, outcomes for twins or higher multiples are likely to be highly correlated although women may use different feeding methods for their babies depending on infant birthweight, behaviour or other considerations. To take account of the non-independence of outcomes for babies from multiple pregnancies we will treat each multiple pregnancy as a cluster, and analyse data using methods described above for cluster-randomised trials. We will seek ICCs for outcomes for twins and higher multiples from trials (if available) from similar trials or from observational studies. Where published ICCs are not available, we will consult with experts in the field to estimate ICCs, and will conduct sensitivity analysis using a range of ICC values.

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 τ^2 , I^2 and χ^2 statistics. We will regard heterogeneity as substantial if the I^2 is greater than 30% and either the τ^2 is greater than zero, or there is a low P value (less than 0.10) in the χ^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 will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials is considered clinically meaningful. 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 τ^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 do not envisage that there will be many studies focusing on education and support for women with multiple pregnancies, but data permitting we would like to carry out the following subgroup analysis:

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 alone, postnatal alone or both);
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);
7. by whether babies were premature or sick or healthy babies delivered at term (> 37 weeks' gestation).

We will use primary outcomes only in 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 Chi² statistic and P value, and the interaction test I² value.

Sensitivity analysis

We will carry out sensitivity analysis to examine any possible effect of risk of bias on results. For our primary outcomes, provided sufficient data are available, we will temporarily remove studies at high or unclear risk of bias (using the allocation concealment domain) to examine whether this has an impact on results. We will also carry out sensitivity analysis to examine the effects of varying the ICC when adjusting data for cluster design effect.

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* Indicates the major publication for the study

APPENDICES

Appendix I. Search terms for ClinicalTrials.gov and ICTRP

ClinicalTrials.gov (will be run as separate lines in ICTRP)

(breastfeeding OR breast-feeding OR breastfeed OR breast-feed OR lactation) AND (twin OR twins OR “multiple pregnancy” OR multiple pregnancies“ OR “higher order pregnancy“ OR “higher order pregnancies“)

The search may be modified once run and any changes will be documented fully in the review.

CONTRIBUTIONS OF AUTHORS

Heather Whitford produced the first draft of the protocol.

Selina Wallis commented on drafts of the protocol.

Therese Dowswell contributed to the methods section of the protocol.

Mary Renfrew contributed to outcome selection and commented on drafts of the protocol.

DECLARATIONS OF INTEREST

Heather Whitford: none known.

Selina Wallis: none known.

Therese Dowswell: is employed through a grant from NIHR to her institution (The University of Liverpool) for her work on this protocol, and in the last 36 months has received funding from WHO to work on other Cochrane reviews.

Mary J Renfrew: has received a grant from HTA for work on related reviews.

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