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Methods of milk expression for lactating women (Review)

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[Intervention Review]

Methods of milk expression for lactating women

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ABSTRACT

Background

Breastfeeding is important, however not all infants can feed at the breast and methods of expressing milk need evaluation.

Objectives

To assess acceptability, effectiveness, safety, effect on milk composition, contamination and costs of methods of milk expression.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (21 March 2016), handsearched relevant journals and conference proceedings, and contacted experts in the field to seek additional published or unpublished studies. We also examined reference lists of all relevant retrieved papers.

Selection criteria

Randomised and quasi-randomised trials comparing methods at any time after birth.

Data collection and analysis

Three review authors independently assessed trials for inclusion and risk of bias, extracted data and checked them for accuracy.

Main results

This updated review includes 41 trials involving 2293 participants, with 22 trials involving 1339 participants contributing data for analysis. Twenty-six of the trials referred to mothers of infants in neonatal units (n = 1547) and 14 to mothers of healthy infants at home (n = 730), with one trial containing mothers of both neonatal and healthy older infants (n = 16). Eleven trials compared one or more types of pump versus hand expression and 14 studies compared one type of pump versus another type of pump, with three of these studies comparing both hand expression and pump types. Twenty studies compared a specific protocol or adjunct behaviour including sequential versus simultaneous pumping protocols, pumping frequency, provision of an education and support intervention, relaxation, breast massage, combining hand expression with pumping and a breast cleansing protocol.

Due to heterogeneity in participants, interventions, and outcomes measured or reported, we were unable to pool findings for most of the specified outcomes. It was not possible therefore to produce a 'Summary of findings' table in this update. Most of the included results were derived from single studies. Trials took place in 14 countries under a variety of circumstances and were published from 1982 to 2015. Sixteen of the 30 trials that evaluated pumps or products had support from the manufacturers. The risk of bias of the included studies was variable.

Primary outcomes

Only one of the 17 studies examining **maternal satisfaction/acceptability** with the method or adjunct behaviour provided data suitable for analysis. In this study, self-efficacy was assessed by asking mothers if they agreed or disagreed with the following statement: 'I don't want anyone to see me (hand expressing/pumping)'. The study found that mothers who were using the electric pump were more likely to agree with the statement compared to mothers hand expressing, (mean difference (MD) 0.70, 95% confidence interval (CI) 0.15 to 1.25; P = 0.01, participants = 68). Mothers who were hand expressing reported that the instructions for expression were clearer compared to the electric pump, (MD -0.40, 95% CI -0.75 to -0.05; P = 0.02, participants = 68). Descriptive reporting of satisfaction in the other studies varied in the measures used, did not indicate a clear preference for one pump type, although there was satisfaction with some relaxation and support interventions.

We found no clinically significant differences between methods related to **contamination of the milk** that compared any type of pump to hand expression (risk ratio (RR) 1.13, 95% CI 0.79 to 1.61; P = 0.51, participants = 28), manual pump compared to hand expression, (MD 0.20, 95% CI -0.18 to 0.58; P = 0.30, participants = 142) a large electric pump compared to hand expression (MD 0.10, 95% CI -0.29 to 0.49; P = 0.61, participants = 123), or a large electric pump compared to a manual pump (MD -0.10, 95% CI -0.46 to 0.26; P = 0.59, participants = 141).

The level of **maternal breast or nipple pain** or damage was similar in comparisons of a large electric pump to hand expression (MD 0.02, 95% CI -0.67 to 0.71; P = 0.96, participants = 68). A study comparing a manual and large electric pump, reported sore nipples in 7% for both groups and engorgement in 4% using a manual pump versus 6% using an electric pump; and in one study no nipple damage was reported in the hand-expression group, and one case of nipple damage in each of the manual pump and the large electric pump groups.

One study examined adverse effects on infants, however as the infants did not all receive their mothers' expressed milk, we have not included the results.

Secondary outcomes

The **quantity of expressed milk** obtained was increased, in some studies by a clinically significant amount, in interventions involving relaxation, music, warmth, massage, initiation of pumping, increased frequency of pumping and suitable breast shield size. Support programmes and simultaneous compared to sequential pumping did not show a difference in milk obtained. No pump consistently increased the **milk volume** obtained significantly.

In relation to **nutrient quality**, hand expression or a large electric pump were found to provide higher protein than a manual pump, and hand expression provided higher sodium and lower potassium compared to a large electric pump or a manual pump. Fat content was higher with breast massage when pumping; no evidence of difference was found for energy content between methods.

No consistent effect was found related to **prolactin change or effect on oxytocin release** with pump type or method. **Economic** aspects were not reported.

Authors' conclusions

The most suitable method for milk expression may depend on the time since birth, purpose of expression and the individual mother and infant. Low-cost interventions including initiation of milk expression sooner after birth when not feeding at the breast, relaxation, massage, warming the breasts, hand expression and lower cost pumps may be as effective, or more effective, than large electric pumps for some outcomes. Variation in nutrient content across methods may be relevant to some infants. Small sample sizes, large standard deviations, and the diversity of the interventions argue caution in applying these results beyond the specific method tested in the specific settings. Independently funded research is needed for more trials on hand expression, relaxation and other techniques that do not have a commercial potential.

PLAIN LANGUAGE SUMMARY

Methods of milk expression for lactating women

What is the issue?

The importance of human milk is well supported with the World Health Organization recommending that all infants should be fed exclusively on human milk from birth to six months of age and continued thereafter with appropriate complementary foods. Not all babies are able to feed at the breast and so expressed milk is needed.

Why is this important?

Babies who do not receive human milk are more likely to suffer health problems both as newborns and later in life. Mothers may also want to express milk for their own comfort or to increase supply.

What evidence did we find?

We searched for evidence to March 21, 2016 and identified 41 trials for inclusion involving 2293 participants, with 22 trials involving 1339 participants contributing data for analysis. Trials came from many countries and involved mothers of infants in neonatal units and healthy infants at home. The findings did not indicate a clear preference for any one pump type. Mothers reported satisfaction with relaxation and support interventions. There was no difference in milk contamination between methods or breast/nipple soreness of mothers.

Greater milk volume was expressed when mothers listened to music or had a relaxation protocol, warmed the breast, massaged the breast, pumped frequently with a suitable breast shield size and started pumping milk sooner after birth if the infant was unable to feed at the breast. Hand expression or a large electric pump provided a higher protein content than a manual pump. Hand expression provided higher sodium and lower potassium compared to pumps. Fat/lipid content was higher with breast massage when pumping. No evidence of difference in energy content was found between methods. No study asked mothers if they had achieved their own goals for expressing milk. None of the studies examined costs involved with the methods. Of the studies that evaluated pumps or products, 16 out of 30 had support from manufacturers. Not all the studies reported whether important basic supports for mothers were provided such as access to food and fluid, a place to rest near their baby, and the availability of knowledgeable health workers.

What does this mean?

The available evidence indicates that effective measures include starting to express milk soon after birth if the infant is unable to feed at the breast, relaxation, breast massage, warming of the breasts, hand expression, and use of low cost pumps.These may be as effective, or more effective, than large more costly electric pumps for some outcomes. The most suitable method for milk expression may depend on the time since birth, purpose of expression and the individual mother and infant. Publications on breast milk pumping should not be taken to imply that use of a pump is a routine part of breastfeeding, rather, practitioners need to be able to justify the use of a pump for an individual mother prior to making a recommendation on its use.

BACKGROUND

This Cochrane review was first published in 2008 and updated in 2011 and 2015.

Description of the condition

The World Health Organization (WHO) recommends that all infants should be fed exclusively on human milk from birth to six months of age and continued thereafter with appropriate complementary foods (WHO 2002). The importance of human milk is well supported (AAP 2012; Horta 2013a; Ip 2007). There is evidence that babies who do not receive human milk are more likely to suffer health problems such as gastrointestinal and respiratory diseases (Blaymore 2002; Horta 2013b; Howie 1990; Quigley 2007), necrotising enterocolitis (Lucas 1990; McGuire 2003; Schanler 1999), urinary tract infection (Marild 2004), otitis media (Paradise 1994), other infectious diseases (Duijts 2010), and late-onset sepsis in preterm infants (Hylander 1998). In both affluent and poorer communities, not receiving human milk may increase infant mortality (Black 2013; Chen 2004; Victora 1987). The long-term health of children may be affected (Fewtrell 2004): increased rates of asthma (Gdalevich 2001) and diabetes (Gerstein 1994; Pettit 1997) are associated with not receiving human milk, as well as less than optimal cognitive development (Bier 2002; Kramer 2008; McCrory 2011) and increased risk of childhood obesity and markers of later cardiovascular disease (CDC 2007; Labayen 2012; Owen 2008). Human milk may act as an analgesic to infants during procedures such as drawing blood (Upadhyay 2004). The ability to express milk may improve the eventual breastfeeding of premature or ill infants (Furman 2002) and assist in sustaining breastfeeding (Schwartz 2002; Win 2006) though expression of milk during the early postpartum days rather than feeding at the breast, may be a marker for earlier discontinuation of breastfeeding (Forster 2015; Jiang 2015).

Not all babies are able to feed at the breast due to illness or ab-

normalities, prematurity, separation, and other reasons, and expressed milk is needed for these babies. Mothers may express their milk for their own comfort in situations of sore nipples (Buchko 1994; Nicholson 1985); engorgement (Meserve 1982); to increase milk supply (Chapman 2001); to provide milk if they are away from their baby (Geraghty 2012; Hills-Bonczyk 1993); for others to feed (Clemons 2010); for their own preference to express and feed by bottle (Fein 2008); in situations of adoption (Auerbach 1981) or surrogacy (Biervliet 2001); or to donate to a milk bank (Arnold 1990; COMA 1981). There is a risk of HIV transmission via human milk. Expressing and heat-treating the milk will destroy the HIV, thereby providing a nutrient source to infants and young children, particularly in resource-poor areas (Newell 2004). Research on human milk requires samples of milk, thus the ability and feasibility of milk expression is critical to this research (Ferris 1984; Hamosh 1984; Hartmann 1985; Mennella 2010b; Picciano 1984).

The Baby Friendly Hospital Initiative, a global programme of the WHO/UNICEF, requires that mothers be assisted to learn the skill of hand expression before discharge from maternity services (WHO/UNICEF 1989). Learning this skill facilitates women to gain familiarity with functioning of their breasts and to see that they have milk thus building confidence, and empowers mothers with the skill to initiate milk production and to remove milk if their baby is not suckling without needing to purchase equipment. There is limited research on the best method of assisting learning how to express milk, the most appropriate situation or the competence of the person to assist this learning (Becker 2008b; Chen 2012). Information on the use of pumps is often provided by the pump manufacturing companies and may be more towards marketing and limited independent information on the relative effectiveness of different mechanical methods of pumping milk available.

Reports on economic aspects have demonstrated that the increased illness associated with not breastfeeding can increase parental income loss due to absence from work (Cohen 1995) and increased healthcare costs (Bachrach 2003; Ball 1999; Bartick 2010; NICE 2006: Patel 2013). There are costs involved in providing assistance with learning to express, and costs in obtaining a pump and other equipment (Jegier 2010).

Description of the intervention

A baby removes milk from the breast by suckling with the tongue extended under and cupping the breast drawing it into the mouth. The baby's oral movements compress the breast in a rhythmic motion. These movements create a changing pressure gradient assisting the flow of milk as well as stimulating release of the maternal hormone oxytocin which contracts the myoepithelial cells which surround the milk producing alveolar cells. This propels milk along the ducts towards the nipple. Milk expression and pumping techniques may focus on compression of the breast, the pressure gradient, assisting the release of oxytocin, or on a mixture of these stimuli.

A variety of methods to obtain milk have been examined (D'Amico 2004; Egnell 1956; Feher 1989; Foda 2004; Groh-Wargo 1995; Hill 1996; Hill 1999; Jones 2001; Mersmann 1993; Mitoulas 2002a; Morton 2009; Sponsel 1983; Wennergren 1985). The main aspects of methods are described in Table 1 though imprecise terminology such as expression and pumping used interchangeably though physiologically different, can hinder comparability. Quantity of milk and acceptability to the mother may vary among methods of expression - hand expression, manual pumps, battery, or electric pumps (Clemons 2010; Green 1982; Paul 1996; Tengku 2012). Milk volumes and continuation of expression and of breastfeeding may be influenced by frequency of expression, proximity to infant, breast massage, combining methods, by using a double-pump system rather than single pumping, pump vacuum pressure and pattern, comfort of the pump, and for infants and mothers separated at birth, and how soon after birth expression commences (Acuña-Muga 2014; Fewtrell 2016; Furman 2002; Hopkinson 1988; Jones 2001; Kent 2008; Morton 2009). There may be differences between hand expressing or mechanical pumping, or both, to initiate milk supply, and expressing or pumping, or both, when the mother already has an established milk supply. A woman initiating milk production following the birth of her baby at 27 weeks' gestation and expecting to be exclusively pumping for many weeks before her baby is feeding at the breast is a very different situation than a woman pumping milk while she is away from her four-month old baby for eight hours at work and feeding directly at the breast other times. Colostrum and mature milk have different viscosity as well as volume. The most effective method may depend on the situation. Quality of milk constituents may vary depending on the method of expression or pumping, for example higher sodium in hand-expressed milk may be important for preterm infants, or differences in fat content (Garza 1982; Lang 1994; Pessoto 2010; Spencer 1981; Widdows 1933). There may be adverse effects from expressing milk, including injury to the mother (Brown 2005; Clemons 2010; Qi 2014; Williams 1989); effect on milk supply (Chapman 2001; Rasmussen 2011); the risk of bacterial contamination (Asquith 1984; Blenkharn 1989; Boo 2001; D'Amico 2004; Karimi 2013; Thompson 1997); and reduced maternal self-confidence (Buckley 2009). Expressing or pumping, particularly when conducted to provide milk for infants in neonatal units, can be stressful for mothers and supports can assist (Acuña-Muga 2014; BLISS 2008; Ryan 2013). The stress experienced by mothers while expressing, and any support they receive, can be very important factors and should be considered in any analysis of expression.

Why it is important to do this review

Reports on expression of milk have appeared for many years, though most relate to the development of commercial pumps

(Egnell 1956; Fewtrell 2001b; Kent 2008; Meier 2012; Mitoulas 2002b; Zoppou 1997). Much of the published research has limited outcomes, often focused on volume expressed in the shortest possible time, and few reports include the impact on ongoing breastfeeding or if mothers achieved their goals regarding expressing or pumping. Milk is expressed for a wide variety of reasons; different methods may better suit different purposes (Table 1). Expressed milk is used by healthy mothers and babies as well as in problem situations. Rates of milk expression and pumping appear to be rising (Binns 2006; Clemons 2010; Fein 2008; Geraghty 2005; Johns 2013; Labiner-Wolfe 2008; Win 2006). Research evidence is lacking towards understanding how pumped and bottle-fed human milk may differ from directly suckled milk and may affect outcomes in both child and mother (Felice 2015). Many women, and their health advisors, rely on web sites for their information on expressing or pumping their milk, often from the manufacturers of pumps seeking to develop a market and increase sales. Reliance on commercial information has the potential to exacerbate health inequalities (McInnes 2015). Environmental considerations including plastic waste from short-use milk collection sets, energy requirements and total life cycle environmental costs from high-tech pumps are being discussed more. There is a need for a review of the evidence about methods of expression of milk that is wider than comparisons of commercial pumps. This review addresses issues of effectiveness and acceptability of all methods of expressing human milk in addition to techniques to assist expressing or pumping.

OBJECTIVES

The main objectives of this review were to assess acceptability, effectiveness, safety, effect on milk composition, bacterial contamination and cost implications of a range of methods of human milk expression including hand expression, manual, battery and electric pumps.

METHODS

Criteria for considering studies for this review

Types of studies

All published and unpublished randomised or quasi-randomised controlled trials that compared one method or technique of milk expression or pumping with another, or others. We extended the scope of the review beyond the usual Pregnancy and Childbirth Group times to include studies more than 28 days after birth. Cross-over trials were eligible. There was no limitation of study by country of origin or language.

Types of participants

Women expressing or pumping milk for any reason by any method, who may or may not also be feeding a child at the breast. The health status of the child was not a defining criterion for inclusion or exclusion. We included both term and preterm, singleton and multiple births, as well as hospitalised and non-hospitalised mother-infant pairs.

Types of interventions

We included studies if they provided instructions (oral, written or other media) or support protocol on hand expression or mechanical pumping specifically for the study, or provided hand expression or mechanical pumping equipment, or if the study required expression or pumping using a specific protocol or adjunct behaviour; for example, frequency of expression, length of time to express, breast massage, relaxation, imagery, conditioning process, expressing breasts sequentially or simultaneously, or support programme specific to milk expression.

Types of outcome measures

Primary outcomes

1. Indicators of maternal satisfaction (or lack of) with method, including acceptability, comfort, ease of use, and achievement of the woman's goal for expressing or pumping.
2. Indicators of possible adverse outcomes for mother or infant as a result of pumping or expressing, including contamination of milk, injury to mother's breast or other anatomy, reduction or cessation of pumping or expressing due to difficulties with pumping or expressing.

Secondary outcomes

1. Transfer to feeding at the breast if expressing preceded feeding at the breast.
2. Quantity of milk expressed.
3. Time taken to express milk.
4. Nutrient quality of expressed milk; for example, fat, sodium, energy.
5. Maternal physiological effects of expressing - prolactin and other hormone levels.
6. Economic - cost of pump equipment, effect on hospital length of stay for infant, level of healthcare service usage to support expressing or pumping.

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

Search methods for identification of studies

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

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting their Information Specialist (21 March 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 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 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 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 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).

In addition we set monthly e-alerts using the search strategy in Appendix 1.

Searching other resources

We handsearched *Journal of Human Lactation* (from 1985 to March 2016), *Breastfeeding Review* (1982 to March 2016), *Maternal and Child Nutrition* (2005 to March 2016) and conference proceedings from both the International Lactation Consultant Association and the Australian Lactation Consultant Association (1995 to 2015). We contacted experts in the field, and used web site notice boards, e-lists, and journals of professional and voluntary organisations related to breastfeeding to seek additional published or unpublished studies. We examined reference lists of all relevant retrieved papers to identify further studies. We did not apply any language or date restrictions.

Data collection and analysis

For this update we used the following methods when assessing the reports identified by the updated search, which were similar to the methods used in the previous version of the review with differences noted in Appendix 2.

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

Selection of studies

The three review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We resolved any disagreement through discussion.

Data extraction and management

We designed a form to extract data. For eligible studies, two of the review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted the third review author. We entered data into Review Manager software (RevMan 2014) and checked for accuracy. Wherever necessary, we requested unpublished or missing data from the trial contact author.

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* (Higgins 2011). We resolved any disagreement by discussion or by involving the third review author.

(1) Sequence generation (checking for possible selection bias)

We described 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 assessed the method as:

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

- unclear risk (insufficient information to permit the judgement of low or high risk).

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

We described for each included study the methods used to conceal the allocation sequence and determined whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. When studies did not report any concealment approach, they were considered unclear. We assessed the methods as:

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

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

We considered that due to the nature of the interventions evaluated, blinding of mothers or their care providers to the intervention was generally not possible. For each study we have assessed if blinding would have been feasible and the effect so as to distinguish between unfeasible blinding and feasible, but not blinded. We assessed all studies for performance bias as:

- low risk (no or incomplete blinding but the review authors judge that the outcome is not likely to be influenced; blinding of study participants and personnel ensured and unlikely that the blinding could have been broken);
- high risk (outcome is likely to be influenced by no or incomplete blinding; blinding of study participants and personnel attempted, but likely that the blinding could have been broken and the outcome is likely to be influenced by lack of blinding;
- unclear risk (insufficient information to access the risk of bias or the study did not address this outcome).

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

We described for each included study the methods 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 the methods as:

- low risk (no blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; or blinding of outcome assessment ensured, and unlikely that the blinding could have been broken);
- high risk (no blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; or blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding);
- unclear risk (insufficient information to permit judgement of 'low risk' or 'high risk; if the outcome was not reported in the study, or clarity was not obtained through communication with the trialist when feasible).

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We indicated for each included study, the completeness of data including attrition and exclusions from the analysis (Characteristics of included studies table). We stated whether attrition and exclusions were reported, 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 included the missing data in the analyses undertaken. We calculated the level of completeness to follow-up for all included studies but did not require a minimum level for inclusion. We assessed the methods as:

- low risk (e.g. where there were no missing data or where reasons for missing data were balanced across groups);
- high risk (e.g. where missing data may have related to outcomes or were not balanced across groups);
- unclear risk (e.g. where there was insufficient reporting of attrition or exclusions to permit a judgement to be made).

(5) Selective reporting bias

For each included study we described how we investigated the possibility of selective outcome reporting bias and on our findings. We assessed the methods as:

- low risk (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 (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.

(6) Other sources of bias

In the notes sections of the Characteristics of included studies table we have recorded any other concerns about bias such as source of funding, any significant deviation from the study protocol, or any

extreme baseline imbalance. We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk (study appears to be free of other sources of bias);
- high risk (at least one important risk of bias, e.g. had a potential source of bias related to the specific study design);
- unclear risk (insufficient information to assess whether an important risk of bias exists or insufficient rationale or evidence that an identified problem will introduce bias).

We assessed cross-over trials to see what measures were used to reduce carry over between interventions, whereby the effects of an intervention given in one period persist into a subsequent period, thus interfering with the effects of the different, subsequent intervention. Depending on the outcome being assessed, we considered if any washout period between interventions was adequate as a means of reducing carry-over effects.

(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). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it likely to impact on the findings. We planned to explore the impact of the level of bias through undertaking sensitivity analyses, temporarily removing studies at high risk of bias from the meta-analysis to see what impact this would have on intervention effects; however, the included studies were not suitable for meta-analysis.

Assessment of the quality of the evidence using the GRADE approach

For this update we planned to 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 specific outcomes. It was planned that GRADEpro Guideline Development Tool would be used 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 would have been 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. However due to the variety in intervention and outcome measures, a 'Summary of findings' table was not created for this update. This will be re-examined in future updates. The following outcomes will be assessed.

1. Maternal satisfaction
2. Adverse effects for mother or infant
3. Quantity of milk
4. Nutrients in milk
5. Maternal physiological effects of expressing
6. Economic implications

Measures of treatment effect

Dichotomous data

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

Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same unit between trials. If outcomes had been measured in different units between trials, we planned to use the standardised mean difference. In instances in which the outcome data distribution was skewed and not available in a format for transformation, we provided a description of the available results in the text.

Unit of analysis issues

Cross-over trials

Cross-over trials were included for this update of the review, if deemed eligible, along with parallel group trials in the analyses, using the methods described in the *Handbook* (Higgins 2011). We did not include unpaired data from cross-over trials in the analyses, as we sought to use only paired data such that information would be available regarding the within-mother comparison of methods of milk expression. In instances where cross-over trials only reported on unpaired data, we elected to report these descriptively in the text, qualifying that the results need to be interpreted with caution as they arose from a limited analysis.

Studies with more than two intervention groups

For studies that had multi-intervention arms, we first assessed which groups were relevant to this review. If we found that more than two comparison groups were applicable, then we entered data as a single pair-wise comparison into RevMan 2014. In instances in which there were more than two groups to be compared, we took measures to avoid double counting or inappropriate totaling.

Dealing with missing data

For included studies, we noted levels of attrition in the Characteristics of included studies table and summarised information in Table 2. We planned to 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 carried out analyses, 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, and analysed all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention.

Assessment of heterogeneity

We intended to assess statistical heterogeneity in each meta-analysis using the Tau², I² and Chi² statistics, regarding heterogeneity as substantial if the T² was greater than zero and either an I² was greater than 30% or there was a low P value (less than 0.10) in the Chi² test for heterogeneity. There were insufficient studies included to undertake meta-analysis at this time.

Assessment of reporting biases

We did not formally assess reporting bias; without access to study protocols it is difficult to know whether or not there has been outcome reporting bias. However, we have noted in the Characteristics of included studies table where we had any concerns about reporting bias (e.g. where key outcomes did not seem to be reported). We were unable to assess publication bias using funnel plots as too few studies contributed data to the analyses. In future updates, 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 carried out statistical analysis using the Review Manager software (RevMan 2014). Studies are presented in the same analysis when referring to a related outcome, however studies were not sufficiently similar to combine for meta-analysis. If further studies are identified in the future for meta-analysis, 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 where we judge the trials' populations and methods to be 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 we consider an average treatment effect across trials clinically meaningful. We will treat the random-effects summary as the average 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, we will present the results as the average treatment effect with 95% confidence intervals, and the estimates of Tau² and I².

Subgroup analysis and investigation of heterogeneity

There were insufficient data to undertake subgroup analyses and investigation of heterogeneity. Had we identified substantial heterogeneity, we had planned to investigate it using subgroup analyses and sensitivity analyses and to consider whether an overall summary was meaningful, and if it was, we planned to use random-effects analysis to produce it. We planned to carry out the following subgroup analyses:

1. gestational age;
2. time since birth when intervention occurred;
3. make and model of pump;
4. trial design;

using the following primary outcomes in subgroup analysis:

1. indicators of maternal satisfaction (or lack of) with method;
2. indicators of possible adverse outcomes for mother or infant

as a result of pumping or expressing.

If there are sufficient data in future updates, 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 planned to carry out sensitivity analysis to explore the effect of trial quality involving analysis based on rating of selection bias and attrition bias to assess for any substantive difference to the overall result. As we have included only a small number of trials, we have not carried out this analysis, but have briefly discussed possible effects of study quality.

RESULTS

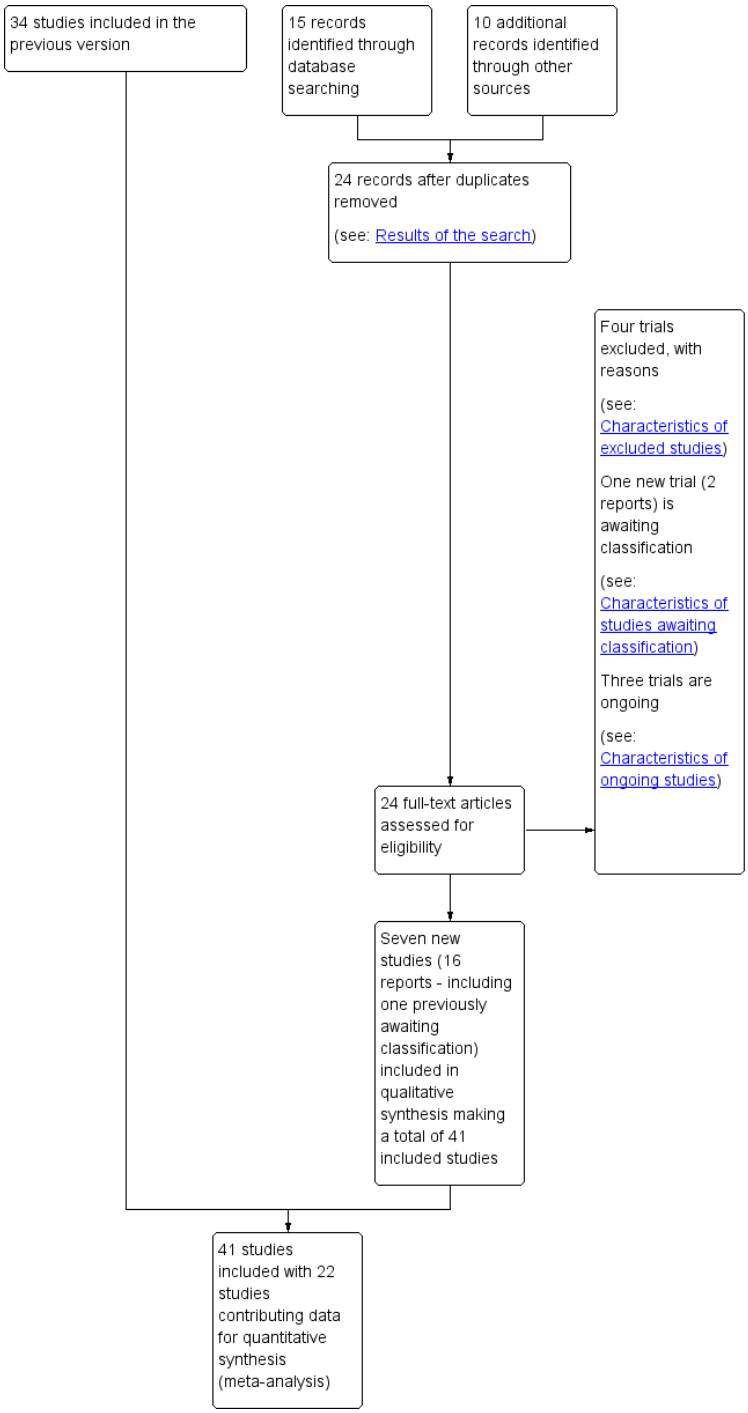
Description of studies

See Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies.

Results of the search

See: Figure 1.

Figure 1. Study flow diagram.



The updated search in March 2016 retrieved 15 trial reports from the Cochrane Pregnancy and Childbirth Group's Trials Register and an additional 10 reports from author searching. After removal of duplicates, we included seven new trials (11 reports) and excluded four trials. Three new trials are ongoing. One extra trial report was added to Parker 2012 and to Rasmussen 2011. Additionally, one trial previously awaiting classification is now included (Heon 2011) and two new reports were added to this. A new study (two reports) for which we could only get limited data from the trialist at this time is awaiting classification (Raguindin 2015). The study is briefly described in Characteristics of studies awaiting classification.

One trial previously awaiting classification is now excluded (Alekseev 1998) as contact with the author clarified that it was not a randomised controlled trial (RCT). One trial previously in the ongoing studies section is now also excluded as the trialist replied that it was abandoned (NCT01802047). One trialist remains unable to be contacted (Yu 2014).

Included studies

After screening there were 41 included studies (n = 2293). Twenty-five studies were parallel design and 16 studies were cross-over designs or include an aspect of the trial with a cross-over design. Twenty-six of the trials referred to mothers of preterm or ill infants in neonatal units (n = 1547) and 14 referred to mothers of healthy term infants at home (n = 730), with one trial containing mothers of both neonatal and healthy older infants (n = 16). We requested clarification or additional data from authors of all included studies and the responses, or lack of, are included in the study details. We have provided study details in the table Characteristics of included studies.

Setting

Trials were conducted in the USA (n = 23), UK (n = 4), two studies each in Australia, India and Canada, and one study each in Malaysia, Brazil, Egypt, Mexico, Israel, Ecuador, Turkey, and a two-site study in Kenya and Nigeria. All mothers were described as healthy, with one trial including only obese mothers (body mass index (BMI) greater than 29 kg/m^2) (Rasmussen 2011).

Interventions

The majority of included studies referred to one or more types of pumps. We have described the types of pumps used in Table 2. Eleven studies (Boo 2001; Flaherman 2012; Garza 1982, Lussier 2015; Mangel 2015; Paul 1996, Pessoto 2010; Pittard 1991; Slusher 2007; Vasan 2004; Zinaman 1992) included hand expression of milk as well as pumping and 14 studies compared two or more types of pumps or vacuum patterns (Bernabe-Garcia 2012; Boutte 1985; Burton 2013; Fewtrell 2001a; Fewtrell 2001b; Francis 2008; Hayes 2008; Hopkinson 2009; Meier 2008; Meier 2012; Pessoto 2010; Rasmussen 2011; Slusher 2007; Zinaman 1992), with three of these studies comparing both hand expression and multiple pump types (Pessoto 2010; Slusher 2007; Zinaman 1992). Twenty studies examined a specified protocol or adjunct behaviour, including sequential versus simultaneous pumping protocols (Auerbach 1990; Groh-Wargo 1995; Hill 1999; Jones 2001; Prime 2012), frequency of expression (De Carvalho 1985), provision of a milk expression education and support intervention to mothers of preterm infants (Ahmed 2008; Heon 2011; Pinelli 2001), provision of audio/visual relaxation to mothers of preterm infants (Feher 1989; Jayamala 2015; Keith 2012), timing of initiation of pumping related to milk volume among mothers of very low birthweight infants (Parker 2012), breast massage before pumping (Jones 2001; Stutte 1988), therapeutic touch (Mersmann 1993), warming breasts before pumping (Yi g it 2012); breast shield sizes (Prime 2010) and a breast cleansing protocol (Costa 1989). Stellwagen 2010 compared a group taught "Hands on Pumping" that combined hand expression with electric pump usage with a control group using the pump only.

Outcomes

The review was able to meet in part its objectives to assess acceptability (including maternal satisfaction with the method), bacterial contamination, effectiveness (including quantity of milk, time taken), effect on milk composition, and cost implication (related to infant length of stay in a neonatal unit only) though not able to assess safety, achievement of maternal goals for expressing or pumping, or other aspects of cost, as none of the studies we found examined these areas in relation to the intervention.

Maternal satisfaction/acceptability

Seventeen studies examined some element of acceptability, maternal satisfaction or mother's views on using pump equipment or technique or protocol, with nine of these studies providing details on the aspects assessed (Bernabe-Garcia 2012; Burton 2013; Fewtrell 2001a; Fewtrell 2001b; Flaherman 2012; Hopkinson 2009; Meier 2008; Meier 2012; Mersmann 1993). Seven studies reported maternal satisfaction findings descriptively only (Ahmed 2008; Auerbach 1990; Boutte 1985; Feher 1989; Hill 1999; Jones 2001; Paul 1996), and one study did not report on this aspect though included it in their methods (Rasmussen 2011). None of the studies found specifically asked mothers if they had achieved their own goals for expressing or pumping. See Characteristics of included studies.

Adverse outcomes/contamination

Adverse effects resulting from bacterial contamination of milk expressed by pump or hand expression were reported in four stud-

ies (Boo 2001; Costa 1989; Pessoto 2010; Pittard 1991), as well as infant death, infants developing necrotising enterocolitis and sepsis (Boo 2001). Maternal pain or nipple damage was reported in three studies (Fewtrell 2001b; Flaherman 2012; Pessoto 2010). See Characteristics of included studies.

Transfer to feeding at the breast

For the secondary outcomes of the review, Ahmed 2008, Boo 2001 and Burton 2013, reported on the proportion of infants breastfeeding on discharge from the neonatal intensive care unit, and Vasan 2004 reported quantity of milk transferred on day of hospital transfer, which are used in this review as a proxy for transfer to feeding at the breast.

Effectiveness: quantity of milk and time taken

The quantity of milk expressed was examined in 34 studies with 18 studies providing data for analysis. The measures used in trials varied widely from a single expression to 60 days, which restricted comparison among trials (Table 3). Most studies instructed the mother to continue pumping until the milk flow slowed or ceased. A maximum time limit per pumping session was set in 12 studies (Table 3).

Milk removal facilitates milk production (Wilde 1995). If use of a pump on one or more occasions enables a mother to remove more milk, her milk production may also be higher on following occasions. Therefore, in a cross-over design comparing pumps, time-lag is important when measuring milk production outcomes: there needs to be sufficient time between pump tests (including any familiarisation period involving pumping) to allow for the effect of any additional milk produced to recede. Eight of the 13 cross-over studies that measured milk volume provided some information on familiarisation times and 'washout' periods and there does not appear to be a standard different time period used (Table 3). Frequency and duration of expression or pumping can also affect the quantity of milk. The frequency recommended or instructed in the trial and the frequency actually achieved by the women frequently differed (Table 4). The baby feeding at the breast immediately prior to a pumping session or baby feeding on the same days as daily pumped volumes were measured would affect the amount of milk measured as removed by the pump; however few of the studies measuring volume stated if the baby was also feeding at the breast during the trial.

Time taken to pump milk was examined in six studies with reference to sequential versus simultaneous pumping protocols (Auerbach 1990; Fewtrell 2001b; Groh-Wargo 1995; Hill 1999; Jones 2001; Prime 2012); measures reported varied (Table 3). Time taken to pump with an additional support protocol was reported from one pilot study (Heon 2011).

Effect on milk composition/nutrients

An aspect of nutrient content was measured in 16 studies. Fat/lipid content was measured in 15 studies with five reporting data in a format suitable for analysis in this review (Feher 1989; Heon 2011; Keith 2012; Mangel 2015; Stutte 1988). Three studies provided data on other nutrients: protein, sodium, potassium and total energy (Pessoto 2010, unpublished data provided by author), protein, carbohydrate and total energy (Mangel 2015), total nitrogen (Garza 1982), and for two other studies the data were not in a format suitable for analysis: protein, lactose, and energy, (Bernabe-Garcia 2012), and energy, protein and carbohydrate content (Stellwagen 2010).

Maternal physiological effects

Maternal physiological effects of expressing or pumping or techniques or co-behaviours related to expressing and pumping are reflected in prolactin, oxytocin and cortisol hormone responses as well as other physiological changes. Nine studies reported a physiological effect, with data from three included for analysis: change in serum prolactin (Groh-Wargo 1995), time to milk ejection (oxytocin release) (Francis 2008 (unpublished manuscript)), and one study with descriptive results included for prolactin and oxytocin response (Hopkinson 2009).

Economic implications

Length of stay in a neonatal unit is an important economic consideration, though the high number of variables in these infants makes the comparison difficult to evaluate. None of the included studies randomised infants. Boo 2001 reported on the median duration of infant stay in the hand-expression and pumping groups; however, these data were not used in this review as many infants were not receiving any of the milk their mothers expressed or pumped. Most of the studies mention staff assisting the mothers to use the methods of milk expression or pumping, though none explored the time cost of providing this assistance or if it varied between method or protocol. Mothers of infants in the neonatal unit in the trial of additional breastfeeding support versus standard support by Pinelli 2001 provided their own pumps and the cost of these pumps and mother's views on the cost are reported. Bernabe-Garcia 2012 discusses that large electric pumps are not affordable in developing countries and their study examined only lower cost manual pumps and reported costs to the mother of the four pumps examined. Slusher 2007 studied two African special care nurseries in Kenya and Nigeria with limited resources including lack of refrigeration to store expressed milk. In this study, the equipment used in the trial was not available locally but rather had been donated by the manufacturers and the USA cost of the electric pumps and other equipment was provided by the author in additional information. Vasan 2004 also referred to the lack of refrigerator prevented storage of expressed milk if pumped beyond what the infant needed. A secondary analysis by Jegier 2010 of data in the study by Meier 2008 describes the costs involved in providing pumped own mother's milk, compared to donor bank human milk and preterm formula, which were not comparisons included in this review. The large electric pumps use individual mother collection sets which may be sterilised between uses, and recently these may be single use before disposal sets. The cost of these plastic collection sets and the waste management costs for their disposal were not included in any of the trials.

Excluded studies

We excluded 28 studies. Twelve were not randomised trials, fifteen did not compare methods of milk expression and one on-going trial was abandoned before completion. Full details are available in the Characteristics of excluded studies.

Risk of bias in included studies

We assessed each trial for quality as outlined in the Methods section. Summary descriptions of the assessments on the risk of bias are available in Figure 2 and Figure 3. Details of the assessment for each trial are set out the Characteristics of included studies.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

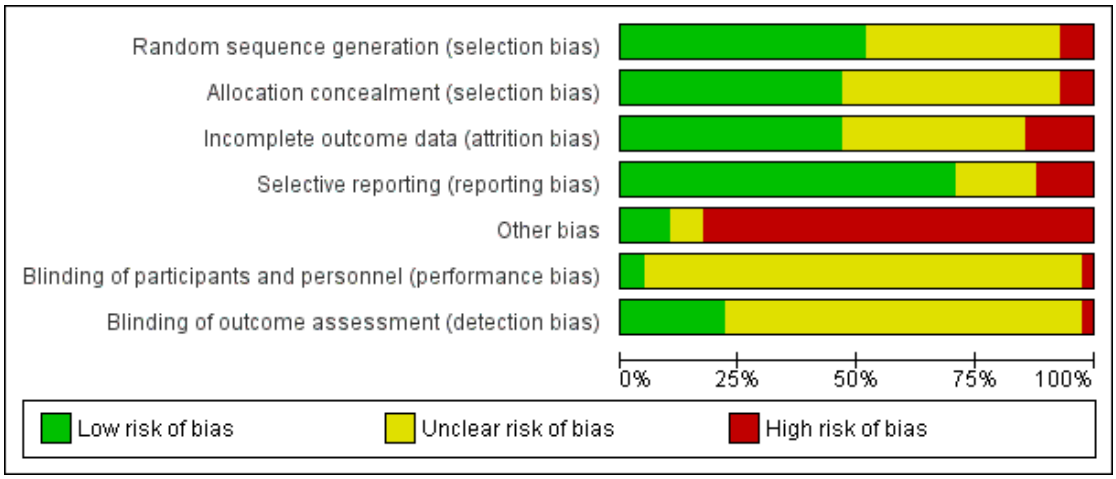
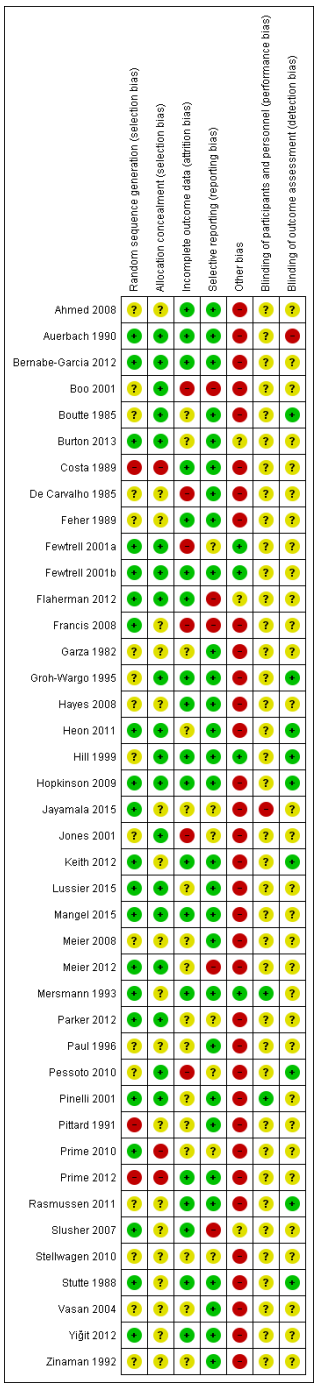


Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Of the 41 included studies, only one used quasi-randomisation (Costa 1989). We judged two of the 41 RCTs to have high risk of bias for sequence generation and allocation concealment (Costa 1989; Prime 2012), 13 to have low risk of bias on both aspects, and another 13 trials to be low risk of bias on only one of these two aspects of allocation. For a further 11 trials, the adequacy of both the sequence generation and allocation concealment was unclear. One study (Pittard 1991) was graded as high risk for sequence generation and unclear risk for allocation concealment and one study (Prime 2010) graded as low risk for sequence generation and high risk for allocation concealment.

The Ahmed 2008 study had twice as many multipara (60%) in the intervention group as in the control group (30%), strongly indicating possible selection bias. As the outcome of interest is breastfeeding, the difference of mothers with prior breastfeeding experience could impact on the results of the study. It is therefore difficult to tell if the difference observed between mothers in the intervention and control group who were breastfeeding on discharge (risk ratio (RR) 2.00, 95% confidence interval (CI) 1.25 to 3.21, P = 0.004) is due to the effectiveness of the intervention or the characteristics of the participants.

Blinding

Blinding of mothers and care providers was not feasible in almost all of these trials and this may be a source of bias. Only one trial clearly reported (as a doctoral thesis) how the blinding of mothers was undertaken, which involved a Theraputic Touch intervention (Mersmann 1993). Blinding of some or all of the outcome assessors was reported for nine trials (Boutte 1985; Groh-Wargo 1995; Heon 2011; Hill 1999; Hopkinson 2009; Keith 2012; Pessoto 2010; Rasmussen 2011; Stutte 1988). For one trial, the same researcher designed the study, carried it out and assessed the results, which we have judged as high risk (Auerbach 1990). For the remainder of the studies there was insufficient information to judge the risk of bias and are thus marked as unclear risk.

Incomplete outcome data

We judged six studies as having a high risk of bias related to incomplete data outcomes reported (Boo 2001; De Carvalho 1985; Fewtrell 2001a; Francis 2008; Jones 2001; Pessoto 2010), including participants missing and not mentioned, unclear cross-over process, no information how incomplete data were handled, and missing samples. Sixteen studies were judged as unclear risk due to no or insufficient information available. The remaining 19 studies were judged to be low risk.

Levels of attrition are described in Table 2 and were quite variable. In some instances, despite responses from trialists, there was insufficient information on the losses of participants or on the missing data to fully assess the quality of all aspects of those studies.

Selective reporting

For most studies, we could only access information reported in the published papers and if the paper reported all the outcomes listed in the study design, then it is marked as low risk (29 studies). Five studies were marked as high risk due to findings not reported in allocated groups, or where one publication (trial register, protocol or linked article) mentioned an intervention or analysis that was not reported on in any publication of the trial, or where the time period reported on was different than stated in the study design (Boo 2001; Flaherman 2012; Francis 2008; Meier 2012; Slusher 2007).

Seven studies are marked as unclear risk due to cross-over data not reported as pair data, results reported descriptively without data shown, published only as a conference abstract with limited details or no information available on which to base a judgement (Fewtrell 2001a; Jayamala 2015; Jones 2001; Parker 2012; Pessoto 2010; Prime 2010; Stellwagen 2010).

Other potential sources of bias

Other potential sources of bias arose from violation of protocol in the use of a special elasticated bra that held the pump "hands free" was provided only to a minority of participants (Hopkinson 2009), lack of clarity about participants receiving the educational intervention (Ahmed 2008), too short a 'wash out period' between pump use, or unclear time since last breastfeed, and the effect of the same participants involved in more than one trial carried out at the same time in cross-over trials (Bernabe-Garcia 2012; Paul 1996; Prime 2010; Prime 2012), participants in the intervention groups receiving additional support and contact from the research nurse above that necessary for the intervention (Groh-Wargo 1995), possible violations of protocol noted by trialists with mothers using different pumps than those assigned (Hayes 2008), and no inclusion/exclusion criteria given (Pittard 1991).

The study procedure used by Boo 2001 did not obtain the same number of further samples from all mothers participating in the study, with more samples being obtained only from mothers whose first sample was contaminated, and later results not reported in randomised groups, resulting in the erroneous finding reported that contaminated samples were more common in one method than the other.

The trial by Lussier 2015 to compare hand expression and electric pump was for 28 days however participants were in their assigned groups only for the first seven days; thereafter participants were allowed to change group and 18 of the 20 hand-expression group

changed to using an electric pump. In the published paper, data analysis was reported by the original assigned groups and presented as cumulative volumes, which had the effect of enhancing any early differences and blurring later differences. Although difficult to match with the published data, the non-cumulative data for the first seven days as provided by the trialist in personal communication was used in this review.

In some studies results were reported as day/week one milk volume or constituents when it was more likely to mean day/week one of the trial rather than the first day after birth, as enrolment into the trial did not occur until some hours or days after birth (Francis 2008; Hill 1999; Hopkinson 2009; Jayamala 2015; Meier 2012; Pessoto 2010; Slusher 2007; Yiğ it 2012). Not all studies reported if milk expression was happening pre-trial enrolment (in the first few days after birth) and if so by what method.

Sixteen of the 30 studies which compared pumps or pumping related equipment stated that support was provided by the manufacturers of the equipment being studied plus one study received funding from the anti-bacterial agent studied. Studies have potential for bias when funded by manufacturers to test their products or to evaluate them compared to other products. Nine studies received funding from their academic institutions or not-for-profit organisations, with some studies receiving funding from more than one source (Table 2).

The most common other bias with the studies (n = 33) was that they lack power to detect a statistically difference between their groups (as reported in published papers) and were rated as high risk for bias. Though power calculations tend not to be found in older studies conducted before current protocols were common, many of these studies were recent. Other biases that are common to other trials, such as possible contamination between groups, additional support to participants or just interest from the researcher, could also apply to these types of studies, as well as publication bias towards interesting results, results favourable to the funders, and English language.

Effects of interventions

Of the 41 studies eligible for inclusion involving 2293 women, 22 studies contributed data, involving 1339 women, which could be entered into RevMan 2014 (Ahmed 2008; Bernabe-Garcia 2012; Boo 2001; Burton 2013; Feher 1989; Fewtrell 2001b; Flaherman 2012; Francis 2008; Garza 1982; Groh-Wargo 1995; Heon 2011; Hill 1999; Hopkinson 2009; Keith 2012; Lussier 2015; Mangel 2015; Meier 2012; Pessoto 2010; Pinelli 2001; Slusher 2007; Stutte 1988; Yiğ it 2012). Seven of the eight outcomes listed in the protocol for this review as described above were addressed by one or more of the 22 included studies with useable data. We added one additional comparison of any pump vacuum pattern versus any other pump vacuum pattern, to accommodate a trial that now had data available for analysis. We were able to populate 13 of the 15 comparisons. The two empty comparisons are not included in this review, "Any battery or small electric pump versus hand expression" and "Any battery or small electric pump versus manual pump".

Variations among protocols, pump equipment and outcomes reported across the included studies allowed only limited statistical comparisons to be made. Data were compared in the most specific comparison; for example, if the pump type was specified as a "manual pump", it was compared as that category rather than "any type of pump" category. Confidence intervals (CIs) in most comparisons indicated a very wide range of values reflecting the variety in women's milk production, and data were insufficient to judge if values were a normal distribution. We have presented full details in the graphs, which are arranged by comparison between pump types or methods.

Primary outcomes

Maternal satisfaction with method

Seventeen studies reported on maternal satisfaction in which there was comparison of various methods of milk expression that included simultaneous versus sequential breast pumping, different types of breast pumps as well as the effects of an educational and a relaxation intervention. One study provided data suitable for analysis in RevMan (Flaherman 2012). The methods examined in each study differed and the descriptive findings reported did not suggest any clear effect related to maternal satisfaction. Descriptive results, where available, are provided in Table 5.

Two studies reported descriptively on maternal satisfaction in trials involving two different types of electric pumps. In a comparison of a standard to a novel small electric pump, Hopkinson 2009 (n = 62) reported that mothers' ranking of the two pumps did not differ on eight of 10 aspects of the pump, based on their experience in using the pump over two to three weeks. Examining another two pump brands, Burton 2013 (n = 71) reported a higher preference for a less costly pump based on its ease of use and the position of the control button than for the large electric pump, with no other items differing significantly between the groups.

The same manual pump (Avent ISIS) was preferred by women, using the same questionnaire and scale, both in a trial comparing it with a small electric/battery hand-held pump (Fewtrell 2001a) and to a large electric pump (Fewtrell 2001b). In a cross-over trial with mothers of term healthy infants aged approximately eight weeks (Fewtrell 2001a) (n = 60), mothers' ratings of a small electric/battery and a manual pump over 48 hours of use are reported. Unpaired analysis of mothers' overall ratings of each pump was reported with no information provided on the within-mother rating of each pump. As a consequence of this, caution is required in the interpretation of the study's results. Overall, mothers reported higher satisfaction with the manual pump but found no difference between the pumps for ease of use. A parallel group trial assessed mothers of preterm infants assigned to either a manual pump or a

large electric pump within three days of giving birth and used for a range of seven to 30 days. This study also reported higher maternal satisfaction for the manual pump compared to the electric pump (Fewtrell 2001b, n = 145).

Comparing a large electric versus a manual pump the subjective responses for each type of pump are reported as being similar apart from ease of operation, for which there was a marked preference (70%) for the electric pump (Boutte 1985). Rasmussen 2011 (n = 39), comparing a manual and large electric pump, did not report their findings related to maternal views in the published paper.

In a cross-over study mothers alternated between hand expression and using a manual pump on postnatal days four and five and expressed a preference for the manual pump in both Phase I (n = 22) and in Phase II with a different sample, (n = 14), however, the Phase II sample also reported at postnatal days eight and nine and found the opposite at the later time, with a preference for hand expression at this time (Paul 1996).

A cross-over trial comparing four manual pumps used by mothers with hospitalised preterm infants reported that the "scale of maternal preference rated higher those with the squeeze-handle mechanism than the cylindrical mechanism (p greater than 0.05)" (Bernabe-Garcia 2012).

Meier 2008 (n = 65) reported there was "no significant difference" in the maternal evaluation of efficiency, efficacy, comfort or convenience in either group comparing two suction patterns of one large electric pump. Meier 2012 (n = 128) in a cross-over study examining varying breast pump suction patterns (BPSPs) descriptively reported "one statistically significant difference" was noticed that "mothers did not like the 'suction strength' of the new experimental maintenance BPSP" and mothers reporting that the new experimental maintenance BPSP was not as comfortable compared to the experimental initiation BPSP.

Comparing simultaneous versus sequential breast pumping, three studies reported on maternal satisfaction. One study (Auerbach 1990, n = 25) reported a preference for simultaneous pumping compared to the single sequential option by three to one, while two studies (Hill 1999 (n = 49) and Jones 2001 (n = 52)) did not report any overall preference among mothers for either of these techniques.

Four studies looked at maternal satisfaction with other interventions to facilitate milk expression. Feher 1989 (n = 55) examined the effect of a 20-minute audio relaxation and imagery tape to increase volume and fat content of milk pumped and reported that mothers were positive in their response on using the relaxation technique. Ahmed 2008 (n = 60) used the acquisition of knowledge and skills as an indicator of mothers reaching their goal of breastfeeding and reported that mothers who received an educational programme were more likely to start milk expression earlier compared to mothers in the control group (P < 0.004). Mersmann 1993 (n = 18) reported that all mothers in this cross-over study found both the Theraputic Touch and the Mimic Therapeutic Touch treatments helped them relax, and reported that "a chi-square analysis showed no significant difference in perception based on treatment order (x^2 = 2.1, df = 2, P >.05)" when asked to choose "which treatment they perceived as better". Heon 2011 provided a multi-component support protocol to assist milk expression with participants who received the experimental intervention reporting they strongly agreed or agreed that components were beneficial for the establishment and maintenance of their breast milk production: the education session (11/14), telephone follow-up (10/12), and two of the four mothers who used the telephone helpline.

One RCT examined mothers self-reported efficacy using either hand expression or an electric pump (Flaherman 2012). Self-efficacy was assessed by asking mothers if they agreed or disagreed with the following statement: 'I don't want anyone to see me (hand expressing/pumping)'. The study found that using a scale scored from one strongly disagree to five strongly agree, mothers who were using the electric pump were more likely to agree with the statement compared to mothers hand expressing (lower score is better) (mean difference (MD) 0.70, 95% CI 0.15 to 1.25; P = 0.01, participants = 68) (Analysis 5.1). Mothers who were hand expressing reported the instructions for expression to be clearer compared to the electric pump, (higher score is better) (MD -0.40, 95% CI -0.75 to -0.05; P = 0.02, participants = 68) (Analysis 5.2).

Adverse effects

Adverse effects on milk

We found no clinically significant differences between methods related to contamination of the milk in two studies providing data for analysis: Boo 2001 compared any type of pump to hand expression (risk ratio (RR) 1.13, 95% CI 0.79 to 1.61; P = 0.51, participants = 28) Analysis 1.1.1; Pessoto 2010 compared a manual pump with hand expression,(MD 0.20, 95% CI -0.18 to 0.58; P = 0.30, participants = 142) Analysis 2.1.1; compared a large electric pump to hand expression, (MD 0.10, 95% CI -0.29 to 0.49; P = 0.61, participants = 123) Analysis 5.3.2; and compared a large electric pump to a manual pump (MD -0.10, 95% CI -0.46 to 0.26; P = 0.59, participants = 141) Analysis 6.1); and Pittard 1991 (n = 16), a cross-over study comparing a large electric pump with hand expression, reported the number of specimens with less than or greater than 10,000 colony-forming units (CFU)/mL did not differ between those collected with hand expression versus an electric pump. Comparing breast cleansing with an antibacterial soap to hand washing descriptively reported lower staphylococcus colony counts in the breast cleansing group (mean count 19,719 colonies of *Staphlococcus epidermis* to 30,905 colonies, P = 0.013, n = 65) (Costa 1989), though as the trialist points out, the feasibility of using soap and an anti-bacterial agent on the breasts six to eight times a day raises concerns both for the mothers' skin and the mothers' willingness to continue this process for a length of time;

there may also be concerns over residues of the anti-bacterial agent in the expressed milk.

Adverse effects on infants

Infant death, infants developing necrotising enterocolitis and sepsis were examined in one study (Boo 2001). However, as the infants did not all receive their mothers' expressed milk, with some receiving only formula milk, a mixture of milks or no enteral feeds, we have not included the results for infant illness related to mother's method of milk expression in this review.

Adverse effects on mothers

The mean breast pain measured on a scale of one to 10 was found to be similar comparing a large electric pump with hand expression (Flaherman 2012, data from a 2010 conference abstract, (MD 0.02, 95% CI -0.67 to 0.71; P = 0.96, participants = 68 Analysis 5.3). In Pessoto 2010, there was no maternal nipple damage reported in the hand-expression group, and one case of nipple damage in each of the manual pump and in the large electric pump groups. Fewtrell 2001b, comparing a different manual and large electric pump, reported similar proportions developed sore nipples (7% both groups) or engorgement (4% manual versus 6% electric) and 2% using the electric pump developed mastitis. Slusher 2007 provided additional data on the reasons mothers gave when they requested to stop using the pump assigned, with four of the seven mothers stating that pumping was uncomfortable. One mother was using an electric pump and three were using the foot pedal powered version of the same pump.

Secondary outcomes

Transfer to feeding at the breast if expressing preceded feeding at the breast

Three studies reported infant breastfeeding at discharge from the neonatal unit and one study reported on milk transfer on the day of hospital discharge, which we took as a surrogate measure for transfer to feeding at the breast. One study found no significant difference between the mothers who pumped and who hand expressed (Boo 2001), (RR (non-event) 1.30, 95% CI 0.63 to 2.67; P = 0.47, participants = 28) (Analysis 1.2); and another study found that mothers who participated in an educational breastfeeding programme were twice as likely to be breastfeeding at discharge (Ahmed 2008), (RR 2.00, 95% CI 1.25 to 3.21; participants = 60) (Analysis 10.1). Burton 2013 reports descriptively that after controlling for potential confounders (birthweight, gestational age and infant age at discharge), the infants of mothers using the small electric pump with 'petal compression' were more likely to be breastfeeding at discharge from the neonatal unit than those using the large electric pump (adjusted odds ratio (OR) 7.52, 95% CI 1.79 to 32.89). One study (Vasan 2004) reported that mothers who were assigned to the hand-expression group had greater milk transfer on the day of hospital discharge compared to mothers in the electric pump group (mean (standard deviation (SD)) 12.6 mL (9.4) versus 9.0 mL (4.6).

Quantity of milk expressed

Techniques

Twenty studies, not all with data for analysis, examined techniques to increase the quantity of milk obtained that were unrelated to a type of pump. The techniques or associated protocols of providing relaxation, music, warmth, massage, initiation of pumping soon after birth if infant is not breastfeeding, increased frequency of pumping and suitable breast shield size, increased the quantity of milk obtained. Support programmes and simultaneous pumping compared to sequential pumping did not show a difference. The variable vacuum pattern with an electric pump indicated a marginal increase in milk quantity with one of the three patterns tested.

Providing a relaxation tape during the second week after birth to mothers with infants in a neonatal unit found a MD of 34.70 mL greater quantity in one from one pumping session than women not provided with the relaxation tape, which is a clinically significant amount (MD 34.70 mL, 95% CI 6.10 to 63.30; P= 0.02, participants = 55) (Analysis 9.1) (Feher 1989).

Providing any of three separate music-listening interventions of approximately 12 minutes duration to use while pumping by mothers of preterm infants (n = 160) obtained significantly more milk than the control group on all 14 days of the study with an increasing difference of quantity (mean over 14 days of study: control 166 mL, any music intervention 317.2 mL, range 297.5 to 449.9 mL) (Analysis 9.1) (Keith 2012).

Exposure to music therapy sessions (flute) before and during pumping sessions over four days for mothers of preterm infants (n = 29) was reported by groups as resulting in a higher mean volume of 7.12 mL (SD 1.57 mL) compared to 6.68 mL (SD 1.37 mL) in the no music group (paired data were not available for this cross-over study so this finding should be interpreted with care) (Jayamala 2015).

Therapeutic touch (TT) is a non-contact treatment where the therapy practitioner assumes a meditative awareness to focus on the energy-field of the recipient (here it is the mother), which can produce relaxation. Mersmann 1993 (n = 18) examined this treatment and reported for intra-participant analyses that "mothers expressed significantly more milk after TT than MTT (mimicTT) (EF = 0.75) or no treatment (EF = 0.85) (P < 0.05)" (EF = effect size).

Massage of the breast with pumping showed a higher quantity obtained over two pumping sessions compared to no massage (MD

4.82 mL, 95% CI 1.25 to 8.39; P = 0.008, participants = 72 (Analysis 11.1) in a cross-over study with paired analysis (Stutte 1988). A higher quantity with massage was also reported (descriptively) by Jones 2001 and by Stellwagen 2010 (data available were insufficient for inclusion in analysis).

Warming the breast compared to a non-warmed breast reported that mothers (n = 39) pumped a MD over all sessions of 11.94 mL with more milk during five of six pumping sessions over three days (MD 11.94mL, 95% CI 7.94 to 15.94; participants = 468; studies = six) (Analysis 12.1) (Yigit 2012). No baseline measurements were reported for the mothers prior to taking part in the trial and thus it is unknown if the intervention of warming the breast significantly increased the production of milk or if the differences found between breasts were independent of the intervention.

Three different breast shield sizes for pumping were examined and reported that mothers (n = 20) removed more milk when they used a breast shield size that was greater than 24 mm (paired data were not available for this cross-over study so this finding should be interpreted with care) (Prime 2010).

Initiation of milk pumping within 60 minutes of birth of a very low birthweight infant obtained higher mean milk quantity at all times measured in the first week than the group who initiated pumping later (mean group total of all milk volume days one to seven, 1374.7 mL versus 608.1 mL, P = 0.05, n = 20 Parker 2012).

A cross-over study (n = 25) descriptively reported that increased frequency of pumping (four or more times per day) was associated with greater milk quantity than infrequent pumping (three or less times a day) (mean 342, SD 229 mL versus 221, SD 141 mL, P greater than 0.02) (De Carvalho 1985).

Two structured support programmes to assist women with milk expression for their very low birth weight infant in a neonatal unit found the milk quantity showed little difference between the groups at various time points (Analysis 10.2) (Heon 2011; Pinelli 2001).

Simultaneous compared to sequential pumping with an electric pump was examined in five studies and did not show difference in milk quantity in two parallel group studies providing data for analysis (Groh-Wargo 1995;; Hill 1999), (Analysis 8.1), or in a cross-over study and paired two-tailed test of differences between the means of unlimited time simultaneous versus unlimited time sequential pumping that was reported as "non-significant" by Auerbach 1990. Two studies did not report on this outcome in a way that their data could be included in the analysis (Jones 2001, Prime 2012, cross-over design without paired data reported).

Two vacuum patterns tested for a large electric pump were reported as not significantly different in total milk output per day (data were not available for analysis) (Meier 2008). The same team also examined the effect of standard compared to experimental breast pump suction pattern for initiation and maintenance of lactation (Meier 2012). Our results show no significant difference across the three comparisons, with wide CIs, although we note that the different patterns are poorly defined in the published material (Analysis 13.1; Analysis 13.2; Analysis 13.3).

Types of pumps or hand expression

Sixteen studies, not all with data for analysis, examined milk volume that involved comparing various types and brands of pump or hand expression and found no pump consistently significantly increased the milk volume obtained.

Manual hand pump versus hand expression

Comparing a manual hand pump and hand expression for the volume of milk on day five after birth showed a large CI and thus may be an inconsistent difference (MD 73.94 mL, 95% CI -64.11 to 211.99; participants = 28) (Pessoto 2010) (Analysis 2.2).

Comparing a manual foot pedal powered version of a large electric pump with double collection set to hand expression found a greater milk volume obtained during a six-day period of pumping in the first two weeks after birth with mothers of infants in a neonatal unit (MD 212.10 mL, 95% CI 9.39 to 414.81; participants = 48) (Slusher 2007) (Analysis 2.2).

Small battery/electric pump versus manual pump or other small battery/electric pump or manual pump

One cross-over study with paired data (Bernabe-Garcia 2012) compared four manual pumps with mothers of infants in a neonatal unit, finding the quantity of milk was lower from the Evenflo pump compared to either the Harmony or Isis with no significant differences in quantity obtained between the other comparisons (additional data from trialist) (Analysis 3.1).

Comparing a small battery/electric pump with a manual pump in a cross-over study with mothers of eight-week old term healthy infants reported "no significant difference" in the total milk quantity from paired results for each mother in single 20-minute test sessions (total mean milk volume small electric pump 144 g (SD 64) versus 146 g (65), n = 58, no data available for analysis) (Fewtrell 2001a).

Comparison of two models of small battery/electric pumps (Medela Swing and Avent Uno) indicated no difference in the mean quantity of milk obtained from one expression (MD 15.00 mL, 95% CI -8.33 to 38.33; P = 0.21, participants = 40) (Francis 2008) (Analysis 4.1). Similarly, two different models of small electric pump (Medela Pump in Style and Playtex Embrace) did not indicate a significant difference in change in 24-hour milk production when compared (MD 62.00 g, 95% CI -46.02 to 170.02; P = 0.26, participants = 59) (Hopkinson 2009) (Analysis 4.2).

Large electric pump versus hand expression

Comparing a large electric pump with hand expression in three studies with mothers of infants in a neonatal unit (Lussier 2015; Pessoto 2010; Slusher 2007), and one study with mothers of healthy newborns (Flaherman 2012) using different measures found inconsistent results (Analysis 5.4).

With mothers of infants in a neonatal unit, a greater mean volume was likely with the pump measured over a six-day total (MD 373.10 mL, 95% CI 161.09 to 585.11; P = 0.0006, participants = 43) (Slusher 2007), however the CI crossed the line of no effect in another study with the volume measured on day five (MD 224.62 mL, 95% CI -59.73 to 508.97; P = 0.12, participants = 25) (Pessoto 2010). Volume of milk days one to day six indicated an overall greater quantity was likely with the pump though the strength of the difference varied over the days with the CI crossing the line of no effect on some days. Selected days: day 1: (MD 13.92 mL, 95% CI -1.72 to 29.56; P = 0.08, participants = 26); day 4: (MD 100.50 mL, 95% CI 18.33 to 182.67; P = 0.02, participants = 26); day 7:(MD 124.90 mL, 95% CI -53.37 to 303.17; P = 0.17, participants = 26) (Analysis 5.4).

With mothers of healthy full-term infants, milk volume for one expression at 12 to 36 hours postpartum indicated little difference in quantity (MD 2.10 cc, 95% CI -0.57 to 4.77; P = 0.12, participants = 68) (Flaherman 2012). A 90% greater quantity was descriptively reported as obtained with the large electric pump compared to hand expression when one breast was pumped in two test sessions during the fourth week of lactation and healthy full-term infants was reported by Garza 1982 (n = 18, no data available for analysis).

Another small study (n = 16) reported greater milk volume obtained by a large electric pump compared to hand expression, however from the published data it appears that milk was only measured at the mother's visits to the neonatal unit and was not a 24-hour volume; no further information was available from the trialist regarding time since delivery when the milk measures were done (Vasan 2004).

Large electric pump versus manual pump or small battery/electric pump

Comparing a large electric pump with a manual pump in three studies with different pumps and measurements and mothers of infants in a neonatal unit (Fewtrell 2001b; Pessoto 2010; Slusher 2007) indicated very wide CIs and no clear difference (Analysis 6.2).

Mean volume measured over a six day total showed a greater quantity was likely with the pump (MD 161.00 mL, 95% CI -66.90 to 388.90; P = 0.017, participants = 53) (Analysis 6.2).

Mean volume per day (MD 5.07 mL, 95% CI -56.59 to 66.73; P = 0.87, participants = 145) (Analysis 6.2).

Volume of milk on day five (MD 150.68, 95% CI -138.02 to 439.38; P = 0.31, participants = 27) (Analysis 6.2).

A cross-over study of mothers of healthy infants with a mean age of 3.2 months reported similar volumes between the pumps though data were nor suitable for inclusion (Boutte 1985).

Two studies compared a large electric pump with one or more small battery/electric pumps with all studies using different brands of pumps and different measures. Francis 2008 found a significantly higher quantity of milk compared to one small electric pump, but not another small pump used once a day on one breast over 60 days (healthy at-home infants), and reporting the overall mean for one expression (MD 20.00 mL, 95% CI 1.28 to 38.72; P = 0.04, participants = 40), (MD 5.00 mL, 95% CI -21.30 to 31.30; P = 0.71, participants = 40) (Analysis 7.1). A different large electric pump, with mothers of preterm infants recruited within 72 hours of birth, did not show an increased quantity of milk compared to a different brand of small electric pump tested (MD -8.00, 95% CI -91.89 to 75.89; P = 0.07, participants = 62) (Burton 2013) (Analysis 7.2).

One cross-over trial with mothers of healthy full-term infants reported that women using the large electric double pump obtained a greater volume in one test session (15 minutes per breast) than when using a manual pump, a battery pump or hand expression (no paired data available) (Zinaman 1992).

Time taken to express milk

Nine studies reported time taken to pump and these reported different measures as well as different pumps, methods of use and techniques or protocols. In all the studies, the time taken related only to actual pumping time and did not report any time used for pump cleaning or assembly. The time taken to pump over a study period may also relate to the frequency of pumping. The frequency of pumping recommended to mothers varied across the studies ranging from three to 12 times a day; however, the recommended frequencies were not achieved by most mothers (Table 4).

Time is measured in connection with mothers seeking to obtain a quantity of milk in the shortest time. Conversely, a more comfortable, supportive environment may encourage women to spend more time pumping more frequently, with the aim of producing more milk.

While some pump types were faster, the variety of pumps tested did not allow a clear conclusion to be drawn about pump types. Findings were also mixed for the volume per time when simultaneous pumping was compared to sequential pumping.

For one expression each morning for 60 days to "empty one breast" (milk flow stopped for one minute) Francis 2008 compared two small electric and one large electric pump and mothers with established milk production pumping at home, finding that one brand of small electric pump (Swing) was faster than the other small electric pump (Uno) MD 4.00 minutes/session, (MD 4.00 minutes, 95% CI 1.19 to 6.81; P = 0.005, participants = 40) (Analysis 4.3)

and both the small electric pumps were slower when compared to the large electric (Whitlestone) pump (UNO) (MD -6.00 minutes, 95% CI -8.81 to -3.19; P = 0.0001, participants = 40) or Swing (MD -2.00 minutes, 95% CI -4.48 to 0.48; P = 0.11, participants = 40) (Analysis 7.3).

Burton 2013 found no difference in the time used each day between the large electric pump (Medela Symphony) and the smaller electric pump (Philips Avent Twin) (MD -7.00 minutes, 95% CI -24.34 to 10.34; P = 0.43, participants = 62) (Analysis 7.3).

Bernabe-Garcia 2012 (n = 28) reported no difference for the mean time for each of the four manual pumps in a cross-over trial reported as between groups, not as paired analysis.

Mothers who used a large electric pump (Ameda) spent approximately 20 minutes less time per day pumping than mothers who used a manual pump (Isis) in another study (MD -20.27 minutes/day, 95% CI -28.30 to -12.24; P = 0.00001, participants = 145) (Analysis 6.3) (Fewtrell 2001b), however, the trialists note that the majority of the mothers using the electric pump were also pumping both breasts simultaneously, which was not possible with the manual pump, and calculated milk output per breast per minute for the whole study, reporting there was no longer a difference noticed in output in the manual pump group compared to exclusively simultaneous pumping with the electric pump (3.1 mL/breast/minute (SD = 2.5) versus 2.4 mL/breast/minute (SD = 1.9), P = 0.2).

Mothers who used simultaneous pumping spent less time pumping than mothers in the sequential pumping group for a similar milk volume produced and a similar number of pumping sessions in one study (MD -3.50 hours/week, 95% CI -5.61 to -1.39; P = 0.001, participants = 32) (Groh-Wargo 1995) (Analysis 8.2).

Auerbach 1990 (n = 26), reporting on the measure of pumping "until the mother no longer observed milk dripping from at least one breast" stated that "during the sequential pumping period, mean pumping time was 10.6 minutes (range seven to 22 minutes), and during simultaneous pumping, mean pumping time was 12 minutes (range five to 22 minutes)". Hill 1999 and Jones 2001 reported only descriptively on the time element, stating that simultaneous pumping took about half the time of sequential pumping and did not report volume per time.

Mothers who received a support programme including an education session, telephone follow-up and a helpline with an International Board Certified Lactation Consultant were likely to spend more time pumping than the group with standard support with the difference increasing in the later weeks of the study. Selected weeks (participants = 33): week 1: (MD 7.70 minutes/day, 95% CI -14.34 to 29.74; P = 0.49); week 3: (MD 23.00 minutes/day, 95% CI -2.14 to 48.14; P = 0.07), week 6: (MD 35.60 minutes/day, 95% CI 7.30 to 63.90) P = 0.01) (Heon 2011) (Analysis 10.4). The time spent pumping increased each week in the additional support group, whereas it decreased in the control group and this time may indicate motivation to continue pumping for their infant in the neonatal unit.

Nutrient quality of milk

Eleven studies reported outcomes related to nutrient content with eight studies providing data for analysis.

Protein

Hand expression or a large electric pump may provide higher protein than a manual pump. Pessoto 2010 found protein was lower in the milk expressed using a manual pump compared to the milk expressed by hand (MD -1.30 g/L, 95% CI -2.56 to -0.04; P = 0.04, participants = 118) (Analysis 2.4); lower with the manual pump compared to using a large electric pump (MD 1.40 g/L, 95% CI 0.08 to 2.72; P = 0.04, participants = 121) (Analysis 6.6), and no difference in protein between in the milk obtained using the large electric pump compared to hand expression, (MD 0.10 g/L, 95% CI -1.20 to 1.40; P = 0.88, participants = 111) (Analysis 5.5). Garza 1982 found no difference in total nitrogen in milk obtained by using a large electric pump compared to hand expression (MD 10.00 mg/dL, 95% CI -3.07 to 23.07; P = 0.13, participants = 36) (Analysis 5.5) and Mangel 2015 in a cross-over study found no difference using a large electric pump compared to hand expression (MD 0.19 g/L, 95% CI -0.92 to 1.30; P = 0.56, participants = 21 women with 42 milk samples) Analysis 5.8 (additional data provided by trialist). Increasing the volume through hand expression combined with pumping ('Hands-on Pumping') was briefly reported in a conference abstract as showing a decrease in milk protein content as the volume increased (r = -0.28, P = 0.004), with no data available from the trialists for analysis (Stellwagen 2010).

Sodium

Many very preterm infants have additional sodium needs and hand-expressed milk may provide more sodium. Pessoto 2010 found there was lower sodium concentration in the milk expressed using a manual pump compared to hand expression (MD -6.00 mmol/L, 95% CI -9.79 to -2.21; P = 0.002, participants = 118) (Analysis 2.4) and lower with the large electric pump compared to hand expression(MD -6.90 mmol/L, 95% CI -10.58 to -3.22; P = 0.0002, participants = 111) (Analysis 5.7); there was no difference in sodium concentration between the electric pump and the manual pump (MD -0.90 mmol/L, 95% CI -3.56 to 1.76; P = 0.51, participants = 121) (Analysis 6.4).

Potassium

Potassium concentration is normally the inverse of sodium concentration, so a lower potassium is beneficial. Pessoto 2010 found that potassium concentration was lower in the milk expressed by hand compared to using the manual pump (MD 1.20 mmol/L, 95% CI 0.04 to 2.36; P = 0.04, participants = 118) (Analysis 2.3) and lower in the milk expressed by hand compared to the

electric pump (MD 1.00 mmol/L, 95% CI -0.17 to 2.17; P = 0.09, participants = 111) (Analysis 5.6); there was no difference in potassium concentration between the large electric pump and the manual pump (MD -0.20 mmol/L, 95% CI -1.36 to 0.96; P = 0.74, participants = 121) (Analysis 6.5).

Energy

There was no significant difference found in energy content (kcal/L) between milk expressed by hand and by two types of pumps. Pessoto 2010 found no difference in energy content (kcal/L) between milk obtained by hand and by using a manual pump (MD 28.80 kcal/L, 95% CI -16.94 to 74.54; P = 0.22, participants = 141) (Analysis 2.3); or using the large electric pump compared to hand expression (MD -11.60 kcal/L, 95% CI -53.73 to 30.53; P = 0.59, participants = 122) (Analysis 5.7), or between the electric pump and the manual pump (MD -40.40 kcal/L, 95% CI -89.92 to 9.12; P = 0.11, participants = 141) (Analysis 6.4). Mangel 2015 in a cross-over study comparing a large electric pump to hand expression also found the CI crossed the line of no difference (MD 45.71 kcal/L, 95% CI -3.39 to 94.81; P = 0.07, participants = 21 women with 42 milk samples) Analysis 5.8 (additional data provided by trialist). Hand expression combined with pumping ('Hands-on Pumping') was briefly reported in a conference abstract as showing no difference in caloric content from the control group not using 'Hands-on Pumping' techniques, with no data available from the trialists for analysis (Stellwagen 2010).

Fat/lipid

Fat content was higher with breast massage when pumping and variable with relaxation methods. Fat content (creamatocrit) was higher with massage of the breast while pumping compared to no massage (MD 1.92%, 95% CI 1.02 to 2.82; P = 0.0001, participants = 72) (Stutte 1988) (Analysis 11.2). A higher fat concentration with massage was also reported (descriptively) by Jones 2001. One study, Keith 2012, which used three relaxation interventions showed a higher fat content for three of the four chosen time points, with an overall mean of 44.8 g/L for the control group compared to 50.9 to 65 g/L of the interventions (Analysis 9.2). No difference was found in the fat content of milk pumped by mothers who were and were not provided with a relaxation tape in another study (MD 0.40%, 95% CI -1.00 to 1.80; P=0.58, participants = 55) (Feher 1989) (Analysis 9.3). Mothers who received an additional support programme showed no difference in lipid levels in their milk compared to the standard care group, day 7: (MD 2.94 g/L, 95% CI -4.43 to 10.31; P = 0.43, participants = 29), day 21: (MD 0.85 g/L, 95% CI -4.15 to 5.85; P = 0.74, participants = 29), day 42: (MD -2.28 g/L, 95% CI -8.01 to 3.45; P = 0.44, participants = 29) (Heon 2011) (Analysis 10.3).
Mangel 2015 in a cross-over study comparing a large electric pump with hand expression found no difference (MD 3.10 g/L, 95% CI -2.22 to 8.41; P = 0.25, participants = 21 women with 42 milk samples) Analysis 5.8 (The published paper reported as groups and showed a difference however the additional data provided by trialists allowed us the calculate paired data). Fat levels were higher at the end of 10 minutes' pumping, and the reported MD for change in fat from beginning to end of pumping for each woman between the standard (Medela Pump In Style) and the novel pump (Playtex Embrace) was 6.72 g/L, SD 21.4 g/L, P = 0.019 (Hopkinson 2009; additional information from trialist, cross-over study).

Carbohydrate

A cross-over study comparing a large electric pump to hand expression found no difference in carbohydrate level (MD 0.05 g/L, 95% CI -0.99 to 1.08; P = 0.93, participants = 21 women with 42 milk samples) Analysis 5.8, Mangel 2015 (additional data provided by trialist). Increasing the volume though Hand Expression combined with pumping ('Hands-on Pumping') was briefly reported in a conference abstract as showing an increase in carbohydrate content as the volume increased (r=+0.38, P = 0.001), with no data available from the trialists for analysis (Stellwagen 2010). Nutritional composition for protein, fat and lactose was reported as similar across four manual pumps in a cross-over study; data were reported as unpaired data and were not entered for analysis (Bernabe-Garcia 2012).

Maternal physiological effect

No consistent effect was found related to prolactin change or effect on oxytocin release with pump type or method.
The mean serum prolactin change was found to be not different for simultaneous versus sequential pumping of milk (MD -3.70, 95% CI -10.62 to 3.22; P = 0.29, participants = 32) (Analysis 8.3) (Groh-Wargo 1995). Prolactin response was descriptively reported to be highest with a large electric pump used simultaneously than with own baby suckling, with hand expression and a manual pump next highest and a battery pump lowest, in a cross-over study (Zinaman 1992). The novel pump was reported to trigger a greater release of prolactin than the standard pump with a median percentage increase in prolactin (%AUC) of 82.8% (29.5% to 122.8%) with the novel pump compared to 16.1% (6.8% to 56.6%) (P = 0.018); cross-over design not reported with pair differences (Hopkinson 2009).
The time to first milk ejection (oxytocin release) between two small electric pumps was similar (MD 7.00 seconds, 95% CI -21.23 to 35.23; P = 0.63, participants = 40) (Analysis 4.4), and no difference was found between a large electric pump (Whittlestone) and either of the smaller pumps -UNO (MD -26.00 seconds, 95% CI -54.49 to 2.49; P = 0.07, participants = 40) or Swing (MD -19.00 seconds, 95% CI -42.86 to 4.86; P = 0.12, participants = 40) (Analysis 7.4) (Francis 2008). No difference in time to first milk

flow was shown between simultaneous versus sequential pumping (Prime 2012) or between variations in breast shield size in two cross-over studies, both reported as group differences and not as pair analysis (Prime 2010).

There was no significant difference in oxytocin rise descriptively reported between two other small electric pumps (Hopkinson 2009), or comparing three types of pumps and hand expression (Zinaman 1992). In a cross-over study, more mothers experienced milk leaking (oxytocin release) with Theraputic Touch (28%) than mimic Theraputic Touch (6%) or no Theraputic Touch (0%), reported by Mersmann 1993.

Salivary cortisol levels were tested in a cross-over trial on the impact of music therapy of mothers of preterm infants expressing with an electric pump, with samples taken before and after the music sessions on two trial days. Data were reported at group level, rather than paired analysis and therefore not included in this analysis, and reported that mothers exposed to the music therapy had a reduction in salivary cortisol level of 3.31 nmol/L (SD 4.35 nmol/L) compared to the no music group which had a reduction of 2.99 nmol/L (4.04) P = 0.001, n = 29 (Jayamala 2015).

Economic outcomes

No study reported data on economic outcomes in a useable way for analysis in this review. In the study of Pinelli 2001 mothers acquired their own pumps, and trialist reported that the cost of pump (Can$ 2001) for the structured breastfeeding counselling program group (SSBC) was a mean $16 SD 8, range $2-50, and for the conventional hospital-based breastfeeding support (CHBS) $20(13) [6-57] and that "About half of the mothers in the SSBC and CHBS groups (47% vs 53% respectively) reported that the cost of the pump was "somewhat" of a burden, compared with an "extreme" burden (20% in both groups), or "not al all) (33% vs 27%, respectively). The high cost of pumps was reported as a barrier also in Bernabe-Garcia 2012 who stated "A low-income mother fully dependent on artificial methods to express her milk would then have to spend 40% of her income to rent an electrical pump; instead she may buy a manual breast pump for longer use".

DISCUSSION

Milk expression occurs for a wide variety of reasons in a variety of settings and using a variety of measures, methods, techniques and equipment and thus a variety of outcomes is not unexpected. A mother initiating her milk production and then maintaining her supply and pumping eight times a day for her very preterm infant who is likely to be in a neonatal unit for three months has very different needs related to milk expression than a mother of a full-term healthy baby who feeds well at the breast and the mother expressing milk a few times a week. Consistent, clinically relevant differences in outcomes for milk expression were positively related to techniques such as initiation of pumping soon after birth if the infant is not breastfeeding, increased frequency of pumping, warming of breast, massage of breast and various methods to encourage relaxation. These techniques are likely to be relevant and useful to mothers expressing in any situation. There were no clear differences for outcomes from comparisons of pumps.

Summary of main results

Maternal satisfaction with milk expression was reported in 17 out of the 41 included studies and among these, only one study provided any data suitable for analysis in RevMan, and it favoured hand expression. The descriptive findings reported did not suggest any clear consistent effect related to maternal satisfaction.

There were insufficient studies to show results for infant morbidity related to mother's method of milk expression. There was no difference in the incidence of milk contamination or normal milk bacterial flora found between hand expression and mother's own choice of any manual pump or between hand expression, a manual pump and an electric pump. Adverse effects related to the mothers such as nipple or breast pain were reported in three studies and showed no difference between methods, though in all these studies the actual numbers reporting adverse effects were small.

It was not possible to answer the question of whether a method of expression was related to the likelihood of the infant in a neonatal unit transferring to breastfeeding at an earlier or later time. Some mothers may provide milk for their preterm infant but not wish to put their baby to the breast at any time, or the condition of the infant may make feeding fully at the breast unlikely. Though the WHO recommendation is to exclusively breastfeed for the first six months, this may not be what mothers intend to do even if adequate support is available. Any study examining this outcome measure would need to be specifically designed to do so and take into account maternal intentions.

The findings reported in earlier versions of this review were further strengthened in this update that an increased quantity of milk was obtained with methods to encourage relaxation, Therapeutic Touch and listening to music are used. Three studies with different measurements showed a difference of 34.7 mL in one pumping session to a difference of 151.2 mL over 14 days, which are clinically significant differences. Music therapy was also associated with measurable reduced stress levels and it may be that any form of relaxation aids the volume of milk obtained.

Higher volumes of milk were found in studies that involved massage of the breast before or with pumping, warming the breast before pumping, using appropriate breast shield sizes, initiation of pumping for a very low birthweight infant within one hour of birth rather than later, increased frequency of pumping (four or more times per day versus three or less times a day). Simultaneous compared to sequential pumping with an electric pump was examined in five studies and did not show differences in milk quantity, nor did two structured support programmes to assist women with

milk expression for their very low birth weight infant in a neonatal unit. The vacuum patterns tested for a large electric pump may show a difference though the pattern of differences was unclear in the published material.

Sixteen studies, not all with data for analysis, examined milk volume that involved comparing various types and brands of pump or hand expression and found no pump consistently significantly increased the milk volume obtained. The studies tended to use different measures, set a maximum pumping time, measured output from one breast or two, and few compared the same pumps, which limited drawing conclusions. The time period over which expression or pumping occurs should be noted when comparing findings as the included studies measured from a single expression from one breast to 60 days (Table 3). Slusher 2007 reports a significant mean difference in total volume during a six-day period during the first two weeks after birth of 161 mL, 212 mL and 373 mL depending on the method. If these amounts were divided by six days and by the number of feeds per day, the differences between methods might not be clinically significant. Similarly, the difference of 2.10 cc reported by Flaherman 2012, whereas the 35 mL higher volume in a single expression when using a relaxation tape, if repeated in each expression, might be more clinically significant (Feher 1989), as would be the up to 500 mL higher amount on day 14 found with relaxation techniques (Keith 2012).

In four studies that used the same brand and model of a large electric pump (Medela Lactina) with double collection set compared to hand expression the results were inconsistent and with small sample sizes (n = 25 to 68). Though the total mean volume over six days within a two-week period was highest with an electric pump; on day one the mean volume was highest with hand expression (Slusher 2007). The volume of milk on day one to day six indicated an overall greater quantity was likely with the pump (Lussier 2015) and in Pessoto 2010 measured on day five, although in both, the strength of the difference varied over the days with the confidence intervals crossing the line of no effect on some days. Milk volume for one expression at 12 to 36 hours postpartum indicated little difference in quantity (Flaherman 2012).

Trials of small electric or manual pumps compared to each other or to large electric pumps or hand expression used different brands of pumps and different measures, and overall showed no difference, inconsistent or non-comparable results. Of particular note is that there was no evidence found in the trials available that expensive large electric pumps show a consistent increased quantity of milk obtained compared to small electric or manual pumps despite a widespread perception that large electric pumps are better than other methods.

Lack of clear results may relate to the wide individual variation between participants and the most effective method differs depending on the days since birth or across the stage of expression. Pessoto 2010 reported on day five after birth a range of nought to 1405 mL (mean 149 to 373), depending on method; Slusher 2007 reported on day five (third day of pumping) a range from nought to 1095 mL (mean 190 to 368), depending on method.

Time taken to obtain milk was reported in some studies as an indicator of the effectiveness of the pump. One study of two small electric pumps and a large electric pump found a significant mean difference of two to six minutes per session between the pumps (Francis 2008), which could accumulate to 12 to 36 minutes for a mother pumping six times per day, with another trial finding sequential pumping took 3.5 hours per week less than simultaneous pumping for the same volume of milk (Groh-Wargo 1995), which is approximately 30 minutes per day difference, and may influence some mothers in their choice of pump. Two other studies comparing two pumps (Burton 2013) and four pumps (Bernabe-Garcia 2012) found no significant time difference (none of the pumps were the same brand). Most studies instructed mothers to continue pumping until the milk flow slowed or ceased, however, a maximum duration was set in some studies, whereas other studies only reported the amount obtained at time points (Table 3). The frequency of pumping or expressing recommended in the included studies ranged from a minimum of three times per day to 12 times per day. However, the recommendation made may not have been the frequency achieved, which (where reported) ranged from approximate means of less than three to more than six expressions per day (Table 4). Time spent pumping may also indicate the motivation to continue pumping for the infant in the neonatal unit, and the time spent increased each week in the additional support group, whereas it decreased in the control group over the six weeks of the study.

Many mothers and clinicians are focused on milk volumes though there is some indication that "feeding the freezer" may affect the milk constituents as well as the mother's time and own body reserves. Hand expression or a large electric pump may provide higher protein than a manual pump. Increasing the volume though hand expression combined with pumping ('Hands-on Pumping') was briefly reported in a conference abstract as showing a significant decrease in milk protein content as the volume increased, which could have clinical implications if further evidence supports this finding (Stellwagen 2010). Hyponatremia can be a concern in preterm infants receiving human milk, and findings from one study indicate a 19.35% to 22.65% (P = 0.002) higher sodium content in hand-expressed milk compared to manual or electric pump use (Pessoto 2010), a similar finding to a previous cross-over trial (Lang 1994). Differences were also found in the potassium content, which was lower in hand-expressed milk reflecting the higher sodium level (Pessoto 2010).

Fat content was higher with breast massage when pumping, the difference was found to be variable with the relaxation methods trials, and mothers who received an additional support programme showed no difference in lipid levels in their milk compared to the standard care group. In relation to pumps tested, fat levels were found to be higher at the end of 10 minutes' pumping in one of the two small electric pumps compared but no difference in another study comparing a large electric pump with hand expression.

There was no significant difference found in energy content (kcal/L) between milk obtained by four methods and no difference in carbohydrate level comparing a large electric pump versus hand expression.

The mean serum prolactin change was found to be no different for simultaneous versus sequential pumping of milk in one study and data were not available for analysis related to prolactin response in two other studies, or effect on oxytocin release with pump type or method.

No significant difference was found in oxytocin response between pumps tested in three studies or in two cross-over studies between simultaneous and sequential pumping or between variations in breast shield size with both reported as group differences and not as pair analysis. In a cross-over study, more mothers experienced milk leaking (oxytocin release) with Theraputic Touch.

No study reported data on economic outcomes in a way that could be analysed in this review.

Breastfeeding and the provision of human milk for human babies is a biologically normal activity and thus is different from many activities investigated by randomised controlled trials (RCTs). In trials comparing interventions, it is important to include, or at least refer to, the outcomes in the normal situation so as to avoid comparing only one abnormal situation with another abnormal situation, and implying that milk expression or pumping is normal and synonymous with breastfeeding.

Overall completeness and applicability of evidence

We attempted to be as inclusive as possible in the search strategy and have included studies reported in languages other than English where translations could be obtained. Researchers known or likely to have studies related to milk expression were contacted by email as well as through their professional organisations and social media. Pump manufacturers were contacted seeking trials on their equipment, though none notified us of any trials.

Interpreting the findings of the studies included in the review was complex. The included studies were published between 1982 and 2015 and equipment, practices and attitudes change over time. It must be noted that within the categories of pump type, such as manual or electric, not all the pumps were the same brand or worked in a similar way. A different pump, though within the same category, might have different outcomes, or the same brand may have changed over the years. The procedure in which the method was used may have varied between studies as there were inconsistent results for the one analysis in which the same make of pump was used in three different settings. Three studies included breast massage or hand expression with pumping as a stated aspect of their trial, whereas another taught all mothers to massage their breasts as a routine part of milk expression, independent of which pump or hand-expression group to which they were allocated. Measures used in trials varied greatly which limited comparisons. The small sample sizes (n = 9 to 280) and very wide standard deviations mean the findings may not be applicable to other women or other settings. The majority of the participants were mothers of infants in neonatal units (n = 1547 women, 26 trials) plus healthy infants at home (n = 730 women, 14 trials) and a mix (n = 16, one trial). Some findings such as sodium levels are particularly relevant to preterm infants, though may be of limited relevance to mothers of healthy full-term infants. Findings related to expensive large electric pumps may be of limited use in a resource-poor setting, whereas the techniques of massage, relaxation, timing, and warmth are all low-resource, low-technology interventions that should generally be available worldwide, though training is required for the specific technique of Therapeutic Touch. Not all results have clinical significance though may be very relevant to a researcher or an equipment manufacturer. Each situation needs to consider this review with regard to its specific situation.

Some studies reported on duration of breastfeeding related to the method used. Duration was not an outcome included in this review as there are many variables. Mothers may have different reasons for expressing or pumping milk, including expressing a small amount to assist the baby to attach to the breast, expressing if overfull and uncomfortable, short separations from a baby otherwise feeding at the breast or expressing larger quantities of milk long term for a baby who cannot feed at the breast. None of the studies addressed whether the mother's own needs for milk expression were met.

Quality of the evidence

This review now includes 41 trials involving 2293 women that took place in 14 countries under a variety of circumstances and published from 1982 to 2015. Twenty-five studies were parallel design and 16 studies were cross-over designs or include an aspect of the trial with a cross-over design. Twenty-two of the studies involving 1339 women provided data that could be analysed in RevMan 2014 contributing to both of the primary outcomes and five of the six secondary outcomes. We were unable to pool findings from studies for most review outcomes due to heterogeneity in interventions, comparison groups, and outcomes measured or reported (in particular reporting outcomes at widely varying time points). For this reason, most of the results were derived from single studies with findings that have not been replicated elsewhere. We have therefore not produced a 'Summary of findings' table for this update. This will be re-examined in future updates.

The methodological quality of the included studies was mixed. We assessed each of the included studies for the risk of bias and the quality of the evidence. Overall, the main concerns noted were the lack of information concerning the blinding of the assessors (objectivity in the management and assessment of the data), how incomplete data were addressed (biasing the measure of effectiveness) and if the studies were free of other potential biases. It would not be possible to blind participants and personnel for most of the interventions as these involved comparing hand expression to

a pump, or comparing two or more different types of pumps, or techniques such as breast massage.

Examining methods of milk expression has many challenges, and some could be addressed through greater attention to study design details. Where cross-over designs were used, results were not always reported as paired data that would take into account individual variations, or examining the order of use of each method, which limited the conclusions that could be drawn from the results.

Unintentional additions or omissions to the care of the participants may have effects on the outcomes, such as providing a bra to assist hands-free pumping to some of the participants in one trial, or fewer staff available to carry out the intervention than needed.

In the absence of a validated tool for the assessment of maternal satisfaction, various authors have devised their own rather disparate methods of assessment. Times at which milk volumes and constituents were measured varied greatly. The lack of consistency in the way outcome data were measured and reported should be kept in mind when interpreting results.

Many trialists were willing to discuss their work and provide clarification or further data, however some gaps remained.

Potential biases in the review process

We acknowledge that there was the potential for bias at all stages in the reviewing process. In order to reduce publication and language bias, we made requests widely through lactation networks and through equipment manufacturers, seeking any additional studies to those found by literature searching that yielded some contacts with researchers and additional studies. We obtained translations of possible studies; however, the non-English language work may be under-represented though requests were made to all world regions. The amount of research related to milk expression appears to have increased in recent years, with hand expression being included more as well as research on techniques. Additional data were willingly provided and discussed by some trialists; we were unable to find some trialists; and some trialists did not reply to queries, which resulted in some data not being used as they were not available in a format suitable for analysis. Three authors from differing areas of expertise worked on all aspects of this review which encouraged discussion, a broader viewpoint and provided a step towards minimising bias.

Agreements and disagreements with other studies or reviews

There are few (if any) other systematic reviews of methods of milk expression. Published descriptive reviews may favour healthcare systems and practices where large electric pumps are widely available and considered the norm. This affects the choice of research outcomes where high volume in the shortest time is considered the ideal outcome with some of the research funded by manufacturers to develop or test their equipment. Our analysis of the data from one included study (Boo 2001) differed markedly from the conclusions of the trialists; however, their conclusion has been frequently referred to in other material stating that milk expressed by pump was at higher likelihood of contamination, for which we found no evidence in two studies reviewed. The differences in sodium level found in the included data of Pessoto 2010 was also found in the cross-over study with mothers of preterm infants by Lang 1994 who discusses the possible underlying physical and physiological differences between extraction by compression and by suction as well as mammary cell permeability at various stages of lactation.

Evidence examined in this update does not substantially change the conclusions of the original 2008 version of this review or the 2011 and 2015 updates, though this update provides some additional conclusions related to the positive effect of basic techniques such as relaxation.

AUTHORS' CONCLUSIONS

Implications for practice

A baby feeding at the breast is the biological norm. Expression of milk is a complex intervention of a very individual nature. Results from individual trials may not be generalisable to other cultures and situations. The results of this updated review suggest that the most suitable method of milk expression may depend on the time since birth, the purpose of expression and the individual mother. Hand expression may be more suitable in the first few days to initiate milk supply, and particularly where the constituents of the milk may be important. A large electric pump may be useful if quantity is the main goal, though pumping may have a higher risk of injury for the mother than hand expression. Findings of our review indicate there are low-cost techniques available to all mothers that may increase milk volume obtained. If a large electric pump is too costly, manual pumps may be as effective as regards volume obtained once milk supply is established. Hand expression or breast massage combined with pumping may be beneficial. The finding of significantly higher sodium content in hand-expressed milk indicates a need to take into account the method of obtaining milk when determining if there is a need for sodium supplementation of the preterm infant. Sodium concentration relates to milk volume, and aiming for high volumes with mechanical pumping may result in lower quality of some nutrients.

Results of this review highlight the importance of considering more than the method or the type of pump in isolation, and looking further to include initiation of expressing soon after birth if the infant is not able to breastfeed and assisting mothers to gain knowledge and skills to express their milk. Practitioners should consider using some means to help women consciously relax to increase the volume of milk obtained when pumping, as four studies

showed a significant increase. From the information available in the included studies, important aspects that positively influenced mothers' satisfaction in their use of pumps included ease of assembly, ease of use and comfort. An understanding of individuals' preferences regarding activities during pump usage is required when choosing between simultaneous versus sequential breast pumping, as is the mother's subjective views on these techniques. We found no evidence that a particular type of pump was associated with a higher level of milk contamination, infant sepsis or transfer to feeding at the breast. Methodological shortcomings of some trials, especially small sample sizes and very large standard deviations, the small number of studies reviewed for each outcome, and the diversity in the nature, duration and frequency of the interventions argue caution in applying these results beyond the specific equipment tested in the specific settings. Publications on methods and types of pumps should not be taken to mean that pumping milk is a normal part of breastfeeding; it is an intervention that should be justified before being recommended to an individual mother by a practitioner.

Implications for research

Findings from this review suggest that future research comparing methods of milk expression and pumping examine the reasons why women express milk and the contexts in which they do so, as well as the techniques, regimens and equipment used, which may require different study designs.

Common measurement points such as days two, seven, day 21, and day 42 would aid in comparisons of outcomes, as would as would consideration of co-interventions such as staff knowledge and support, staffing levels and maternal education, as well as mother's access to her baby, rest, food and fluids. Trials should include economic analyses of the relative costs and benefits of a milk expression method. It would be enlightening to include information on the life cycle environment cost of equipment related to different methods of milk expression and pumping.

Well-designed and well-reported studies are needed. Cross-over studies have the potential to examine how an individual mother responds to two or more methods of milk expression. Much of the data from of the cross-over studies could not be used in the analysis as they were not reported as between-mother difference or pair analysis, thus negating the value in using a cross-over design. This problem occurred both in small studies carried out by an individual in their own setting and in funded studies carried out by researchers in academic units.

Sixteen of the 30 studies that evaluated pumps or products reported support from the manufacturers. Independently funded research is needed, particularly to include methods such as hand expression and relaxation that do not have a commercial potential. There is a lack of data relating to how various methods and techniques of milk expression or pumping assist mothers to meet their own goals for milk expression, rather than goals set by the researchers. Research on mothers' views of effective methods is needed.

Some other apparent gaps in the research evidence are investigating back massage as a means of relaxation and stimulating oxytocin release and the "hot jar" technique of milk expression, as these method are widely suggested in health worker training materials particularly in lower-income countries; drinking a warm beverage, eating, watching TV (and if humorous or distressing programmes) or other activities while expressing or pumping, which all have the potential to affect maternal physiological responses. It was surprising that no research was found on the constituents of milk related to their immunological effects in relation to methods of expression.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Ahmed 2008

Methods	RCT with a convenience sample comparing 5 sessions of a breastfeeding educational programme for mothers of preterm infants verses routine care
Participants	Convenience sample of 60 mothers, who could read Arabic, to preterm (< 37 weeks' gestation) infants who were able and willing to breastfeed in Cairo, Egypt Mothers with medical problems or mothers of infants who had a serious illness that would affect breastfeeding were excluded from the study
Interventions	Educational intervention programme to improve mothers' knowledge of breastfeeding their preterm infants and to improve breastfeeding practices. Follow-up was for 3 months
Outcomes	Reported on when mothers started milk expression and their use of effective practices, which are included as an outcome measure of maternal satisfaction of achieving milk expression, and transfer to feeding at breast (breastfeeding on discharge)
Notes	There is no information available on funding for the study.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information is given. Author has stated that a simple randomisation method was used
Allocation concealment (selection bias)	Unclear risk	No information is given. Author has stated that a simple randomisation method was used
Incomplete outcome data (attrition bias) All outcomes	Low risk	In correspondence with the author it is stated there were no incomplete data
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	Study was not powered to detect a significant differences between groups (convenience sampling) Contamination could have occurred between the intervention and control groups, although the author states that this may only have happened with a small number of participants It is not clear from the published article if

Ahmed 2008 (*Continued*)

		all intervention group received the 5 education sessions and not less or more sessions Selection bias appears to have occurred in assigning participants to the intervention and control groups, as the intervention group had twice as many multiparas (60%) compared to the control group (30%)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information given. Given the nature of the intervention blinding of the mothers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information is given.

Auerbach 1990

Methods	RCT with cross-over took place at a range of 5 to 35 weeks' postnatal comparing 4 different regimens using an EP. Used a structured interview to obtain mother's views on which pumping method they preferred
Participants	26 breastfeeding mothers of healthy infants 5-35 weeks in age, already using a pump or planning to use a pump in the future. Data reported for 25 mothers. USA
Interventions	Compared 4 regimens: 5-minute sequential pumping (the breast pumped first assigned by random number table); 5-minute simultaneous pumping; unlimited time sequential pumping (first breast randomly assigned); or unlimited time simultaneous pumping. All mothers used the same type EP. Pumped at researcher's office, each regimen on a different day. No information on time between regimens other than that they were on different days
Outcomes	At each breast at each session: milk volume, time, milk fat concentration (creamatocrit) ; overall mother's views on pumping regimens
Notes	Insufficient data available in published article. Author contacted and provided some information; additional numerical data not available due to length of time since study. Pump and collection kits were provided by Medela, Inc

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number table.
Allocation concealment (selection bias)	Low risk	Pumping sequences printed on cards, random number assigned a card to a mother

Auerbach 1990 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Explanation given for any missing data.
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	High risk	1 researcher designed and conducted the study and analysed the data

Bernabe-Garcia 2012

Methods	"randomised cross-over trial was conducted from November 2004 to June 2005." For each mother over a 4-day test period
Participants	"Inclusion criteria were as follows: 1) healthy breastfeeding women, 2) 18 years or older, 3) delivered a singleton preterm infant (gestational age at birth <37 weeks with attending physician's indication that the infant would be unable to breastfeed for at least 1 week due to critical illness), 4) more than14 days postpartum, 5) intention to continue breastfeeding, 6) using only hand expression to obtain their milk (as was the policy for hospitals affiliated with the IMSS at time of the study), and 7) willingness to be at the hospital for 4 consecutive days for 5 hour/day." A total of 116 preterm infants were admitted to the SCN during the 8-month study period. Of these candidates, 35 mothers (30%) were lactating during recruitment. Of those, 32 women agreed to participate. They were at 21.2 + 1.4 postpartum days and all were using hand expression of their milk prior to the study Mexico City.
Interventions	"Aim to compare four models of manual breast pumps (MBP) in regard to volume and nutritional composition of preterm milk, breast emptying, duration of expression, and negative pressure of the MBP, as well as maternal preference." Those mothers who agreed to participate were randomly assigned to 1 of 4 pump sequences, using Avent Isis and Medela Harmony (with squeeze handle mechanism), and Medela Little Heart/Caricia, and Evenflo - with cylinder-type mechanism "Each sterilized pump was tested for a 24-hour period that included a 5-hour period under hospital observation, conducting milk expression at 8:00 AM, 10:00 AM, and 12:00 noon. A MBP was then provided on loan to be used on the same day at home, where milk expression was conducted at least 3 additional times at 3-hour intervals to reach a minimum of 6 expressions per day, following the same procedures as used in the hospital. In order for each mother to use the four pumps, they participated for 4 consecutive days." At the end of the 4-day period, mothers were asked to complete a questionnaire to

	evaluate maternal MBP preference "to determine presence of hind milk…Electric pump (Lactina) was used after the first three expressions with each MBP per mother at the hospital setting."
Outcomes	"Milk volume was measured after both breasts were emptied with a MBP. Milk expression stopped when cessation of milk drops was reached. Extracted milk from right and left breasts was combined for total volume and labelled with date and hour at every expression….; home expressions were brought to the hospital the next morning. The sum of the milk volume expressed at the hospital and at home was considered as volume per 24 hours from each MBP." For each pump, "Nutritional composition was determined only in a sub-sample from mixed milk from both breasts collected at 12:00 noon by research personnel". Protein, lipids, and lactose, energy content "Breast emptying." "Duration of expression was determined as the pumping session measured in minutes, starting from the first drop of milk until cessation of milk drops from both breasts in the 3 pumping sessions at the hospital. The average from this was then considered as duration per mother per MBP." The data for this cross-over study were not available in paired format for inclusion in the analysis Maternal preference questionnaire (scale 1-7) (Fewtrell).
Notes	"Medela breast pumps were donated but without monetary donations and without establishing any compromise with the manufacturer. Evenflo and Isis breast pumps were purchased by a grant." "This investigation was supported by a financial grant from Fondo para el Fomento de la Investigación (FOFOI), IMSS, Mexico (No. IMSS-2004/006 to MBG)." "The authors declare that there is no contractual or commercial relationship with any manufacturers of the breast pumps studied." Published paper reported outcomes by group. Extensive additional data were provided by trialist on paired results for volume

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Not stated.
Allocation concealment (selection bias)	Low risk	"Assignment of the sequence was established prior to recruitment using sealed opaque envelopes consecutively numbered by one of the researchers who did not participate in the recruitment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	4 mothers did not complete the study protocol because their children were transferred to another hospital. 1 mother did not perform the evaluation with Harmony due to failure to arrive for the appointment on

Bernabe-Garcia 2012 (*Continued*)

		the third day. This was considered as missing data in the analyses
Selective reporting (reporting bias)	Low risk	None apparent.
Other bias	High risk	Pumps tested as 3 and 4 showed higher milk yield than pumps used 1 and 2 - as more milk was removed more was produced. Too short a "wash-out" period to allow an effect to recede before the next pump was tested is possible Authors state: "Power analysis was at least 80% for all outcomes" but authors do not give any information on how their group sizes of 27 and 28 achieved a power of at least 80% for nine outcomes (quantitative and qualitative) measured using 4 pumps
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unfeasible due to nature of intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated.

Boo 2001

Methods	RCT comparing hand expression with use of a hand-held pump.
Participants	N = 28 participants. Control (hand expression) = 13, intervention (pump) = 15. Mothers of infants in NICU < 1501 g birthweight who were expressing at home or hospital and able to provide at least 2 milk samples of 5 mL. Mothers assigned to use breast pump group required to purchase their own hand-held pump that was capable of being disinfected with boiling water. Malaysia
Interventions	Control group taught hand-expression techniques. Intervention group taught techniques of using a hand-held pump (mother purchased hand-held pump of her choice). Written instruction provided in 3 languages and re-education provided as needed. Prior to each expression, hands were washed with soap and water and breasts with water and dried on a clean towel. Mothers who were at home stored their milk in home refrigerator and transported it to NICU in portable cooler within 24 hours of collection
Outcomes	Contamination of milk samples, infant illness (sepsis, NEC), infant death, breastfeeding on discharge
Notes	No loss of participants reported; however, 1 participant missing from the pump group in the table reporting comparison of mothers with at least 1 sample contaminated.

Boo 2001 (*Continued*)

	Additional information provided by author that infants may not have received the milk that their mother expressed. Planned to recruit 42 mothers to each group in order to detect a 30% difference in rates of bacterial contamination, however, study stopped early due to high levels of contamination and infant illness. Project was funded by a grant from the Faculty of Medicine, Universiti Kebangsaan Malaysia

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficent information in published article to make a judgement
Allocation concealment (selection bias)	Low risk	Consecutively numbered sealed envelopes. Participants randomised by the opening of a prepared envelope to 1 of 6 groups stratified for parity and gestational age
Incomplete outcome data (attrition bias) All outcomes	High risk	Data missing from report.
Selective reporting (reporting bias)	High risk	Findings not reported in allocated groups, infant outcomes reported in relation to mother's method of expression though infants may not have received the milk
Other bias	High risk	Trial stopped early. More samples were included for mothers whose previous sample was contaminated. Reported analysis is by randomised groups for some items and by results of milk sampling for other items. No sample size calculation described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information on blinding of outcome assessors.

Boutte 1985

Methods	Randomised controlled cross-over trial comparing a large EP to a MP
Participants	9 breastfeeding mothers of healthy, middle class infants, mean age 3.2 months. South-west USA
Interventions	Milk samples collected by large EP (Egnell) and by MP (Medela piston) used at home. During each 24-hour period, milk pumped from a single breast was weighed at each nursing by mother and breast to be pumped alternated at each nursing. Breastfeeding continued as normal. Pumps used approximately 1 week apart
Outcomes	Volume of milk mL/day, fat g/day, energy kcal/day, and asked mothers to rate the following: pump assembly, operation, dismantling, cleaning, physical discomfort, pain or anxiety during use and pump usage
Notes	Insufficient data available in published article. Not able to make contact with author. No funding source was declared. No loss of participants was reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"statistician prepared envelopes containing group assignment". Not able to make contact with author for further information
Allocation concealment (selection bias)	Low risk	Sequentially numbered envelopes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No loss of participants reported. Not able to make contact with author for further information
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	No sample size calculation described. Not able to make contact with author for further information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessor reported as blinded.

Burton 2013

Methods	RCT comparing 2 different EPs.
Participants	71 mothers of preterm infants in neonatal unit. Pump A = 36, Pump S = 35. "Mothers were eligible if they delivered their infant(s) < 34 weeks' gestational age (including twin and singleton deliveries) and planned to express breast milk. Infant(s) were younger than 72 hours old at randomisation and were expected to stay in the NICU for at least 10 days; mothers who delivered at other hospitals but were transferred to a study unit were eligible if recruited by 72 hours postpartum." UK.
Interventions	Compare: "The Medela Symphony pump (pump S; Medela AG, Baar, Switzerland) has an initial "let-down" mode with rapid low suction (120/minute, vacuum -50 to -200 mmHg), followed by "expression mode" (45-78/minute, vacuum -50 to -250 mmHg) with slower rate and deeper suction. The duration of the letdown mode can be altered by the mother and the vacuum strength altered at any time. The Philips AVENT Twin electronic breast pump (pump A; Philips Consumer Lifestyle, Amsterdam, The Netherlands) incorporates a petal massage cushion in the breast shield, designed to massage the areola and surrounding breast during pumping, in an electronic pump that offers flexibility of rate and suction (vacuum range, 0 to -250 mmHg), with the rate/suction strength control button positioned on the breast shield to allow greater ease of control." "Following randomization, mothers were given verbal and written information (Appendix 1 and 2, available online) and help with expressing breast milk by the staff of the NICU or postnatal ward with additional help from the research nurses, who had specific experience in advising on breastfeeding in the NICU setting and who also provided specific instruction on the optimal use of the assigned breast pump. At 1 hospital, manual expression was used during the first 48 hours before introducing a breast pump, while at the other site, mothers started using a breast pump immediately after delivery. Pump S was the standard pump in both NICUs and was therefore used prior to study entry. Breast pumps were located in a designated room in the NICUs but pumps could also be used at the infant's bedside and were available for home use if a mother was discharged home. After the initial 10-day study period, mothers were encouraged to continue expressing milk using their allocated pump until their infant was discharged." Mothers recorded volume, time, etc, in a diary. On day 10, mothers completed a maternal perception questionnaire using expanded Fewtrell scale to include "flexibility regarding the rate and amount of suction, location of control button, (and) speed of milk flow" "Between days 3 and 10 (ideally days 5-7) postpartum, each mother was asked to express milk for a single fixed 15-minute period using her assigned breast pump…. to determine the total weight of milk, the time to the first appearance of milk, and the time taken to produce specific milk weights."
Outcomes	"Primary outcome measures were total weight of milk expressed during the initial study period (to day 10); total weight of milk expressed in a single fixed 15-minute pumping session between 3 and 10 days (physiological test); and the time to first appearance of milk and time taken to express a fixed weight of milk (20 g, 40 g, 60 g) during this test Secondary outcome measures were total number of pumping sessions and total time spent expressing milk in the study period; mother's opinion of the assigned pump; total volume of maternal breast milk expressed and consumed by the infant while in the NICU; number of days taken for the infant to achieve full enteral feeds (150 mL/kg/day); and whether or not the mother was breastfeeding her infant(s) at discharge."

Notes	Flow chart of participants through the study in published paper Intended that 176 participants, however only reached 71 (36 + 35) "The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was supported by a grant from Philips AVENT (Philips Consumer Lifestyle, Amsterdam, The Netherlands), who also provided the breast pumps, and sponsored by the UCL Institute of Child Health. The funders and sponsors were not involved in conducting the study or analysing or interpreting the data." Contact was made with co-author Fewtrell and additional information provided. Previously reviewed as conference poster

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	" mothers were randomized to use 1 of the study pumps for a 10-day study period; randomization was stratified by the infant's gestation (≤ 28 weeks, and 29-33 weeks) and by parity."
Allocation concealment (selection bias)	Low risk	"Randomization schedules (permuted blocks of randomized length) were prepared by a member of the study team who was not involved in practical aspects of the study, and assignments were held in sealed opaque envelopes."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"The number of subjects with complete 10-day milk diary data was 33 (92%) vs 29 (83%) for pump A and pump S, respectively, with discharge data available for 30 (83%) vs 25 (74%) subjects."
Selective reporting (reporting bias)	Low risk	No indication of selective reporting. All outcomes in trial registration are reported in published paper
Other bias	Unclear risk	"The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: The study was funded by Philips AVENT. Dr Burton, Dr Fewtrell, and Professor Lucas have also received an unrestricted research grant from Philips AVENT." Sample size of study was determined using power calculation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible

Burton 2013 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information.

Costa 1989

Methods	Quasi-randomised trial using infant ID number.
Participants	65 mothers of preterm infants in neonatal unit who intended to provide breast milk for tube feeding, able to read and write English. C = 34, I = 31. Mid-USA
Interventions	Control group were instructed verbally and in writing to shower daily using mild soap, to wash their hands with Phisoderm soap (provided) immediately before pumping intervention, and not to use special preparations on their breasts. Intervention group had the same instructions plus to clean their breasts from the nipple outwards in a circular pattern with a cloth dampened with water and Phisoderm soap, then to rinse with a clean cloth. Both groups were given sterile milk collection equipment and had pump use demonstrated
Outcomes	Bacterial colony counts in a 1-time 15 cc sample of milk. Excessive colony counts were reported as containing > 50,000 CFU/mL
Notes	Insufficient data were available in the published article. Not able to make contact with author. No loss of participants reported. Incomplete data reported for 1 participant. Support was provided by grants from the American Nurses Foundation and Wintrop-Breon Laboratories makers of the anti-bacterial soap

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Assigned by odd or even infant ID number.
Allocation concealment (selection bias)	High risk	Assigned by odd or even infant ID number.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss of participants reported. Incomplete data reported for 1 participant
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible

Costa 1989 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information available.

De Carvalho 1985

Methods	Cross-over trial in first 28 days after birth to examine relationship of milk production to frequency of milk expression. Study started postnatal day 5. Both arms lasted 1 week, each consecutively. There was no follow-up
Participants	25 healthy mothers of premature non-nursing infants in the NICU. USA
Interventions	Different frequencies of breast-milk expression with an electric breast pump (Egnell) Arm 1: express milk $\geq$ 4 times a day. Arm 2: express milk $\leq$ 3 times a day.
Outcomes	Total milk production over 24 hours.
Notes	Unable to contact study author to answer any queries on study design or methods. Unable to obtain any useable data. Of the 25 women, 9 changed frequency after the first week and 9 stayed at the same frequency. It is unclear from the published report if this was part of the study design or if some participants refused to change frequency in the second week

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Paper just stated "card selection process", no other information provided
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	Do not know how many mothers were assigned to the different arms in the study, how many completed the study or if there are any incomplete outcome data 1 mother used manual expression on the Sabbath (no information on how the quantity of milk expressed differed on the Sabbath compared to the assigned study methods or if the quantity if milk expressed by hand was included in the analysis)
Selective reporting (reporting bias)	Low risk	Outcomes reported in the study design are reported.

De Carvalho 1985 (*Continued*)

Other bias	High risk	No sample size calculation described. Limited information given on study design and methods. No information if there was a 'washout period' between pumps tested
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided but due to study design this would not have been possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.

Feher 1989

Methods	RCT assessing the effect of a relaxation intervention during milk pumping
Participants	Mothers of preterm infants expected to be in NICU for at least 10 days in 2 sites were approached 3-5 days postpartum. 71 participants randomised and 55 completed the study (77.5%). Control group = 33 randomised and 25 (76%) completed the study. Intervention group = 38 randomised and 30 (79%) completed the study. Reasons for failure to complete the study are described. South-west USA
Interventions	Intervention group given 20-minute audio cassette tape of progressive relaxation exercises and guided imagery to listen to daily, especially before pumping milk, with tape player loaned if needed. Both groups received information on use of "the electric pump" (type not stated) and routine care. Unclear if milk sample was from a time-restricted expression
Outcomes	A single expression of breast milk obtained at the hospital during the second week of life. Measured for volume of milk and fat content/creamatocrit %. Mothers were asked about their use of the relaxation tape, and mothers' view of using the tape
Notes	Unsuccessful in attempt to contact authors. Authors carried out subgroup analysis of ventilated babies and of low income primiparous woman. These subgroups were not used in the review as the published data were insufficient. Partial funding was provided by the University of New Mexico School of Medicine through a National Institutes of Health grant

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described.
Allocation concealment (selection bias)	Unclear risk	Unclear. Unsuccessful in attempt to contact authors.

Feher 1989 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for withdrawal described.
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information available.

Fewtrell 2001a

Methods	RCT with cross-over to compare a manual pump (MP) and an electric pump (EP) among mothers of term infants commencing at approximately 6 weeks of age
Participants	Mothers of infants over 37 weeks' gestation were approached on the postnatal ward to participate. If they agreed, they were contacted at home when their infant was about 6 weeks old. 60 participants recruited and 58 completed both arms of the cross-over (96. 6%). UK
Interventions	Avent ISIS (manual) and Medela mini-electric breast pumps were each tested on 1 occasion by breastfeeding mothers when infant was approximately 8 weeks old. Each pump was given 48 hours before the test to allow familiarisation. Second pump was tested 2-3 days after the first pump. Pump was used for 10 minutes on each breast in the presence of 2 research staff and milk collected. Each mother completed a questionnaire of their opinion for each pump
Outcomes	Volume (weight) of milk from each breast in the set time period, weight of milk produced minute by minute to examine milk flow pattern, creamatocrit at 1-minute intervals, and mother's opinion on pumps
Notes	Mothers could choose a pump to keep. Additional data requested from author. Insufficient data were available to include in analysis; the average of each woman's difference in outcomes between the 2 treatments and its confidence interval was not reported, only reported the average result for each treatment over all women. "This study was supported by a grant from Canon Avent who also provided the breast pumps."

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Fewtrell 2001a (*Continued*)

Random sequence generation (selection bias)	Low risk	Randomisation was in permuted blocks of randomised length.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes.
Incomplete outcome data (attrition bias) All outcomes	High risk	Participants missing and not mentioned.
Selective reporting (reporting bias)	Unclear risk	The average of each woman's difference in outcomes between the 2 treatments and its confidence interval was not reported, only reported the average result for each treatment over all women
Other bias	Low risk	No indication of other bias.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information available.

Fewtrell 2001b

Methods	RCT comparing a MP (Avent Isis) and an EP (Egnell/Ameda) among mothers of preterm infants
Participants	145 mothers who delivered a preterm infant < 35 weeks' gestation were recruited within 3 days of birth. If necessary mothers started pumping using a standard pump on their unit before entry into trial. MP group = 74, data reported on 60 (81%); EP group = 71 data reported on 58 (81.7%) for milk expression frequency, time and volume data, however, maternal satisfaction data were reported for only 78.4% in the MP group and 69% in the EP group. UK
Interventions	Both groups received standard information from the midwifery/nursing staff of the unit which recommended pumping at least 6 times a day, starting with 5 minutes each breast and increasing as tolerated. Mothers using the EP were encouraged to simultaneously pump but it was up to the mother to chose to do this or not and could vary method at different times. Mothers completed a form each time they pumped or attempted breastfeeding. At 7-10 days postpartum mothers completed a questionnaire on their views of their assigned pump (ease of use, comfort, pleasant to use, overall opinion and amount of suction). Mothers left the study at first of the end points reached: stopped using assigned pump, stopped completing forms, infant no longer in the unit, infant fully breastfeeding. Median (25th, 75th centile) length of stay was 14 (7, 25) days in the EP group and 16 (9, 30) days in the MP group

Fewtrell 2001b (*Continued*)

Outcomes	Mother's opinion of pump used (questionnaire), volume of milk over the trial period and at a set time, time spent pumping, and proportions of women that developed sore nipples, engorgement or mastitis in each group
Notes	A sub-sample of mothers volunteered to provide a milk sample at 1 20-minute session during 2nd week postpartum for a creamatocrit and for the volume of milk expressed in the set time. These mothers also were studied for the time taken to express a set amount of milk. Additional information provided by author. "This study was supported by a grant from Canon Avent who also provided the Isis manual pumps."

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised using permuted blocks of randomised length stratified by infant's sex and gestation (< 30 weeks and 31-34 weeks)
Allocation concealment (selection bias)	Low risk	Assignments were in sealed opaque envelopes prepared by a research team member not involved in practical aspects of the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Additional details provided by author.
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	Low risk	No indication of other bias.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information given. Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information available.

Flaherman 2012

Methods	RCT comparing hand expression with use of an EP.
Participants	68 mothers of healthy newborns who were latching or sucking poorly during birth hospitalisation with Level I care only. Enrolled 12-36 hours post delivery 35 allocated to hand expression, 33 allocated to pump. Sample drawn in 2007-2009 from 3 postpartum units in California Exclusion: mothers less than 18 years old, non English speaking, history of low milk supply or breast surgery other than cyst removal, infants less than 37 weeks' gestation, less than 2000 g birthweight, or needing level II or III care
Interventions	EP (Ameda Elite hospital Grade and Medela Lactina, with mothers instructed to double pump) vs hand expression (taught) "Single intervention 15 minute session of pumping or hand expression under supervision of study staff." Milk volume measured. Baby weighed before and after feeding on the same scale. Follow-up survey questions at 1 week, 1 month, and 2 months assessed breastfeeding, milk expression and formula use
Outcomes	Breast pain on scale 1-10 (Holdcroft scale) (only in published conference abstract, not in full published paper), expressed milk volume (in 1 expression), breastfeeding self-efficacy (modified Dennis scale), breastfeeding prevalence at 1 week, 1 month & 2-month, newly developed breast milk experience measure (BMEE) that "included questions about social support for milk expression and personal and learning experience of milk expression" and reports some aspects in table form and some aspects descriptively across 3 published papers
Notes	Included in the 2011 version of this review as a conference poster. Breast pain and volume used as reported in the conference proceedings only, as data in published paper were not in a format suitable for analysis This project was supported by grant number KL2 RR024130 from the National Center for Research Resources and grants number 5 K12 HD052 and 1K23HD059818-01A1 from the National Institute of Children Health and Human Development

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Stratified randomization, with randomly permuted blocks of 2 and 4. Stratified by site and delivery method."
Allocation concealment (selection bias)	Low risk	"The allocation sequence for randomisation was generated by an independent biostatistician; assignments were placed into sealed opaque envelopes by an independent administrative assistant. Immediately following enrolment, the study investigator opened sequential envelopes in the pres-

Flaherman 2012 (*Continued*)

		ence of a second clinician and revealed the randomisation arm."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Additional details provided by trialist. "68 mothers participated in the one session intervention. Final outcome assessment at 2 months for 48 mothers (70.6%): 9 Hand Expression, 11 pump group (P = 0.49). Difficulty finding the mothers the main reason for missing outcome data."
Selective reporting (reporting bias)	High risk	Description of BMEE and outcomes measured differs between published papers. Items mentioned in the initial poster were checked with published paper and companion paper on BMEE scale examined. The BMEE scale was under development as a companion study to this RCT. It then had 16 items. The items subsequently dropped from the scale included the items reported on in this paper (scale reduced to 11 items) Trialist's reply was " Pain scale results were dropped due to space at one point" and that the reported "11 items are the final scale"
Other bias	Unclear risk	None of the hand expression group mothers were using hand expression at 2 months; were using a pump (if any milk expression). Sample size of study was determined using power calculation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unfeasible.

Francis 2008

Methods	RCT comparing 3 different EPs.
Participants	60 term breastfeeding women approached within 3 days postpartum and completed the study. USA

Francis 2008 (*Continued*)

Interventions	"Assigned one of three single electric pumps: Avent Isis IQ Uno (AIU); the Medela Swing (MSW); and the Whittlestone single electric (WSE). Instructed as per manufacturer's instructions. For 60 days, each participant completely expressed one breast on one occasion each morning alternating breasts daily, recorded pumping time in minutes, and volume in mL. For the first 7 days of the study, the participants were observed pumping in their home by an IBCLC and time to milk ejection was observed and recorded."
Outcomes	Time to milk ejection during the first week postpartum, mean time to empty 1 breast, milk volume pumped, time to express milk, milk flow rate, and infant growth tracked over the 60 days of pump use
Notes	Study was presented as a conference poster presented in 2008. This review was unsuccessful in obtaining suitable data for inclusion in the 2011 publication. Lead study author J Francis provided unpublished data for this (2014) review

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Group assignment using a random number generator.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Incomplete outcome data (attrition bias) All outcomes	High risk	The authors state they only used complete data (60 mothers), 24 mothers dropped out. No information is given if or how the incomplete data affected the results of the study. Each arm of the study had 20mothers with complete data
Selective reporting (reporting bias)	High risk	Initial study outcomes (as per email communication Feb 2007) mentioned lipid analysis and vitamin content that are not mentioned in this conference poster abstract or unpublished paper
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information is provided but due to study design this would not have been possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided.

Garza 1982

Methods	Cross-over study, in the 4th week of lactation, with mothers 'randomly' assigned to compare the effect of method and storage of expressed breast milk on nutritional composition of breast milk. 3 experiments examined method of expression (experiment 1) and storage of expressed breast milk (experiment 2 and 3). Experiment 1 was applicable to this review, the remaining experiments were excluded as they were not relevant to this review
Participants	At time of study: non-smoking mothers, in good health, aged 20-35 years, who were exclusive breastfeeding their first or second child (also in good health). 18 mothers were recruited. USA
Interventions	Experiment 1: hand expression compared with large EP (Egnell)
Outcomes	Experiment 1: nutrient quantity (fat and total nitrogen) and quantity of milk expressed. Complete data only available for total nitrogen
Notes	Unable to contact study author to clarify any questions concerning study design, methods or results

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information available.
Allocation concealment (selection bias)	Unclear risk	No information available.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information available.
Selective reporting (reporting bias)	Low risk	Outcomes reported in the study design are presented in the results
Other bias	High risk	No sample size calculation described. Limited information presented in the paper on study design, methods and results
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information given but due to study design this would not have been possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information available.

Groh-Wargo 1995

Methods	RCT comparing simultaneous and sequential pumping with an EP in mothers of infants in a NICU
Participants	32 mothers of infants < 1500 g at birth, who were providing breast milk and willing to keep a log of milk production and to submit it weekly for 6 weeks or until infant was nursing freely, were included in the analyses. 16 were allocated to sequential pumping group and 16 were allocated to simultaneous pumping group. 4 weeks minimum participation time was required for inclusion. Infants < 7 days old at entering study. Level III NICU. Mid-west USA
Interventions	Simultaneous group used double pumping kit provided and instructed to pump for total of 20 minutes every 3 hours except at night, with a minimum of 4 times in 24 hours. Amended to mothers pumping for as long as milk was flowing without time limits. Sequential group pumped initially 10 minutes per breast and amended to no restriction on time. Minimum pumping was for 4 weeks, maximum for 6 weeks or until the baby able to nurse freely. Both groups were provided with a Medela EP
Outcomes	Quantity of milk expressed (mL/week), time taken to express milk (hours/week), change in serum prolactin
Notes	No loss of participants reported. Both research groups received more support and encouragement (from research nurse) than did mothers not in the research groups. Also assessed State-Trait Anxiety (not an outcome in this review). Additional information provided by author. Supported by a grant from Medela, Inc, and by National Institutes of Health

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Author reply: "statistician prepared envelopes containing group assignment"
Allocation concealment (selection bias)	Low risk	Envelopes pulled in sequence as participants recruited by the researcher
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss of participants reported.
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	Both research groups received more support and encouragement (from research nurse) than did mothers not in the research groups.No sample size calculation described
Blinding of participants and personnel (performance bias)	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping

Groh-Wargo 1995 (*Continued*)

All outcomes		milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessor reported as blinded.

Hayes 2008

Methods	RCT to determine whether an electric breast pump vs a MP would increase breastfeeding duration
Participants	280 healthy women (and healthy babies) using state support services for low-income families (WIC) and planning to return to work or education were enrolled during last prenatal or first postnatal visit. Data on duration analysed for 229. 34 women did not complete the study and data from 17 women were excluded for inconsistency or other data collection difficulties. USA
Interventions	Loan of EP or MP and instructions on their use.
Outcomes	Breastfeeding for at least 6 months.
Notes	No response from authors. Not an outcome specified in the protocol. Power calculation reported and authors state study may be underpowered The electric breast pump loan evaluation project was made possible by a co-operative agreement (TS-0619-17/17) from the Association of Teachers of Preventive Medicine and the Division of the Nutrition and Physical Activity, National Center for Chronic Disease and Health Promotion, at the Centers for Disease Control and Prevention

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information in published article. No reply from authors.
Allocation concealment (selection bias)	Unclear risk	No information in published article. No reply from authors.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Described.
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	Authors note there may have been some violations of protocol with mothers using pumps other than that assigned to them.

Hayes 2008 (*Continued*)

		No sample size calculation described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information in published article. No reply from authors.

Heon 2011

Methods	Parallel RCT which was a "Pilot study of a randomised clinical trial to examine study design and feasibility"
Participants	40 mothers aged over 18 years who had decided to breastfeed who had given birth to a very or extremely preterm infant, born before 30 weeks of gestation and hospitalised at the NICU in a university teaching hospital in Montreal, Canada. "Eligible mothers were approached by the principal investigator within 24 hours after birth." Excluded were mothers who had either opted for mixed feeding method (breast milk and formula), had previous breast surgery or had severe physical or mental health problems impeding their participation in the study
Interventions	In this study, all participants were given a loan of a Symphony double electric breast pump and instructed in data collection which included keeping a diary on the frequency and duration of their breast milk expressions and volume of expressed breast milk for the first 42 day postpartum period of the study. Mothers were taught to accurately measure the volume of expressed breast milk by using graded sterile containers, according to standard care The mothers allocated to the experimental group received additional help in form of breast milk expression education and provision of support in form of telephone follow-up on 7 days spread over the 6-week study and access to a helpline. This was delivered individually to the experimental group by an International Board Certified Lactation Consultant nurse. The mothers in the control group received the routine education and support that was normally provided by staff nurses to mothers of preterm infants at this centre
Outcomes	Effect of support on milk volume (mean vol mL/day for 42 days calculated from "the daily mean of measured volumes for a given week."), lipid content (sample on days 7, 21, and 42 of the study, at the first breast milk expression in the morning), frequency and time taken to express. Acceptability to participants and feasibility of the study were as measured and reported descriptively in published papers
Notes	PhD thesis in French, with sections translated to English and 2 publications in English. Trialist provided additional information Refers to "sample on Days 7, 21, and 42 of the study".

Heon 2011 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computerised blocked randomisation was used, with participants placed into blocks of 4, According to trialist, the rationale for blocks was to synchronise numbers into both groups in a structured way over the entire study period
Allocation concealment (selection bias)	Low risk	Sequentially numbered sealed opaque envelopes prepared by a neutral 3rd party
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	40 mothers of preterm infants were randomly allocated to the 1 of 2 groups,14 mothers in the experimental group and 19 in the control group completed the study Reasons for attrition included death of the preterm infant (n = 3), transfer of the preterm infant to a regional hospital (n = 1), and cessation of breastfeeding (n = 2). Reasons given by mothers who discontinued breastfeeding were personal and not related to their participation in the study. Also exclusion of 1 mother arising from only partial completion of diary Of the 33 women retained in the study, all completed the diary reliably for 42 out of 42 days. 82% of 33 collected all 3 milk samples - 11/14 experimental group and 16/19 control group
Selective reporting (reporting bias)	Low risk	Full and detailed description on attrition and outcomes is provided
Other bias	High risk	No sample size calculation described. Authors state that data on confounding variables that may have affected the activation of lactogenesis, such as fatigue, maternal obesity, alcohol, opioids, and Depo-Provera, as well as confounding variables that may have affected breast milk production, like galactagogues and stress were not collected in this pilot study but should be considered in a full-scale trial

Heon 2011 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The laboratory analysts and statistician were kept blinded to the allocation

Hill 1999

Methods	RCT comparing sequential and simultaneous pumping with an EP
Participants	49 mothers in 2 tertiary care centres over a 24-month period who were planning to exclusively pump their milk for the first 6 weeks for their preterm (< 32 weeks) and low birthweight (<= 1500 g) infant(s), who spoke English or Spanish, had a telephone, were non-smokers and had no history of thyroid or other endocrine disorders. "Mothers entered the study on various days during the first week postpartum." Time to initiation of pumping in hours after birth is provided and was mean 55.35 hours (SD 45.65) single and 56.92 (28) hours double pumping group hours for each group
Interventions	Mothers instructed on the use of the assigned pumping system by the research staff. Protocol consisted of pumping 8 times per day. SEQ group was to pump for a minimum of 5 minutes, then switch to the other side and repeat this twice for a minimum of 10 minutes for each breast. SIM group was instructed to pump for 10 minutes or until 1 breast was no longer dripping. Mothers kept a log for 6 weeks after delivery recording day and time of each pumping Phone questionnaire was used 3 weeks after the study period. Data were reported on 39 mothers (20.4% loss) SEQ = 20/26 (83.3%), SIM = 19/23 (82.6%). Mothers were paid $150 and allowed to continue using the EP for 6 weeks after end of trial. USA
Outcomes	Mean weekly weight of milk pumped, pumping frequency (only descriptive data provided), relationship of selected variables to adequate (>= 3500 g/week) milk supply (only descriptive data provided), mothers' views of pump at 9 weeks (only descriptive data provided)
Notes	Author provided additional data. The research was supported by the University of Illinois at Chicago, College of Nursing; National Institutes of Health; National Institute of Nursing Research, and Medela, Inc

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information provided.

Hill 1999 (*Continued*)

Allocation concealment (selection bias)	Low risk	Participants randomly assigned to either SEQ or SIM pumping system by means of blocks of 6 to balance the pumping regimen after each 6 participants were enrolled. Information on allocation concealment not provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Author provided further information.
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	Low risk	No indication of other bias. Pilot study, no power calculation for sample size
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"data analyst was not part of data collection."

Hopkinson 2009

Methods	RCT with cross-over at 5 weeks postpartum comparing a standard EP to a novel EP commencing at 3 weeks postpartum among mothers of term infants, with cross-over after 2 weeks of pump use
Participants	Inclusion criteria: healthy mother and infant, term birth (> 37 weeks' gestation) intention to breast feed exclusively for at least 4 months and no or minimal experience using an electric breast pump. Recruited before or within 2 weeks of delivery. 69 women enrolled; 34 for the full protocol (with blood samples for hormonal analysis) and 35 for a truncated protocol (no blood sampling). USA
Interventions	All mothers were randomised to 1 of 2 EPs for use over a 2-week period once in the morning and once later in the day. The standard pump, Pump in Style®, Medela was compared to a novel pump, Embrace®, Playtex. After the initial 2-week period of use, there was 1 10-minute controlled laboratory test session, followed by (at 5 weeks postpartum) the cross-over with assignment to the other pump for a period of several days and the other test session. Following this, mothers were invited to select 1 of the pumps to keep
Outcomes	Indicators of maternal satisfaction with maternal ranking of pump performance using an adapted scale graded on a Likert scale of 1-7 on 10 aspects (ease of use, strength of suction, feeling of suction, sound, comfort, assembly, overall opinion, plus 3 aspects of maternal expectation based on continued use of a pump on effect on milk supply, effect

	on nipples and effect on frequency of use of pump and pump preference Indications of adverse effects: breast or nipple pain. Quantity of milk was assessed in 2 ways: stimulation of milk volume and milk extraction test (cross-over design) Nutrient quality by milk fat on creamatocrit of milk expressed at the beginning and end of the 10-minute period and reported as in g/L at baseline, at the end of the 10-minute test and as the change (0 to10 minutes) in a cross-over design; as the data were not available in a paired data format, it was not suitable for inclusion in the analysis. Maternal physiological effects: prolactin and oxytocin response to pumping at 5 weeks postpartum at pre and up to 40 minute post initiation of 10-minute pumping were reported as group medians and not suitable for inclusion in the analysis
Notes	Further information was provided by the author. Regarding intervention integrity, among the full protocol group, 34 were assigned, 3 dropped out before received pump (2 standard, 1 novel). Of the 31 remaining, blood sampling carried out on 30 and of these paired oxytocin samples were available on 24 women. In the truncated protocol, 35 assigned, 3 dropped out before providing data (2 standard and 1 novel), leaving 32 participants. Overall, of the 62 participants referred to by the trialists, 59 were available for the volume tests, 58 for the fat content and up to 58 reported on maternal satisfaction Use of a special elastic bra: from email from author on 7/1/11 "The first 11 mothers in the study were given the hands-free pumping bra by the nursing staff at the beginning of the study to facilitate pumping....[It] apparently did bias the results because it was much easier to insert the standard pump flange into the bra and more difficult to insert the novel flange" Other outcomes described included: time to express; maternal compliance with recommended frequency of use in the home setting; duration of breastfeeding following return to the workforce at 6/12 postpartum and milk extraction efficiency/degree of breast emptying Support was provided through a grant from Playtex Products, Inc, manufacturers of 1 of the pumps being tested

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number table.
Allocation concealment (selection bias)	Low risk	Assignments were conveyed to study assistants by phone from a central co-ordinating office
Incomplete outcome data (attrition bias) All outcomes	Low risk	All loss of participants or samples described. Incomplete outcome data were adequately addressed
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.

Hopkinson 2009 (*Continued*)

Other bias	High risk	Use of a commercially available special elastic bra for hands-free pumping by 11 mothers. Sample size of study was determined using power calculation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided. Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data entry was conducted by personnel blinded to group assignment as were laboratory tests of prolactin and oxytocin

Jayamala 2015

Methods	Cross-over RCT.
Participants	30 mothers of premature infants born at less than 34 weeks' gestation and admitted to the NICU at a tertiary care centre. Excluded were mothers with severe hearing deficiency and those who did not give consent. Mothers were enrolled when they attended NICU to express milk. Study "conducted in first week of lactation". India
Interventions	All study participants were educated and trained in use of a large EP (Medela Lactina Select advanced version 1997). Each participant was assessed for 4 sessions on music therapy and 4 sessions on no music therapy, over a 4-day period. The music therapy session was over 30 minutes, with music played for 15 minutes before and for 15 minutes during milk expression. Raga malkauns and yaman by flute was used for music therapy
Outcomes	Volume of milk expressed was measured for 2 sessions each day at 11.00 am and at 4.00 pm for subjects receiving music therapy and no music therapy Salivary cortisol level was measured on salivary samples collected on all mothers on last day of study (day 4), during both music therapy and no music therapy sessions Perceived stress was assessed for all participants receiving music therapy on day 1 and day 4 using a perceived stress scale self-evaluation questionnaire, PSS-14. Participants responded to each PPS item by rating themselves on a 5-point scale
Notes	Email messages were sent to corresponding author with queries but no reply was received. In order to include results, information on within woman differences needs to be available. No funding noted in paper

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Jayamala 2015 (*Continued*)

Random sequence generation (selection bias)	Low risk	"Randomised permuting number method."
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	1 withdrawal out of 30 participants. No information available on within-participant differences
Selective reporting (reporting bias)	Unclear risk	Insufficient information.
Other bias	High risk	No sample size calculation described. No information on how mothers expressed milk at other times other than the test sessions, no information on mothers residence during trial - hospital, or home with travel, etc
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information.

Jones 2001

Methods	RCT comparing sequential and simultaneous pumping with an EP Cross-over design was used to examine effect on expressed milk volume from breast massage with each mother acting as her own control
Participants	UK Neonatal unit. Mothers wishing to pump their milk for their own preterm infant, approached 24 hours after birth. Mothers excluded if they were unable to pump a minimum of 5 times a day or had retained products of conception. 52 participants randomised and 36 completed the study (69%). Sequential group = 27 randomised and 19 (70%) completed the study. Simultaneous group = 25 randomised and 17 (68%) completed the study. Study period started day 4-7 postpartum and lasted 4 days. "Day 5 post partum was the first day of study for 30 subjects. For 6 patients, the start of the study was delayed until day 7 because of unrelieved breast engorgement."
Interventions	Large electric breast pump (Egnell Ameda Elite) was loaned to all mothers for the duration of the trial. 1 group pumped breasts sequentially and 1 group pumped breasts simultaneously. Both groups encouraged to pump 8 times a day, until milk no longer entered the collection set. A variety of pump flange sizes were provided On 2 of the days pumping was preceded by breast massage, with the first day for familiarisation and data only collected on the second day Log book was used to record date, time and duration of pumping. Researchers calculated milk volume and fat content Women completed 2 questionnaires using an analogue scale for their opinion of pump comfort and performance, and perception of the effect of breast massage

Jones 2001 (*Continued*)

Outcomes	Volume of milk in a single expression, fat content of expressed milk in a single expression, mother's opinion on pump comfort and effectiveness, feeding method at 37 weeks' gestation (reported descriptively). The data were not available in a format that could be included in RevMan analysis
Notes	Calculated sample size was 39 participants in each arm of the study. Recruitment ceased after data analysed on 36 women were found to be significant. Insufficient data were provided in the published article and author was unable to provide additional data when contacted Project funded by Baby Lifeline. Ameda Egnell donated collection sets

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient data were provided in the published article and author was unable to provide additional data when contacted
Allocation concealment (selection bias)	Low risk	Participants randomised by the opening of a prepared envelope to 1 of 6 groups stratified for parity and gestational age. "Randomisation for massage on either days 1,2 or days 3,4 using sets of sealed envelopes."
Incomplete outcome data (attrition bias) All outcomes	High risk	Trial stopped early as "interim analysis .. . showed highly significant results". 31% without complete data
Selective reporting (reporting bias)	Unclear risk	Descriptive reporting made it difficult to judge.
Other bias	High risk	Author did not appear to have access to the data to respond to queries. Study stopped early. Sample size of study was determined using power calculation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information available.

Keith 2012

Methods	RCT, parallel.
Participants	Mothers (mixed parity) of infants in NICU born before 38 weeks or critically ill and providing breast milk. 162 completed the study. No withdrawals. Mean age of infant at enrolment was 1.4 to 2.1 days across groups. Mean gestation: 31.3 to 32.5 across groups. No infants over 38 weeks' gestation. Exclusion criteria included mothers receiving medications known to alter breast milk production, mothers experiencing mastitis, mothers with prior breast surgery, and mothers who smoke. Georgia, USA
Interventions	Control plus 3 intervention groups. A = control, no recordings, B = verbal guided imagery + music guitar lullabies ("second experimental group"), C = verbal + music + images of own infant ("third experimental group"), D = verbal only ("first experimental group") "Each group received standard medical, nursing, lactation education, and support in initiating and maintaining breast milk production. Generally, mothers were encouraged to pump 8 times daily for about 10 minutes." Double pump provided for use at home. 3 experimental groups received mp3 players with a recording of approximately 12 minutes in duration. Instructed to listen to tape "as often as possible" while double pumping
Outcomes	Data collected for 14 days with each participant. The following research questions guided this study: A. Are music-listening interventions efficacious in increasing the amount of milk produced by preterm mothers? There were 3 experimental treatments and 14 days, with 42 comparisons made to assess efficacy and reported mean milk obtained (mL/day) by group B. Are music-listening interventions efficacious in improving the quality of breast milk as measured by fat content or caloric content? 1 mL fat sample collected by mother daily near to noon and presented as mean percentage fat content/day by group No other outcomes reported. Published paper displayed results in figure and tables and further data were provided by researchers. 4 days (day 1, 5, 10 and 14) were selected for entry into analysis with any of the interventions vs no intervention
Notes	Supported in part by the MedCen Foundation, Macon GA, grant 23750 (10/1/08-9/30/09)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Simple randomization was based on a randomized permutation as obtained from SAS Proc Plan."
Allocation concealment (selection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"No adverse events, 100% compliance once treatment assigned to patient; no withdrawals during study."
Selective reporting (reporting bias)	Low risk	None apparent.
Other bias	High risk	No sample size calculation described.

Keith 2012 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, listening to a recording or not, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Data collectors performing the Creamatocrit measurement were blinded to group membership of the participants."

Lussier 2015

Methods	RCT, parallel in assigned groups for the first 7 days of study only For remaining 21 days of the study, participants were permitted to select the method of their choice. We included data from the parallel period only as after the 7^{th} day, all but 2 mothers used an EP.
Participants	40 mothers aged 18 years or older who delivered infants weighing < 1500 g and at gestational age < 32 weeks. Excluded were mothers who did not speak English or Spanish, were too ill to express milk, had prior breast surgery, had a recent history of substance abuse, or if their infant was moribund or transferred to another facility. USA "all participants began expressing/pumping within 6 hours of delivery."
Interventions	Early exclusive hand expression vs early exclusive EP expression for milk removal in mothers of VLBW "All mothers were instructed to massage their breasts and use moist heat prior to expressing their milk. They were taught how to massage by a lactation consultant." "All mothers were seen daily by an International Board Certified Lactation Consultant for the first postpartum week to review milk expression techniques and to answer questions. "
Outcomes	Number of expression sessions per day. Volume of mother's milk obtained per session.
Notes	Additional information provided by trialist.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	40 envelopes containing a card with group type HE (hand expression) or EE (electric expression) written on it were pooled, mixed, randomly drawn, and numbered sequentially from 1 to 40
Allocation concealment (selection bias)	Low risk	As a mother was enrolled in the study, the researcher opened the next consecutive envelope and the participant was placed in either the HE or EE cohort as stated on the

		card
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Describe: 40 mothers randomised, data analysed for 26 (65% of cohort) who were fully compliant with study protocol Of the 14 participants not included in the analysis there were 3 neonatal deaths, 4 mothers decided to stop milk expression and 7 mothers did not hand in their data collection sheets. Authors stated in the published paper "We were unable to detect significant differences between mothers excluded due to lack of complete data and those included in the analysis with respect to age, parity, multiple vs singleton gestation or expression method. Given the small sample size, we acknowledge the potential for group differences between those with and without follow up with respect to unmeasured factors"
Selective reporting (reporting bias)	Low risk	All outcomes are reported.
Other bias	High risk	No sample size calculation described. Participants were asked to exclusively use the assigned method of expression for the first 7 days postpartum, after which they could use either or both methods for the remaining 21 days of the trial. 18 of the 20 hand expression group changed to using an EP. Data used in this review have been confined to the results from the parallel period of the trial which was for the first 7 postpartum days. In the published paper, data analysis was reported by the original assigned groups and presented as cumulative volumes which had the effect of enhancing any early differences and blurring later differences. Although difficult to match with the published data, the non-cumulative data for the first 7 days as provided by the trialist in personal communication was used in this review
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants not possible.

Lussier 2015 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding not applied for outcome assessors.

Mangel 2015

Methods	Cross-over RCT.
Participants	Healthy breastfeeding mothers, who were not taking any medication, between 48 and 72 hours after delivery of healthy full-term infants (n = 21). No exclusion criteria is given but out of the 50 mothers who agreed to participate, 29 were not included in the randomisation process, for various reasons (listed in paper), leaving 21 mothers randomised and providing samples. Israel
Interventions	The participants were randomly assigned to express breast milk by hand followed by pump or to express milk by pump followed by hand expression. Mother provided 1 sample for each method in a randomised sequence (pump expression followed by manual expression, or in reverse order) and from the same breast during the same session For the mothers assigned to express breastmilk by hand followed by pump (n = 9), hand expression commenced at the start of a new breastfeeding session and continued until 2 mL of milk was expressed and then followed immediately with a switch, using the same breast, to the EP and continued until 2 mL collected. The other group (n = 12) carried out the same process, but beginning with the EP. Researchers demonstrated the use of the Medela Symphony pump on participants as well as instruction in hand expression, also demonstrated directly on the mother's breast. At least 2 mL of breast milk was collected per method of expression from the same breast during the same session; carried out in the lactation room in the hospital
Outcomes	Fat, energy, protein and carbohydrate content of breast milk
Notes	Funding:Authors state: 'No competing financial interests exist' Trialist contacted and replied with further information and provided raw data which allowed us to do paired comparison (SPSS) of electric minus hand expression

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Trialist replied: we used computer-generated numbers in sealed opaque envelopes for all randomisation allocation
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Samples were provided for all 21 participants.
Selective reporting (reporting bias)	Low risk	No indication of selective reporting bias.

Mangel 2015 (*Continued*)

Other bias	High risk	No sample size calculation described. No washout period - potential for the second method used to be higher in fat
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information.

Meier 2008

Methods	Randomised controlled multi-site trial comparing 2 EPs as well as suction patterns in 2 protocols Protocol I examining single-and multi-phase patterns in the SBP on 6 occasions, after which mothers selected 1 of the 3 suction patterns to use during the rest of their baby's stay in the neonatal unit Protocol II examined 1 of 2 suction patterns for 7 days.
Participants	Protocol 1: 35 English or Spainsh speaking mothers of infants who weighed < 1250 g and/or were born ≤ 32 weeks' gestation who were pumping and had achieved a daily milk output of at least 350 mL/day. Protocol I was undertaken in 1 tertiary care hospital in the USA Protocol 2:65 English or Spainsh speaking mothers of infants who weighed < 1250 g and/or were born ≤ 32 weeks' gestation who were pumping and had achieved a daily milk output of at least 350 mL/day. Protocol II was undertaken at 3 tertiary care hospitals in the USA
Interventions	Protocol 1: women were randomised to single-and multi-phase patterns in the Symphony breast pump (SBP) on 6 occasions Protocol 2: women were randomised to 1 of 2 suction patterns of the Symphony breast pump (SBP) for all pumping for 7 days
Outcomes	Protocol 1: time to milk ejection, total pumping time, milk output at 5-minute intervals, total milk output, maternal perceptions questionnaires using a 5-point Likert scale. Scores were reported by categories: efficiency and effectiveness measured by maternal ratings of the quickness of flow, rhythm of suction pattern, milk removal; comfort measured by natural feel of suction and overall comfort; convenience measured by rating ease of use and timesaving, and not a format that could be included in the analysis Protocol 2: mean total daily milk output; post-pumping creamatocrit values; and maternal perception of the efficiency, efficacy, comfort and convenience of the suction pattern. Reported by randomised group the mean percentage post-pumping creamatocrit values measured on hind-milk samples obtained at the completion of pumping for approximately half of their sample. The reported data are divided into left and right breast and not in a format that could be included in the analysis so we report it descriptively

Meier 2008 (*Continued*)

Notes	Meier 2008 had 2 protocols in this cross-over trial, and they were treated as separate studies. The data provided in the published paper were not suitable for inclusion in the analysis and we were unsuccessful in attempts to obtain useable data for this review

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.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information is given just that 35 women completed the study
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Protocol I states that mothers were blinded but no information is given for personnel, it is for this reason that the risk of bias is marked as unclear. In protocol II the paper reports that both researchers and mothers were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information is given.

Meier 2012

Methods	Parallel RCT to compare the effectiveness,efficiency, comfort and convenience of breast pump suction patterns (BPSP)
Participants	128 breast-pump dependent mothers with infants (born ≤ 34 weeks' gestation) admitted to a level 3 NICU and anticipate to remain in NICU for ≥ 15 days. "Mothers were approached for inclusion in the study within 24 hours after birth if they and their infants met inclusion criteria". No mothers were excluded on the basis of pre-existing medical conditions, perinatal complications or other lactation-related risk factors USA.
Interventions	Standard vs experimental BPSP for initiation and maintenance of lactation: Arm 1: experimental initiation BPSP vs experimental maintenance BPSP Arm 2: experimental initiation BPSP vs standard maintenance BPSP Arm 3: standard initiation BPSP vs standard maintenance BPSP (control) "Mothers were instructed to use the breast pump eight times daily for 15 min each

	pumping until the milk output was at least 20 ml from the two breasts combined." "Mothers were given an initiation BPSP card to be used in the Symphony pump, according to their randomized group assignment. This card was used for all pumping sessions until the OOL-II. Mothers completed the Time-1 questionnaire within 72 hours after enrolment. If mothers experienced the OOL-II before hospital discharge, they were given the maintenance card at that time. If mothers were discharged before the onset of lactogenesis II, they were provided with the maintenance card at the time of hospital discharge with specific instructions about changing from the initiation to the maintenance card once they had experienced two consecutive pumping sessions with a total milk output of at least 20 ml for each session. Mothers completed the Time-2 questionnaire within 96-h of switching from the initiation to the maintenance BPSP. The Time-3 questionnaires were completed at the end of the study."
Outcomes	Daily milk volume (days 1, 5 and 14 daily milk volume/mL and cumulative over study) "Maternal perceptions of effectiveness, efficiency, comfort and convenience were measured by two time period questionnaires that contained Likert-type and multiple-choice items derived from previous studies of BPSPs" (reported descriptively in publications)
Notes	Unclear explanations of the patterns tested. We have assumed the E(M)-BPSP to be only referring to the second phase - the maintenance phase. There was no arm reported for standard initiation BPSP vs experimental maintenance BPSP, which is in effect the E (M)-BPSP described in the pump design part of the methods No information if mothers were expressing/pumping before enrolment in the study which could be up to 24 hours after giving birth Additional information was provided by trialists. 2 trialists reported they received research funding and honoraria for projects from Medela. Rest of the trialists declare no conflict of interest

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A randomized block design was used to assure a representative sample of mothers with infants <27 and ≥27 weeks' gestation…The randomized block design also ensured that within every block of three infants, one infant was randomly assigned to each group so that environmental and clinical conditions within the neonatal intensive care unit were consistent among the groups."
Allocation concealment (selection bias)	Low risk	All BPSPs were embedded in identical appearing cards that were coded only by number and inserted into the breast pump

Meier 2012 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Only included data from mothers with at least 9 days of consecutive data collection but study duration was 14 days "Of the 128 mothers who were enrolled, 105 (82.0%) completed the study with usable data, defined as at least nine consecutive days from the onset of the study of complete milk output records."
Selective reporting (reporting bias)	High risk	All outcomes listed in the design of the study are presented, however study duration was 14 days and it is not stated why only data from mothers with 9 days of data are included for analysis
Other bias	High risk	No sample size calculation described. "Day 1" reported is likely to be day 1 of the trial not day 1 after birth. Time from birth to starting pumping in the trial differed between groups
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Mothers were blinded but no information is provided about blinding of personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information is given.

Mersmann 1993

Methods	RCT 3 treatment cross-over design, assignment to 1 of 6 treatment sequences. Data collected for 14 days with each participant
Participants	26 mothers asked, 21 agree to participate, 2 did not meet criteria and 1 did not complete the study due to illness of the investigator = 18 mothers of 21 non-nursing hospitalised preterm infants completed the study Exclusions: non-English speaking, expressing milk for less than 2 weeks, mothers with medical conditions, mothers who had previously received Therapeutic Touch (TT) New York, USA.
Interventions	Each participant acted as their own control receiving TT, Mimic Therapeutic Touch (MTT), and No Treatment (NT) administered by nurses trained in either TT or MTT, with investigator outside the room Minimum of 24 hours between treatments scheduled on 3 of 5 consecutive days. Interval since last expression and time of day was kept constant for each mother Mothers maintained their usual milk pumping routine (Egnell lact-e EP - single); diary documented routine

	Mothers instructed to pump until they were "finished". "After expressing the first breast, 1-2 mL of the hind milk was expressed into a separate container for fat measurement immediately after each expression. Mother completed a VAS on her perception of infant's health status before each session (mother's stress)" "Therapeutic Touch is the knowledgeable and purposive patterning of the human-environmental energy field process in which the [practitioner] assumes a meditative form of awareness and without physical contact uses her hands as a focus for the patterning." In MTT the purposive patterning by the (nurse) is done while focusing on repetitive hand movements and distraction
Outcomes	Mothers' comments on treatments (descriptive). Did leaking occur during treatment (dichotomous). Quantity of expressed milk (continuous). Length of time of milk pumping (continuous). Fat content - 3 creamatocrits (percentage fat) on hind milk sample (1-2 mL) (continuous) Reported by group with no participant specific/paired data available for inclusion in the analysis
Notes	Reported by group, no participant-specific/paired data available for inclusion in RevMan No funding source listed. Full thesis was used as no publications could be found. Unable to make contact

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random numbers table to assign treatment sequence.
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 participant did not complete the study due to illness of the investigator and data not collected. The participant's data were not included
Selective reporting (reporting bias)	Low risk	This thesis provides a high level of detail and no indication of selective reporting
Other bias	Low risk	Detailed description of training of treatment nurses in TT, MTT and NT and measures to avoid bias in this thesis. Sample size of study was determined using power calculation
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants received each treatment and were not told which treatments they were receiving Personnel were aware which treatment they

Mersmann 1993 (*Continued*)

		were providing.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information.

Parker 2012

Methods	Randomised control pilot trial comparing the effects of timing of initiation of pumping following delivery. Reported at days 1-7, 21 and 42
Participants	Mothers of VLBW in tertiary care neonatal unit. Mean infant birthweight was 9994.2 g, mean gestation age 27.4 weeks. Participants: 10 in each of 2 groups reported "A convenience sample of 20 pregnant women carrying a singleton fetus with an estimated gestational age <32 weeks and an estimated fetal weight of <1500 g were recruited for this feasibility study from a labor and delivery unit associated with a level III tertiary neonatal intensive care unit. Exclusion criteria consisted of (1) younger than 18 years, (2) no intention to breastfeed, (3) non-English speaking, (4) presence of major fetal anomalies, (5) illicit maternal drug use, (6) history of breast reduction or augmentation, (7) positive HIV status or (8) the fetus not expected to live over 2 weeks following delivery." 32 mothers consented during pregnancy, 10 were excluded as infant did not meet the inclusion criteria after birth. Researcher did not get to randomise within 1 hour for 2 consented and eligible mothers. 1 pregnant woman approached declined to participate. USA
Interventions	Group I began using EP within 1 hour following delivery, and Group II between 1-6 hours. Mothers pumped in neonatal unit or at home "Simultaneous expression Symphony pump (Medela), instructed to pump simultaneously for 15 minutes at least 8 times a day, though if the mother choose, to pump 10 minutes on each side sequentially. If milk was still flowing, instructed to continue for 2 min after flow of milk ceased." Given written and verbal instructions "Mothers in both groups were instructed to record in a daily log book the date, time and duration of each pumping session, type of pump used and whether they received lactation consultation. Frequency, timing and length of Kangaroo care were also recorded. If the infant breastfed during the 24-h milk volume measurement session, intake was measured by test weighing prior to and following breastfeeding."
Outcomes	Mean milk volumes days 1 to 7, day 21 and day 42 by weighing each container of expressed milk brought in by the mother and summing together and timing of LGS2 (lactogenesis stage II) by mother's report of sudden breast fullness
Notes	Trialist provided responses by email for 2011 review (conference poster) though did not respond to queries following publication of full paper more recently. Data were not in a format suitable for inclusion in analysis

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Parker 2012 (*Continued*)

Random sequence generation (selection bias)	Low risk	"Sequentially numbered, identical, opaque sealed envelopes, each containing a 2-inch by 2-inch paper designating Group I or Group II."
Allocation concealment (selection bias)	Low risk	"Assignment were made upon delivery. Envelopes were opened sequentially after writing the subject's tracking information on the envelope."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	20 mothers commenced (10 early + 10 late initiation). At 3 weeks, data reported for 8 early + 7 late initiation. At 6 weeks, data reported for 6 early + 4 late initiation. No information available regarding the other participants, if they ceased pumping because infant was feeding effectively at the breast, ceased using mother's milk, or were lost to contact
Selective reporting (reporting bias)	Unclear risk	None apparent.
Other bias	High risk	Authors state: "Due to the small sample size of 20 mothers, this pilot study was not powered to detect statistically significant differences between groups"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information is given.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information is given.

Paul 1996

Methods	Cross-over RCT comparing hand expression and MP (Medela) expression. Study done in 2 phases Phase 1: 22 women expressed on postnatal days 4 and 5. Phase 2: 14 women, separate to phase 1, expressed on postnatal days 4 and 5 and postnatal 8 and 9
Participants	Mothers of neonates in the neonatal unit (mean gestation age 34 weeks) who were unable to suck at the breast and their mothers wished to breastfeed. Mothers were 'well enough' to visit the feeding room and already expressing prior to the start of the study. India

Paul 1996 (*Continued*)

Interventions	Arm 1: M-P-M-P-M-P sequence of expression. Arm 2: P-M-P-M-P-M sequence of expression. Express 3 times a day for a fixed 15 minutes at 10 am, 12 pm and 2 pm (Total of 6 expressions in phase 1 and 42 in phase 2). Alternate method each expression (no 'washout period)
Outcomes	Maternal preference of the method (dichotomous data included) Quantity of milk during a 15-minute session is presented by session and method overall and no between-participant data are provided to include in the analysis
Notes	Author did not respond to queries on study methods (i.e. intervention integrity) and only mention of the study being a RCT is that the mothers 'In a randomised fashion' were assigned to their group. Phase 2 appears that it was not included in the original study design but was added following completion of phase 1 No information was available to clarify if these 3 test times were the only times milk volume was measured or if mothers only expressed 3 times in total over 24 hours for their infants who were not nursing at the breast Study formed part of an ICMR Study on nutrition of low birthweight neonates

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"In a randomised fashion, a subgroup of 11 subjects used the manual (M) method at the initial expression, while the other 11 subjects started with the pump (P) expression."
Allocation concealment (selection bias)	Unclear risk	No information given.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information given.
Selective reporting (reporting bias)	Low risk	Outcomes reported in study design are reported in the results section
Other bias	High risk	No sample size calculation described. Author did not respond to queries on study methods (i.e. intervention integrity). Potential for the use of 1 method to extract more milk at 1 session thus increasing the amount of milk produced for the next session as there was no "washout period" between methods
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information is given but due to study design this would not have been possible

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information given.

Pessoto 2010

Methods	RCT comparing hand expression, MP and EP among mothers of preterm infants
Participants	45 mothers of infants with a birthweight of less than 1250 g were recruited and randomised in the first 48 hours after birth and followed up for a 5-week period post delivery. 15 were allocated to group 1 using hand expression, 15 to group 2 using the MP and 15 to group 3 using the EP. Median start of pumping reported as 22-24.5 hours after birth and mothers may have started expressing/pumping before entering trial. The exclusion criteria included: contraindications to breastfeeding, breast malformation or reductive breast surgery, severe maternal diseases and multiple pregnancy. University Hospital in Brazil
Interventions	Mothers were assigned for randomisation into 1 of 3 groups. Group 1 - hand expression; group 2 - MP (Medela Caricia®); group 3 - EP (double collection Medela Lactina Select®). Verbal instructions and a practical explanation were provided about standardised hygienic procedures, milk collection, home storage and transportation of the expressed breast milk. All the equipment to collect and transport the expressed breast milk was donated to the study participants
Outcomes	Indications of adverse effects: description of any maternal breast complications. assessment of expressed milk for Dornic acidity (bacterial activity), off-flavour or foreign body; quantity of milk: mean diary volume of expressed breast milk; nutrient quality: sodium, potassium, protein concentration and mean energy content. Other outcomes, not included in this review: assessments by State-trait Anxiety Inventory; time of first expression in hours post delivery and average number of expressions per day. Day of study rather than day since birth
Notes	Conference poster. Author provided extensive information in addition to the published abstract which has been used in this review Non-commercial funding from the Fundacao de Amparo a Pesquisa do Estado de Sao Paulo - Foundation for Research Support of Sao Paulo State (FAPESP)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Information on the details of the actual sequence generation have not been provided
Allocation concealment (selection bias)	Low risk	"assignments were held in sealed envelopes prepared by a member of the research team and it was opened at the moment of ran-

		domisation". . . "Assignments were randomised by blocks of three. Mothers were .... randomised according to the order of birth to one of three groups using sequential sealed opaque envelope."
Incomplete outcome data (attrition bias) All outcomes	High risk	45 mothers who met the inclusion criteria agreed to participate, 1 of whom was excluded because she used her own pump following discharge from hospital not the allocated pump. 44 participants adhered to full protocol. 9 mothers were lost to follow-up There were missing samples in assessments of energy content and Dornic acidity, estimated to be 68% to 89% of what would be expected if 6 samples were received from all trialists in each of the 3 groups There was a higher numbers of missing samples in tests for sodium, potassium and protein: 60% to 70% of what would be expected if 6 samples were received from all trialists in each of the 3 groups.
Selective reporting (reporting bias)	Unclear risk	This study is not yet published.
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Abstract states "not blinded study". Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Bottles of expressed milk were weighted by an employee blinded to the group." No information about any blinding of assessors of other outcomes

Pinelli 2001

Methods	Parallel RCT. "All parents who met the inclusion criteria were approached by a research assistant to participate in the study. After obtaining informed consent, infants were stratified by birth weight (<= 1000 g or > 1000 g) and parents were randomly assigned, using random-number tables and sealed opaque envelopes, to receive either CHBS (n = 64 couples) or SSBC (n = 64 couples) within 72 hours of birth." Follow-up for 12 months Participants recruited over a 2-year period.
Participants	Canada. "The setting for the study was a 33-bed, tertiary-level neonatal intensive care unit (NICU) of a teaching hospital that is the referral center for a geographically defined region in central-west Ontario, delivering approximately 29 000 infants per year. Inclusion criteria were: infants with birth weights less than 1500 g (VLBW), who were inborn or transferred with their mother within 72 hours of birth if they were out-born, and fed mother's milk by parental choice Exclusion criteria were: multiple births; infants with severe congenital, surgical, or chromosomal abnormalities; and non-English-speaking parents. Fathers, as well as mothers, were included" "The sample size for the total project was determined a priori and was based on the primary objective of the intervention study. The sample size was based on the difference between the success rate of breastfeeding at 3 months corrected age in the study setting, which was about 10%, and the desired success rate defined for the intervention study, which was 30%. The sample size for the intervention study was 58 infants per group based on a 1-tailed test, an alpha of 0.05, and a beta of 0.2." (Pinelli 2003)
Interventions	"structured breastfeeding counselling program (SSBC) for parents of preterm infants, compared with conventional hospital-based breastfeeding support (CHBS)" "The SSBC consisted of (1) viewing a video on breastfeeding preterm infants; (2) individual counselling by the research lactation consultant, who was not a member of the hospital staff; (3) weekly personal in-hospital contact; and (4) frequent post discharge contact through the infant's first year or until breastfeeding was discontinued. The CHBS group had standard support confined to the period of hospitalization in the NICU, which included contact with the regular hospital staff (i.e. nurses, nutritionists, neonatal nurse practitioners, physicians). No specialized breastfeeding clinic was available to parents in the hospital at the time of the study, and only a limited number of staff had any formal education in lactation or breastfeeding support." "During hospitalization, the 24-hour volume of expressed milk was recorded once per week from the milk brought to the NICU "Specific information about the type of pump used was not collected; however, most mothers in our NICU are encouraged to use an EP if they are intending to pump for longer than 1 month." All mothers encouraged to pump every 3 hours.with a double pump set available while mother remains in hospital. Mother encouraged to rent an EP for home use after her discharge
Outcomes	1) Age (days) when baby first put to breast in NICU. 2) Amount of milk pumped each time, mL (while in NICU) (no details available on what time points or if this is the mean of the means from each test day) 3) Frequency of pumping in 24 hours in NICU (no details available on what time point) Neurodevelopmental outcomes were reported as a separate paper (Pinelli 2003) though not by assigned groups

Pinelli 2001 (*Continued*)

	Anthropometric measures (weight, length, and head circumference) were taken during the hospitalisation and at each follow-up visit - though not reported (Pinelli 2003)
Notes	Triallists contacted and replied that data were no longer available to provide further details "This study was funded by grant 6606-5242-VF from the National Health Research Development Program, Ottawa, Ontario."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using random-number tables.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Additional paper states there were losses but no information by group or when these losses occurred in the 12-month follow-up
Selective reporting (reporting bias)	Low risk	Reports of the study are free of suggestion of selective outcome reporting
Other bias	High risk	The sample size of the study can detect a significant (P =< 0.005) difference but power of the study is not stated
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Unfeasible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not mentioned in publications.

Pittard 1991

Methods	Cross-over RCT to examine bacterial contamination of breast milk obtained through manual or electric expression and stored in clean or sterile containers
Participants	16 healthy nursing mothers recruited within 6 to 171 days postnatal, mix of preterm infants with mother regularly expressing and full-term infants feeding at the breast. USA
Interventions	4 arms to the study with 1 sample by each method. Arm 1: manual expression into clean containers. Arm 2: manual expression into sterile containers. Arm 3: EP (Medela) expression into clean containers.

Pittard 1991 (*Continued*)

	Arm 4: EP expression into sterile containers.
Outcomes	Bacterial CFU (CFU)/mL in expressed milk.
Notes	Data presented in paper as a bar chart showing number of specimens with less than or greater than 10,000 CFU/mL and not suitable for inclusion in the analysis. Results reported as: "The number of milk specimens containing $>10^4$ CFU/mL was not different between those collected in clean vs sterile containers or between those collected with a manual vs a mechanical technique". Attempts to contact trialist were not successful

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	'Card selection technique'. No additional information on 'card selection technique' was given in the paper and we were unable to make contact with the lead author
Allocation concealment (selection bias)	Unclear risk	No information given.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information given.
Selective reporting (reporting bias)	Low risk	All outcomes reported in the study design are reported.
Other bias	High risk	No sample size calculation described. No inclusion/ exclusion criteria given
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information is given but due to study design this would not have been possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information given.

Prime 2010

Methods	Cross-over RCT comparing 3 breast shield sizes (24 mm, 27 mm and 30 mm)
Participants	20 breastfeeding mothers of healthy term infants were included. No inclusion/exclusion criteria is given. Australia
Interventions	24 mm, 27 mm and 30 mm breast shield sizes, PersonalFit^{TM} breast shields, Medela AG, Switzerland, were compared using the left breast. Each shield was tested once on different days and was tested for 15 minutes

Outcomes	1. Degree of breast fullness. 2. % of available milk removed. 3. Total volume expressed (g) in 15 minutes. 4. Time (min) to 80% removal. 5. Time (sec) until first milk ejection (oxytocin release). 6. Number of milk ejections.
Notes	Contact was made with the lead author, who provided her thesis but unfortunately the results presented in the thesis were analysed as a parallel trial not as a cross-over and therefore could not be used in this review Poster abstract acknowledges funding from Medela.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random table number.
Allocation concealment (selection bias)	High risk	Random table number was not sealed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information is provided.
Selective reporting (reporting bias)	Unclear risk	No information is provided.
Other bias	High risk	No sample size calculation described. Mothers who took part in this cross-over RCT also took part in an observational study (examining vacuum tolerance with breast shields for left and right breasts). Follow-up visits for both studies occurred on the same day. It is not clear if mothers completed the RCT visit first (as milk volume was an outcome) and then completed observational study? The effectiveness of the breast shield could be influenced by the order of assessment. Study was funded by Medela AG
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information is provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information is provided.

Prime 2012

Methods	Cross-over RCT comparing simultaneously (SIM) and sequentially (SEQ) technique with an electric breast pump (Symphony)
Participants	31 healthy breastfeeding mothers with an established milk supply with no concerns about their milk production prior to starting study. Australia
Interventions	Compare SIM and sequentially SEQ breast-milk expression with an electric breast pump (Symphony) at 1 pumping session for each method. Up to 5 weeks between methods studied and there was no prescribed interval between feeding at the breast or pumping and the test session
Outcomes	Time to first recorded milk flow (seconds); total milk yield (g) at 15 minutes, which were outcomes for this review, plus percentage of total milk yield at 2, 5 and 10 minutes; time (seconds) to 50% and 80% of milk yield; cream content of first 1 mL of milk, in the "bulk of the milk" and as "last milk" in a restricted pumping session of 15 minutes after milk flow commenced; number of milk ejections; percentage of available milk removed at 15 min, which are not outcomes of this review. The overall difference between cream content between simultaneous and sequential pumping was only reported descriptively. Reported as group differences, not between individual difference
Notes	In 2010, author stated that the study was observational with a cross-over element (so was excluded from 2011 review). Study was published as a RCT in 2012. Author was contacted in 2013 and replied that study is now considered a RCT

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	List was predetermined and when the participant arrived to take part in the study was assigned the next available space. Odd numbered participants would simultaneously express first and even numbered participants would sequentially express first
Allocation concealment (selection bias)	High risk	No information given in the paper.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Author reports no incomplete data.
Selective reporting (reporting bias)	Low risk	All outcomes listed in study design are reported.
Other bias	High risk	No sample size calculation described.No prescribed time interval between previous breastfeeding or expression and study visit. The study population could have been participating on more than 1 breastfeeding research study

Prime 2012 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information is given but due to study design this would not have been possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information given.

Rasmussen 2011

Methods	RCT comparing a manual to an EP among obese mothers as a part of the Bassett Improving Breastfeeding Study (BIBS). 2 protocols reported in 1 paper with only BIBS 2 relevant to this review
Participants	Pregnant women who at the time of enrolment were obese with a BMI > 29 kg/m^2, over 19 years of age, carrying a single fetus and who then gave birth to term healthy infant who was ever put to the breast and available for telephone follow-up. 39 enrolled and randomised, 5 excluded before or immediately at delivery = 34. USA
Interventions	Mothers (n = 12) received a manual (Medela Harmony) or EP (n = 13) (Medela Symphony), to stimulate their lactation, for 10-14 days or no pump provided (usual care) n = 12. Written instructions to pump after 5 nursing sessions every day for 10 minutes at each breast until "milk came in" or infant 5 days old. MP group could keep pump, EPs were collected by 14 days postpartum
Outcomes	Timing of lactogenesis 2, feeding method at 30 and 90 days, duration of exclusive breastfeeding. Pumping satisfaction questionnaire. Between pumps and either pump vs no pump comparisons
Notes	Author provided further information. "randomisation failed to distribute mothers of differing body mass index adequately among the treatment groups... in future studies of obese women, stratified randomisation may be necessary." Electric pumps were donated by Medela, Inc. Reply from author: "No competing financial interests exist"

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"We used a random number table to generate this."
Allocation concealment (selection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Withdrawals accounted for in published paper.

Rasmussen 2011 (*Continued*)

Selective reporting (reporting bias)	Low risk	No evidence of selective reporting.
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research assistants (collecting data) did not know the participants' assigned treatment group

Slusher 2007

Methods	RCT comparing hand expression, manual and EPs.
Participants	72 mothers enrolled and 65 mothers completed the study (90%). "Of those mothers who participated in the study,the majority (n = 64) entered the study within two days after giving birth." 7 mothers requested to stop pumping and their reasons were provided in additional response of author. Hand expression (standard care) = 19 (all completed study); EP = 24 (data for 22 - 91.6%); pedal-operated pump = 29 (data for 24 - 82.7%). Inclusion criteria were mothers of infants unable to breastfeed directly due to prematurity or illness and expected to be unable to breastfeed for at least 1 week. Mothers resided in the hospital during the study period and had unrestricted physical contact with their infants. Peer and professional support were available. Hospital had a reliable electric supply though surrounding community did not. 1 hospital in Nigeria and 1 hospital in Kenya
Interventions	Control group taught hand expression techniques by a group of trained nurses and 1 of the research team. All mothers pumped/expressed for a minimum of 6 days and a maximum of 10 days. All mothers had completed the study by postnatal day 13. Breast milk volumes were measured and recorded at each pumping session. No time limits on pumping. Instructed to pump at 2-3 hour intervals and to continue until milk droplets ceased flowing. Milk was not stored. It was either given immediately to the infant or discarded. EP was a double-collection Medela Lactina. Pedal pump was a double collection pedal operated version of the Lactina
Outcomes	Quantity of milk expressed. Reported as day since entering the trial rather day since birth
Notes	Additional information provided by author on economic aspects and the mothers' reasons for dropout. Pumping equipment was donated by Medela USA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Slusher 2007 (*Continued*)

Random sequence generation (selection bias)	Low risk	Random number table.
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Additional information provided by author on missing data and the mothers' reasons withdrawal
Selective reporting (reporting bias)	High risk	Reasons for drop-out and economic aspects of pump availability in low-income country not reported in article
Other bias	Unclear risk	Evidence of sample-size power calculation although it does appear to be done post-hoc
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information.

Stellwagen 2010

Methods	RCT comparing the effect of the use of hand pumping in addition to the use of an EP in mothers of VLBW
Participants	42 mothers were enrolled, of whom 34 provided milk samples. The mean gestational age of the infants was 27.5 weeks and mean birthweight was 924 g. No information on time of enrolment post-birth. USA
Interventions	All mothers were given a hospital grade pump and educated about the importance of human milk. All received lactation support. The intervention group (Hands on Pumping) used hand expression in combination with electric pumping and the control group used electric pumping only. The intervention group viewed a video (circumstances of this viewing not specified) demonstrating the use of hands on pumping to fully empty the breast
Outcomes	Volume of milk (g) in a 24-hour period. Results are reported on expressed milk volumes from day 16 to day 47 postpartum. Chan 2010 is another aspect of the same participants and reported on the energy, protein and carbohydrate content of the expressed milk

Stellwagen 2010 (*Continued*)

Notes	These conference abstracts briefly reported but the information was insufficient for use in this review. Lead trialist replied that no further data were available No information available on funding.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information.
Allocation concealment (selection bias)	Unclear risk	No information.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information.
Selective reporting (reporting bias)	Unclear risk	No information.
Other bias	High risk	Study was not powered to detect a significant differences between groups
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information.

Stutte 1988

Methods	Cross-over trial comparing effect of breast massage and no breast massage
Participants	18 lactating women who routinely nursed their infants on both breasts. Infant age range 1 week to 1 year, mean 2 months. As each breast was separate, resulted in 36 experimental and 36 control participants. Exclusion criteria was breast engorgement and prior breast surgery or injury that might affect circulation or innervation. USA
Interventions	Infants nursed and 2 hours later mothers pumped both breasts simultaneously with an electric breast pump while massaging 1 breast and using 1 breast as a control. The following day the procedure was repeated massaging the opposite breast. Massage was a specific technique taught and included in the published article
Outcomes	Volume of milk pumped and the fat content creamatocrit for the massaged and unmassaged breasts at 1 session of each protocol

Stutte 1988 (*Continued*)

Notes	Contact made with co-author Bowles. Other trialists with more expertise on the data are not available Pumps were loaned from Medela (Additional info).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"We flipped a coin to decide which breast to massage at the first session. At the second session the following day, the opposite breast was massaged" (additional information from trialist)
Allocation concealment (selection bias)	Unclear risk	No concealment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants completed the 2 parts of the study.
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the intervention blinding of mothers or personnel was not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Laboratory technician examining samples was not aware of allocation (additional information from trialist)

Vasan 2004

Methods	Parallel RCT.
Participants	16 mothers of infants in hospital. No information is given other than infants had a birthweight less than 2500 g Ecuador.
Interventions	Mothers were randomly assigned to either use the EP (Lactina, Medela) (n = 7) or to hand express (n = 9) during hospital stay
Outcomes	Milk transfer on day of hospital discharge (mL) and mean maternal milk volume (mL) expressed during visits to the neonatal unit
Notes	This study was presented as a poster abstract at the 2004 ISRHML conference and co-author confirmed it was never published as a study. Therefore, information is limited on the study's methodology. No further information was available from the trialists and

Vasan 2004 (*Continued*)

	data available in the poster were not suitable for inclusion. This study was funded by Medela

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information is given.
Allocation concealment (selection bias)	Unclear risk	No information is given.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information is given.
Selective reporting (reporting bias)	Low risk	Data are provided for all reported outcomes.
Other bias	High risk	No sample size calculation described. Due to the limited information provided it is difficult to assess the study's risk of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated blinding of mothers or their care providers would not have been possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information is given.

Yi it 2012

Methods	RCT comparing the effect of warming a breast prior to expressing milk on volume of milk expressed
Participants	Mothers had no history of breast surgery. Baby in NICU and was less than 21 days old and unable to suck at the breast. Turkey.
Interventions	Breast compress made from gel (in the form of a single bra cup) was warmed in the microwave for 1 minute at 180 W and applied to 1 breast for 20 minutes. The mothers other breast acted as the control. Both breasts were pumped with an electric breast pump for 15 minutes simultaneously
Outcomes	Amount of milk produced by both breasts (study and control) over each day of the study. In total 6 expressions of milk over 3 consecutive days
Notes	

Risk of bias

Yi, 2012 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Computerized randomization programme" determined random sequence generation
Allocation concealment (selection bias)	Unclear risk	No information presented.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 1 mother withdrew from the study and her data were excluded
Selective reporting (reporting bias)	Low risk	All outcomes outlined in the study design are reported.
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information is given but due to study design this would not have been possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information given.

Zinaman 1992

Methods	RCT with cross-over comparing 4 different methods of milk expression/pumping
Participants	23 mothers exclusively breastfeeding their full-term healthy infants, 28-42 days postpartum. USA
Interventions	Milk collected by large EP (White River), battery-operated pump (Gentle Expressions) , MP (Medela), hand expression (Marmet technique), and infant suckling. 4 methods tested (3 pumps and hand expression) within 1 week with a minimum of 1 method tested per day. USA
Outcomes	For each method: oxytocin levels over a 60-minute sampling session (data available), serum prolactin levels over 60-minute sampling session (data not available), volume over 30-minute sampling session (data not available)
Notes	Published paper reports mean net AUC and SEM for oxytocin numerically by method. Insufficient data were available to include in analysis; the average of each woman's difference in outcomes between the 2 treatments and its confidence interval was not reported, only reported the average result for each treatment over all women. Prolactin and volume graphically displayed not by numbers. Some additional information provided by author, however, additional numerical data no longer available. Study was supported by the Institute for International Studies in Natural Family Planning/US Agency for International Development

Zinaman 1992 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Information on method of randomisation not available.
Allocation concealment (selection bias)	Unclear risk	Method not described.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to judge.
Selective reporting (reporting bias)	Low risk	No indication of selective reporting.
Other bias	High risk	No sample size calculation described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Given the nature of the interventions evaluated, involving expressing or pumping milk, blinding of mothers or their care providers was generally not possible
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information.

AUC: area under curve
BMI: body mass index
cc: cubic centimetres
CFU: colony forming units
EP: electric pump
g: grams
IBCLC: International Board Certified Lactation Consultant
ICMR: Indian Council of Medical Research
kcal: kilocalories
mL: millilitres
MP: manual pump
NEC: necrotising enterocolitis
NICU: neonatal intensive care unit
RCT: randomised controlled trial
SCN: special care nurseries
SEM: standard error of the mean
SEQ: sequential single pumping
SIM: simultaneous double pumping
VAS: visual analogue scale
VLBW: very low birthweight infants
vs: versus
WIC: Women, Infants and Children (public health program)

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

Study	Reason for exclusion
Alekseev 1998	Contact made with researcher who confirmed this was not an RCT
Batista 2014	Does not compare methods of expression. Treatment for engorgement/mastitis by using a breast pump is not within the scope of our review
Chapman 2001	Does not compare methods of expression. Compares pump used with suction with placebo (pump without suction) to measure effect of breast stimulation by pump suction on lactogenesis
Fewtrell 2006	Does not compare methods of expression. More suitable for other Cochrane review - *see* Donovan 2012.
Flores-Huerta 1995	Observational design not RCT. Examined the effect on the duration, volume and composition when a nurse used a manual or electric pump on post-caesarian section mothers in 3 studies
Forster 2011	Involves antenatal expression of colostrum versus no expression
Fujimoto 2006	Not randomised. Mothers chose method - hand expression or electric breast pump
Green 1982	Previous version excluded as a cross-over design within first 28 days after birth to evaluate volume and fat content with 4 methods of milk expression. Re-assessed and no information available to determine if all women were randomised to all 4 methods of expression. Due to age of study, contact authors were unable to provide any additional information to the paper
Junior 2008	Intervention was to provide a package of support to mothers of preterm infants. Additional or specific support related to milk expression is not mentioned as part of the intervention, nor is milk expression listed as an outcome
Kent 2003	"Seven different stimulation patterns of the breast pump were tested in a predetermined random order." When further details were requested, author replied: "Our studies of milk expression have not been randomized controlled trials."
Kent 2008	Varing pump vacuums were tested in a randomised order. When further details were requested, author replied: "Our studies of milk expression have not been randomized controlled trials"
Kimani-Murage 2013	(Trial) Intervention will involve personalised, home-based counselling of pregnant women and mothers of infants on optimal MIYCN practices by CHWs. Participants will receive information about milk expression among other topics. More suitable for a review on support interventions related to infant health and breastfeeding
Lang 1994	Cross-over design within first 24 days after birth to examine nutrient (sodium) in milk when expressed by hand and by pump of mothers of infants in neonatal unit (UK). Intention was to "try to randomly allocate as many mothers as possible" to commence a method for 6 days before changing method. Unclear if randomisation was carried out with all mothers and many mothers choose whatever method they preferred. Results reported without attention to any randomisation and included mothers from another non-randomised part of the study. After discussion with trialist the study was considered not suitable for inclusion

(*Continued*)

Lewis 2005	Compared pump versus no pump. Not randomised.
Mennella 2010a	Did not contain relevant intervention. Breast pumping was carried out to examine ethanol pharmacokinetics in lactating women
Mennella 2010b	Did not contain relevant intervention. Breast pumping was carried out to examine associations in family history of alcoholism, alcohol intake and prolactin levels in lactating women
Morton 2009	Examined the effect of combining hand expression and pumping. Observational design not RCT
NCT00393640	Does not compare methods of expression. Compares pump use and non-pump use in regard to lactogenesis II markers
NCT01802047	Trialist response to email: "Due to changes in routine modality of milk expression by electric pump in our department, we have abandoned this trial. The trial was withdrawn prior to enrolment of first participant"
Ohyama 2010	No randomisation in study design or methods. Alternate participants were assigned to 1 of 2 methods to use first and method alternated for subsequent expression sessions within the first 48 hours after birth to examine milk volume and maternal comfort
Pepino 2008	Did not contain relevant intervention. Breast pumping was carried out to examine ethanol pharmacokinetics in lactating women
Pound 2015	Intervention is contact with IBCLC which included information on using a pump as 1 of a variety of information topics. Outcomes related to milk expression are not included
Slusher 2012	Study is not an RCT. Published paper states mothers of infants in a special care nursery were assigned 1 of 3 methods of milk expression: double electric pump, single non-electric pump and hand expression using a "non-random sequential assignment"
Thompson 1997	Study does not mention "randomised" and thus excluded as trialist could not be contacted for clarification. This was mistakenly listed in the previous version of this review as a cross-over design within first 28 days after birth and thus excluded. Study examined bacterial counts in milk following breast cleansing techniques
Waller 1946	Does not compare methods of expression. Compares teaching antenatal hand expression of colostrum to no antenatal expression with regard to postnatal milk production, prevention of engorgement, and duration of breastfeeding
Williams 1985	Does not compare methods of expression. Compares 2 methods of obtaining milk samples for analysis
Yoshidome 2014	No mention of randomised in published abstract. Not a study on methods of breast milk expression but rather study on impact of breast massage on milk constituents
Zhen 1990	Does not compare methods of expression. Compares breast massage versus no breast massage and milk production and duration of breastfeeding. Mothers were directly feeding their babies, not expressing/pumping milk

CHWs: Community Health Workers
IBCLC: International Board Certified Lactation Consultant
MIYCN: maternal, infant and young child nutrition (MIYCN)
RCT: randomised controlled trial

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

Raguindin 2015

Methods	Randomised controlled trial (parallel).
Participants	Inclusion criteria: mothers (minimum age 18 years) who gave birth to neonates less than or equal to 2000 g with an Apgar score of more than or equal to 7 on the 5th minute of life. Exclusion criteria: mothers who gave birth to extremely low birthweight infants; neonates with chromosomal and life-threatening congenital anomalies; severely ill neonates requiring intubation, oxygen or inotropic support; mothers who are severely ill requiring intubation or any form of oxygen support; who had mastectomy; diagnosed with prolactinoma; who are mentally ill Phillippines.
Interventions	Kangaroo mother care - mother will keep her newborn infant between the breasts, in close contact with her body and will be covered with the kangaroo tube for 4 hours minimum per day for 7 days. The infants will only wear a diaper and a cap Control: routine newborn care. Breastfeeding will be standard infant nutrition.
Outcomes	Expressed milk volume (on day 3 and 7); maternal serum prolactin (on day 3 and 7); infant's weight gain
Notes	Contact made with trialist May 2016. Awaiting more details.

Yu 2014

Methods	Randomised controlled trial with cross-over design.
Participants	48 lactating women using their own breast pump. China.
Interventions	Assigned to a relaxation activity of a breathing exercise or listening to music for 10-15 minutes (women's own choice) first, or to no relaxation activity, then change over on the next day. Questionnaire used to measure relaxation and comfort
Outcomes	Amount of milk produced from both breasts with and without relaxation. Mother's view of her comfort
Notes	Requested further data from trialist via company which funded the trial and on whose web site it was reported. Repeated attempts did not yield contact (to March 2016)

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

Fewtrell NCT02128295

Trial name or title	Randomised trial comparing the efficacy and acceptability of 2 single electric breast pump in mothers exclusively breastfeeding their healthy term infants
Methods	"Allocation: Randomized. Intervention Model: Parallel Assignment. Masking: Open Label."
Participants	Inclusion: "Mothers who have delivered healthy, term, singleton infants with no contra-indications for successful breast feeding Mothers who are exclusively breast feeding and are willing to be randomised to either use a breast pump or to continue breastfeeding without using a breast pump. Not already using a breast pump. Can speak, read and write in English (or Chinese for Beijing centre or Russian for Moscow centre)" Exclusion: "If they are mixed or formula feeding. Have an illness that may prevent them from expressing breast milk. Are not willing to be randomly assigned to the pump or the control group. Already expressing milk regularly"
Interventions	"Mothers will be recruited when their infants are around a month old, they will be randomised either to use one of two state of the art modern single electric breast pumps or to act as controls with no breast pump (but will receive a baby care voucher of similar value). If allocated to a breast pump, mothers will be asked to take part in a physiological study when their babies are 6 weeks old. In this test the mothers will be asked to express breast milk for 10 minutes on each breast. The primary hypothesis is that the total weight of milk produced in a 20 minute period and the weight of milk produced at 1 minute intervals at age 6 weeks will be greater for mothers using 1 of the pumps. A small sample of breast milk (~5ml) will be collected for analysis, the remaining expressed milk will returned to the mother Each month between the age of 3 and 6 months, all the mothers will be asked to complete online questionnaires about their breast-feeding and the use of their breast pumps (if they have one). At the end of the 6 months the mothers will be given a small voucher for a child-care store as a way of saying 'thank-you' for the inconvenience caused."
Outcomes	The total weight of milk expressed in a set 20-minute period (10 minutes/breast). The weight of milk expressed will be measured every minute for 20 minutes (10 minutes/side) when the infants are around 5-6 weeks old. Exclusive and partial breastfeeding. Data will be collected at the end of each month when infants are 3 to 6 months of age to record if the infants are still being exclusively or partially breast-fed
Starting date	June 2015.
Contact information	Katherine Kennedy and Mary Fewtrell Nutrition Unit, Institute of Child Health, University College, London UK. 0044 20905 2256 k.kennedy@ucl.ac.uk m.fewtrell@ucl.ac.uk
Notes	ClinicalTrials.gov Identifier: NCT02128295.

Parker NCT01892085

Trial name or title	Early initiation of milk expression in mothers of very low birthweight infants
Methods	"Allocation: Randomized. Intervention Model: Parallel Assignment. Masking: Open Label."
Participants	"stated intent to breastfeed, anticipating the birth of a very low birth weight infant (≤1500 grams) between 23-32 weeks gestation." Exclusion: " · mother not transported to recovery by 45 minutes following delivery or infant not expected to live over 2 weeks following delivery"
Interventions	"Mothers will be randomly assigned to one of three groups. Group 1 will begin pumping their breasts with the assistance of medical or nursing personnel within 60 minutes following delivery. Group 2 will begin pumping their breasts with the assistance of medical or nursing personnel within 1- less than 3 hours following delivery. Group 3 will begin pumping their breasts with the assistance of medical or nursing personnel 3-6 hours following delivery. Mothers will also do the following 1. Complete a log with information about their daily breast pumping sessions for 6 weeks. 2. Bring your breast milk to the neonatal intensive care unit when they visit and the milk will be weighed to determine the volume of milk. 3. Episodes of kangaroo care (placing the infant on your bare chest) will be collected. 4. Receive a call beginning the day after you delivery and then daily until their milk comes in to ask about a feeling of fullness in their breasts. In addition the following will be done 1. If their infant breastfeeds, he/she will be weighed before and after feeding to collect data on how much milk he/she ate from the breast 2. Information regarding infant's weekly breast milk intake and breast milk intake at discharge will be collected."
Outcomes	"Primary: Volume of breast milk will be measured at days 1-7, 14,21,28,35 and 42 Secondary: Timing of lactogenesis stage 2, Weekly percentage of infant breast milk intake, Percentage of breast milk feedings of infant at discharge."
Starting date	November 2013.
Contact information	Leslie A Parker, PhD 352-215-9360 University of Florida parkela@ufl.edu
Notes	ClinicalTrials.gov record accessed on February 17, 2016.

Sahler NCT01893047

Trial name or title	Effect of quiet or listening to music while breastfeeding on the production and lipid and sodium content of the milk
Methods	"The mother will be randomized to receive each of three experimental conditions: live music, recorded music, no music in random order over the course of three pumping sessions. She will then experience all three conditions again in random order."
Participants	40 mothers. Inclusion criteria: first time mothers between the ages of 18 and 45 who have had a vaginal or caesarean delivery of an infant less than 32 weeks' gestation, who are well, intending to breastfeed and are planning to pump milk on site in the NICU at least once/day. Recruited 7-10 days postpartum. Able to understand the directions and sign a consent form in English. Mothers who smoke, are taking medication

Sahler NCT01893047 (*Continued*)

	that may interfere with breastfeeding, and who have undergone prior breast surgery will not be excluded since they are their own control. Exclusion criteria: mothers whose infant has a low likelihood of survival as determined by the attending physician, mothers who have been diagnosed with mastitis This sample size will allow us to detect an effect size of 0.5, assuming a paired t-test and a Bonferroni-corrected P value of 0.025 (to account for 2 primary comparisons)
Interventions	Only 1 breast pumping session will be assessed on a given day with 1 of the music modes each time. The amount of milk pumped in 15 minutes will be measured and a 2 cc aliquot taken for analysis
Outcomes	Mother's experience of pumping and music, fat and sodium content of the milk
Starting date	July 2013, estimated completion date July 2017.
Contact information	OJ Sahler, MD, University of Rochester Medical Center, Rochester, New York, United States, 14642 oj_sahler@urmc.rochester.edu
Notes	Trial register last updated March 21, 2016 (accessed May 4 2016)

Sisk NCT01167517

Trial name or title	Education study in mothers of very low birthweight infants.
Methods	"Allocation: Randomized, Endpoint Classification: Efficacy Study, Intervention Model: Parallel Assignment, Masking: Single Blind (Caregiver), Primary Purpose: Prevention. Test the effectiveness of breast milk expression discharge instructions in digital video disc (DVD) format for home use by mothers of very low birthweight infants on the dose and duration of mother's breast milk feeding in their infants compared to breast milk expression discharge instructions in printed format."
Participants	40 mothers. Inclusion criteria: 1. infant birthweight less than 1500 g; 2. maternal educational attainment less than/equal to 12 years; 3. maternal low-income status (Medicaid participant prior to delivery). Exclusion criteria: 1. non-English speaking; 2. illicit drug use during pregnancy.
Interventions	Randomly assigned to receive a breast milk expression instruction digital video disc (DVD) in addition to standard of care lactation education or assigned to receive written instructions in addition to standard of care lactation education
Outcomes	"In addition to comparing infant intake of maternal breast milk intake, pre and post intervention lactation and breast milk expression knowledge will be compared between groups and DVD viewing frequency and acceptability will be determined with a log and questionnaire to be completed by the intervention group and collected the first month after delivery."
Starting date	July 2010.

Sisk NCT01167517 (*Continued*)

Contact information	Paula M Sisk, PhD Wake Forest Baptist Medical Center/Forsyth Medical Center, Winston Salem, North Carolina, United States Tel: 336-718-3277 psisk@wfubmc.edu. Mary Showalter, IBCLC Tel: 336-718-8233 mdshowalter@novanthealth.org
Notes	ClinicalTrials.gov NCT01167517. Status: enrolling by invitation. Trialist Paula Sisk reply May 5, 2013: "study not yet completed, maybe for next update". Trialist reply Feb 2016: "still on-going"

NICU: neonatal intensive care unit

DATA AND ANALYSES

Comparison 1. Any type of pump versus hand expression

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Adverse effects for mother or infant	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 At least 1 expressed milk sample contaminated	1	28	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.79, 1.61]
2 Transfer to feeding at breast	1	28	Risk Ratio (M-H, Fixed, 95% CI)	1.3 [0.63, 2.67]

Comparison 2. Any manual pump versus hand expression

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Adverse effects for mother or infant	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Bacterial level (Dornic degrees of acidity)	1	142	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.18, 0.58]
2 Quanity of milk expressed	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Volume of milk expressed (mL) on day 4-5	1	28	Mean Difference (IV, Fixed, 95% CI)	73.94 [-64.11, 211.99]
2.2 Mean volume over 6 days pumping (mL)	1	48	Mean Difference (IV, Fixed, 95% CI)	212.10 [9.39, 414.81]
3 Nutrients (potassium, energy) in milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Potassium concentration (mmol/L)	1	118	Mean Difference (IV, Fixed, 95% CI)	1.20 [0.04, 2.36]
3.2 Energy content (kcal/L)	1	141	Mean Difference (IV, Fixed, 95% CI)	28.80 [-16.94, 74.54]
4 Nutrients (sodium, protein) in milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 Sodium concentration (mmol/L)	1	118	Mean Difference (IV, Fixed, 95% CI)	-6.0 [-9.79, -2.21]
4.2 Protein concentration (g/L)	1	118	Mean Difference (IV, Fixed, 95% CI)	-1.30 [-2.56, -0.04]

Comparison 3. Any manual pump versus any other manual pump

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quantity of milk expressed (mL/24 hours)	1		Mean Difference (Fixed, 95% CI)	Subtotals only
1.1 Isis vs Harmony	1		Mean Difference (Fixed, 95% CI)	4.57 [-13.42, 22.56]
1.2 Isis vs Little Heart	1		Mean Difference (Fixed, 95% CI)	15.02 [-13.32, 43.36]
1.3 Isis vs Evenflo	1		Mean Difference (Fixed, 95% CI)	30.49 [3.40, 57.58]
1.4 Harmony vs Little Heart	1		Mean Difference (Fixed, 95% CI)	12.13 [-9.68, 33.94]
1.5 Harmony vs Evenflo	1		Mean Difference (Fixed, 95% CI)	28.5 [12.11, 44.89]
1.6 Litle Heart vs Evenflo	1		Mean Difference (Fixed, 95% CI)	15.47 [-75.30, 106.24]

Comparison 4. Any battery or small electric pump versus any other battery or small electric pump

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quantity of milk expressed	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Volume of milk one expression (mL)	1	40	Mean Difference (IV, Fixed, 95% CI)	15.00 [-8.33, 38.33]
2 Change in 24 hour milk production (g)	1	59	Mean Difference (IV, Fixed, 95% CI)	62.0 [-46.02, 170.02]
3 Time taken to express	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Minutes per one expression	1	40	Mean Difference (IV, Fixed, 95% CI)	4.0 [1.19, 6.81]
4 Maternal physiological effects - hormone levels	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 Time (seconds) to milk ejection	1	40	Mean Difference (IV, Fixed, 95% CI)	7.0 [-21.23, 35.23]

Comparison 5. Any large electric pump versus hand expression

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Maternal satisfaction (self-efficacy) measured using BSES, Breastfeeding Self-Efficacy Scale.	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 "I don't want anyone to see me (hand expressing/ pumping)"	1	68	Mean Difference (IV, Fixed, 95% CI)	0.70 [0.15, 1.25]

2 Maternal satisfaction (with instructions) measured using BMEE, breast milk expression experience	1	68	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-0.75, -0.05]
3 Adverse effects for mother or infant	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Maternal breast pain on scale 1-10	1	68	Mean Difference (IV, Fixed, 95% CI)	0.02 [-0.67, 0.71]
3.2 Bacterial level (Dornic degrees of acidity)	1	123	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.29, 0.49]
4 Quantity of milk expressed	4		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 Mean volume over 6 days of pumping (mL)	1	43	Mean Difference (IV, Fixed, 95% CI)	373.1 [161.09, 585.11]
4.2 Volume (cc) for 1 expression 12-36 hours postpartum	1	68	Mean Difference (IV, Fixed, 95% CI)	2.10 [-0.57, 4.77]
4.3 Volume of milk Day 1 (mL)	1	26	Mean Difference (IV, Fixed, 95% CI)	13.92 [-1.72, 29.56]
4.4 Volume of milk Day 2 (mL)	1	26	Mean Difference (IV, Fixed, 95% CI)	15.65 [0.95, 30.35]
4.5 Volume of milk Day 3 (mL)	1	26	Mean Difference (IV, Fixed, 95% CI)	51.11 [5.12, 97.10]
4.6 Volume of milk Day 4 (mL)	1	26	Mean Difference (IV, Fixed, 95% CI)	100.50 [18.33, 182.67]
4.7 Volume of milk Day 5 (mL)	2	51	Mean Difference (IV, Fixed, 95% CI)	128.25 [30.64, 225.87]
4.8 Volume of milk Day 6 (mL)	1	26	Mean Difference (IV, Fixed, 95% CI)	124.87 [-22.09, 271.83]
4.9 Volume of milk Day 7 (mL)	1	26	Mean Difference (IV, Fixed, 95% CI)	124.9 [-53.37, 303.17]
5 Nutrients (protein, nitrogen) in milk	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
5.1 Protein concentration (g/L)	1	111	Mean Difference (IV, Fixed, 95% CI)	0.10 [-1.20, 1.40]
5.2 Total Nitrogen (mg/dL)	1	36	Mean Difference (IV, Fixed, 95% CI)	10.0 [-3.07, 23.07]
6 Nutrients (potassium) in milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
6.1 Potassium concentration (mmol/L)	1	111	Mean Difference (IV, Fixed, 95% CI)	1.0 [-0.17, 2.17]
7 Nutrients (sodium, energy) in milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
7.1 Sodium concentration (mmol/L)	1	111	Mean Difference (IV, Fixed, 95% CI)	-6.90 [-10.58, -3.22]
7.2 Energy content (kcal/L)	1	122	Mean Difference (IV, Fixed, 95% CI)	-11.60 [-53.73, 30.53]
8 Nutrients (protein, carbohydrate, fat, energy) in milk	1		Mean Difference (Fixed, 95% CI)	Subtotals only
8.1 Protein (g/L)	1	42	Mean Difference (Fixed, 95% CI)	0.19 [-0.92, 1.30]
8.2 Carbohydrate (g/L)	1	42	Mean Difference (Fixed, 95% CI)	0.05 [-0.99, 1.08]
8.3 Fat (g/L)	1	42	Mean Difference (Fixed, 95% CI)	3.10 [-2.22, 8.41]
8.4 Energy (kcal/L)	1	42	Mean Difference (Fixed, 95% CI)	45.71 [-3.39, 94.81]

Comparison 6. Any large electric pump versus manual pump

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Adverse effects for mother or infant	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Bacterial level (Dornic degrees of acidity)	1	141	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.46, 0.26]
2 Quantity of milk expressed	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Mean volume 6 days pumping (mL)	1	53	Mean Difference (IV, Fixed, 95% CI)	161.0 [-66.90, 388.90]
2.2 Mean volume per day pumped (mL)	1	145	Mean Difference (IV, Fixed, 95% CI)	5.07 [-56.59, 66.73]
2.3 Volume of milk expressed (mL) on day 5	1	27	Mean Difference (IV, Fixed, 95% CI)	150.68 [-138.02, 439.38]
3 Time taken to express milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Mean time per day spent pumping (min)	1	145	Mean Difference (IV, Fixed, 95% CI)	-20.27 [-28.30, -12.24]
4 Nutrients (sodium, energy) in milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 Sodium concentration (mmol/L)	1	121	Mean Difference (IV, Fixed, 95% CI)	-0.90 [-3.56, 1.76]
4.2 Energy content (kcal/L)	1	141	Mean Difference (IV, Fixed, 95% CI)	-40.40 [-89.92, 9.12]
5 Nutrients (potassium) in milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
5.1 Potassium concentration (mmol/L)	1	121	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-1.36, 0.96]
6 Nutrient (protein) in milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
6.1 Protein concentration (g/L)	1	121	Mean Difference (IV, Fixed, 95% CI)	1.40 [0.08, 2.72]

Comparison 7. Any large electric pump versus battery or small electric pump

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quantity of milk expressed (one expression)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Volume milk one expression (mL) (Whittlestone vs UNO pump)	1	40	Mean Difference (IV, Fixed, 95% CI)	20.0 [1.28, 38.72]
1.2 Volume milk one expression (mL) (Whittlestone vs Swing pump)	1	40	Mean Difference (IV, Fixed, 95% CI)	5.0 [-21.30, 31.30]
1.3 Milk weight from 15 minute simultaneous pumping (g)	1	58	Mean Difference (IV, Fixed, 95% CI)	22.80 [-1.47, 47.07]

2 Quantity of milk expressed (g/one day)	1	62	Mean Difference (IV, Fixed, 95% CI)	-8.0 [-91.89, 75.89]
3 Time taken to express	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Minutes expressing each day (Symphony vs Avent Twin)	1	62	Mean Difference (IV, Fixed, 95% CI)	-7.0 [-24.34, 10.34]
3.2 Minutes for one expression (Whittlestone vs UNO pump)	1	40	Mean Difference (IV, Fixed, 95% CI)	-6.0 [-8.81, -3.19]
3.3 Minutes for one expression (Whittlestone vs Swing pump)	1	40	Mean Difference (IV, Fixed, 95% CI)	-2.0 [-4.48, 0.48]
4 Maternal physiological effects - hormone levels	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
4.1 Time (seconds) to milk ejection (UNO pump)	1	40	Mean Difference (IV, Fixed, 95% CI)	-26.0 [-54.49, 2.49]
4.2 Time (seconds) to milk ejection (Swing pump)	1	40	Mean Difference (IV, Fixed, 95% CI)	-19.0 [-42.86, 4.86]

Comparison 8. Any method with a specified protocol of simultaneous versus sequential pumping

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quantity of milk expressed	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Total grams in weeks 2-5	1	49	Mean Difference (IV, Fixed, 95% CI)	4298.94 [-1056.80, 9654.68]
1.2 Total mL per week	1	32	Mean Difference (IV, Fixed, 95% CI)	102.0 [-1268.57, 1472.57]
2 Time taken to express milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Hours per week	1	32	Mean Difference (IV, Fixed, 95% CI)	-3.5 [-5.61, -1.39]
3 Maternal physiological effects - hormone levels	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Serum prolactin change, fold increase	1	32	Mean Difference (IV, Fixed, 95% CI)	-3.7 [-10.62, 3.22]

Comparison 9. Any method with a specified relaxation technique versus no specified relaxation technique

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quanity of milk expressed	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Volume at one expression (mL)	1	55	Mean Difference (IV, Random, 95% CI)	34.70 [6.10, 63.30]
1.2 Volume on day 1 (mL)	1	160	Mean Difference (IV, Random, 95% CI)	17.0 [9.27, 24.73]
1.3 Volume on day 5 (mL)	1	160	Mean Difference (IV, Random, 95% CI)	85.1 [63.13, 107.07]
1.4 Volume on day 10 (mL)	1	160	Mean Difference (IV, Random, 95% CI)	277.4 [207.75, 347.05]

1.5 Volume on day 14 (mL)	1	160	Mean Difference (IV, Random, 95% CI)	503.3 [410.76, 595.84]
2 Nutrients in milk (g/L)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Fat content on day 1 (g/L) per day	1	160	Mean Difference (IV, Random, 95% CI)	8.60 [3.66, 13.54]
2.2 Fat content on day 5 (g/L) per day	1	160	Mean Difference (IV, Random, 95% CI)	12.0 [5.17, 18.83]
2.3 Fat content on day 10 (g/L) per day	1	160	Mean Difference (IV, Random, 95% CI)	14.0 [2.25, 25.75]
2.4 Fat content on day 14 (g/L) per day	1	160	Mean Difference (IV, Random, 95% CI)	21.30 [-2.46, 45.06]
3 Nutrients in milk (%)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Creamatocrit % (one sample)	1	55	Mean Difference (IV, Fixed, 95% CI)	0.40 [-1.00, 1.80]

Comparison 10. Any method plus specific instruction or support provided versus any method with no specific instruction provided

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Transfer to feeding at breast	1	60	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [1.25, 3.21]
2 Quantity of milk expressed	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Volume of milk (mL) pumped each time while in NICU	1	128	Mean Difference (IV, Fixed, 95% CI)	6.00 [-16.35, 28.35]
2.2 Volume mL/day, Week 1	1	33	Mean Difference (IV, Fixed, 95% CI)	-71.13 [-189.56, 47.30]
2.3 Volume mL/day, Week 2	1	33	Mean Difference (IV, Fixed, 95% CI)	-38.89 [-261.49, 183.71]
2.4 Volume mL/day, Week 3	1	33	Mean Difference (IV, Fixed, 95% CI)	51.0 [-198.00, 300.00]
2.5 Volume mL/day, Week 4	1	33	Mean Difference (IV, Fixed, 95% CI)	42.69 [-222.22, 307.60]
2.6 Volume mL/day, Week 5	1	33	Mean Difference (IV, Fixed, 95% CI)	47.38 [-252.82, 347.58]
2.7 Volume mL/day, Week 6	1	33	Mean Difference (IV, Fixed, 95% CI)	42.47 [-274.99, 359.93]
3 Nutritents in milk	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Lipids (g/L) Day 7	1	29	Mean Difference (IV, Fixed, 95% CI)	2.94 [-4.43, 10.31]
3.2 Lipids (g/L) Day 21	1	29	Mean Difference (IV, Fixed, 95% CI)	0.85 [-4.15, 5.85]
3.3 Lipids (g/L) Day 42	1	29	Mean Difference (IV, Fixed, 95% CI)	-2.28 [-8.01, 3.45]
4 Time taken to express	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.1 Mean minutes per day Week 1	1	33	Mean Difference (IV, Random, 95% CI)	7.70 [-14.34, 29.74]
4.2 Mean minutes per day Week 2	1	33	Mean Difference (IV, Random, 95% CI)	12.30 [-6.76, 31.36]
4.3 Mean minutes per day Week 3	1	33	Mean Difference (IV, Random, 95% CI)	23.00 [-2.14, 48.14]

4.4 Mean minutes per day Week 4	1	33	Mean Difference (IV, Random, 95% CI)	31.30 [7.11, 55.49]
4.5 Mean minutes per day Week 5	1	33	Mean Difference (IV, Random, 95% CI)	28.0 [4.35, 51.65]
4.6 Mean minutes per day Week 6	1	33	Mean Difference (IV, Random, 95% CI)	35.60 [7.30, 63.90]

Comparison 11. Any method plus breast massage versus no breast massage

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quantity of milk expressed (mL from two expressions)	1	72	Mean Difference (Fixed, 95% CI)	4.82 [1.25, 8.39]
2 Nutrients in milk	1		Mean Difference (Random, 95% CI)	Subtotals only
2.1 Fat content (creamatocrit)	1	72	Mean Difference (Random, 95% CI)	1.92 [1.02, 2.82]

Comparison 12. Any method plus warming the breast versus not warming the breast

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quanity of milk expressed (mL)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Expression 1	1	78	Mean Difference (IV, Fixed, 95% CI)	9.64 [-0.50, 19.78]
1.2 Expression 2	1	78	Mean Difference (IV, Fixed, 95% CI)	11.18 [3.00, 19.36]
1.3 Expression 3	1	78	Mean Difference (IV, Fixed, 95% CI)	11.10 [-2.48, 24.68]
1.4 Expression 4	1	78	Mean Difference (IV, Fixed, 95% CI)	12.39 [2.19, 22.59]
1.5 Expression 5	1	78	Mean Difference (IV, Fixed, 95% CI)	13.87 [4.31, 23.43]
1.6 Expression 6	1	78	Mean Difference (IV, Fixed, 95% CI)	13.02 [3.81, 22.23]

Comparison 13. Any vacuum protocol versus vacuum protocol

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quantity of milk expressed (EXP-EXP vs EXP-STD)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Day 1 (mL)	1	67	Mean Difference (IV, Fixed, 95% CI)	-0.80 [-8.46, 6.86]
1.2 Day 5 (mL)	1	67	Mean Difference (IV, Fixed, 95% CI)	-120.60 [-252.76, 11.56]
1.3 Day 14 (mL)	1	67	Mean Difference (IV, Fixed, 95% CI)	-138.20 [-346.19, 69.79]
2 Quantity of milk expressed (EXP-EXP vs STD-STD)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

2.1 Day 1 (mL)	1	71	Mean Difference (IV, Fixed, 95% CI)	-2.80 [-13.23, 7.63]
2.2 Day 5 (mL)	1	71	Mean Difference (IV, Fixed, 95% CI)	12.80 [-96.28, 121.88]
2.3 Day 14 (mL)	1	71	Mean Difference (IV, Fixed, 95% CI)	50.0 [-120.56, 220.56]
3 Quantity of milk expressed (EXP-STD vs STD-STD)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Day 1 (mL)	1	72	Mean Difference (IV, Fixed, 95% CI)	-2.0 [-12.46, 8.46]
3.2 Day 5 (mL)	1	72	Mean Difference (IV, Fixed, 95% CI)	133.40 [-0.89, 267.69]
3.3 Day 14 (mL)	1	72	Mean Difference (IV, Fixed, 95% CI)	188.20 [-3.29, 379.69]

Analysis 1.1. Comparison 1 Any type of pump versus hand expression, Outcome 1 Adverse effects for mother or infant.

Review: Methods of milk expression for lactating women

Comparison: 1 Any type of pump versus hand expression

Outcome: 1 Adverse effects for mother or infant

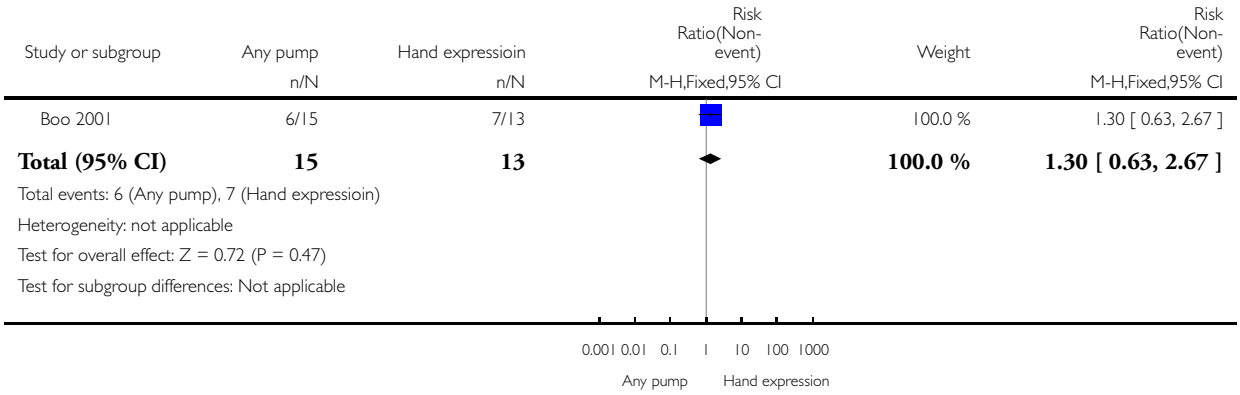
Study or subgroup	Any pump n/N	Hand expression n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 At least 1 expressed milk sample contaminated					
Boo 2001	13/15	10/13		100.0 %	1.13 [0.79, 1.61]
Subtotal (95% CI)	**15**	**13**		**100.0 %**	**1.13 [0.79, 1.61]**
Total events: 13 (Any pump), 10 (Hand expression)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.65 (P = 0.51)					

Analysis 1.2. Comparison 1 Any type of pump versus hand expression, Outcome 2 Transfer to feeding at breast.

Review: Methods of milk expression for lactating women

Comparison: 1 Any type of pump versus hand expression

Outcome: 2 Transfer to feeding at breast

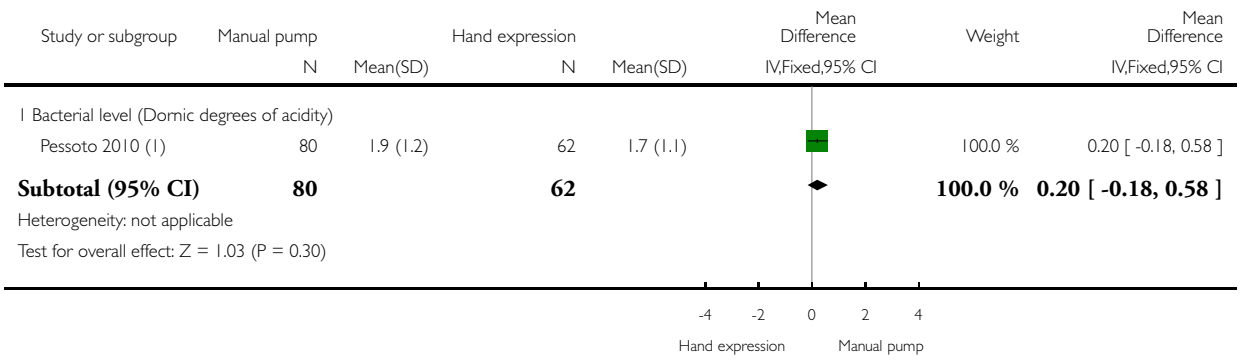


Analysis 2.1. Comparison 2 Any manual pump versus hand expression, Outcome 1 Adverse effects for mother or infant.

Review: Methods of milk expression for lactating women

Comparison: 2 Any manual pump versus hand expression

Outcome: 1 Adverse effects for mother or infant



(1) The more acidic milk is and the lower is its quality. Acidity less than 4 Dornic degrees is top quality and over 7 Dornic degrees is unsuitable for use in a donor human milk bank

Analysis 2.2. Comparison 2 Any manual pump versus hand expression, Outcome 2 Quanity of milk expressed.

Review: Methods of milk expression for lactating women

Comparison: 2 Any manual pump versus hand expression

Outcome: 2 Quanity of milk expressed

Study or subgroup	Manual/ Pedal pump N	Mean(SD)	Hand expression N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Volume of milk expressed (mL) on day 4-5							
Pessoto 2010	15	222.4 (205.12)	13	148.46 (167.42)		100.0 %	73.94 [-64.11, 211.99]
Subtotal (95% CI)	**15**		**13**			**100.0 %**	**73.94 [-64.11, 211.99]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.05 (P = 0.29)							
2 Mean volume over 6 days pumping (mL)							
Slusher 2007	29	631.7 (426)	19	419.6 (290.4)		100.0 %	212.10 [9.39, 414.81]
Subtotal (95% CI)	**29**		**19**			**100.0 %**	**212.10 [9.39, 414.81]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.05 (P = 0.040)							
Test for subgroup differences: Chi^2 = 1.22, df = 1 (P = 0.27), I^2 =18%							

Analysis 2.3. Comparison 2 Any manual pump versus hand expression, Outcome 3 Nutrients (potassium, energy) in milk.

Review: Methods of milk expression for lactating women

Comparison: 2 Any manual pump versus hand expression

Outcome: 3 Nutrients (potassium, energy) in milk

Study or subgroup	Manual Pump N	Mean(SD)	Hand expression N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Potassium concentration (mmol/L)							
Pessoto 2010 (1)	64	15.2 (3.3)	54	14 (3.1)		100.0 %	1.20 [0.04, 2.36]
Subtotal (95% CI)	**64**		**54**			**100.0 %**	**1.20 [0.04, 2.36]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.03 (P = 0.042)							
2 Energy content (kcal/L)							
Pessoto 2010 (2)	80	630.5 (169.8)	61	601.7 (106)		100.0 %	28.80 [-16.94, 74.54]
Subtotal (95% CI)	**80**		**61**			**100.0 %**	**28.80 [-16.94, 74.54]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.23 (P = 0.22)							

(1) Lower potasium is the desired outcome.

(2) Higher energy is the desired outcome.

Analysis 2.4. Comparison 2 Any manual pump versus hand expression, Outcome 4 Nutrients (sodium, protein) in milk.

Review: Methods of milk expression for lactating women

Comparison: 2 Any manual pump versus hand expression

Outcome: 4 Nutrients (sodium, protein) in milk

Study or subgroup	Manual pump N	Mean(SD)	Hand expression N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Sodium concentration (mmol/L)							
Pessoto 2010 (1)	64	25 (8.1)	54	31 (12.1)		100.0 %	-6.00 [-9.79, -2.21]
Subtotal (95% CI)	**64**		**54**			**100.0 %**	**-6.00 [-9.79, -2.21]**
Heterogeneity: not applicable							
Test for overall effect: Z = 3.10 (P = 0.0019)							
2 Protein concentration (g/L)							
Pessoto 2010 (2)	64	10.8 (3.7)	54	12.1 (3.3)		100.0 %	-1.30 [-2.56, -0.04]
Subtotal (95% CI)	**64**		**54**			**100.0 %**	**-1.30 [-2.56, -0.04]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.02 (P = 0.044)							

(1) Higher sodium is the desired outcome.

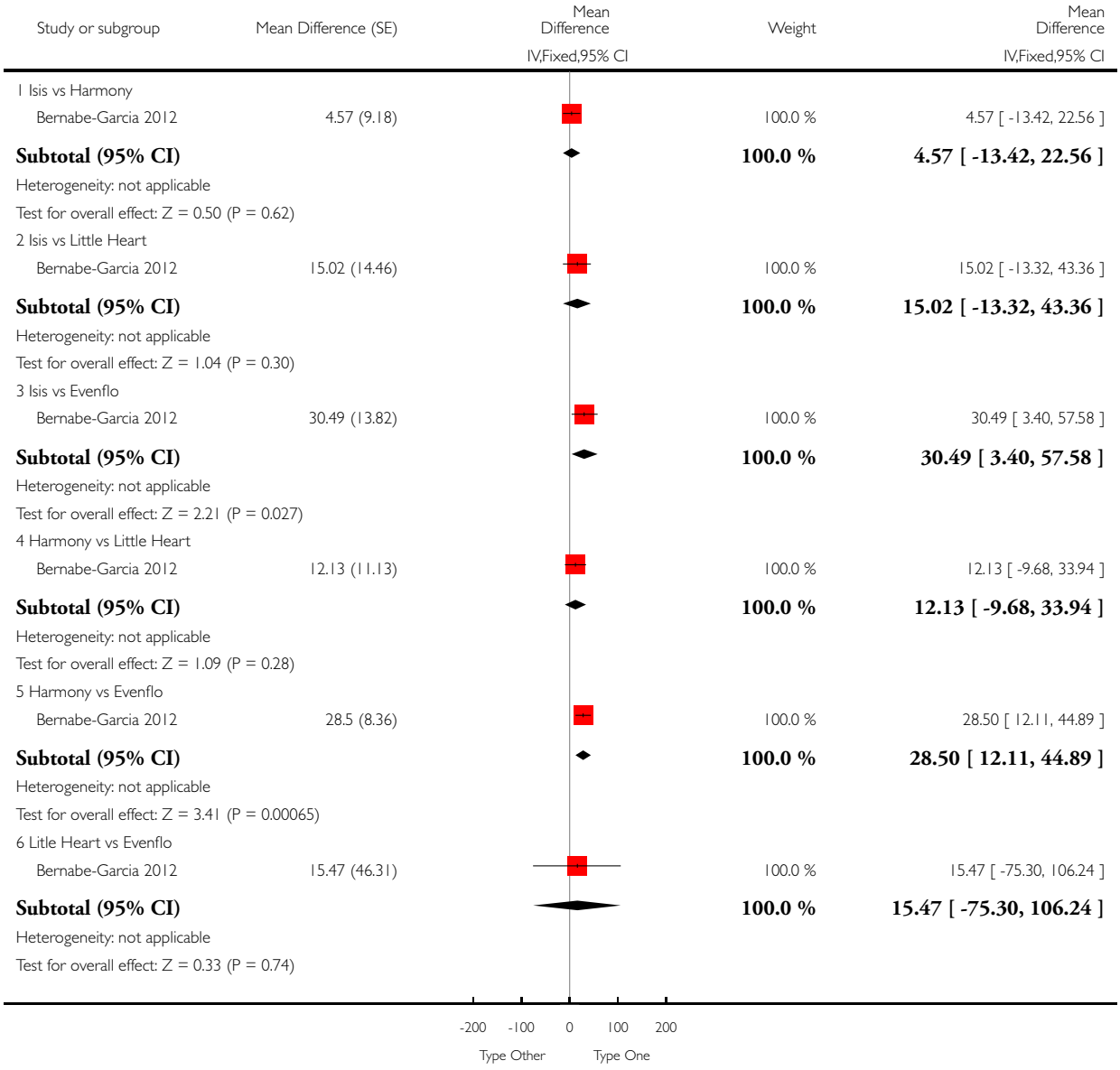
(2) Higher protein is the desired outcome.

Analysis 3.1. Comparison 3 Any manual pump versus any other manual pump, Outcome 1 Quantity of milk expressed (mL/24 hours).

Review: Methods of milk expression for lactating women

Comparison: 3 Any manual pump versus any other manual pump

Outcome: 1 Quantity of milk expressed (mL/24 hours)

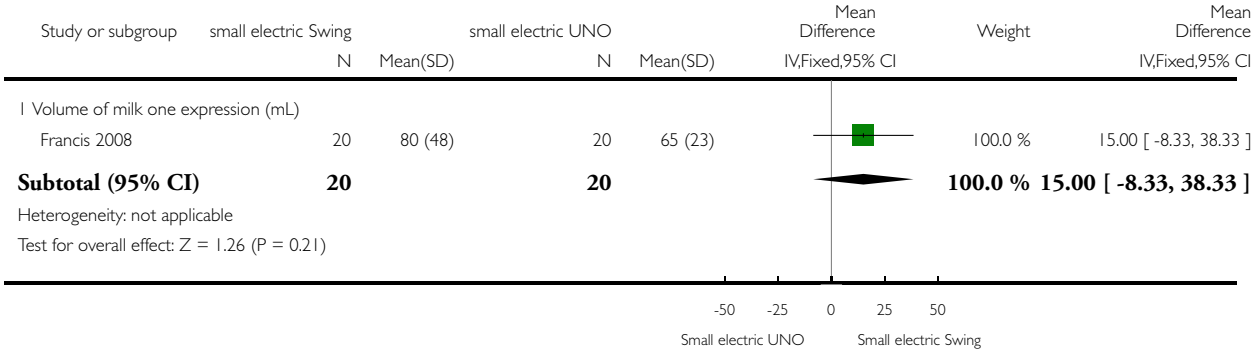


Analysis 4.1. Comparison 4 Any battery or small electric pump versus any other battery or small electric pump, Outcome 1 Quantity of milk expressed.

Review: Methods of milk expression for lactating women

Comparison: 4 Any battery or small electric pump versus any other battery or small electric pump

Outcome: 1 Quantity of milk expressed

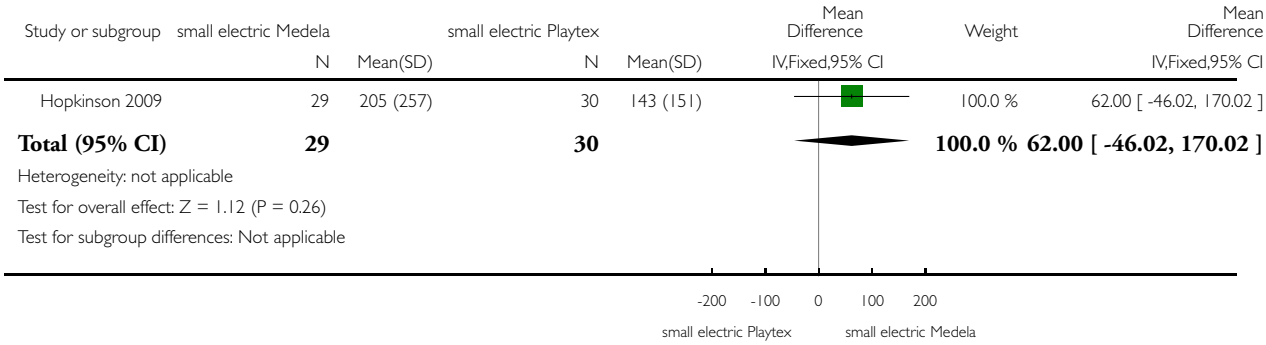


Analysis 4.2. Comparison 4 Any battery or small electric pump versus any other battery or small electric pump, Outcome 2 Change in 24 hour milk production (g).

Review: Methods of milk expression for lactating women

Comparison: 4 Any battery or small electric pump versus any other battery or small electric pump

Outcome: 2 Change in 24 hour milk production (g)

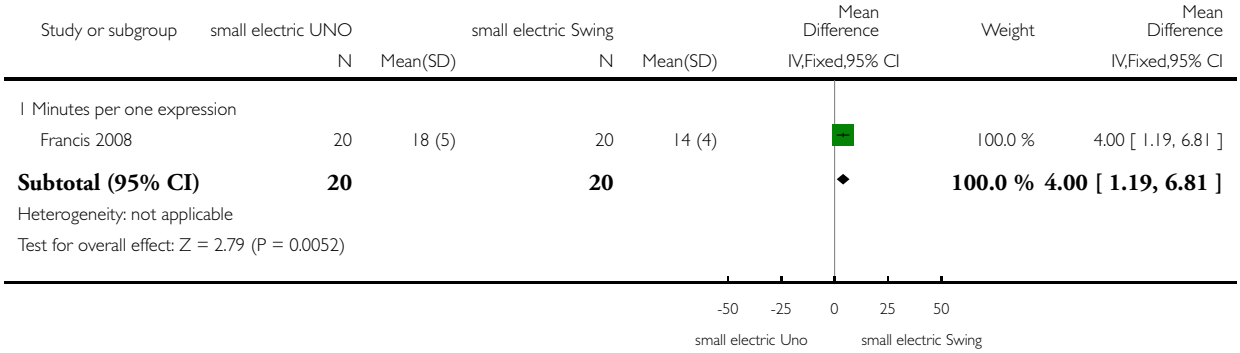


Analysis 4.3. Comparison 4 Any battery or small electric pump versus any other battery or small electric pump, Outcome 3 Time taken to express.

Review: Methods of milk expression for lactating women

Comparison: 4 Any battery or small electric pump versus any other battery or small electric pump

Outcome: 3 Time taken to express

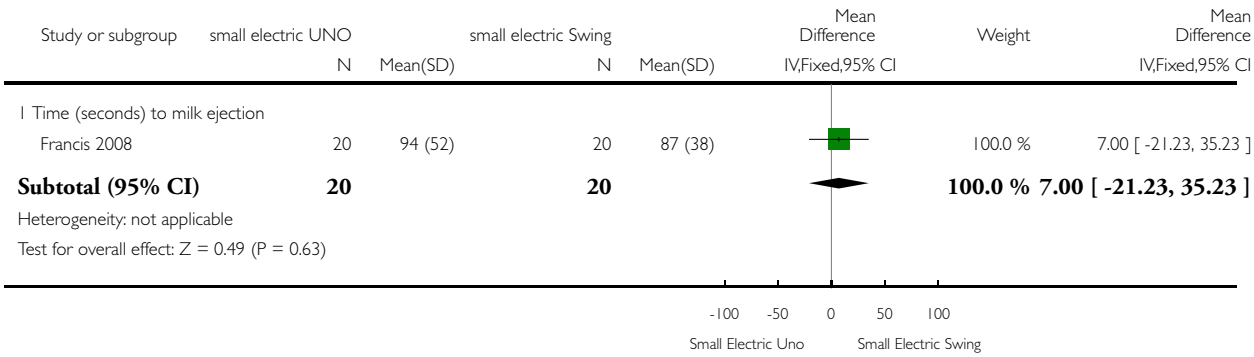


Analysis 4.4. Comparison 4 Any battery or small electric pump versus any other battery or small electric pump, Outcome 4 Maternal physiological effects - hormone levels.

Review: Methods of milk expression for lactating women

Comparison: 4 Any battery or small electric pump versus any other battery or small electric pump

Outcome: 4 Maternal physiological effects - hormone levels

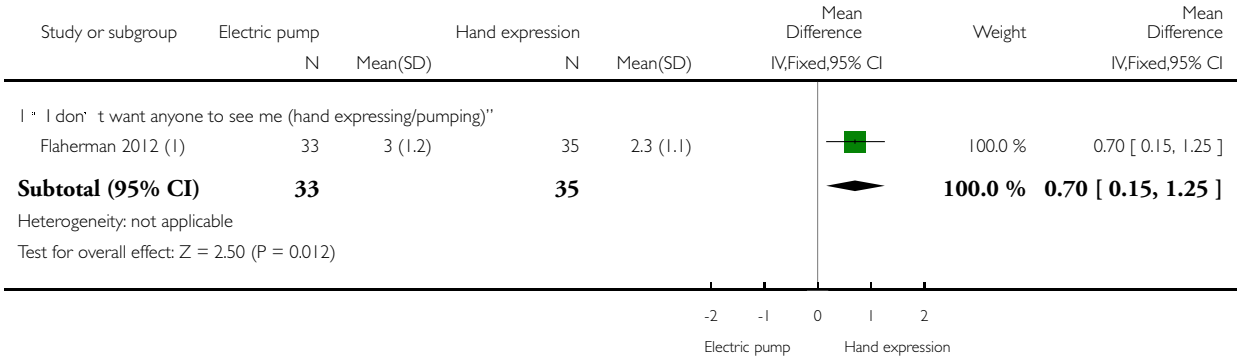


Analysis 5.1. Comparison 5 Any large electric pump versus hand expression, Outcome 1 Maternal satisfaction (self-efficacy) measured using BSES, Breastfeeding Self-Efficacy Scale..

Review: Methods of milk expression for lactating women

Comparison: 5 Any large electric pump versus hand expression

Outcome: 1 Maternal satisfaction (self-efficacy) measured using BSES, Breastfeeding Self-Efficacy Scale.



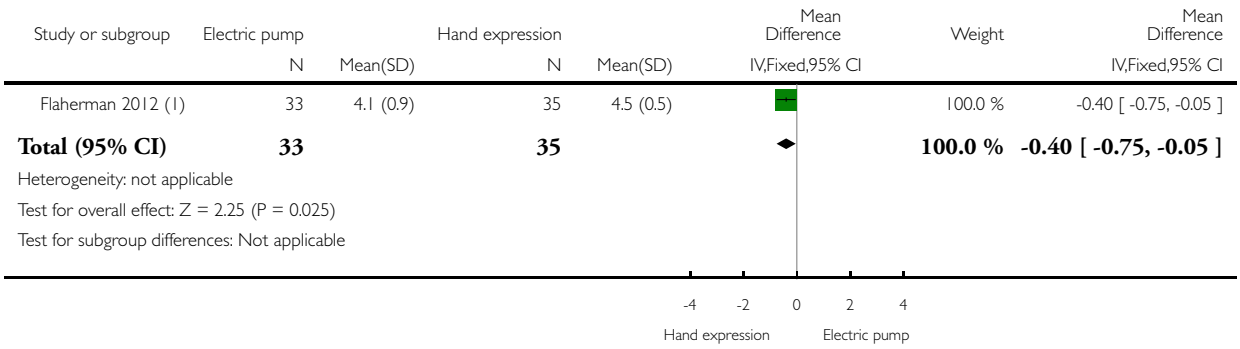
(1) Items scored on 1-5 scale, from 1 strongly disagree to 5 strongly agree (lower score is better)

Analysis 5.2. Comparison 5 Any large electric pump versus hand expression, Outcome 2 Maternal satisfaction (with instructions) measured using BMEE, breast milk expression experience.

Review: Methods of milk expression for lactating women

Comparison: 5 Any large electric pump versus hand expression

Outcome: 2 Maternal satisfaction (with instructions) measured using BMEE, breast milk expression experience



(1) Items scored on 1-5 scale, from 1 strongly disagree to 5 strongly agree (higher score is better)

Analysis 5.3. Comparison 5 Any large electric pump versus hand expression, Outcome 3 Adverse effects for mother or infant.

Review: Methods of milk expression for lactating women

Comparison: 5 Any large electric pump versus hand expression

Outcome: 3 Adverse effects for mother or infant

Study or subgroup	Electric pump N	Mean(SD)	Hand expression N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Maternal breast pain on scale 1-10							
Flaherman 2012 (1)	33	0.73 (1.5)	35	0.71 (1.4)		100.0 %	0.02 [-0.67, 0.71]
Subtotal (95% CI)	**33**		**35**			**100.0 %**	**0.02 [-0.67, 0.71]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.06 (P = 0.95)							
2 Bacterial level (Dornic degrees of acidity)							
Pessoto 2010 (2)	61	1.8 (1.1)	62	1.7 (1.1)		100.0 %	0.10 [-0.29, 0.49]
Subtotal (95% CI)	**61**		**62**			**100.0 %**	**0.10 [-0.29, 0.49]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.50 (P = 0.61)							

(1) Reported by trialist as mean measured pain using a modified Holdcroft scale of 1-10, no further information available.

(2) Acidity less than 4 Dornic degrees is top quality and over 7 Dornic degrees is unsuitable for use in a donor human milk bank

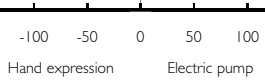
Analysis 5.4. Comparison 5 Any large electric pump versus hand expression, Outcome 4 Quantity of milk expressed.

Review: Methods of milk expression for lactating women

Comparison: 5 Any large electric pump versus hand expression

Outcome: 4 Quantity of milk expressed

Study or subgroup	Electric pump N	Mean(SD)	Hand expression N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Mean volume over 6 days of pumping (mL)							
Slusher 2007	24	792.7 (417.5)	19	419.6 (290.4)		100.0 %	373.10 [161.09, 585.11]
Subtotal (95% CI)	**24**		**19**			**100.0 %**	**373.10 [161.09, 585.11]**
Heterogeneity: not applicable							
Test for overall effect: Z = 3.45 (P = 0.00056)							
2 Volume (cc) for 1 expression 12-36 hours postpartum							
Flaherman 2012	33	2.9 (7.7)	35	0.8 (1.4)		100.0 %	2.10 [-0.57, 4.77]
Subtotal (95% CI)	**33**		**35**			**100.0 %**	**2.10 [-0.57, 4.77]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.54 (P = 0.12)							
3 Volume of milk Day 1 (mL)							
Lussier 2015	14	17.12 (29.23)	12	3.2 (5.63)		100.0 %	13.92 [-1.72, 29.56]
Subtotal (95% CI)	**14**		**12**			**100.0 %**	**13.92 [-1.72, 29.56]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.74 (P = 0.081)							
4 Volume of milk Day 2 (mL)							
Lussier 2015	14	19.9 (27.49)	12	4.25 (5.24)		100.0 %	15.65 [0.95, 30.35]
Subtotal (95% CI)	**14**		**12**			**100.0 %**	**15.65 [0.95, 30.35]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.09 (P = 0.037)							
5 Volume of milk Day 3 (mL)							
Lussier 2015	14	69.86 (85.8)	12	18.75 (17.22)		100.0 %	51.11 [5.12, 97.10]
Subtotal (95% CI)	**14**		**12**			**100.0 %**	**51.11 [5.12, 97.10]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.18 (P = 0.029)							
6 Volume of milk Day 4 (mL)							
Lussier 2015	14	181.98 (136.51)	12	81.48 (71.54)		100.0 %	100.50 [18.33, 182.67]
Subtotal (95% CI)	**14**		**12**			**100.0 %**	**100.50 [18.33, 182.67]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.40 (P = 0.017)							
7 Volume of milk Day 5 (mL)							
Lussier 2015	14	231.79 (156.78)	12	116.41 (112.58)		88.2 %	115.38 [11.45, 219.31]



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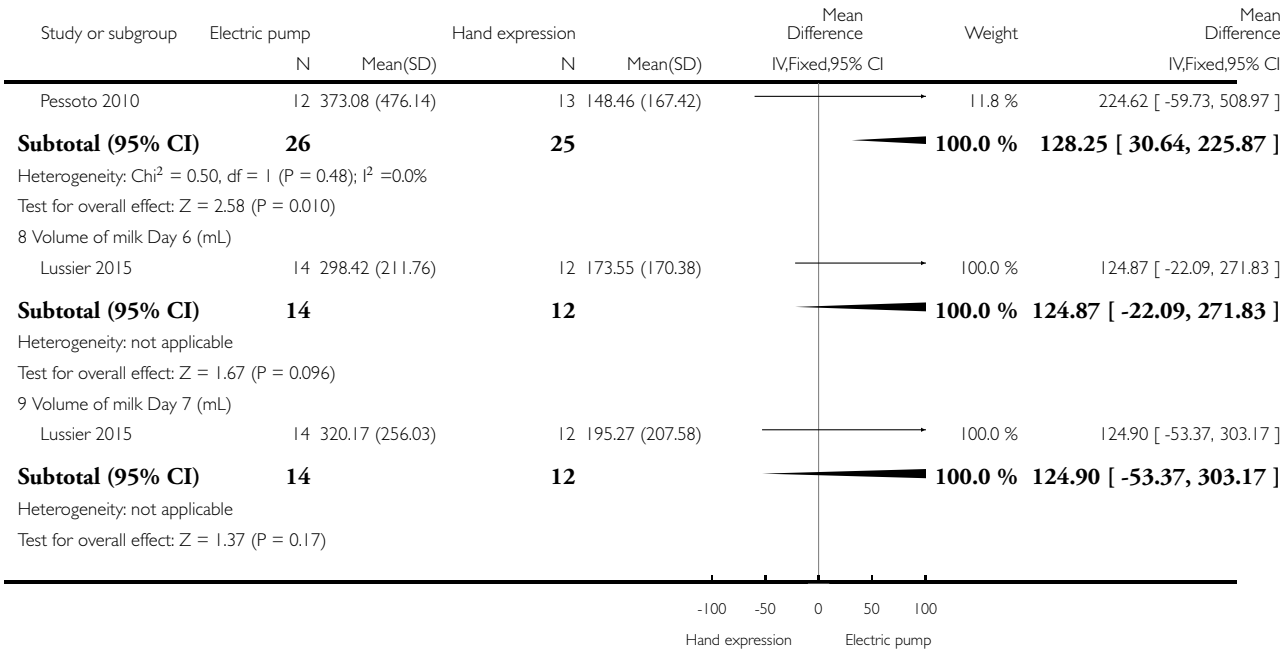


Analysis 5.5. Comparison 5 Any large electric pump versus hand expression, Outcome 5 Nutrients (protein, nitrogen) in milk.

Review: Methods of milk expression for lactating women

Comparison: 5 Any large electric pump versus hand expression

Outcome: 5 Nutrients (protein, nitrogen) in milk

Study or subgroup	Electric pump N	Mean(SD)	Hand expression N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Protein concentration (g/L)							
Pessoto 2010 (1)	57	12.2 (3.7)	54	12.1 (3.3)		100.0 %	0.10 [-1.20, 1.40]
Subtotal (95% CI)	**57**		**54**			**100.0 %**	**0.10 [-1.20, 1.40]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.15 (P = 0.88)							
2 Total Nitrogen (mg/dL)							
Garza 1982 (2)	18	220 (20)	18	210 (20)		100.0 %	10.00 [-3.07, 23.07]
Subtotal (95% CI)	**18**		**18**			**100.0 %**	**10.00 [-3.07, 23.07]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.50 (P = 0.13)							

(1) Higher protein is the desired outcome.

(2) Higher nitrogen is the desired outcome.

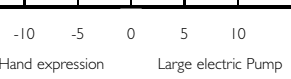
Analysis 5.6. Comparison 5 Any large electric pump versus hand expression, Outcome 6 Nutrients (potassium) in milk.

Review: Methods of milk expression for lactating women

Comparison: 5 Any large electric pump versus hand expression

Outcome: 6 Nutrients (potassium) in milk

Study or subgroup	Large electric Pump N	Mean(SD)	Hand expression N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Potassium concentration (mmol/L)							
Pessoto 2010 (1)	57	15 (3.2)	54	14 (3.1)		100.0 %	1.00 [-0.17, 2.17]
Subtotal (95% CI)	**57**		**54**			**100.0 %**	**1.00 [-0.17, 2.17]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.67 (P = 0.094)							
Test for subgroup differences: Not applicable							



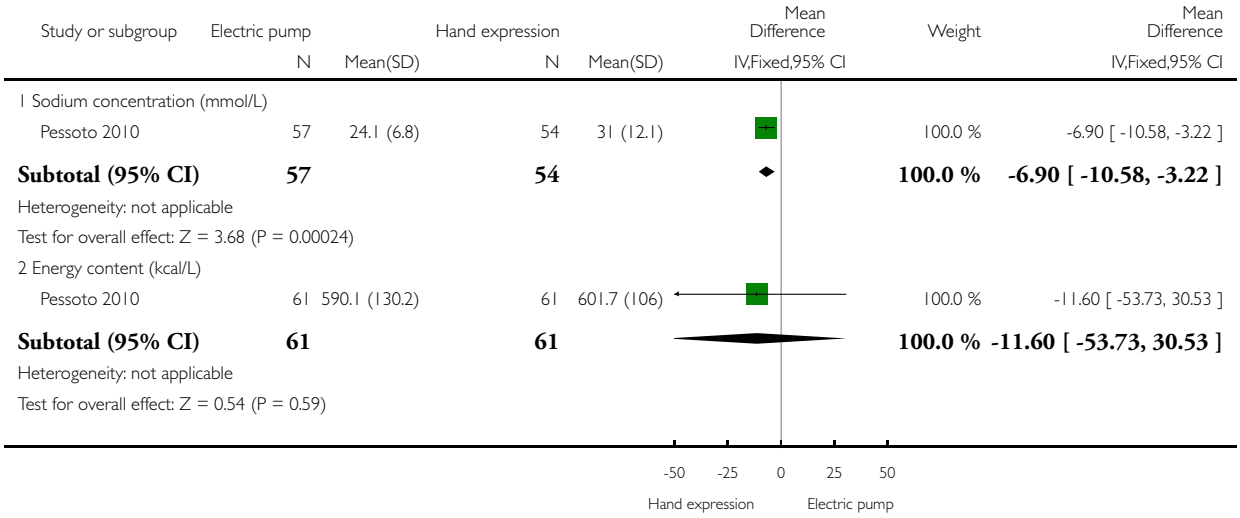
(1) A lower potassium level is the desired outcome.

Analysis 5.7. Comparison 5 Any large electric pump versus hand expression, Outcome 7 Nutrients (sodium, energy) in milk.

Review: Methods of milk expression for lactating women

Comparison: 5 Any large electric pump versus hand expression

Outcome: 7 Nutrients (sodium, energy) in milk



Analysis 5.8. Comparison 5 Any large electric pump versus hand expression, Outcome 8 Nutrients (protein, carbohydrate, fat, energy) in milk.

Review: Methods of milk expression for lactating women

Comparison: 5 Any large electric pump versus hand expression

Outcome: 8 Nutrients (protein, carbohydrate, fat, energy) in milk

Study or subgroup	Electric pump N	Hand expression N	Mean Difference (SE)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Protein (g/L)						
Mangel 2015	21	21	0.19 (0.567)		100.0 %	0.19 [-0.92, 1.30]
Subtotal (95% CI)	**21**	**21**			**100.0 %**	**0.19 [-0.92, 1.30]**
Heterogeneity: not applicable						
Test for overall effect: Z = 0.34 (P = 0.74)						
2 Carbohydrate (g/L)						
Mangel 2015	21	21	0.048 (0.528)		100.0 %	0.05 [-0.99, 1.08]
Subtotal (95% CI)	**21**	**21**			**100.0 %**	**0.05 [-0.99, 1.08]**
Heterogeneity: not applicable						
Test for overall effect: Z = 0.09 (P = 0.93)						
3 Fat (g/L)						
Mangel 2015	21	21	3.095 (2.713)		100.0 %	3.10 [-2.22, 8.41]
Subtotal (95% CI)	**21**	**21**			**100.0 %**	**3.10 [-2.22, 8.41]**
Heterogeneity: not applicable						
Test for overall effect: Z = 1.14 (P = 0.25)						
4 Energy (kcal/L)						
Mangel 2015	21	21	45.714 (25.051)		100.0 %	45.71 [-3.39, 94.81]
Subtotal (95% CI)	**21**	**21**			**100.0 %**	**45.71 [-3.39, 94.81]**
Heterogeneity: not applicable						
Test for overall effect: Z = 1.82 (P = 0.068)						

Analysis 6.1. Comparison 6 Any large electric pump versus manual pump, Outcome 1 Adverse effects for mother or infant.

Review: Methods of milk expression for lactating women

Comparison: 6 Any large electric pump versus manual pump

Outcome: 1 Adverse effects for mother or infant

Study or subgroup	Electric Pump N	Mean(SD)	Manual Pump N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Bacterial level (Dornic degrees of acidity)							
Pessoto 2010 (1)	61	1.8 (1)	80	1.9 (1.2)		100.0 %	-0.10 [-0.46, 0.26]
Subtotal (95% CI)	**61**		**80**			**100.0 %**	**-0.10 [-0.46, 0.26]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.54 (P = 0.59)							

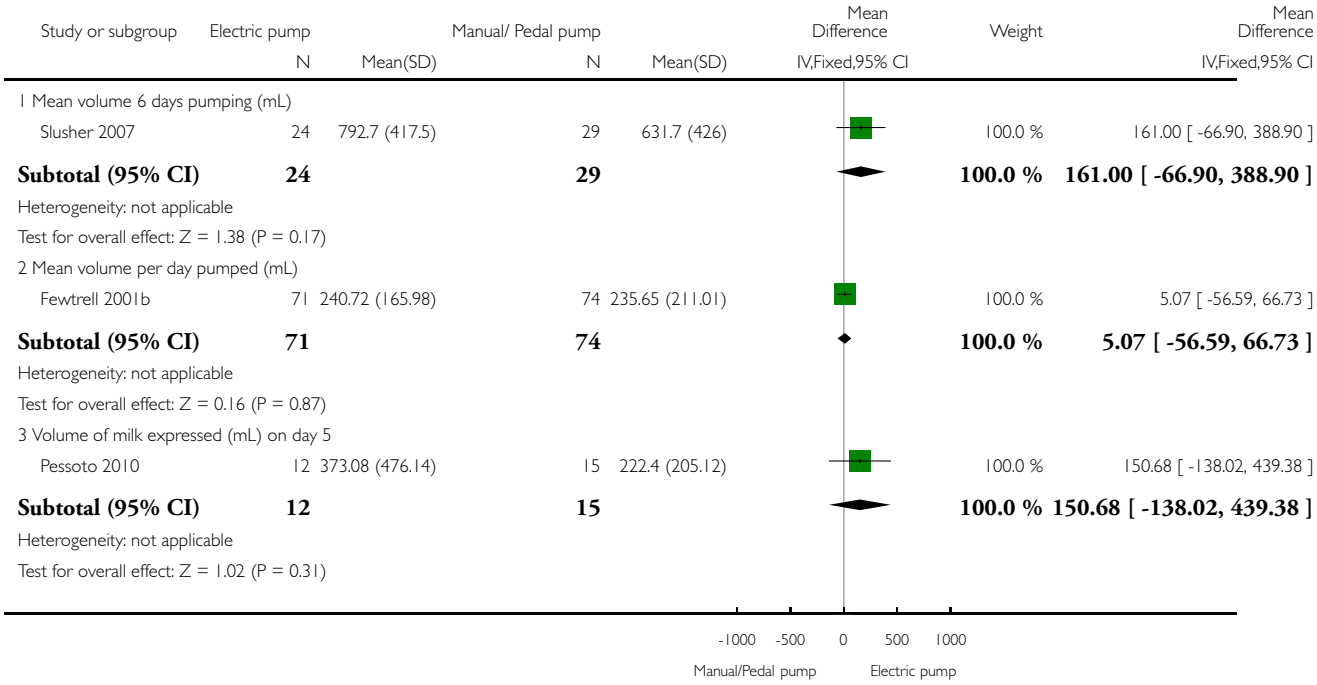
(1) Acidity less than 4 Dornic degrees is top quality and over 7 Dornic degrees is unsuitable for use in a donor human milk bank

Analysis 6.2. Comparison 6 Any large electric pump versus manual pump, Outcome 2 Quantity of milk expressed.

Review: Methods of milk expression for lactating women

Comparison: 6 Any large electric pump versus manual pump

Outcome: 2 Quantity of milk expressed



Analysis 6.3. Comparison 6 Any large electric pump versus manual pump, Outcome 3 Time taken to express milk.

Review: Methods of milk expression for lactating women

Comparison: 6 Any large electric pump versus manual pump

Outcome: 3 Time taken to express milk

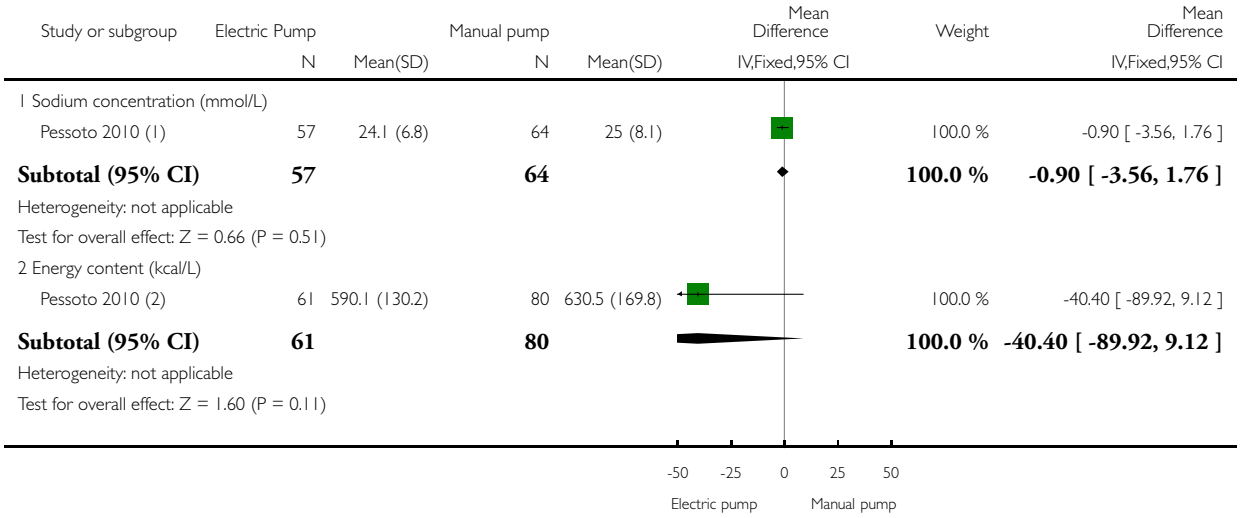
Study or subgroup	Electric pump N	Mean(SD)	Manual pump N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 Mean time per day spent pumping (min)							
Fewtrell 2001b	71	53.26 (22.56)	74	73.53 (26.68)		100.0 %	-20.27 [-28.30, -12.24]
Subtotal (95% CI)	**71**		**74**			**100.0 %**	**-20.27 [-28.30, -12.24]**
Heterogeneity: not applicable							
Test for overall effect: Z = 4.95 (P < 0.00001)							

Analysis 6.4. Comparison 6 Any large electric pump versus manual pump, Outcome 4 Nutrients (sodium, energy) in milk.

Review: Methods of milk expression for lactating women

Comparison: 6 Any large electric pump versus manual pump

Outcome: 4 Nutrients (sodium, energy) in milk



(1) Higher sodium is the desired outcome.

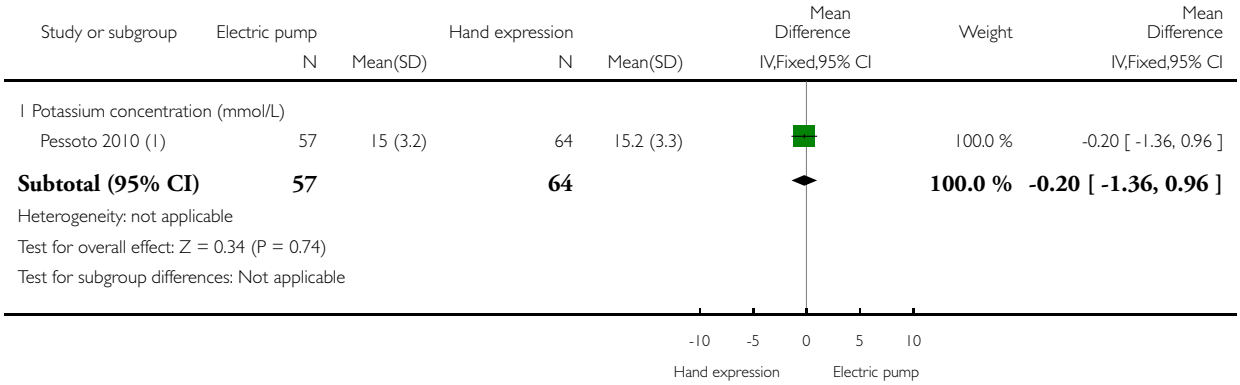
(2) Higher energy is the desired outcome.

Analysis 6.5. Comparison 6 Any large electric pump versus manual pump, Outcome 5 Nutrients (potassium) in milk.

Review: Methods of milk expression for lactating women

Comparison: 6 Any large electric pump versus manual pump

Outcome: 5 Nutrients (potassium) in milk



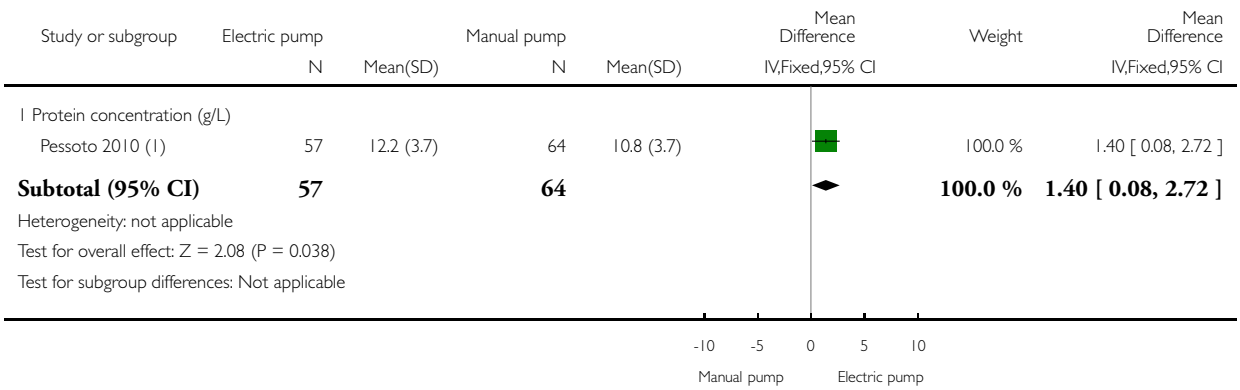
(1) Lower potasium is the desired outcome.

Analysis 6.6. Comparison 6 Any large electric pump versus manual pump, Outcome 6 Nutrient (protein) in milk.

Review: Methods of milk expression for lactating women

Comparison: 6 Any large electric pump versus manual pump

Outcome: 6 Nutrient (protein) in milk



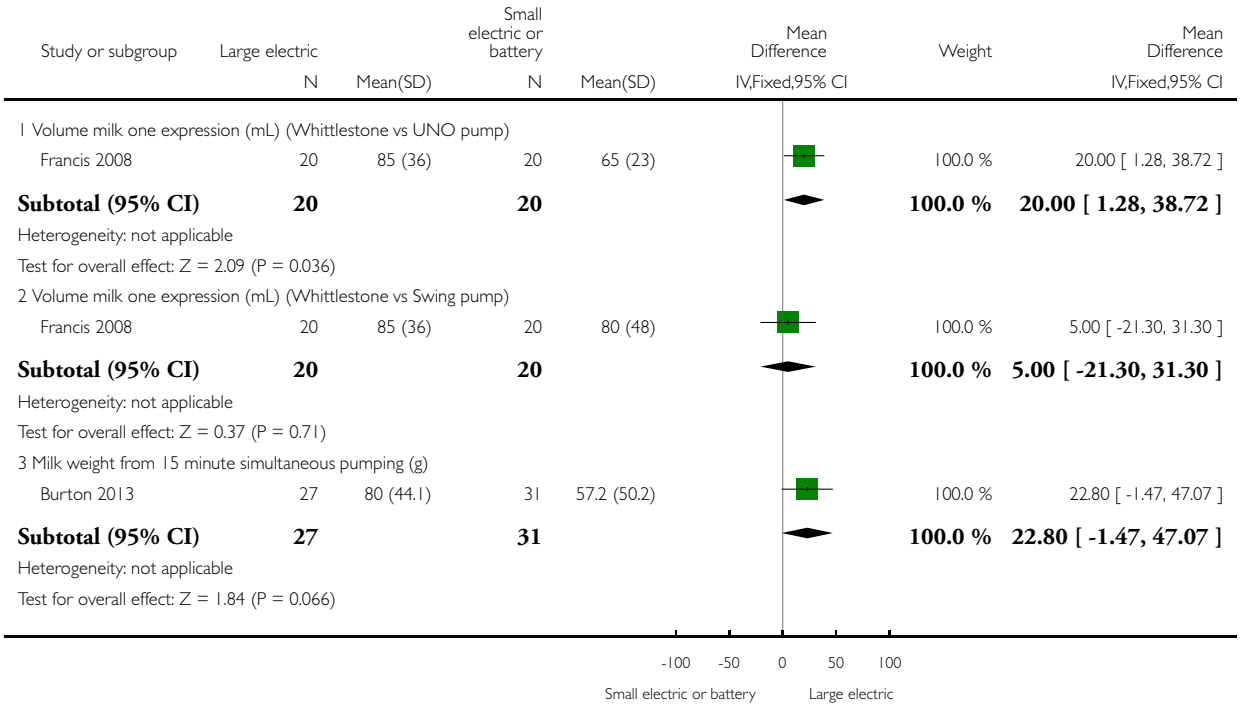
(1) A high protein level is the desired outcome.

Analysis 7.1. Comparison 7 Any large electric pump versus battery or small electric pump, Outcome 1 Quantity of milk expressed (one expression).

Review: Methods of milk expression for lactating women

Comparison: 7 Any large electric pump versus battery or small electric pump

Outcome: 1 Quantity of milk expressed (one expression)

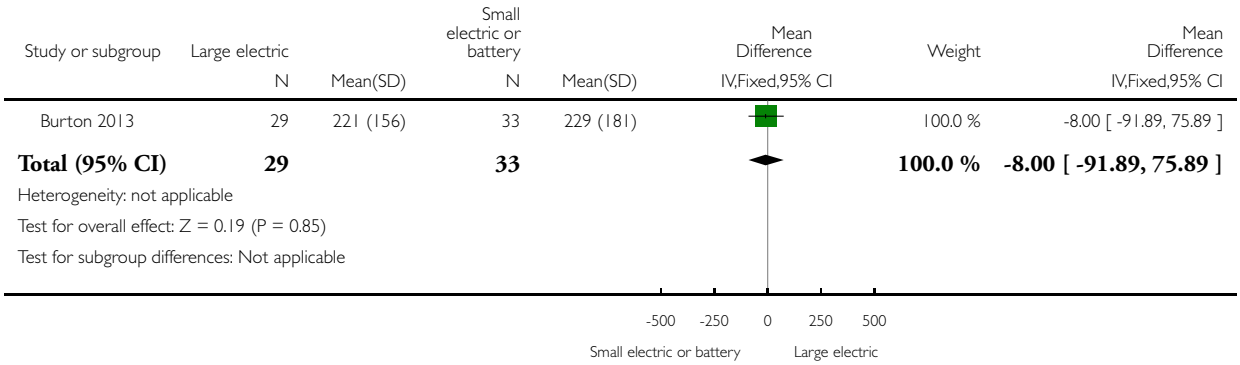


Analysis 7.2. Comparison 7 Any large electric pump versus battery or small electric pump, Outcome 2 Quantity of milk expressed (g/one day).

Review: Methods of milk expression for lactating women

Comparison: 7 Any large electric pump versus battery or small electric pump

Outcome: 2 Quantity of milk expressed (g/one day)

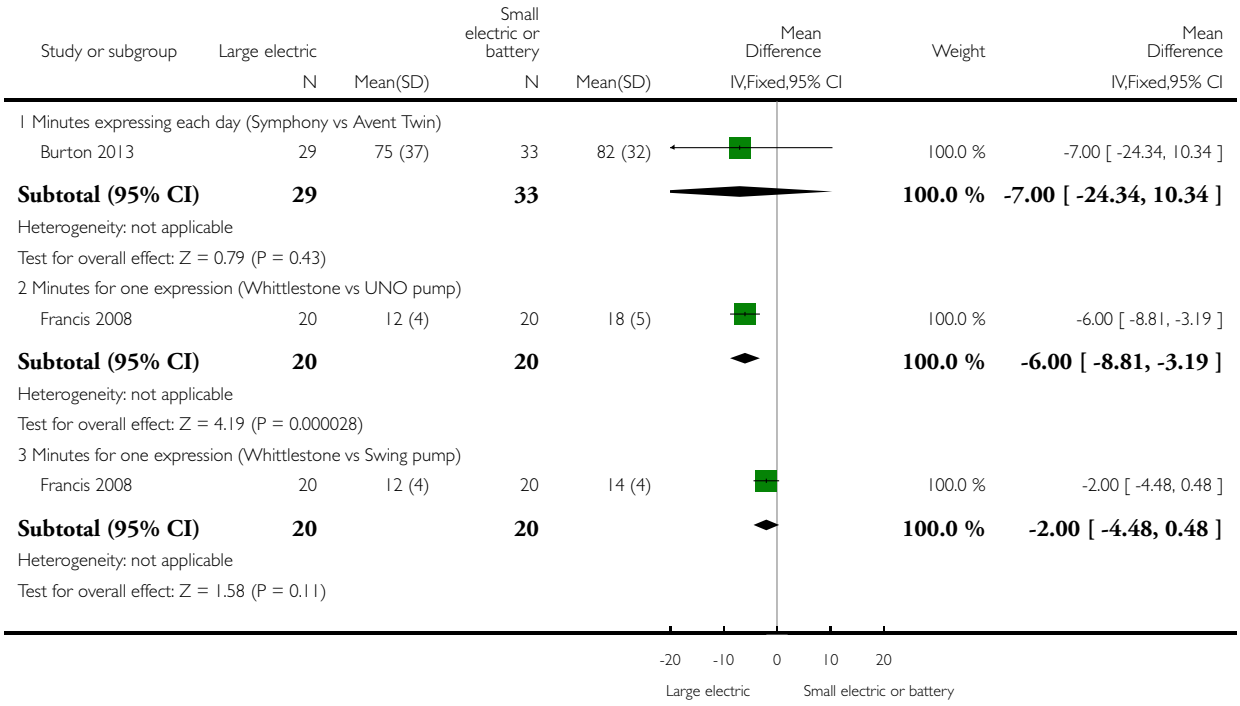


Analysis 7.3. Comparison 7 Any large electric pump versus battery or small electric pump, Outcome 3 Time taken to express.

Review: Methods of milk expression for lactating women

Comparison: 7 Any large electric pump versus battery or small electric pump

Outcome: 3 Time taken to express

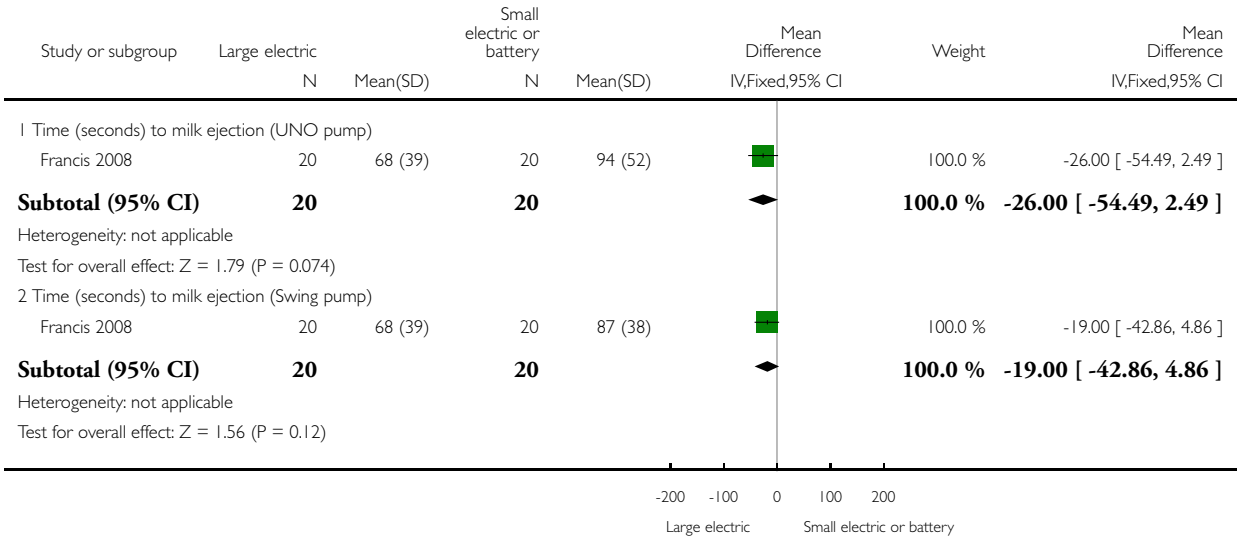


Analysis 7.4. Comparison 7 Any large electric pump versus battery or small electric pump, Outcome 4 Maternal physiological effects - hormone levels.

Review: Methods of milk expression for lactating women

Comparison: 7 Any large electric pump versus battery or small electric pump

Outcome: 4 Maternal physiological effects - hormone levels

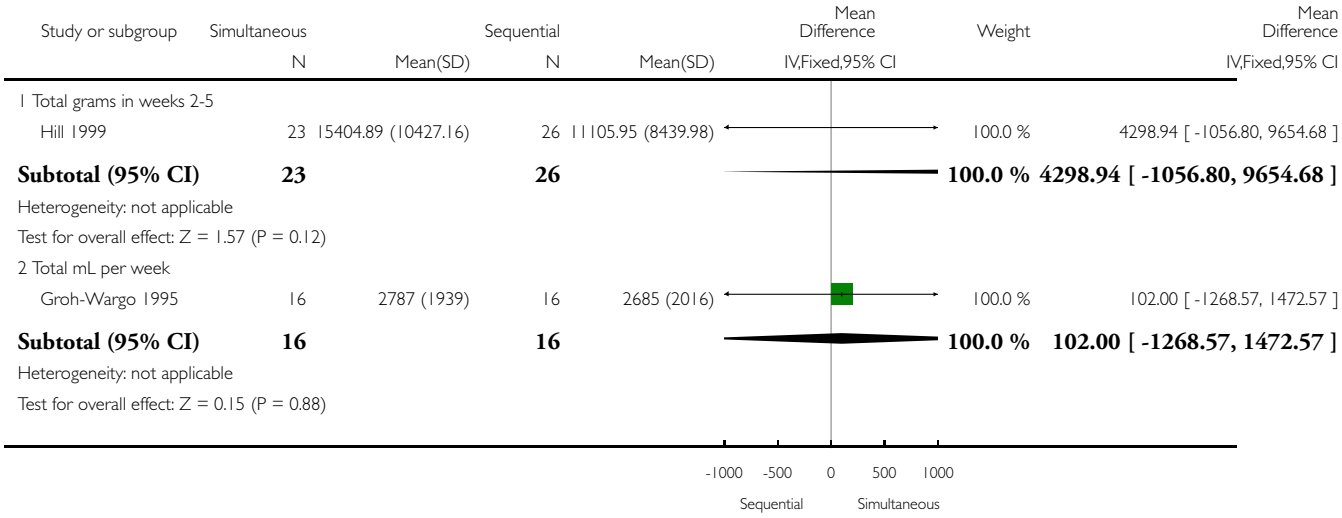


Analysis 8.1. Comparison 8 Any method with a specified protocol of simultaneous versus sequential pumping, Outcome 1 Quantity of milk expressed.

Review: Methods of milk expression for lactating women

Comparison: 8 Any method with a specified protocol of simultaneous versus sequential pumping

Outcome: 1 Quantity of milk expressed

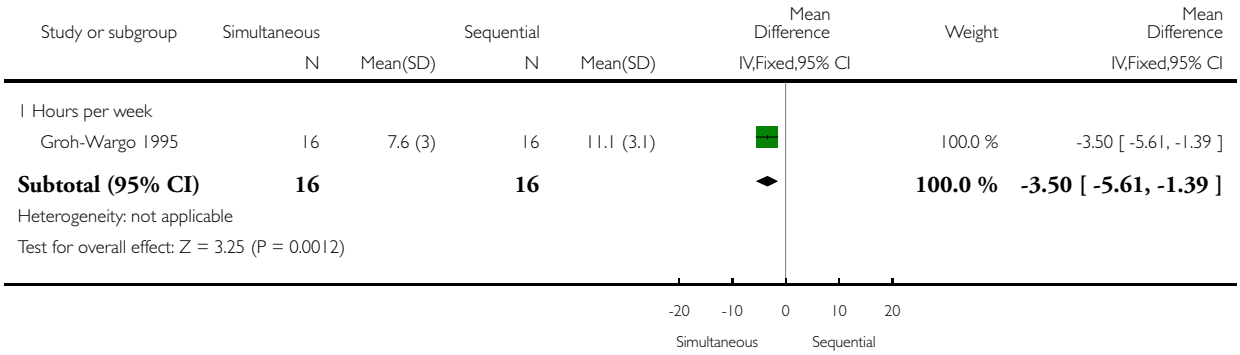


Analysis 8.2. Comparison 8 Any method with a specified protocol of simultaneous versus sequential pumping, Outcome 2 Time taken to express milk.

Review: Methods of milk expression for lactating women

Comparison: 8 Any method with a specified protocol of simultaneous versus sequential pumping

Outcome: 2 Time taken to express milk

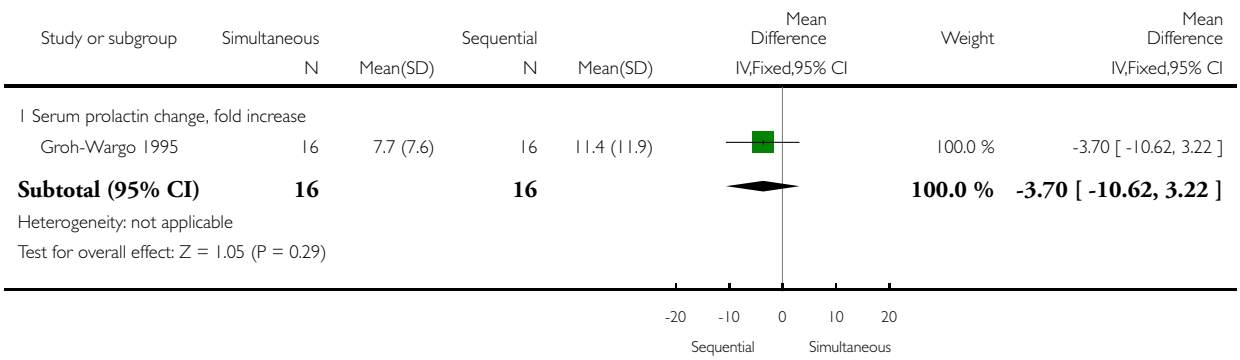


Analysis 8.3. Comparison 8 Any method with a specified protocol of simultaneous versus sequential pumping, Outcome 3 Maternal physiological effects - hormone levels.

Review: Methods of milk expression for lactating women

Comparison: 8 Any method with a specified protocol of simultaneous versus sequential pumping

Outcome: 3 Maternal physiological effects - hormone levels

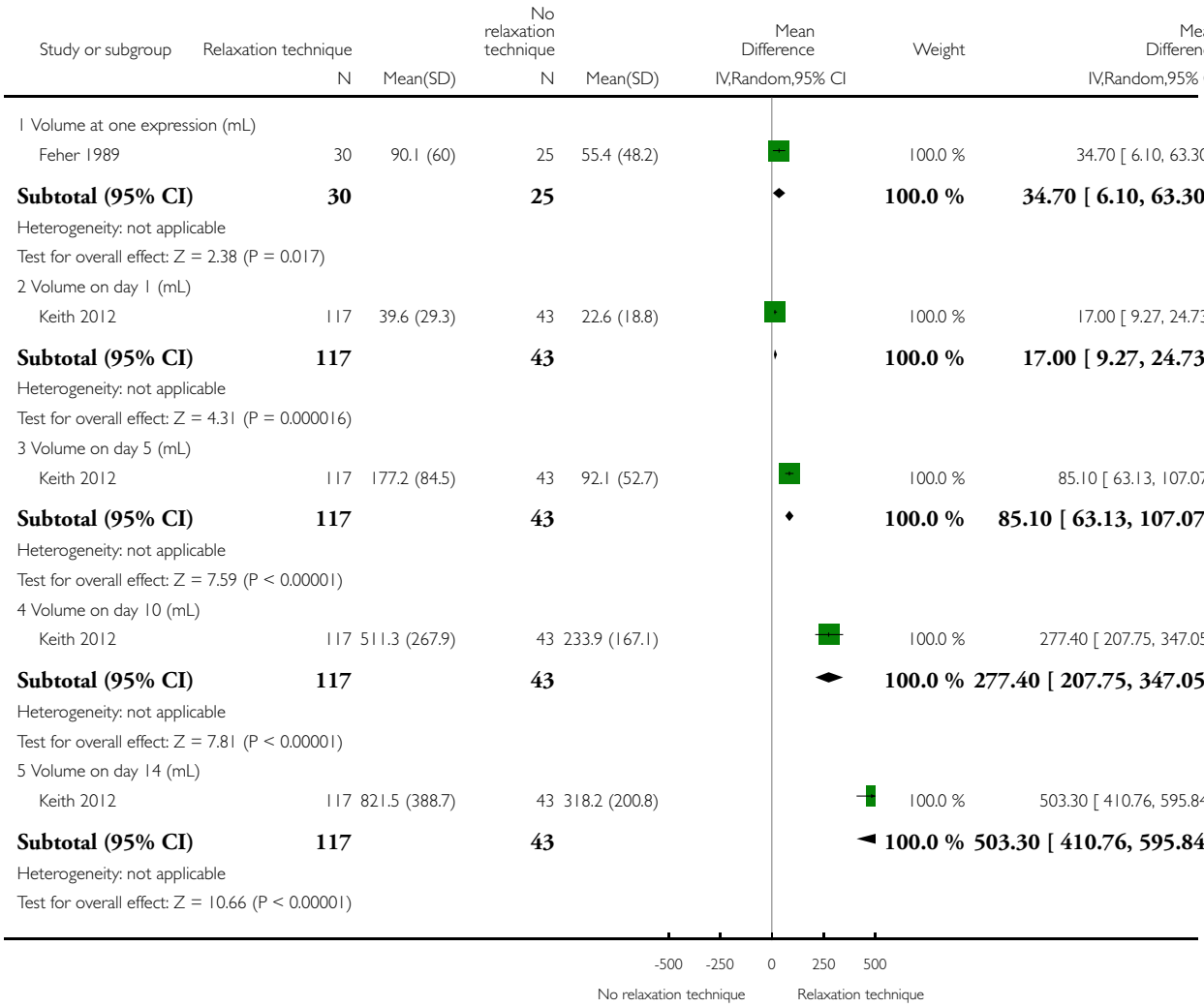


Analysis 9.1. Comparison 9 Any method with a specified relaxation technique versus no specified relaxation technique, Outcome 1 Quanity of milk expressed.

Review: Methods of milk expression for lactating women

Comparison: 9 Any method with a specified relaxation technique versus no specified relaxation technique

Outcome: 1 Quanity of milk expressed

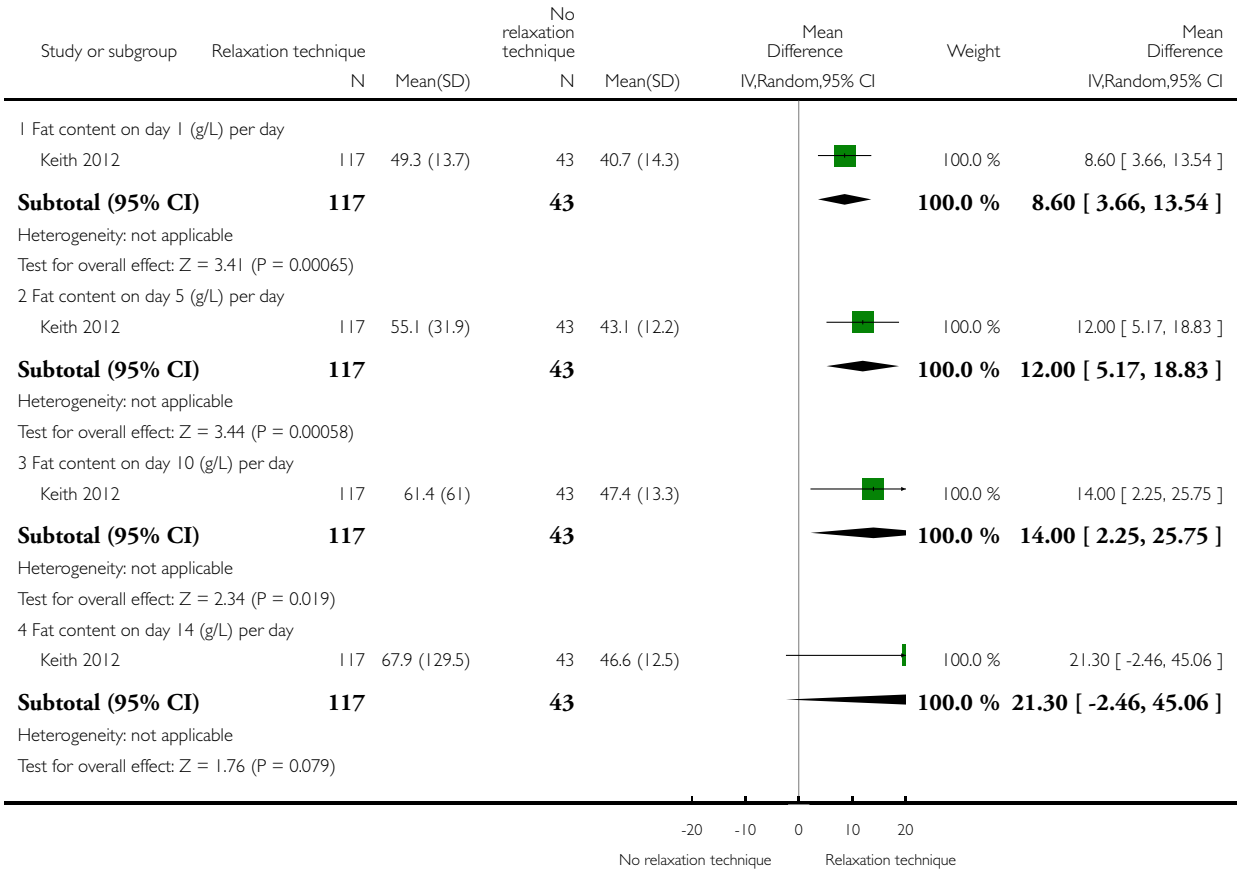


Analysis 9.2. Comparison 9 Any method with a specified relaxation technique versus no specified relaxation technique, Outcome 2 Nutrients in milk (g/L).

Review: Methods of milk expression for lactating women

Comparison: 9 Any method with a specified relaxation technique versus no specified relaxation technique

Outcome: 2 Nutrients in milk (g/L)

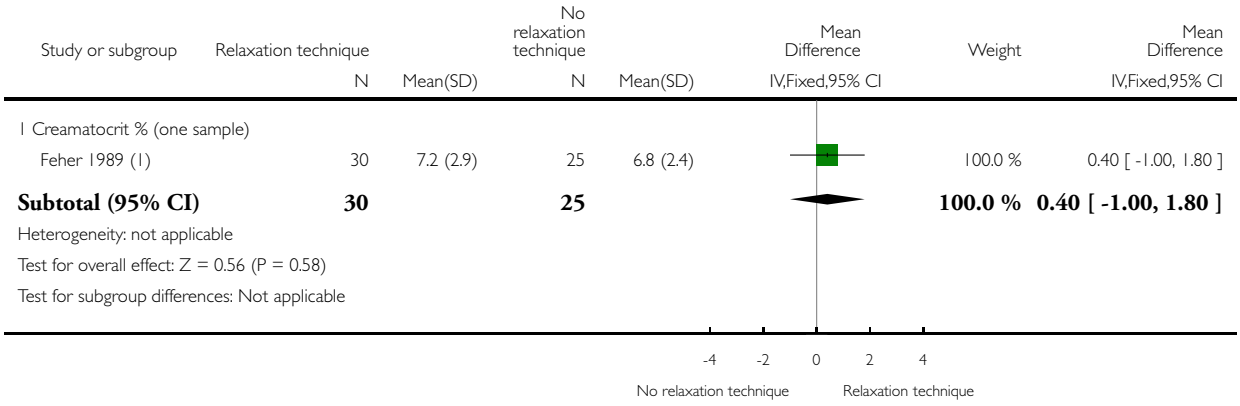


Analysis 9.3. Comparison 9 Any method with a specified relaxation technique versus no specified relaxation technique, Outcome 3 Nutrients in milk (%).

Review: Methods of milk expression for lactating women

Comparison: 9 Any method with a specified relaxation technique versus no specified relaxation technique

Outcome: 3 Nutrients in milk (%)



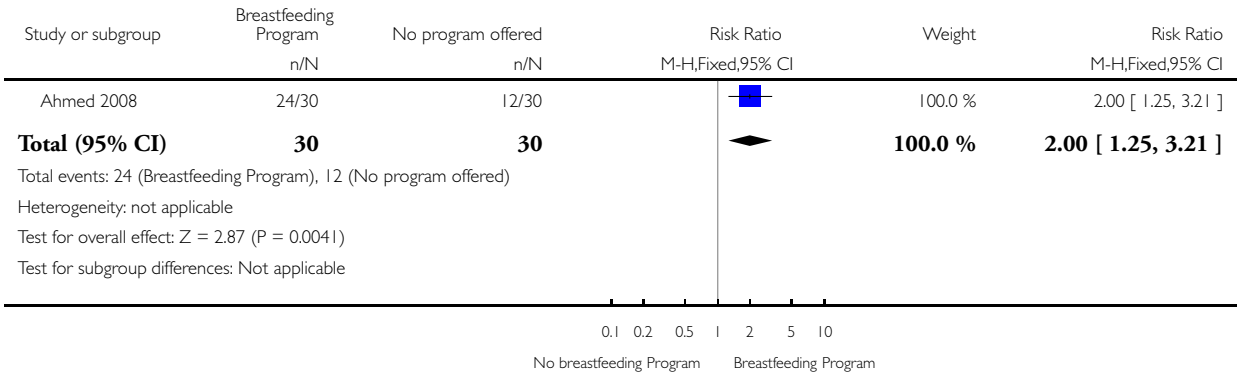
(1) High creamatocrit (fat percentage) is a desired outcome

Analysis 10.1. Comparison 10 Any method plus specific instruction or support provided versus any method with no specific instruction provided, Outcome 1 Transfer to feeding at breast.

Review: Methods of milk expression for lactating women

Comparison: 10 Any method plus specific instruction or support provided versus any method with no specific instruction provided

Outcome: 1 Transfer to feeding at breast

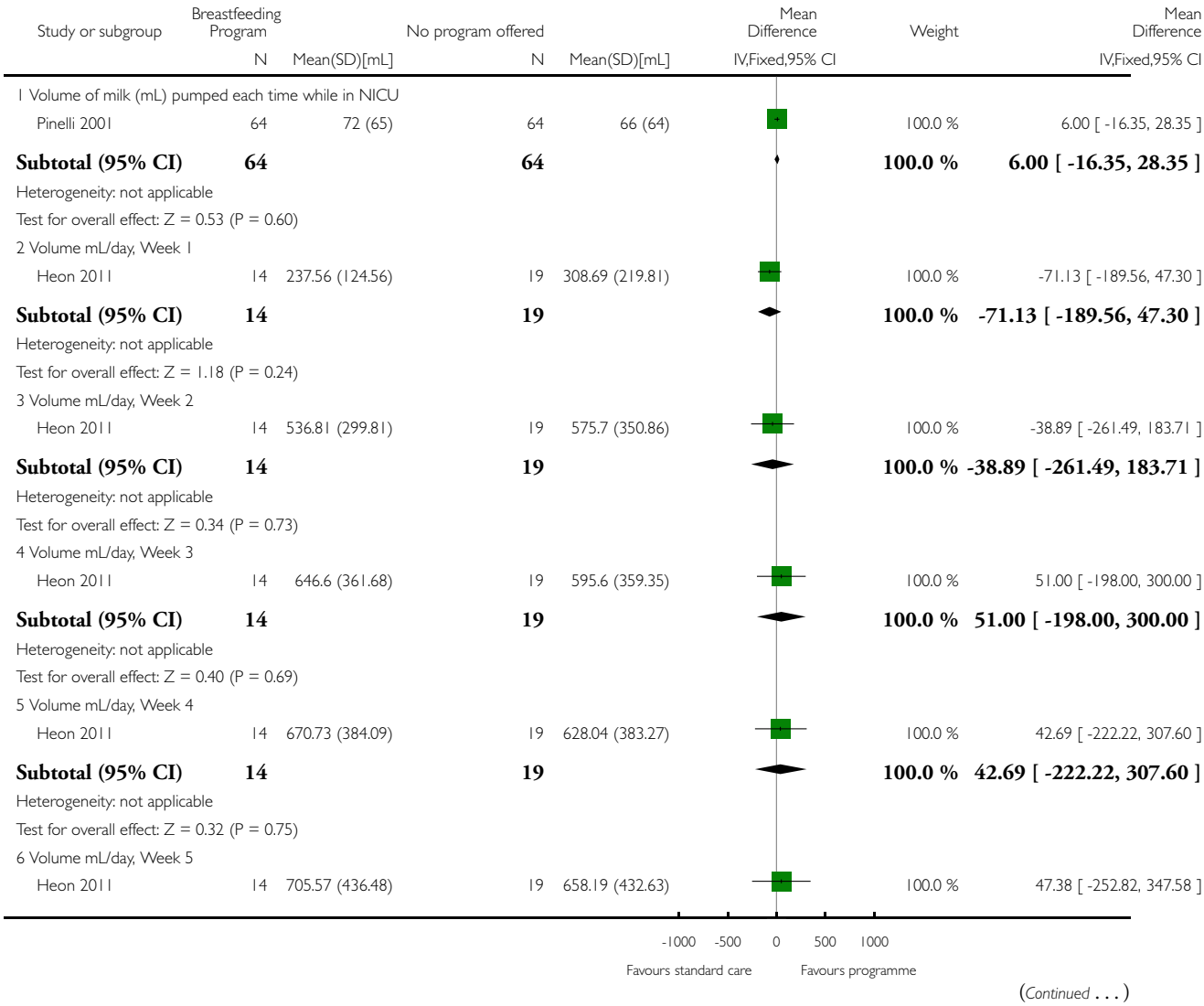


Analysis 10.2. Comparison 10 Any method plus specific instruction or support provided versus any method with no specific instruction provided, Outcome 2 Quantity of milk expressed.

Review: Methods of milk expression for lactating women

Comparison: 10 Any method plus specific instruction or support provided versus any method with no specific instruction provided

Outcome: 2 Quantity of milk expressed



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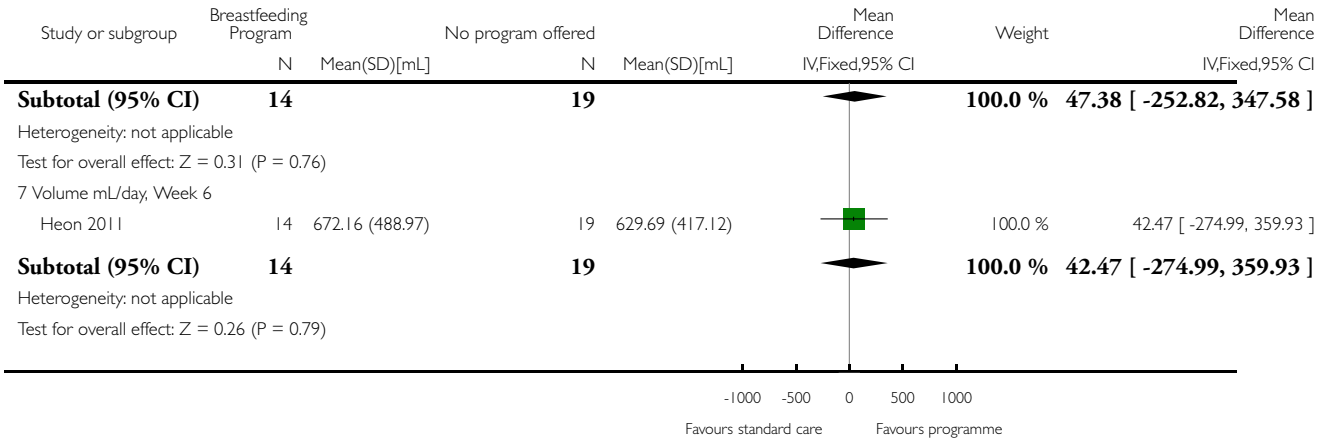
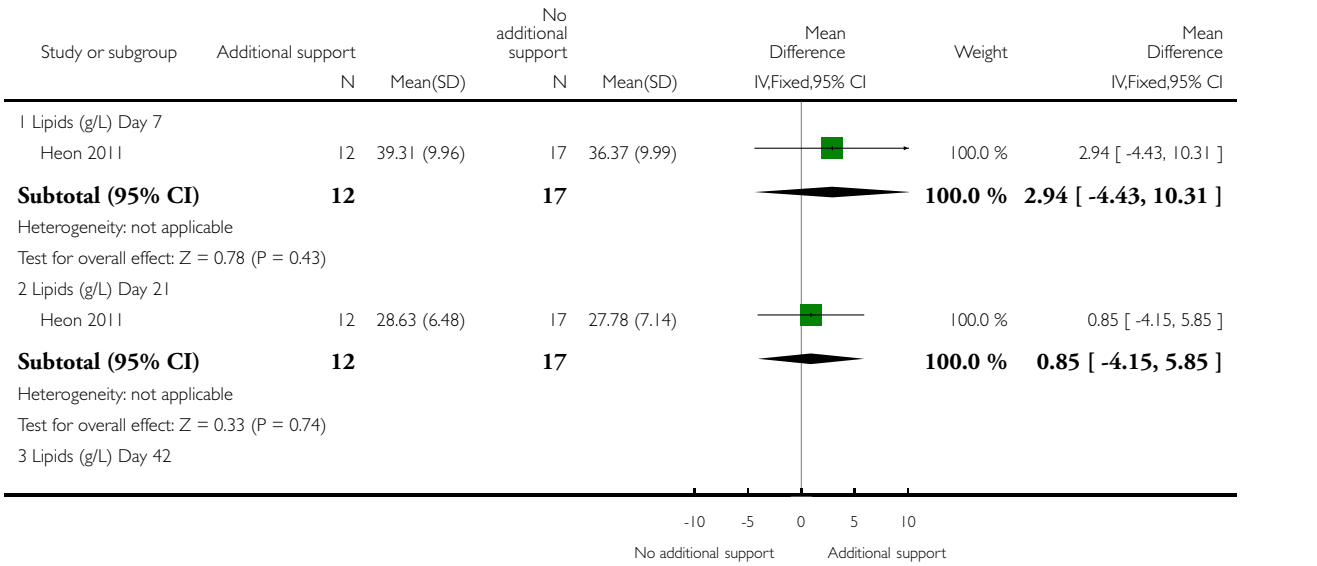


Analysis 10.3. Comparison 10 Any method plus specific instruction or support provided versus any method with no specific instruction provided, Outcome 3 Nutritents in milk.

Review: Methods of milk expression for lactating women

Comparison: 10 Any method plus specific instruction or support provided versus any method with no specific instruction provided

Outcome: 3 Nutritents in milk



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Study or subgroup	Additional support N	Mean(SD)	No additional support N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Heon 2011	12	25.32 (6.8)	17	27.6 (8.93)		100.0 %	-2.28 [-8.01, 3.45]
Subtotal (95% CI)	**12**		**17**			**100.0 %**	**-2.28 [-8.01, 3.45]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.78 (P = 0.44)							
Test for subgroup differences: Chi^2 = 1.32, df = 2 (P = 0.52), I^2 =0.0%							

Analysis 10.4. Comparison 10 Any method plus specific instruction or support provided versus any method with no specific instruction provided, Outcome 4 Time taken to express.

Review: Methods of milk expression for lactating women

Comparison: 10 Any method plus specific instruction or support provided versus any method with no specific instruction provided

Outcome: 4 Time taken to express

Study or subgroup	Additional support N	Mean(SD)	No additional support N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Mean minutes per day Week 1							
Heon 2011 (1)	14	112.1 (31.2)	19	104.4 (32.9)		100.0 %	7.70 [-14.34, 29.74]
Subtotal (95% CI)	**14**		**19**			**100.0 %**	**7.70 [-14.34, 29.74]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.68 (P = 0.49)							
2 Mean minutes per day Week 2							
Heon 2011 (2)	14	117.7 (26.3)	19	105.4 (29.3)		100.0 %	12.30 [-6.76, 31.36]
Subtotal (95% CI)	**14**		**19**			**100.0 %**	**12.30 [-6.76, 31.36]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.26 (P = 0.21)							
3 Mean minutes per day Week 3							
Heon 2011 (3)	14	119.7 (36.8)	19	96.7 (35.9)		100.0 %	23.00 [-2.14, 48.14]
Subtotal (95% CI)	**14**		**19**			**100.0 %**	**23.00 [-2.14, 48.14]**

(*Continued* . . .)

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Study or subgroup	Additional support		No additional support		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Random,95% CI		IV,Random,95% CI
Heterogeneity: not applicable							
Test for overall effect: Z = 1.79 (P = 0.073)							
4 Mean minutes per day Week 4							
Heon 2011 (4)	14	126.7 (35.8)	19	95.4 (34)		100.0 %	31.30 [7.11, 55.49]
Subtotal (95% CI)	**14**		**19**			**100.0 %**	**31.30 [7.11, 55.49]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.54 (P = 0.011)							
5 Mean minutes per day Week 5							
Heon 2011 (5)	14	123.1 (35.3)	19	95.1 (32.8)		100.0 %	28.00 [4.35, 51.65]
Subtotal (95% CI)	**14**		**19**			**100.0 %**	**28.00 [4.35, 51.65]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.32 (P = 0.020)							
6 Mean minutes per day Week 6							
Heon 2011 (6)	14	128.3 (41.7)	19	92.7 (40)		100.0 %	35.60 [7.30, 63.90]
Subtotal (95% CI)	**14**		**19**			**100.0 %**	**35.60 [7.30, 63.90]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.47 (P = 0.014)							

(1) Longer time is the desired outcome in this trial as it is taken to indicate greater motivation to continue pumping.

(2) Longer time is the desired outcome in this trial as it is taken to indicate greater motivation to continue pumping.

(3) Longer time is the desired outcome in this trial as it is taken to indicate greater motivation to continue pumping.

(4) Longer time is the desired outcome in this trial as it is taken to indicate greater motivation to continue pumping.

(5) Longer time is the desired outcome in this trial as it is taken to indicate greater motivation to continue pumping.

(6) Longer time is the desired outcome in this trial as it is taken to indicate greater motivation to continue pumping.

Analysis 11.1. Comparison 11 Any method plus breast massage versus no breast massage, Outcome 1 Quantity of milk expressed (mL from two expressions).

Review: Methods of milk expression for lactating women

Comparison: 11 Any method plus breast massage versus no breast massage

Outcome: 1 Quantity of milk expressed (mL from two expressions)

Study or subgroup	Not massaged breast N	Massaged breast N	Mean Difference (SE)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Stutte 1988	36	36	4.82 (1.82)		100.0 %	4.82 [1.25, 8.39]
Total (95% CI)	**36**	**36**			**100.0 %**	**4.82 [1.25, 8.39]**
Heterogeneity: not applicable						
Test for overall effect: Z = 2.65 (P = 0.0081)						
Test for subgroup differences: Not applicable						

Analysis 11.2. Comparison 11 Any method plus breast massage versus no breast massage, Outcome 2 Nutrients in milk.

Review: Methods of milk expression for lactating women

Comparison: 11 Any method plus breast massage versus no breast massage

Outcome: 2 Nutrients in milk

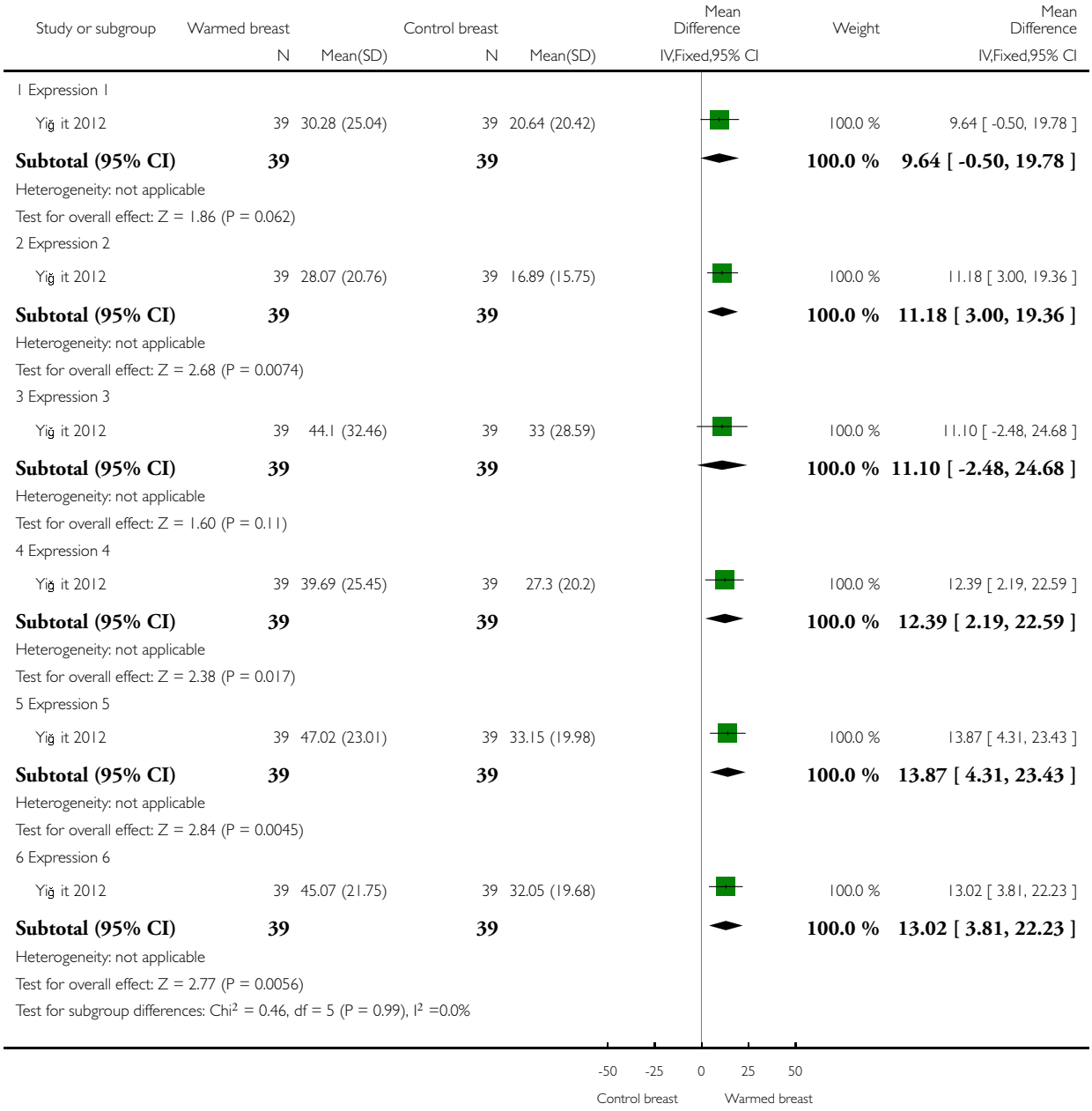
Study or subgroup	Not massaged breast N	Massaged breast N	Mean Difference (SE)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Fat content (creamatocrit)						
Stutte 1988	36	36	1.92 (0.46)		100.0 %	1.92 [1.02, 2.82]
Subtotal (95% CI)	**36**	**36**			**100.0 %**	**1.92 [1.02, 2.82]**
Heterogeneity: not applicable						
Test for overall effect: Z = 4.17 (P = 0.000030)						
Test for subgroup differences: Not applicable						

Analysis 12.1. Comparison 12 Any method plus warming the breast versus not warming the breast, Outcome 1 Quanity of milk expressed (mL).

Review: Methods of milk expression for lactating women

Comparison: 12 Any method plus warming the breast versus not warming the breast

Outcome: 1 Quanity of milk expressed (mL)

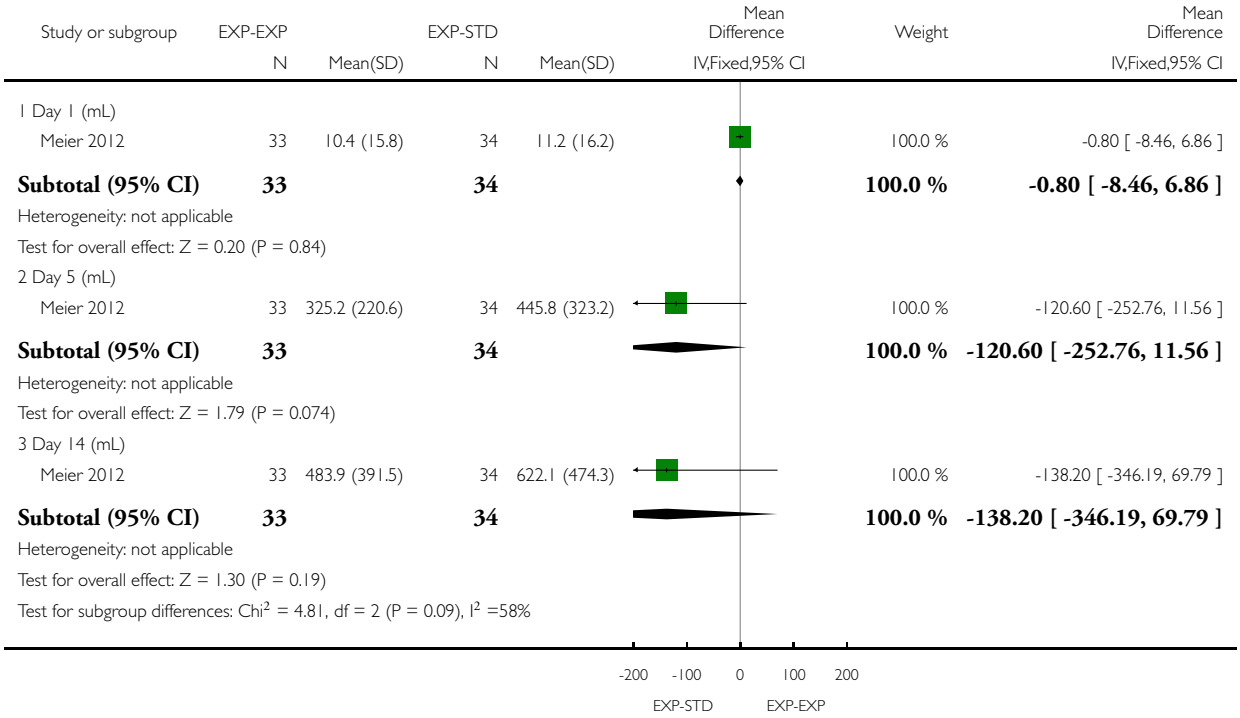


Analysis 13.1. Comparison 13 Any vacuum protocol versus vacuum protocol, Outcome 1 Quantity of milk expressed (EXP-EXP vs EXP-STD).

Review: Methods of milk expression for lactating women

Comparison: 13 Any vacuum protocol versus vacuum protocol

Outcome: 1 Quantity of milk expressed (EXP-EXP vs EXP-STD)

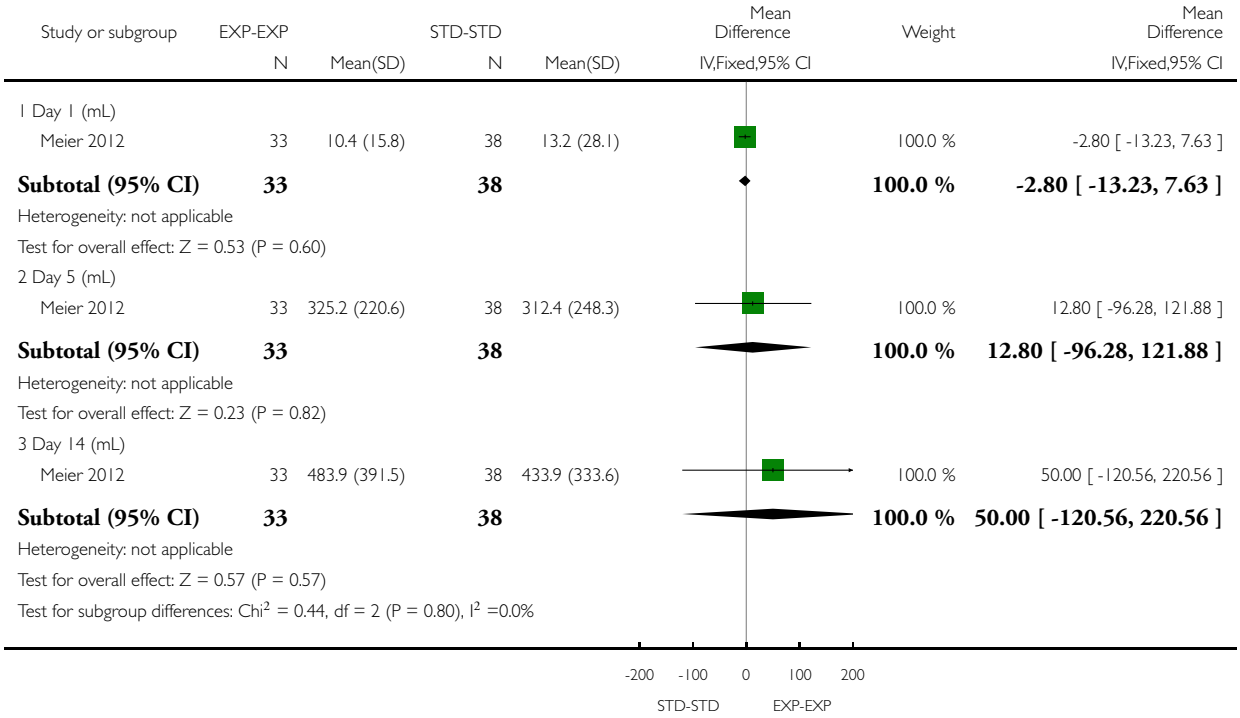


Analysis 13.2. Comparison 13 Any vacuum protocol versus vacuum protocol, Outcome 2 Quantity of milk expressed (EXP-EXP vs STD-STD).

Review: Methods of milk expression for lactating women

Comparison: 13 Any vacuum protocol versus vacuum protocol

Outcome: 2 Quantity of milk expressed (EXP-EXP vs STD-STD)

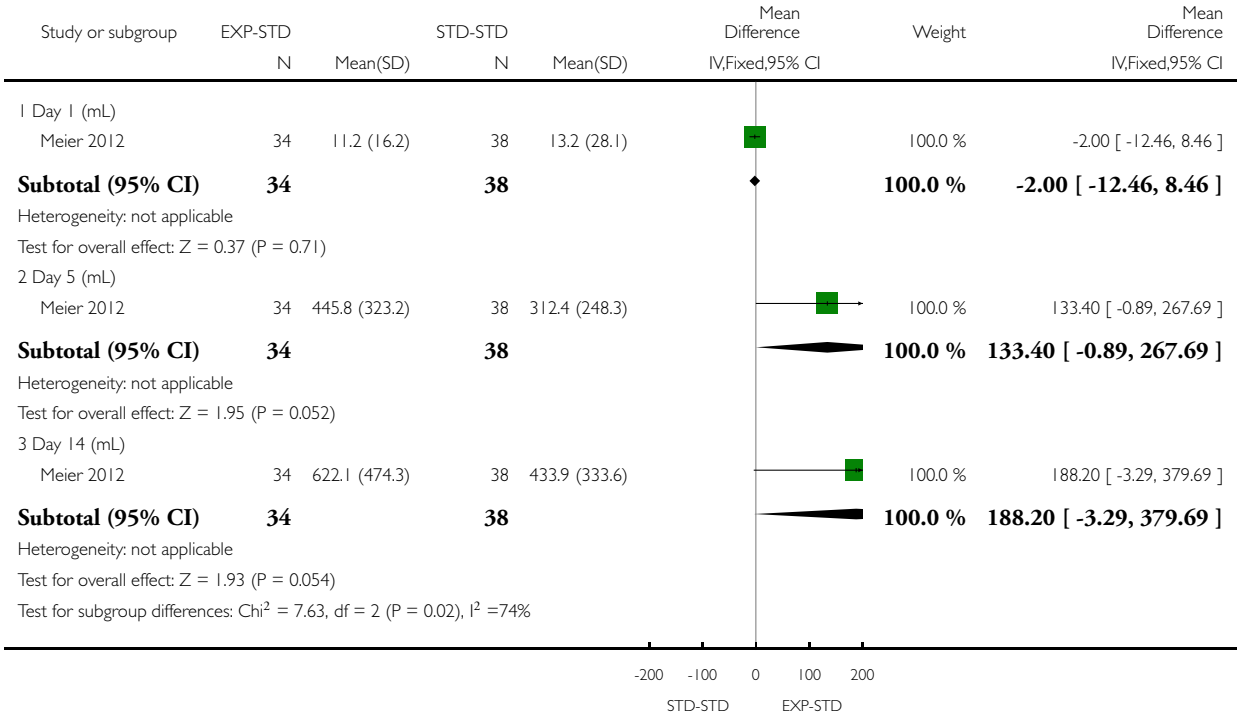


Analysis 13.3. Comparison 13 Any vacuum protocol versus vacuum protocol, Outcome 3 Quantity of milk expressed (EXP-STD vs STD-STD).

Review: Methods of milk expression for lactating women

Comparison: 13 Any vacuum protocol versus vacuum protocol

Outcome: 3 Quantity of milk expressed (EXP-STD vs STD-STD)



ADDITIONAL TABLES

Table 1. Expression and pumping methods

Type	Action	Equipment	Availability
Hand expression.	Hand action stimulates milk ejection reflex and compresses milk ducts	None.	Universal.
Hot jar (base cooled with cold cloth).	Cooling creates a vacuum so that the milk flows from breast (higher pressure) to the jar (lower pressure). Suction pres-	Suitable glass jar, hot water, cold water, cloth.	Widespread.

Table 1. Expression and pumping methods (*Continued*)

	sure may be difficult to control		
Manual pump: compressing a bulb, pulling on 2 connected cylinders, or squeezing and releasing a handle	Negative pressure created by hand/arm action of the pump causes milk to flow from breast to pump. Suction pressure may be difficult to control. Some brands designed to reduce arm/hand fatigue. Some work on a 'draw and hold' principle rather than an even in-out action	Pump. Cleaning supplies. Most pumps have at least 3 parts. 1-handed pumps available and 2 pumps can be used for double pumping	Depends on market demand/ distribution.
Battery pump: power provided by battery, manner of creating pressure may vary	Negative pressure at pump causes milk to flow from breast to pump. Adjustable suction pressure and cycling time in some brands. Some work on a 'draw and hold' principle rather than even in-out action	Pump. Batteries. New batteries may be needed after 2-4 hours use. Some have AC adapters available. Cleaning supplies. Most pumps have at least 4 parts. Most are hand-held so weight of pump plus milk may be a concern	Depends on market demand/ distribution.
Small electric: diaphragm pump.	Negative pressure created by pump action of the pump causes milk to flow from breast to pump. Adjustable suction pressure and cycling time in some brands	Pump. Electricity supply. Cleaning supplies. Most pumps have many parts. 2 collection sets can be used for double pumping for some brands	Depends on market demand/ distribution.
Large electric: piston pump, rotary vane pump, diaphragm pump. Power may also be provided by car battery or by foot treadle	Negative pressure created by action of the pump causes milk to flow from breast to pump. Pressure level may be controlled for some models. Some brands designed to reduce arm/hand fatigue. Some work on a 'draw and hold' or pulsating principle rather than an even in-out action	Pump. Electricity supply or other power source. Cleaning supplies. Most pumps have 10 or more parts. 2 collection sets can be used for double pumping.	Depends on market demand/ distribution. Larger pumps generally purchased by hospitals or rental companies for loan to mothers

Note:

- Some brands of pumps have a flexible breast cup that compresses the breast and some have a choice of sizes of breast cup. Multi-user pumps require high-quality cleaning procedures and frequent servicing.
- There is no one type of pump that is suitable for all mothers and all circumstances. To obtain quantities of milk by any method requires an effective milk ejection reflex.

Table 2. Overview of Included Studies

Study	Equipment/ method	Group (mothers of)	Length of trial	Funding	No. of participants randomised	Percentage of participants with incomplete data (n)
Ahmed 2008	Pumps not compared, education and support intervention	Preterm infants < 37 weeks in neonatal unit	At least 4 education sessions	Not stated	60	None reported
Auerbach 1990 cross-over	SIM vs SEQ with Medela large electric pump	Healthy, full-term infants 5-35 weeks of age	1 expression per pump	Received support from the company whose product was tested	26	3.8% (1)
Bernabe-Garcia 2012 cross-over	4 manual pumps compared: Avent Isis and Medela Harmony (with squeeze handle mechanism) and Medela Little Heart/Caricia and Evenflo (with cylinder-type mechanism)	Preterm infants	Each pump used at least 6 times for 1 day, over a consecutive 4-day test period, plus some use of an large electric pump	Received support from 1 company whose 2 products were tested. Non-commercial support described also	32	12.5% (4)
Boo 2001	Hand expression vs mother's own choice of manual pump	Infants < 1501 g birthweight in neonatal unit	While infants were in NICU	Non-commercial support described	28	3.6% (1)
Boutte 1985 cross-over	Egnell large electric pump vs Medela piston manual pump	Healthy, full-term infants mean age 3.2 months	24-hour period per pump	Non-commercial support described	9	0% (0)
Burton 2013	Medela Symphony large electric vs Philips Avent Twin electronic (small electric)	Preterm infants < 34 weeks in neonatal unit	Reporting on first 10 days of longer trial	Received support from the company whose products were tested	71	Not available

Table 2. Overview of Included Studies (*Continued*)

Costa 1989	Pumps not compared, hygiene procedure	Preterm infants in neonatal unit	1 expression	Received support from the company whose product were tested	65	1.5% (1)
De Carvalho 1985 cross-over	Differences in frequency of expression with Egnell large electric pump (> 4 times/day vs < 3 times/day)	Non-nursing preterm neonates in the newborn intensive care unit	Starting day 5, 2 weeks with changed frequency on second week for some of the participants	Non-commercial support described	25	28 % (7)
Feher 1989	Pumps not compared, relaxation tape	Preterm infants in neonatal unit	1 expression	Non-commercial support described	71	22.5% (16)
Fewtrell 2001a cross-over	Avent Isis manual pump vs Medela mini-electric pump	Healthy, full-term infants at home, 8 weeks old	1 expression per pump	Received support from the company whose product they were testing	60	3.3% (2)
Fewtrell 2001b	Egnell Ameda large electric pump vs Avent Isis manual pump	Preterm infants in neonatal unit	Not stated	Received support from the company whose product were tested	145	18.6% (27)
Flaherman 2012	Ameda Elite or Medela Lactina Select (both large electric) vs. hand expression	Healthy newborns	Single event	Non-commercial support described	68	Not applicable
Francis 2008	Compared Avent Isis IQ Uno (small battery/ electric); Medela Swing (small battery/electric); and Whittlestone electric (large electric)	Healthy term infants	60 days	Not stated	60	Not available

Table 2. Overview of Included Studies (*Continued*)

Garza 1982	Egnell large electric pump vs hand expression	Breastfeeding mothers and infants who were in good health	1 expression per method 2-3 days apart	Non-commercial support described	18	Not available
Groh-Wargo 1995	SIM vs SEQ with Medela large electric pump	Infants < 1500 g birthweight in neonatal unit	Minimum 4 weeks	Received support from the company whose product were tested	32	0% (0)
Hayes 2008	Electric and manual pumps, type not stated	Healthy mothers and infants at home	At least 6 months	Non-commercial support described	280	18% (51)
Heon 2011	Pumps not compared, education and support intervention	Infant born before 30 weeks of gestation and in neonatal unit	42 days	Non-commercial support described	40	17.5% (7)
Hill 1999	SIM vs SEQ with Medela large electric pump	Infants < 1500 g birthweight or preterm in neonatal unit	6 weeks	Received support from the company whose product were tested	49	20.4% (10)
Hopkinson 2009 cross-over	Playtex Embrace small electric vs Medela Pump in Style small electric	Healthy mothers and infants at home	7 weeks and up to 6 months on other outcomes not included in this review	Received funding from 1 company whose product was tested	62 (34 in a subgroup to include hormonal analysis)	Milk volume change 4.8%(3) Fat conc. change 6.5%(4) Pump choice 1. 6%(1) Prolactin 11.8% (4 out of 34) Oxytocin 29.4% (10 out of 34)
Jayamala 2015 Cross-over	Relaxing music versus no music. Pumps not compared.	Preterm infants in neonatal unit	4 days	None stated	30	3.3% (1)
Jones 2001 Protocol II cross-over	Protocol I: SIM vs SEQ with Egnell Ameda Electric Elite pump (large electric) Protocol II:	Preterm infants in neonatal unit	4 days (day 4-7 postpartum)	Received support from the company whose product was tested	52	30.8% (16)

Table 2. Overview of Included Studies (*Continued*)

	Breast massage before pumping					
Keith 2012	Control versus 3 types of relaxing recordings. Pumps not compared	Infants in neonatal unit < 38 weeks' gestation	14 days	Non-commercial support described	162	0%
Lussier 2015	Early exclusive hand expression (HE) versus early exclusive electric pump expression	VLBW infants in neonatal unit	Participants were asked to exclusively use the assigned method of expression for the first 7 days postpartum, after which they could use either or both methods	None stated	40	35% (14)
Mangel 2015 Cross-over	Hand expression or Symphony (large electric pump)	Healthy full-term infants 48 and 72 hours after birth	1 sample by each method at single point in time	None stated	21	0%
Meier 2008 Protocol I: cross-over Protocol II: RCT and cross-over	Symphony large electric pump differing suction patterns	Infants with birthweight < 1250 g and /or < 32 weeks	Protocol I: 6 occasions over a 2-week period Protocol II: More than 12 days	Received support from the company whose products were tested	Protocol I: 35 Protocol II: 65	Protocol I: none reported Protocol II:0% (0) for satisfaction 30.76% (20) for total milk output 50.8% (33) for creamatocrit value
Meier 2012	Medela large electric 2-phase pump (Standard 2.0) vs experimental breast pump suction patterns	Infants ≤ 34weeks' gestation admitted to NICU	14 days	Received support from the company whose products were tested. Non-commercial support described also	128	21.9% (23)
Mersmann 1993 cross-over	Compared Therapeutic touch to Mimic Therapeutic Touch to	Non-nursing hospitalised preterm infants	3 or 5 consecutive days	No funding source listed	18	None reported

Table 2. Overview of Included Studies (*Continued*)

	No Treatment. Pumps not compared					
Parker 2012	Pumps not compared, time of initiation of pumping	VLBW infants	42 days	No external funding	20	0% (0)
Paul 1996 cross-over	Compared manual pump (Medela "cylindric ...piston") and hand expression. Study done in 2 phases	Non-nursing infants in neonatal unit	Phase 1: postnatal days 4 & 5 Phase 2: postnatal days 4 & 5 and 8&9	Non-commercial funding described	Phase 1: 22 Phase 2: 14 (different people)	None reported
Pessoto 2010	Medela Caricia (manual) vs Medela Lactina Select (large electric) vs hand expression	Preterm infants < 37 weeks	35 days	Non-commercial funding described	45	22.2% (10) overall day 5 quantity: 11% (5) For nutrient quality and Dornic acidity, the missing proportions ranged from 11% to 40% depending on the analysis
Pinelli 2001	Education and support intervention. Pumps not compared.	Infants with birth weights less than 1500 g	While in NICU	Non-commercial funding described	128	No information given
Pittard 1991 cross-over	Hand expression vs Medela electric pump and clean vs sterile containers	Mix of preterm and full-term infants 6-171 days old	All 4 arms occurred during 1 session	Funding not stated	16	No information given
Prime 2010 cross-over	Pump breast shield sizes compared	Healthy mothers with an established milk supply	Each shield was tested once for 15 minutes on separate days	Received support from the company whose products were tested	20	No information given

Table 2. Overview of Included Studies (*Continued*)

Prime 2012 cross-over	SIM-v-SEQ technique with a large electric breast pump (Medela Symphony)	Healthy mothers with an established milk supply	Pumped twice over a 5-week period	Received support from the company whose products were tested. Non-commercial support described also	31	None stated
Rasmussen 2011	Medela Harmony (manual) or Medela Symphony large electric pump	Healthy infants (obese mothers BMI > 29 kg/m ^{2})	14 days	Received support from the company whose products were used	34	0% (0)
Slusher 2007	Hand expression vs double collection Medela Lactina large electric pump vs double collection foot pedal powdered Medela Lactina pump	Preterm or ill infants in special care unit	Minimum 6 days	Received support from the company whose product were tested	72	9.7% (7)
Stellwagen 2010	Pumps not compared, "Hands on Pumping" tested	VLBW infants	47 days	Not stated	42	19% (8)
Stutte 1988	Breast massage before pumping vs no massage. Pumps not compared	Mothers and healthy infants aged 1 week to 1 year	1 pumping per method a day apart	Pumps on loan from company (pump not being tested)	18 women reported as 36 breasts	None reported
Vasan 2004	Hand expression vs Large electric pump (Lactina, Medela)	Babies with a birthweight less than 2500g	Duration of hospital stay	Received support from the company whose products were used	16	Not reported
Yi̧ it 2012	Warming the breasts before expression	Non-nursing neonates (<21 days old) in the newborn intensive care unit	3 days	Not stated	40	2.5% (1)

Table 2. Overview of Included Studies (*Continued*)

Zinaman 1992 cross-over	Hand expression Marmet technique vs double collection White River Electric large pump medium setting vs Gentle Expression battery-operated pump vs Medela Manu-electric pump used manually vs infant suckling	Healthy, full-term infants, 28-42 days old	1 expression per pump	Non-commercial funding described	23	Not available
	(SIM = simultaneous pumping SEQ = sequential pumping)					N/A = data not available

BMI: body mass index
NICU: neonatal intensive care unit
VLBW: very low birthweight
vs: versus

Table 3. Measures of milk quantity

Study	Measure reported	Time instructed to pump Familiarisation and 'Washout' period in cross-over	Data included (for outcome of quantity)
Auerbach 1990 cross-over	Mean volume/session (4 occasions)	Maximum time: 5 minutes per breast, then unlimited (until milk no longer dripped) No information on familiarisation or 'washout' period between pumps	Descriptive
Bernabe-Garcia 2012 cross-over	Volume/24 hours with each pump	Until the milk flow ceased No information on familiarisation. Used a different pump on each of the 4 consecutive days	For analysis
Boutte 1985 cross-over	Volume/24 hours for a single breast	"emptied completely" One week between each pump	Descriptive
Burton 2013	Total g/single test session median g/day	15-minute test period (plus other measures)	For analysis

Table 3. Measures of milk quantity (*Continued*)

	total g/10 days		
De Carvalho 1985 cross-over	Total volume/day	"completely empty" Appeared to use second method the week after first method with no 'washout' period	Descriptive
Feher 1989	mL/single session (once)	No information	For analysis
Fewtrell 2001a cross-over	Total volume/breast/single session (once)	Timed:10 minutes per breast 48 hours familiarisation before each test and the second pump was tested 2 to 3 days after the first	Descriptive
Fewtrell 2001b	Total volume/study mean volume/day	"5 minutes each breast, then increasing as tolerated" Up to mother to decide to use simultaneous or sequential sub-sample 10 minute per breast test period	For analysis
Flaherman 2012	Median volume/single session (once)	Timed:15 minutes simultaneous pumping or hand expression	For analysis
Francis 2008	Mean volume/single expression	1 breast once each day for 60 days	For analysis
Garza 1982	Mean volume 1 breast over 2 samples	No information. Samples were collected 2 to 3 days apart	Descriptive
Groh-Wargo 1995	Weekly average volume over 4-6 weeks	Timed: initially limited to 10 minutes then amended to no limit	For analysis
Hill 1999	Total weight of milk/week (over 5 weeks)	Minimum 10 minutes each breast and until the milk flow ceased	For analysis
Heon 2011	Mean volume mL/day (each day for 42 days) calculated from "the daily mean of measured volumes for a given week."	15-20 minutes/session or until breast milk flow has stopped, for at least 100 minutes/day	For analysis
Hopkinson 2009 cross-over	24-hour volume by test weighing infants g/session	Once in morning and once in evening plus usual breastfeeding,1 x 10 minute session	For analysis

Table 3. Measures of milk quantity (*Continued*)

		2 weeks familiarisation for first method testing and then the other pump for several days before the second testing session	
Jayamala 2015 cross-over	"volume"/twice per day for 4 days	Timed: 15 minutes Order of cross-over unclear	Descriptive
Jones 2001 Protocol II cross-over	g/single session (once)	Continue pumping until the milk flow ceased One day of familiarisation with data collected following day, followed by 1 day familiarisation with other method then data collection next day	Descriptive
Keith 2012	Volume/day for 14 days	"about 10 minutes"	For analysis
Lussier 2015	mean volume / day	every 3 hours for 15-20 minutes	For analysis
Meier 2008 Protocol I: cross-over Protocol II: RCT and cross-over	Volume/session	Unclear, at least 15 minutes One session to familiarise in Protocol I and 5-7 days familiarisation in Protocol II	Descriptive
Meier 2012	Mean volume /day over 14 days cumulative output	For 15 minutes until the milk output was at least 20 mL from the 2 breasts combined, and on the days after that until 2 minutes after milk flow ceased	For analysis
Mersmann 1993 cross-over	/single session (once)	Continue pumping until the milk flow slowed or ceased Minimum of 24 hours between treatments scheduled on 3 of 5 consecutive days. Interval since last expression and time of day was kept constant for each mother	Descriptive
Parker 2012	Total volume on days 1-7, day 21 and 24	Until 2 minutes after milk flow ceased	Descriptive
Paul 1996 cross-over	Mean volume/session (42 sessions)	Timed:15 minutes in total Method alternated at each expression/pumping session each day	Descriptive

Table 3. Measures of milk quantity (*Continued*)

Pessoto 2010	Total volume/1 day/week for 5 weeks	At least 10 minutes each breast or until 2 minutes after milk flow ceased	For analysis
Pinelli 2001	Amount of milk pumped each time while in NICU (assumed to be mean of the once weekly 24 hour measure)	No information	For analysis
Prime 2010 cross-over	Total volume (g)	One 15 minute session Each shield was tested once on separate days (as part of other variations in pumps being tested, unclear if all tests at same session)	Descriptive
Prime 2012 cross-over	Single session (once)	Timed: 15 minutes for simultaneous pumping and 15 minutes per breast for sequential pumping timed from after milk flow started Up to 5 weeks between methods studied though there was no prescribed interval between feeding at the breast or pumping and the test session	Descriptive
Stellwagen 2010	5 weekly pooled 24 hour samples	"to fully empty breast"	Descriptive
Slusher 2007	Mean volume/day over 6 days	At least 15 minutes or until 2 minutes after milk flow ceased	For analysis
Stutte 1988	mL/single session (once)	No information	For analysis
Vasan 2004	"maternal milk volume" (mL) expressed during visits to the neonatal unit	No information	Descriptive
Yi g it 2012	Mean volume/session (6 sessions)	Timed:15 minutes simultaneous pumping	For analysis
Zinaman 1992 cross-over	Single session (once)	Timed: 30 minutes 4 methods tested within 1 week with a minimum of 1 method tested per day	Descriptive

Table 4. Pumping frequency recommended and achieved

Study	Recommendation	Mean (SD) expressions I	Mean (SD) expressions II	
Bernabe-Garcia 2012	Minimum 6 times/day	Isis 6.2 (0.3)/day	Little Heart, Harmony, and Evenflo 6.4 (0.6)/day	
Burton 2013	"around 8 times per day"	3.6 (1.2)/day	3.5 (1.3)/day	
De Carvalho 1985	Arm 1: express milk ≥ 4 times a day Arm 2: express milk ≤ 3 times a day	Arm 1: 5.7 (0.6)/day	Arm 2: 2.4 (0.6)/day	
Fewtrell 2001b	6 times/day	3.96 (1.66)/day Electric Pump	3.74(1.15)/day Manual Pump	
Groh-Wargo 1995	Minimum of 4 times/24 hours	28.4 (5.5)/week Sequential (~ 4/day)	28.8 (5.5)/week Simultaneous (~ 4/day)	
Hill 1999	8 times/day	40.18 (8.77)/week Sequential (~5.7/day)	42.87(9.75)/week Simultaneous (~ 6/day)	
Jones 2001	8 times/day	Mean 5 times/day over both groups Sequential	Simultaneous	
Lussier 2015	Every 3 hours for 15-30 minutes	Hand expression median 5/day (IQR 4,7) over full 28 days (assigned group only 1st 7 days	Electric pump median 6/day (IQR 4,7) over full 28 days (assigned group only 1st 7 days	
Meier 2012	Eight times daily for 15 min each pumping	STD-STD suction pattern range of means over 14 days 3-5 times/day EXP-STD suction pattern range of means over 14 days 2.5-4.5 times/day	EXP-EXP suction pattern range of means over 14 days 2.7-5 times/day	
Parker 2012	At least 8 times per day	Early initiation: 5.7 (1.0) /day	Late initiation: 3.4 (3.8)/day	
Paul 1996	Express 3 times a day for 15 minutes at 10 am, 12 pm and 2 pm	"Achieved"	"Achieved"	
Pessoto 2010	At least 6 times/day	2.94 (1.51)/day Hand expression	3.02 (1.01)/day Manual Pump 3.39 (0.94)/day Electric Pump	

Table 4. Pumping frequency recommended and achieved (*Continued*)

Pinelli 2001	3 hourly	6 (2) /24 hours support programme	6 (2) /24 hours standard care	
Slusher 2007	2-3 hourly (8-12/24)	Not reported		
Heon 2011	Optimally 8-10 times per day, minimally 5-6 times per day	Additional support Week 1 5.6 (1.4)/day Week 2 6.0 (1.5)/day Week 3 5.7 (1.1)/day Week 4 5.9 (0.0)/day Week 5 5.7 (1.0)/day Week 6 5.9 (0.9)/day	No additional support Week 1 5.0 (1.3)/day Week 2 5.4 (1.4)/day Week 3 4.9 (1.8)/day Week 4 4.8 (1.7)/day Week 5 5.0 (1.6)/day Week 6 5.0 (2.0)/day	

IQR: interquartile range

Table 5. Descriptive results provided by study authors

Study	Descriptive results provided by study authors
Maternal satisfaction with method	
Bernabe-Garcia 2012	Significant difference was found between at least of the 4 pumps tested in this cross-over study and reported in a table in the published paper with median rating and range. Parameters of ease of use, comfort, pleasing to use, and overall opinion, (P < 0.001) and amount of suction (P = 0.007). Paper states :"Isis generally received better scores on the items easy to use, comfort, and overall opinion, followed by Harmony and Little Heart, which were equally accepted, and then by Evenflo. Scores for perceived amount of suction and pleasing to use were both more favourable for Isis, Harmony, and Little Heart than for Evenflo."
Hopkinson 2009	Mean rankings were reported in the paper. Standard pump was better for ease of assembly (P = 0.04) and in expectation of nipple irritation if continued to use (P = 0.034). No differences reported in nipple irritation between the pumps or for overall pump preference. Among the 61 mothers who selected a pump to keep for their own use, there was no overall pump preference reported. However, among the 51 mothers who had not been inadvertently issued with a special elastic bra, which permitted hands-free pumping and happened to fit the standard pump better, there was a preference for the novel pump (P = 0.05)
Fewtrell 2001a	More mothers reported satisfaction with the manual pump compared to the electric pump for comfort (73% versus 20%), pleasant to use (58% versus 20%) and overall opinion of pump used (69% versus 42%). No differences were found in ease of use (63% versus 65%) and amount of suction (67% versus 71%). Mothers were permitted to select a pump to keep and 64% chose the manual pump, with 34% selecting the small electric/battery pump (P = 0.049) and 2 women selecting neither pump
Fewtrell 2001b	The manual pump received better scores than the large electric pump for all items: ease of use (P = 0.03), comfort (P = 0.003), pleasant to use (P = 0.01), overall opinion (0.003), amount of suction (P = 0.05)

APPENDICES

Appendix 1. Search strategy for CINAHL

1 Milk Expression/
2 Breast Pumps/
3 Milk, Human/
4 milk.ti,ab.
5 breastmilk.ti,ab.
6 breast-milk.ti,ab.
7 express$ or extract$.ti,ab.
8 pump.ti,ab.
9 3 or 4 or 5 or 6
10 2 or 7 or 8
11 10 and 9
12 1 or 11
13 exp Clinical Trials/
14 clinical trial.pt.
15 (clinic$ adj trial$1).tw.
16 ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$3 or mask$3)).tw.
17 randomi?ed control$ trial$.tw.
18 exp Random Assignment/
19 random$ allocat$.tw.
20 placebo$.tw.
21 Quantitative studies/
22 allocat$ random$.tw.
23 Placebos/
24 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23
25 12 and 24

Appendix 2. Methods used to assess trials included in previous versions of this review

Selection of studies

2008: Genevieve Becker (GB) and Mary Renfrew (MJR) independently read articles identified by the initial searches to determine inclusion or exclusion. GB and Felicia McCormick (FM) independently read articles identified by secondary searches. Two authors (GB, FM) used the data extraction forms independently and then jointly reviewed findings. GB entered the data into Review Manager software (RevMan 2003) and FM checked it.

2011: Genevieve Becker (GB), Fionnuala Cooney (FC), and Hazel Ann Smith (HAS) independently read articles identified by the initial searches and secondary searches to determine inclusion or exclusion, used the data extraction forms independently and then jointly reviewed findings. Data were entered by each author into Review Manager software (RevMan 2014) and then jointly checked and reviewed findings.

Assessment of methodological quality of included studies

2008: We assessed the method of allocation concealment used in each included study using criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2006). Quality scores for allocation concealment were assigned to each trial, where A = adequate, B = unclear, C = clearly inadequate. We did not require a minimum quality score for inclusion. We carried out statistical analysis using RevMan 2003.

WHAT'S NEW

Last assessed as up-to-date: 21 March 2016.

Date	Event	Description
21 March 2016	New citation required but conclusions have not changed	The results have changed though conclusions have not changed. In some analyses we switched the intervention and control groups to ensure that when two pumps were compared the less technological intervention was placed as the intervention and appeared on the left in the analysis tables and comparisons. One additional comparison was added
21 March 2016	New search has been performed	Search updated and seven new trials added. Additional data for a previously included trial have been incorporated. Three new ongoing trials have been added and six trials have been excluded This review is now comprised of: • 41 included studies involving 2293 participants, with 22 trials involving 1339 participants providing data for analysis; • 28 excluded studies.

HISTORY

Protocol first published: Issue 4, 2006

Review first published: Issue 4, 2008

Date	Event	Description
3 June 2014	New citation required but conclusions have not changed	Four additional comparisons were added. The results have changed though conclusions have not changed substantially
2 April 2014	New search has been performed	We have incorporated five new included trials and three new excluded trials. We amended the inclusion criteria to include cross-over studies within 28 days of birth and now include five such studies which were previously excluded. One study previously classified as not a randomised controlled trial was reclassified following further discussion with the trialist. Three trials are awaiting classification and two trials are ongoing This review is now comprised of: • 34 included studies involving 1998 participants, with 17 trials involving 961participants providing data

(*Continued*)

		for analysis; • 22 excluded studies.
20 January 2011	New search has been performed	Search updated. We have incorporated 11 new included trials and nine new excluded trials. One trial is awaiting classification (Alekseev 1998a) and one trial is ongoing (Fewtrell 2010) This review is now comprised of: • 23 included studies (with 10 trials providing data for analysis); • 24 excluded studies. The results and conclusions have not substantially changed.
20 January 2011	New citation required but conclusions have not changed	New authors helped prepare this update.
6 July 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

For this update, Genevieve Becker co-ordinated the review, undertook the searches, obtained the papers and with Hazel Ann Smith screened the search results. Each study was reviewed, data extracted and quality appraised by the three review authors, with each review author taking the lead for a group of studies to contact authors for additional information. Hazel Ann Smith led related to quality and analysis sections and Genevieve Becker led related to drafting of other sections. Fionnuala Cooney provided review and advice as needed. All authors reviewed the final submission.

DECLARATIONS OF INTEREST

Genevieve Becker works in the general area of infant and young child feeding, but is not specifically connected with the topic of this review. She is not in receipt of any financial relationship with any commercial entity.

In October 2012 Hazel A Smith registered as a PhD student to study the effects of infant's milk diet at two months of age on their body composition, growth and neurodevelopment in the first 2 years of life. Hazel is the Research Coordinator for the Paediatric Intensive Care Unit in Our Lady's Children's Hospital, Ireland. Hazel is not in receipt of any financial relationship with any commercial entity.

Fionnuala Cooney works as a Specialist in Public Health Medicine. She received no funds for work on this review, has no relationship to any commercial organisation involved in research on this topic, and has no known conflict of interest to declare.

SOURCES OF SUPPORT

Internal sources

- G Becker and HA Smith undertook the update of this review as volunteers with no funding or protected time support., Other.
- G Becker: Unit for Health Services Research and International Health, WHO Collaborating Centre for Maternal and Child Health, Institute for Maternal and Child Health, IRCCS Burlo Garofolo, Trieste, 8232, Italy. For part of the time of the 2015 update, G Becker was employed by the Unit for Health Services Research and International Health with time allocated to work on this review., Italy.

External sources

- Cochrane Fellowship - Health Research Board, Ireland.

Provided to G Becker for the original version 2008

- Evidence and Programme Guidance Unit, Department of Nutrition for Health and Development, World Health Organization, Switzerland.

Provided financial support to the Pregnancy and Childbirth Group, not to the review authors, during the time of this update.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The methods section was updated in 2011 to reflect changes in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) and Review Manager (RevMan 2014), including changes to the 'Risk of bias' tool.

In the protocol and review versions 2008 and 2011, we considered possible period effects in cross-over trials whereby a systematic difference can arise between the two periods of the trial, such as natural variations in the first few weeks after birth. The possibility of such a period effect was the rationale behind the selection criterion that any included cross-over study must have the cross-over commencing at least 28 days after birth. This criterion resulted in the possible exclusion of many trials involving preterm infants, the group most at risk from lack of mother's milk. Thus, the 2015 update (Becker 2015) included cross-over studies commencing within the first 28 days after birth, which would be then evaluated for any period effect.

In this 2016 review, we have switched the intervention and control groups around in some analyses. We wanted to ensure that the less technological intervention when two pumps were compared, was the intervention and appeared on the left in the analysis tables and comparisons.

INDEX TERMS

Medical Subject Headings (MeSH)

*Lactation; *Randomized Controlled Trials as Topic; Breast Milk Expression [instrumentation; *methods; statistics & numerical data]; Personal Satisfaction; Specimen Handling [instrumentation; *methods]

MeSH check words

Female; Humans