Avoidance of bottles during the establishment of breast feeds in preterm infants (Review)

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[Intervention Review]

Avoidance of bottles during the establishment of breast feeds in preterm infants

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ABSTRACT

Background

Preterm infants start milk feeds by gavage tube. As they mature, sucking feeds are gradually introduced. Women who choose to breast feed their preterm infant are not always available and an alternative approach to feeding is needed. Most commonly, milk (expressed breast milk or formula) is given by bottle. There is some controversy about whether using bottles during the establishment of breast feeds is detrimental to breastfeeding success.

Objectives

To determine the effect of avoidance of bottle feeds during the establishment of breastfeeding on the likelihood of successful breastfeeding and to determine if alternatives to bottle feeds are safe.

Search strategy

We searched the Cochrane Central Register of Controlled Trials, MEDLINE, CINAHL and EMBASE in any language. The search was updated in July 2008.

Selection criteria

Randomised or quasi randomised controlled trials comparing avoidance of bottles with use of bottles in women who have chosen to breast feed their preterm infant.

Data collection and analysis

Two review authors independently assessed trial quality and extracted data. When appropriate, we contacted study authors for additional information. Standard methods of the Cochrane Collaboration and the Cochrane Neonatal Review Group were used.

Main results

Five trials of 543 infants were included. Four trials used a cup feeding strategy and one trial used a tube feeding strategy when supplements to breast feeds were needed. The single study of tube feeding had a high risk of bias. In the analysis of all five trials, significant heterogeneity was evident in two of the primary outcomes. This was reduced when the tube feeding trial was removed from analyses.

Cup feeding significantly decreased 'no breastfeeding or only partial breast feeding' on discharge home (summary RR 0.75, 95% CI 0.61 to 0.91). However, cup feeding significantly increased length of hospital stay by 10 days (95% CI 3.87 to 16.29). There was a high degree of noncompliance in the largest study of cup feeding indicating dissatisfaction with this method by staff and/or parents.

The one trial of a tube alone approach significantly reduced 'no breastfeeding or only partial breastfeeding' and 'no breastfeeding at all' at all time periods but the results need to be interpreted with caution due to the high risk of bias.

Authors' conclusions

Supplementing breast feeds by cup confers no breastfeeding benefit beyond discharge home and delays discharge considerably. There is currently insufficient evidence on which to base recommendations for a tube alone approach to supplementing breast feeds. Further research is needed to evaluate a tube alone approach.

PLAIN LANGUAGE SUMMARY

Avoidance of bottles during the establishment of breast feeds in preterm infants

Preterm infants start milk feeds by tube and as they mature they are able to manage sucking feeds. The number of sucking feeds each day are gradually increased as the baby matures. For women who choose to breast feed their preterm infant it is not always possible for them to be there every time the baby needs a sucking feed. Conventionally, bottles with mother's milk or formula are used. It has been suggested that using bottles may interfere with breast feeding success. Five trials have investigated alternatives to bottles in the establishment of breast feeds; four trials used cup feeds and one trial used tube feeds. The one study that used tube feeds was of poor quality and the results of this study need to be interpreted cautiously. When cup feeds were used, more women were discharged home fully breastfeeding, but there was no effect on any (fully and partially combined) breastfeeding. Using cup feeds also increased the length of hospital stay by 10 days. In the one study of tube feeds, breastfeeding (both fully and partially) was increased at discharge and at three and six months after discharge with no effect on length of hospital stay. However, because of the poor quality of this one study, we cannot recommend a tube feeding strategy until further studies of high quality are undertaken.

BACKGROUND

Preterm infants begin sucking feeds when they are mature enough to coordinate sucking and swallowing, which occurs at around 32 to 34 weeks gestation (Lemons 1996). Milk feeds, therefore, need to be given through a gavage tube until infants are able to have all their intake by sucking feeds. Once sucking feeds begin they are increased gradually, usually beginning with one a day and increasing as the infant demands or he/she is assessed to be ready to progress. As the number of sucking feeds increase the number of tube feeds decrease until sucking feeds alone provide sufficient intake for growth and development.

It is general clinical practice for milk (breast or formula) to be given by bottle in addition to any breast feeds. This most commonly occurs when the mother is unavailable to breast feed. It may also occur if the infant is assessed to have received insufficient milk during a breast feed and is 'topped up' with expressed breast milk or formula using a bottle. It has been suggested that using bottles may interfere with establishing successful breastfeeding, possibly because of a difference in the sucking action required for breast versus an artificial nipple (Bu'Lock 1990; Neifert 1995). Alternatives to bottles during this transition time have been reported and

include feeding the infant by cup (Lang 1994a), gavage tube (Stine 1990), finger feeding (Kurokawa 1994; Healow 1995) and paladai, a traditional feeding device used in India (Malhotra 1999). An increased breastfeeding prevalence was reported when bottle feeds were replaced by cup feeds (Lang 1994a; Gupta 1999) or by tube feeds (Stine 1990); however, these trials were small and uncontrolled.

Alternatives to breast feeds are not necessarily benign. With both bottle feeds (Bier 1993; Young 1995; Blaymore Bier 1997; Chen 2000) and cup feeds (Freer 1999; Dowling 2002) mean oxygen saturation was lower and the frequency of oxygen desaturation greater than when breastfeeding, highlighting the importance of considering safety aspects of any alternatives to bottle feeds. With cup feeds a tendency for infants to 'spill' a large proportion of the feed has been reported. Dowling 2002 reported that in two thirds of the feeding sessions infants spilled milk on to the bib, which amounted to 39% of the volume that had been removed from the cup. However, other trials have not reported problems associated with cup feeding Lang 1994a; Gupta 1999).

For women who wish to breast feed their preterm infant it is important to establish the most efficacious and least harmful method of supplementing breast feeds.

OBJECTIVES

The primary objective is to determine the effect of avoidance of bottle feeds during the establishment of breastfeeding on the likelihood of successful breastfeeding and to determine if alternatives to bottle feeds are safe.

Subgroup analyses were carried out to determine if the outcomes were altered by type of intervention.

METHODS

Criteria for considering studies for this review

Types of studies

All trials using random or quasi-random patient allocation.

Types of participants

Infants born less than 37 weeks gestation whose mother's had chosen to breast feed and who had not had 'sucking' feeds by bottle or any alternative feeding device at study entry. At enrolment, infants may have been receiving enteral feeds only, parenteral feeds only, or a combination of parenteral and enteral feeds. Their enteral milk intake may have been via tube (using expressed breast milk and/or formula) or breast feeds. Tube feeds could be either continuous or intermittent and tube placement could be gastric or duodenal.

Types of interventions

Experimental intervention: complete avoidance of bottles during the transition to breast feeds. Instead of bottles, alternative feeding devices were used for complementing or supplementing breast feeds including gavage tube, cup, spoon, dropper, finger feeding, paladai or other.
Control intervention: complementing or supplementing breast feeds with bottles during the transition to breast feeds.

Types of outcome measures

Primary outcomes:
Not breastfeeding or only partial breastfeeding compared with fully breastfeeding on discharge home and at three and six months post-discharge.
Not breastfeeding compared with any breastfeeding on discharge home and at three and six months post-discharge.
Secondary efficacy outcomes:
1 Feeding and growth as assessed by:
1.1 time (days) to reach full sucking feeds
1.2 average daily weight gain (grams/day or g/kg/day) to discharge home
1.3 length of hospital stay (days)
1.4 duration (minutes) of supplementary or complementary feed
1.5 volume of supplementary feed taken compared to volume prescribed (millilitres)
Secondary safety outcomes:
2.1 cardiorespiratory stability during and after intervention (mean heart and respiratory rate; proportion of bradycardic and apnoeic events during feed; mean oxygenation measured by oximetry or transcutaneous monitor; proportion of hypoxic events during feed)
2.2 episodes of choking/gagging per feed
2.3 milk aspiration - on radiologic assessment
Secondary satisfaction outcomes:
1. Dissatisfaction with feeding method
1.1 parental dissatisfaction as measured by self report
1.2 health personnel dissatisfaction as measured by self report

Search methods for identification of studies

Electronic searches

The standard search strategy of the Neonatal Review Group as outlined in the Cochrane Library was used. Computerised searches were conducted of the Cochrane Central Register of Controlled

Trials (The Cochrane Library 2007, Issue 4), MEDLINE (1950 to July week 1, 2008), CINAHL (1982 to July Week 1, 2008) and EMBASE (1980 - 2008 Week 28) using MeSH headings: breastfeeding; Milk, human; Lactation; Bottle Feeding; Intubation, Gastrointestinal. The following text words were used: Neonat$, Cup, Cup Fe?d$, Cupfe?d$, Gavage, Gavage fe?d$, Tube fe?d$, Spoon, Dropper, Finger Fe?d$, Pal??da$. The search was not restricted by language.

Searching other resources

Bibliographies of published trials were checked. Neonatal nursing professional organisations in Australia, New Zealand, USA, UK and the International Lactation Consultants Association were contacted to determine access to conference proceedings. Electronic access was not available and, therefore, searching of past conference proceedings was not possible.

Data collection and analysis

Standard methods of the Cochrane Collaboration (Alderson 2004) and the Cochrane Neonatal Review Group were used. The titles and abstract of each study were independently reviewed by two review authors (CC and JG) to determine eligibility. Where there was uncertainty about inclusion of the study the full text was retrieved. Disagreements on inclusion of studies were resolved between two review authors (CC, JG). Once inclusion of trials was established, the methodology of the trial was independently assessed by two review authors (CC, JG). The data were extracted onto paper forms and quality assessment was undertaken. The standard review method of the Neonatal Review Group was used to assess the methodological quality of the included trials. This included assessing the trial for adequacy of sequence generation and allocation concealment, blinding of intervention and outcome measurement and completeness of follow up. Results of assessment were reported as 'Yes', 'Unclear', or 'No'. Categorical data were analysed using relative risk (RR) and risk difference (RD) with 95% confidence intervals (CI). The number needed to treat (NNT) are reported where results showed a statistically significant difference. For continuous data weighted mean differences (WMD) with 95% confidence intervals were calculated. The difference in the number of events for outcomes measured as count data (for example episodes of choking/gagging) were analysed by comparing rates of events in the two groups.

Meta-analyses were performed using a fixed effects model. The heterogeneity of the included trials was tested using an I-squared test. Where substantial heterogeneity existed (I-squared > 50%) the potential sources for this were investigated (differences in study quality, participants or treatment regimen). Where heterogeneity was explained by subgroup analysis results were presented in this way.

Additional information was requested from Kliethermes 1999; Rocha 2002 and Gilks 2004. Additional information was provided by Kliethermes 1999 (breastfeeding prevalence and apnoeic/bradycardic episodes, blinding of assessment outcome) and Gilks 2004 (exclusions post-randomisation, years study conducted, type of cup used, days to reach full sucking feeds, milk aspiration).

RESULTS

Description of studies

See: Characteristics of included studies.

Results of the search

Five studies were identified and none were excluded. No ongoing trials were identified.

Included studies

Details of each of these included studies (Collins 2004; Gilks 2004; Kliethermes 1999; Mosley 2001; Rocha 2002) are given in the Table of Included Studies. Collins 2004 is the primary report of the study; data related to this study was also reported in a PhD thesis (extent of breastfeeding, not or partially, at three and six months post-discharge, time to full sucking feeds, weight gain, milk aspiration, and reasons for noncompliance). The studies were undertaken in neonatal units in the United States (Kliethermes 1999), England (Mosley 2001; Gilks 2004), Brazil (Rocha 2002) and Australia (Collins 2004).

Participants

All the studies were single centre studies with the exception of Collins 2004. The total number of infants included in each study ranged from 14 (Mosley 2001) to 303 (Collins 2004). All studies included preterm infants, although the limits for gestational age at birth or birthweight differed. Two studies had no lower limit for gestational age at birth but differed in upper limits; less than 34 weeks for Collins 2004 and less than 35 weeks for Gilks 2004. The study of Rocha 2002 was limited to a gestational age at birth of 32 to 34 weeks and the study of Mosley 2001 was limited to 32 to 37 weeks. Kliethermes 1999 used a birth weight criteria of 1000 to 2500 grams. Three studies stratified infants at randomisation, one by birth weight (Rocha 2002) and two by gestational age (Collins 2004; Gilks 2004).

Intervention

Alternative feeding device (cup, gavage tube, paladai, finger feeding, dropper, spoon or other) were classified as the experimental group and bottle feeding was classified as the control group.

Four studies compared breastfeeding with supplementary feeds by cup with breastfeeding with supplementary feeds by bottle (

Mosley 2001; Rocha 2002; Collins 2004; Gilks 2004). One trial compared breastfeeding with supplementary feeds by bottle to breastfeeding with supplementary feeds by gavage tube alone (Kliethermes 1999). In all the studies, bottle feeds or alternative (cup/tube alone) were not to replace a breast feed and were only given when the mother was not available to breast feed or if extra milk was thought necessary after a breast feed and the infant was assessed to be able to take this orally.

For the cup feeding studies, three (Rocha 2002; Collins 2004; Gilks 2004) followed the cup feeding recommendations of Lang (Lang 1994a; Lang 1994b). Rocha 2002 used the protective cap from a bottle, Collins 2004 used a 60 ml medicine cup, and Gilks 2004 an Ameda baby cup. Mosley 2001 did not state the type of cup used or the cup feeding procedure. An indwelling nasogastric tube remained *in situ* for both experimental and control groups in two studies where feeds were given by tube if insufficient milk was taken during the cup or breast feed or if the infant was not scheduled for a sucking feed (Collins 2004; Gilks 2004). It is not stated whether this occurred for cup feeds in the other studies (Mosley 2001; Rocha 2002).

For breastfeeding with supplementary feeds by bottle compared with breastfeeding with supplementary feeds by gavage tube trial (Kliethermes 1999), all infants received standard care (including non-nutritive breastfeeding) until written orders for oral feedings were given. For the control group, all supplementary feeds were given by bottle and the indwelling nasogastric tube was removed as directed by the clinical care team. For the experimental group (gavage tube), feeds were given by an indwelling 3.5 French Gauge nasogastric tube. The tube was removed during the last 24 - 48 hour parent 'rooming-in' period, where a cup or syringe was used if needed.

Skin to skin contact and non-nutritive sucking at the breast were encouraged for all infants in two studies (Collins 2004; Kliethermes 1999). It was not reported in the remaining studies (Mosley 2001; Rocha 2002; Gilks 2004).

Sucking feeds for experimental and control groups were begun and advanced according to individual hospital policy. In one trial this was weight based at 1600 grams (Rocha 2002). Sucking feeds begun when the infants were assessed to be mature enough to coordinate a suck-swallow-breathe-reflex in Collins 2004. In three studies sucking feeds occurred at the discretion of the nurse, midwife (Collins 2004), neonatologist (Kliethermes 1999; Mosley 2001; Collins 2004) or neonatal nurse practitioner (Kliethermes 1999; Mosley 2001) and was not reported in the other study (Gilks 2004).

Use of a dummy (also known as pacifier) in the included studies varied. Collins 2004 randomised infants to cup/no dummy, cup/dummy, bottle/no dummy and bottle/dummy. There was no statistically significant interaction between infants randomised to no dummy or cup and, therefore, results from the marginal groups (cup vs. bottle and dummy vs. no dummy) were able to be analysed independently. A dummy was available during tube feedings for the experimental group in Kliethermes 1999 and it was not reported whether a dummy was available outside feeding times in either group. A dummy was not used for the experimental (cup) group in Rocha 2002 and Mosley 2001 reports that six infants were given a dummy. Dummy use was not reported in Gilks 2004.

Outcomes

Not all outcomes were reported in each study.

All studies measured breastfeeding outcomes (Kliethermes 1999; Mosley 2001; Rocha 2002; Collins 2004; Gilks 2004).

Fully breastfeeding was measured at discharge home from hospital in four studies (Kliethermes 1999; Mosley 2001; Collins 2004; Gilks 2004) and at three and six months post-discharge in two trials (Kliethermes 1999; Collins 2004). Any breastfeeding was measured at discharge home from hospital in all studies (Kliethermes 1999; Mosley 2001; Rocha 2002; Collins 2004; Gilks 2004); at three months post-discharge in three studies (Kliethermes 1999; Rocha 2002; Collins 2004) and at six months post discharge in two studies (Kliethermes 1999; Collins 2004).

Two studies (Kliethermes 1999; Collins 2004) used the following definition of fully breastfeeding: no other solid or liquid was given apart from vitamins, minerals, juice or ritualistic feedings given infrequently. One study (Mosley 2001) used the term 'exclusive' breastfeeding, but did not define the term. On discharge, infants who were receiving supplementary feeds of expressed breast milk were considered as partially breast fed by Kliethermes 1999 and Gilks 2004 and fully breast fed by Collins 2004. Two percent of women (n = 6) with 2% of infants (n = 7) had chosen to feed their infants expressed breast milk by bottle; three were randomised to cup feeds and four to bottle feeds (Collins 2004). At three and six months post-discharge Collins 2004 used the term 'all breast feeds' to mean that the infant's milk feeds were only breast feeds with no other types of milk given and 'partial breast feeds' to mean that the infant's milk feeds were a combination of breast feeds and other types of milk. The intent was to determine the type of milk feeds infants were receiving (breast or formula) irrespective of whether they were receiving solids. This does not fit with the conventional definition of full breastfeeding (Labbok 1990); that is, if an infant is on solids and all milk feeds are breast feeds they are usually classified as 'partially' breastfeeding.

Two studies measured the time taken to reach full sucking feeds (Collins 2004; Gilks 2004). Weight gain was reported in two studies (Rocha 2002; Collins 2004); length of hospitalisation in two studies (Kliethermes 1999; Collins 2004); duration of supplementary feeds in one trial (Rocha 2002). None of the studies reported volume of supplementary feed taken compared to volume prescribed.

Cardiorespiratory stability was reported in two studies. Kliethermes 1999 reported apnoeic or bradycardic episodes and Rocha 2002 oxygen saturation associated with mode of feeding. None of the studies reported episodes of choking/gagging and two trials reported milk aspiration (Collins 2004; Gilks 2004). Parental satisfaction was reported in Collins 2004.

Excluded studies

No studies were excluded.

Risk of bias in included studies

Details of the methodological quality of each study are given in the Characteristics of Included Studies table.

Allocation

Generation of allocation sequence was adequate in all studies (Kliethermes 1999; Mosley 2001;Rocha 2002; Collins 2004; Gilks 2004). Allocation concealment was adequate in four of the studies (Kliethermes 1999; Mosley 2001; Collins 2004; Gilks 2004) and unclear in one (Rocha 2002).

Blinding

Blinding of treatment was not possible in any study. Whether there was blinding of outcome assessment was not clearly stated in three studies (Kliethermes 1999; Mosley 2001; Rocha 2002). Data for outcomes were stated to have been collected unblinded in two studies (Collins 2004; Gilks 2004).

Incomplete outcome data

Protocol violations were handled differently in the studies; four studies excluded such infants (Kliethermes 1999; Mosley 2001; Rocha 2002; Gilks 2004), and one study (Collins 2004) analysed those infants with protocol violations in the groups to which they were randomised.

Kliethermes 1999 excluded five infants from analyses because of non-compliance. Two infants randomised to the bottle group needed the tube reinserted because of poor tolerance of bottle feeding and three infants randomised to the tube group received bottle feeds. Mosley 2001 excluded two infants randomised to cup feeds from analyses since a supplementary feed (presumably bottle) had been given. Similarly, Rocha 2002 excluded one infant randomised to cup feeds because a bottle had been introduced. Gilks 2004 counted 14 women as withdrawals since they no longer wanted to breast feed; however, the data were re-analysed in this review with additional information from the author.

There was a high proportion of non-compliance in the trial of Collins 2004. In the experimental group, 85/151 (56%) had a bottle introduced and in the control group 1/152 (0.7%) had a cup introduced. Infants were analysed in the group to which they were randomised (Collins 2004).

The proportion of incomplete outcome data was as follows: Kliethermes 1999 15%, Mosley 2001 13%, Rocha 2002 6%, Collins 2004 5%, Gilks 2004 0%.

We judged the risk of bias due to incomplete outcome data as low in the studies of Rocha 2002; Mosley 2001 and Collins 2004 and high in the study of Kliethermes 1999 (see risk of bias tables).

Effects of interventions

This review includes five studies with 543 infants.

As specified *a priori* subgroup analyses were carried out to determine if the outcomes were altered by type of intervention. The interventions for avoidance of bottles differed, with the studies of Mosley 2001; Rocha 2002; Collins 2004 and Gilks 2004 comparing breastfeeding with supplemental feeds by cup vs. breastfeeding with supplemental feeds by bottle and the trial of Kliethermes 1999 comparing breastfeeding with supplemental feeds by tube vs. breastfeeding with supplemental feeds by bottle. The subgroups were incorporated into the main structure of the graph.

Comparison 1: Breastfeeding with supplemental feeds by other than bottle vs. breastfeeding with supplemental feeds by bottle

No breastfeeding or only partial breastfeeding at discharge home (Outcome 1.1)

Four studies reported this outcome in 455 infants (Kliethermes 1999; Mosley 2001; Collins 2004; Gilks 2004). Three studies showed a decreased prevalence of the outcome in the breastfeeding plus avoidance of bottles groups (Kliethermes 1999; Collins 2004; Gilks 2004). The meta-analysis of the four studies showed a significant reduction in no breastfeeding or only partial breastfeeding (i.e. an increase in fully breastfeeding) with the breastfeeding plus avoidance of bottles groups (summary RR 0.63, 95% CI 0.41 to 0.96; RD -0.23, 95% CI -0.42 to -0.03; NNT 5, 95% CI 4 to 10). However, there was a substantial degree of heterogeneity among the studies (I^2 64%). The heterogeneity was most likely due to the different intervention or the poor quality of the Kliethermes 1999 study.

- **Subgroup analyses by intervention type: No breastfeeding or only partial breastfeeding at discharge home (Outcomes 1.1.1 and 1.1.2)**

For the subgroup of three studies with 371 infants that compared breast feeds supplemented with cup vs. breast feeds supplemented with bottle (Mosley 2001; Collins 2004; Gilks 2004) a significant decrease in no breastfeeding or only partial breastfeeding (i.e. an increase in fully breastfeeding) remained (summary RR 0.75, 95% CI 0.61 to 0.92; RD -0.14, 95% CI -0.24 to -0.04; NNT 7, 95% CI 4 to 25) with no heterogeneity (I^2 0%).

In the one study (Kliethermes 1999) that compared breastfeeding supplemented with tube vs. breastfeeding supplemented with

bottle a significant decrease in the risk of no breastfeeding or only partial breastfeeding was found (RR 0.22, 95% CI 0.10 to 0.53).

No breastfeeding or only partial breastfeeding at three months post discharge (Outcome 1.2)

This outcome was reported for 84 infants in one study of breastfeeding with supplemental feeds by tube (Kliethermes 1999) and showed a significant decrease (i.e. an increase in fully breastfeeding) in the breastfeeding plus avoidance of bottle group (RR 0.59, 95% CI 0.40 to 0.87; RD -0.31; 95% CI -0.51 to -0.11; NNT 3, 95% CI 2 to 9).

No breastfeeding or only partial breastfeeding at six months post discharge (Outcome 1.3)

This outcome was reported for 84 infants in one trial of breastfeeding with supplemental feeds by tube (Kliethermes 1999) and showed a significant decrease (i.e. an increase in fully breastfeeding) in the avoidance of bottles group (RR 0.65, 95% CI 0.48 to 0.89; RD , 95% CI ; NNT 3, 95% CI 2 to 9).

As stated earlier, the accepted definition for fully breastfeeding was unable to be used at three and six months post discharge in Collins 2004. Therefore, the prevalence for 'not all breast feeds' cannot be combined with 'no breastfeeding or only partial breastfeeding' reported in other studies and so it is reported in the text only. There was no significant difference in the proportion of infants with 'not all breast feeds' at three months post-discharge (breastfeeding with supplemental feeds by cup group n = 101/144; breastfeeding with supplemental feeds by bottle n = 104/139; RR 0.94, 95% CI 0.81 to 1.08). At six months post-discharge, significantly fewer infants in the breastfeeding with supplemental feeds by cup group were not receiving all breast feeds (i.e. significantly more infants milk intake was breast feeds), (n = 106/142; bottle 118/139; RR 0.88, 95% CI 0.78 to 0.99) (Collins 2004).

No breastfeeding at all at discharge home (Outcome 1.4)

The outcome no breastfeeding at all compared with any breastfeeding on discharge home was reported for 519 infants in four studies (Kliethermes 1999; Rocha 2002; Collins 2004; Gilks 2004). One study showed a significantly decreased prevalence of this outcome in the breastfeeding plus avoidance of bottle group (Kliethermes 1999). The meta-analysis of the four studies showed a significant decrease in the risk of no breastfeeding at all (i.e. increase in any breastfeeding) in the breastfeeding plus avoidance of bottle groups (summary RR 0.74, 95% CI 0.56 to 0.97; RD -0.09, 95% CI -0.16 to -0.01; NNT 11, 95% CI 6 to 100). There was minimal heterogeneity with I^2 20%.

- **Subgroup analyses by intervention type: No breastfeeding at all at discharge home (Outcomes 1.4.1 and 1.4.2)**

For the subgroup of three studies with 435 infants that compared breastfeeding with supplemental feeds by cup vs. breastfeeding with supplemental feeds by bottle (Rocha 2002; Collins 2004; Gilks 2004) the decrease in not breastfeeding on discharge home was not significant (summary RR 0.82; 95% CI 0.62 to 1.09).
In the one study with 84 infants (Kliethermes 1999) comparing breastfeeding with supplemental feeds by tube vs. breastfeeding with supplemental feeds by bottle, a significant decrease in the risk of not breastfeeding (i.e. increase in any breastfeeding) was found (RR 0.30, 95% CI 0.11 to 0.83; RD -0.24, 95% CI -0.41 to -0.07; NNT 4, 95% CI 2 to 14).

No breastfeeding at all at three months post discharge (Outcome 1.5)

At three months post-discharge, three studies with 444 infants reported the outcome no breastfeeding at all compared with any breastfeeding (Kliethermes 1999; Rocha 2002; Collins 2004). Kliethermes 1999 showed a significant reduction in no breastfeeding at all in the breastfeeding plus avoidance of bottle group. The meta-analysis of the three studies showed a significant decrease in the risk of no breastfeeding at all (i.e. increase in any breastfeeding) with breastfeeding plus avoidance of bottle groups (summary RR 0.82, 95% CI 0.71 to 0.96; RD -0.11, 95% CI -0.20 to -0.03; NNT 9, 95% CI 5 to 33). There was minimal heterogeneity (I^2 47%).

- **Subgroup analyses by intervention type: No breastfeeding at all at three months post discharge (Outcome 1.5.1 and 1.5.2)**

Two studies in the subgroup breastfeeding with supplemental feeds by cup vs. breastfeeding with supplemental feeds by bottle (Collins 2004; Rocha 2002) measured no breastfeeding at all at three months post discharge in 361 infants. No difference in the risk of no breastfeeding at all was found (summary RR 0.88, 95% CI 0.76 to 1.03).
In the subgroup breastfeeding with supplemental feeds by tube vs. breastfeeding with supplemental feeds by bottle (Kliethermes 1999, 83 infants) there was a significant reduction in the risk of not breastfeeding (RR 0.45, 95% CI 0.23 to 0.90; RD -0.26, 95% CI -0.45 to -0.06; NNT 4, 95% CI 2 to 7).

No breastfeeding at all at six months post discharge (Outcome 1.6)

Two studies with 364 infants reported this outcome (Kliethermes 1999; Collins 2004). Kliethermes 1999 showed a significant decrease in the prevalence of no breastfeeding at all breastfeeding plus avoidance of bottle groups. On meta-analysis of the two trials,

there was a significant decrease in the risk of no breastfeeding at all in the breastfeeding plus avoidance of bottle group (summary RR 0.84, 95% CI 0.73 to 0.96; RD -0.12; 95% CI -0.21 to -0.03; NNT 8, 95% CI 5 to 33). There was a high degree of heterogeneity among the two studies (I^2 72%). Again, the heterogeneity was most likely due to the difference in intervention or the poor quality of the Kliethermes 1999 trial.

- **Subgroup analyses by intervention type: No breastfeeding at all at six months post discharge (Outcome 1.6.1 and 1.6.2)**

The one study in the subgroup breastfeeding with supplemental feeds by cup vs. breastfeeding with supplemental feeds by bottle showed no difference in no breastfeeding at all at six months post discharge (Collins 2004) (RR 0.90, 95% CI 0.78 to 1.05).
The one study in the subgroup breastfeeding with supplemental feeds by tube vs. breastfeeding with supplemental feeds by bottle (Kliethermes 1999) showed a significant reduction in risk of no breastfeeding at all, (i.e. increase in any breastfeeding), (RR 0.61, 95% CI 0.41 to 0.91; RD -0.29, 95% CI -0.49 to -0.08; NNT 4, 95% CI 2 to 13).

Time (days) to reach full sucking feeds (Outcome 1.7)

Three studies assessed this outcome in 416 infants (Kliethermes 1999; Collins 2004; Gilks 2004). Collins 2004 (290 infants) showed a significant increase in the days to reach full sucking feeds in the breastfeeding plus supplementary feeds by cup group (MD 10.4 days, 95% CI 4.65 to 16.09). Gilks 2004 found a non-significant reduction in time to reach full sucking feeds in breastfeeding plus supplementary feeds by cup group (MD -1.44 days, 95% CI -10.85 to 7.97). Kliethermes 1999 showed a significant increase in the days to reach full sucking feeds in the breastfeeding plus supplementary feeds by tube group (MD 7.5 days). The above authors have not reported standard deviations so this was unable to be included in a meta-analysis. The mean increase in days to full sucking feeds found in the Kliethermes 1999 study is of the same magnitude as that found in Collins 2004.
On meta-analysis of Collins 2004 and Gilks 2004, there was a significant increase in the days to reach full sucking feeds in the breastfeeding plus avoidance of bottle group (WMD 7.2; 95% CI 2.3 to 12.0). There was substantial heterogeneity (I^2 77%), which is unexplained by intervention type as both studies used breastfeeding with supplemental feeds by cup as the intervention. The results are dominated by the larger sample size of the Collins 2004 trial.

Weight gain (g/kg/day) (Outcome 1.8.1 and 1.8.2)

Two studies with 371 infants reported weight gain. Rocha 2002 reported weight gain for the first week after beginning oral feeds and Collins 2004 calculated weight gain from birth to discharge home. Due to the collection of data over such widely different postnatal age intervals in the two trials the data have not been included in a meta-analysis.
There were no statistically significant differences in weight gain reported as grams/kilogram/day in either study: Rocha 2002 MD -0.60 g/kg/day, 95% CI -3.21 to 2.01; Collins 2004 MD -0.09 g/kg/day, 95% CI -0.77 to 0.59.
The intervention for both these studies was breastfeeding with supplemental feeds by cup.

Length of hospital stay, days (Outcome 1.9)

Length of hospital stay was assessed in two studies with 385 infants (Kliethermes 1999; Collins 2004). Collins 2004 showed a significantly increased length of hospital stay of 10 days with breastfeeding plus avoidance of bottle (MD 10.08 days, 95% CI 3.87 to 16.29). There was a significant increase in length of stay in the meta-analysis of the two studies (WMD 6.6 days, 95% CI 1.9 to 11.4); however, there was moderate heterogeneity (I^2 66%). The intervention differed between the two studies with Collins 2004 using breastfeeding with supplemental feeds by cup and Kliethermes 1999 using breastfeeding with supplemental feeds by tube. Caution needs to be used in interpreting the meta-analysis due to the moderate degree of heterogeneity. Again, the difference in intervention or the poor quality of the Kliethermes 1999 trial most probably explain the heterogeneity.
The overall length of stay differed between the two studies. In the trial of Kliethermes 1999, the length of stay for those in the breastfeeding plus avoidance of bottle group was nearly 28 days less and 19 days less for those in the breastfeeding plus bottle group when compared with Collins 2004. The infants in Kliethermes 1999 study were more mature, their study sample consisted of gestational age at birth: 32 weeks, SD not reported, range 26 - 35 weeks for breastfeeding with supplemental feeds by tube and 32 weeks, SD not reported, range 28 - 35 weeks for breastfeeding with supplemental feeds by bottle. The study sample of Collins 2004 consisted of gestational age at birth: 29.4 weeks, SD 2.6, range 23 - 33 for breastfeeding with supplemental feeds by cup; and 30.0 weeks, SD 2.5, range 24 - 33 for breastfeeding with supplemental feeds by bottle. This difference in maturity most likely explains the differences in the overall length of stay seen between the studies.

- **Subgroup analyses by intervention type: Length of hospital stay, days (Outcome 1.9.1 and 1.9.2)**

The one study in the subgroup breastfeeding with supplemental feeds by cup vs. breastfeeding with supplemental feeds by bottle showed a significant increase in length of hospital stay of 10 days with cup feeding (Collins 2004) (MD 10.1 days, 95% CI 3.9 to 16.3).
The one study in the subgroup breastfeeding with supplemental feeds by tube vs. breastfeeding with supplemental feeds by bottle (Kliethermes 1999) showed no difference in length of stay (MD 1.6 days, 95% CI -5.9 to 9.9).

Duration (minutes) of supplementary feed (Outcome 1.10)

One trial measured duration of supplementary feeds (Rocha 2002) and found no significant difference between the breastfeeding plus avoidance of bottles group (in this trial the intervention was cup feeds) and the breastfeeding plus bottle group (MD -1.6 minutes, 95% CI -3.7 to 0.5).

Cardiorespiratory stability

The total number of episodes of apnoea and bradycardia per infant were reported in one trial (Kliethermes 1999). The intervention in this trial was breastfeeding with supplemental feeds by tube. Significantly fewer apnoeic and bradycardic incidents were reported for the breastfeeding plus avoidance of bottle group (mean 127, SD not reported) compared with bottle (mean 136, SD not reported; P = 0.0006). However, the breastfeeding plus bottle group had significantly more episodes that required stimulation (mean 32.7 episodes, SD not reported versus 23.3 episodes, SD not reported; P = 0.0001). The apnoeic and bradycardic episodes were measured over the entire hospital stay and not just those episodes associated with feeding.

One trial of breastfeeding with supplemental feeds by cup reported mean oxygen saturation during feeds (Rocha 2002) and found no significant difference in the mean of the lowest oxygen saturation during feeds (breastfeeding plus avoidance of bottle mean 90.8, SD 4.8, range 75-99; breastfeeding plus bottle mean 87.7, SD 7.6, range 68-97).

Rocha 2002 also reported oxygen desaturation during feeds and showed no difference in desaturation episodes of less than 90% in breastfeeding plus avoidance of bottle group (18/44, 40.9%) compared with the breastfeeding plus bottle group (19/34, 55.9%). They reported a statistically significant difference in the proportion of desaturation episodes less than 85% with fewer occurring in breastfeeding plus avoidance of bottle groups (6/44, 13.6%) compared with breastfeeding plus bottle group (12/34, 35.3%; P = 0.02).

Milk aspiration - on radiologic assessment

No episodes of milk aspiration occurred in the two studies that reported this outcome (Collins 2004; Gilks 2004).

Dissatisfaction with feeding method

One study included views of parents on the method of feeding (Collins 2004). In this study, there was a high rate of noncompliance with 56% of infants in the intervention (breastfeeding with supplemental feeds by cup) group (n = 85/151) having a bottle introduced. Compliance differed between the recruiting hospitals with the hospital where cup feeding was introduced specifically for the study having a higher rate than the other recruiting hospital where cup feeding had been practiced for three years prior to the study. Data on reasons for the introduction of a bottle were collected from the medical records or after discussion with the attending nurses or midwives. Reasons for introducing a bottle were available for 74% (n = 63) of the 85 infants randomised to cup feeds and who had a bottle introduced. In 65% (n = 41) of cases the reason given for introduction of a bottle was that it was at the request of the mother, while the staff initiated 29% (n = 18) of cases. For 10% (n = 6) of cases a bottle was introduced because the baby was unsatisfied with cup feeds or would not settle down. One infant randomised to the bottle group had a cup introduced and this was because of transfer to a peripheral hospital where cup feeding was routinely done.

A question was included in the three month post-discharge questionnaire to the mother on reasons for introduction of a bottle. Reasons for introducing a bottle were available for 91% (n = 77) of the 85 infants randomised to cup feeds and who had a bottle introduced. Women could select from a list of options and additional space was provided for any other comments. 44% (n = 34) indicated that the decision to introduce a bottle was theirs, with 33% (n = 25) being advised by the nurse or midwife (some responded yes to both of these statements). 26% (n = 20) had problems with cup feeding; this included the infant not being able to do it, spilling a lot, not satisfied with cup feeds or taking too long to feed. Ten (13%) of the respondents did not like cup feeds and changed because of this. Nine (12%) of the respondents said that the staff refused to cup feed their infant. Collins 2004 reported that some infants became less satisfied with cup feeds and more difficult to feed by this method as they neared discharge, generally during the last week of their hospital stay. Because of this, if the mother was unable to be present to breast feed, the infant would be tube fed. The criteria for discharge home was for the infant to be on full sucking feeds. This may have contributed to the increased length of stay in their study. However, the author also cautions that reliable data were not collected on this point (Collins 2004).

Outcomes not reported

None of the studies reported volume of supplementary feed taken compared with volume prescribed, or episodes of choking or gagging.

DISCUSSION

This review found five studies that met pre-specified eligibility criteria.

Four of the five included studies attempted to conceal the randomisation process (Kliethermes 1999; Mosley 2001; Collins 2004; Gilks 2004). The intervention could not be blinded in any study and, therefore, was subject to caregiver influence. We judged the risk of bias due to incomplete outcome data as high in the study of Kliethermes 1999.

Interventions varied by the type of alternative to the bottles. Four of the five studies used a strategy of breastfeeding with supplements by cup (Mosley 2001; Rocha 2002; Gilks 2004; Collins 2004) and one study used supplements by tube alone (Kliethermes 1999). The trials of breastfeeding with supplemental feeds by cup are dominated by the trial of Collins 2004, which was the largest study.

There was substantial heterogeneity of treatment effects on two of four primary outcomes where meta-analyses could be performed. These two outcomes were no breastfeeding or only partial breastfeeding (i.e. fully breastfeeding) at discharge and no breastfeeding at all (i.e. any breastfeeding) at six months post-discharge. There was no heterogeneity of treatment effect on the primary outcome no breastfeeding at all at discharge and at three months post discharge. Although the direction of effect of all the included trials was consistent (favouring avoiding bottles), the magnitude of effect of Kliethermes 1999 is inconsistent with the other four trials. The most likely reason for the heterogeneity was the difference in the intervention or the poor quality of the Kliethermes 1999 study. Kliethermes 1999 used supplemental feeding by tube, whereas the remaining trials used supplemental feeds by cup.

A strategy of supplementing breast feeds with cup feeds reduced the risk of no breastfeeding or only partial breastfeeding on discharge home (i.e. increased fully breastfeeding). On meta-analysis of all included trials, breastfeeding plus avoiding bottles reduced the risk of no breastfeeding at all at discharge home and at three months post-discharge (i.e. increased any breastfeeding). However, on subgroup analysis, cup feeding had no effect, with only the single study tube alone approach demonstrating a significant reduction in not breastfeeding (i.e. increase in any breastfeeding) at these time points and at six months post-discharge. The outcome no breastfeeding or only partial breastfeeding at three and six months was not reported in the cup feeding trials but the single tube alone study showed a significant reduction in risk (i.e. increase in fully breastfeeding).

A cup feeding strategy significantly increased the length of hospital stay by a mean of 10 days in the one trial in which this was measured (Collins 2004). An increase in length of stay of this degree has considerable financial implications for the health care system as well as social and emotional implications for parents in increasing the time they are separated from their infant. The tube alone strategy showed no difference in length of hospitalisation (Kliethermes 1999).

The method of feeding did not affect weight gain (Rocha 2002; Collins 2004). There was limited evidence from the two trials that assessed cardiorespiratory stability suggesting improved stability with avoidance of bottles (Kliethermes 1999; Rocha 2002).

As infants mature they can become less satisfied with the lack of sucking experience during a feed. There were no reports of infants being dissatisfied with tube or cup and compliance with the intervention was high in four of the included studies (Kliethermes 1999; Mosley 2001; Rocha 2002; Gilks 2004). In the study of Collins 2004 compliance with the intervention was poor. Some parents reported that their infants were not satisfied with cup feeds and introduced a bottle because of this. Lang 1997 suggests that as preterm infants mature they may be able to bottle feed without this activity interfering with breast feeds, but she cautions that the introduction of a bottle should only occur when breastfeeding is well established. It may be possible that such a strategy could reduce the length of hospitalisation; however, no randomised controlled trials have been conducted investigating this approach.

Supplementing breast feeds with cup feeding, dominated by the large study of Collins 2004, confers no breastfeeding benefits after discharge to home and delays discharge considerably. There is insufficient evidence on which to base conclusions for supplementing breast feeds with a tube alone strategy.

AUTHORS' CONCLUSIONS

Implications for practice

There is evidence of benefit of supplementing breast feeds with cup feeding on breastfeeding rates at discharge; however, this is not sustained beyond discharge and increases length of hospital stay considerably. There is insufficient evidence on which to base recommendations for supplementing breast feeds with a tube alone strategy.

Implications for research

There is need for further studies in other centres of a supplementing breast feeds with a tube alone approach. Such studies should have concealed random allocation, complete follow-up of all randomised infants, adequate sample size to evaluate length of hospital stay, weight gain, breastfeeding prevalence on discharge home and at three and six months post-discharge as well as data on and infant, parental and staff satisfaction with feeding method.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Collins 2004

Methods	Randomised controlled trial, stratified by gestational age <28 weeks and 28 to <34 weeks and study centre. Study duration - 3 years 1996 to 1999.
Participants	Two Australian tertiary centres. Inclusion criteria: gestational age <34 weeks (Experimental: mean 29.4 weeks, SD 2.6, range 23-33; Control: mean 30.0 weeks, SD 2.5, range 24-33), mother wishes to breast feed, had not been fed by cup or bottle, no congenital abnormality precluding sucking feeds, dummy use less than or equal to 48 hours. Sample size 319 randomised, 303 included in analysis. Number randomised to each group 151 (experimental/cup), 152 (control/bottle).
Interventions	Randomised to cup/no dummy, cup/dummy, bottle/no dummy, bottle/dummy. Experimental: supplementary feeds given by cup according to Lang 1994b recommendations. 60 ml medicine cup used. Control: supplementary feeds given by bottle. Both groups: infants breast fed when mother present ; cup/bottle used in addition to nasogastric tube.
Outcomes	breastfeeding prevalence any and fully at discharge, and 'all' and any at 3 and 6 months; days to all sucking feeds; length of hospitalisation; weight gain from birth to discharge home.
Notes	Initial analyses showed no clinically important or significant interaction between use of cups and dummies and therefore further comparison were performed on the marginal groups cup versus bottle. High proportion of non compliance: experimental group 85/151 (46%) had bottle introduced, control group 1/152 (0.7%) had a cup introduced). Participants were analysed in the groups to which they were randomised regardless of the intervention they actually received.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Quote: "An independent researcher developed a separate randomisation schedule for each recruiting hospital by using a random number table to select balanced blocks of varying size with stratification for gestation (<28 weeks, 28-<34 weeks)."
Allocation concealment?	Yes	Quote: "Assignments were sealed in sequentially numbered, opaque envelopes. Researchers determined allocation by telephoning an independent ward, available 24

Collins 2004 (*Continued*)

		hours a day, within the recruiting hospitals."
Blinding? All outcomes	No	Quote: "Particpants, care providers, and researchers were not blinded to treatment allocation; data entry and analysis were undertaken unblinded." Comment: Blinding of intervention not possible.
Incomplete outcome data addressed? On discharge home	Yes	Missing outcome data n=16 (5%) due to attrition (experimental 10, control 6): • Died 4: experimental 8, control 4 • Withdrawals 4: 2 in each group Comment: Low risk of bias due to incomplete outcome data
Incomplete outcome data addressed? 3 months post discharge	Yes	Missing outcome data n=36 (11%) due to attrition (experimental 17, control 19): • Died 4: experimental 8, control 4 • Withdrawals 4: 2 in each group • Unable to locate 20: experimental 7, control 13 Comment: Low risk of bias due to incomplete outcome data
Incomplete outcome data addressed? 6 months post discharge	Yes	Missing outcome data n=38 (12%) due to attrition (experimental 19, control 19): • Died 4: experimental 8, control 4 • Withdrawals 4: 2 in each group • Unable to locate 22: 9 experimental, 13 control Comment: low risk of bias due to incomplete outcome data

Gilks 2004

Methods	Randomised controlled trial, stratified by gestational age <31 weeks and 31 to <35 weeks. Study duration - two years 2002 to 2004.
Participants	Single centre tertiary institution UK. Inclusion criteria <35 weeks gestation (Experimental: median 31 weeks, range 25 to 34); Control median 32 weeks, range 26 to 34), >30 weeks post menstrual age at trial entry, tolerating full strength, full volume nasogastric feeds for 48 hours or more, anticipated stay of at least one week, mother intention to breast feed. Sample size 54 randomised, 54 included in analysis (additional information from author). Number randomised to each group 27 (experimental/cup), 27 (control/bottle).

Gilks 2004 (*Continued*)

Interventions	Experimental: supplementary feeds given by cup when mother not present to breast feed. Control: supplementary feeds given by bottle when mother not present to breast feed. Both groups: infants breast fed when mother present ; cup/bottle used in addition to nasogastric tube.
Outcomes	Breastfeeding prevalence any and fully on discharge home, term and six weeks post term; post menstrual age at nasogastric tube withdrawal
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Quote: "randomised, non-blinded stratified controlled trial". Comment: unable to determine if adequate sequence generation
Allocation concealment?	Yes	Quote: "randomisation was by selection of concealed cards in envelopes, stratified by gestation"
Blinding? All outcomes	No	Quote: "randomised, non-blinded stratified controlled trial". Quote: (from correspondence): "no one was blinded in the study once the envelope was opened." Comment: Blinding of intervention not possible.
Incomplete outcome data addressed? On discharge home	Yes	3 infants not accounted for in paper, additional information provided by author. 14 women counted as withdrawals in the paper as they no longer wanted to breast feed. With additional information from author, re-analysed in this review. Comment: outcome data complete.

Kliethermes 1999

Methods	Randomised controlled trial. Study duration - 22 months.
Participants	Inclusion criteria: birth weight 1000 g - 2500 g, less than one week of age, no congenital or neurological abnormalities that interfered with cardiopulmonary status. Gestational age at birth: Experimental 32 weeks, SD not reported, range 26 to 35 weeks; Control 32 weeks, SD not reported, range 28 to 35 weeks; birth weight experimental

Kliethermes 1999 (*Continued*)

	1.73 kg, range 1.05 kg to 2.43 kg; control 1.64 kg, range 1.0 kg to 2.35 kg, twins experimental 8 (21%); control 16 (35%). Sample size 99 randomised (47 experimental, 52 control); 84 included in analysis. Number randomised to each group 38 (Experimental/tube alone), 46 (Control/bottle).
Interventions	Both groups infants breast fed when mother present. Experimental group: Feeds given by indwelling size 3.5 FG nasogastric tube when mother not available or top-up after breast feed required. Tube removed during last 24-48 hour parent 'rooming-in' period, a cup or syringe used during this time if needed. Control group: Fed by bottle when mother not available or top-up after breast feed required. Indwelling nasogastric tube removed as directed by clinicians.
Outcomes	Breastfeeding, exclusive and partial, at discharge home, and at 3 days, 3 months and 6 months post discharge. Length of hospital stay, apnoea/bradycardia, weight gain to discharge home.
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Quote: "Randomization was achieved by using sealed envelopes, which were physically mixed and drawn in random sequence after enrolment of the dyad into the study."
Allocation concealment?	Yes	Quote: "...sealed envelopes"
Blinding? All outcomes	No	Comment: Blinding of intervention not possible. Blinding of outcome assessment not reported.
Incomplete outcome data addressed? On discharge home	No	Missing outcome data n=15 (15%) (experimental 9, control 6) • Died 1: experimental • Clinical conditions 4: experimental 2 (chronic lung disease, congenital heart defect) ; control 2 (NEC, subglottic stenosis) • Transfer to another hospital 2: 1 in each group • Protocol violation 5: experimental 3, control 2 • Maternal conditions 3: experimental 2 (scleroderma, +ve cocaine screen), control 1 (+ve cocaine screen) Comment: high risk of bias due to incom-

		plete outcome data. Difference in proportion of missing data across groups (19% experimental, 12% control). For 4 infants there were valid reasons for missing outcome data (one died, 2 transferred to another hospital). By imputing the worst case scenario for the outcome 'no breastfeeding or only partial breastfeeding on discharge home' (i.e. those excluded in the treatment group did not breast feed and those excluded in the control group did breast feed) made the result less pronounced but still significant in favour of avoid bottle. By imputing the worst case scenario for the outcome 'no breastfeeding at all on discharge home' (i.e. those excluded in the treatment group did not breast feed and those excluded in the control group did breast feed) the result was now non-significant.
Incomplete outcome data addressed? 3 months post discharge	No	Missing outcome data n=15 (15%) (experimental 9, control 6) • Died 1: experimental • Clinical conditions 4: experimental 2 (chronic lung disease, congenital heart defect) ; control 2 (NEC, subglottic stenosis) • Transfer to another hospital 2: 1 in each group • Protocol violation 5: experimental 3, control 2 • Maternal conditions 3: experimental 2 (scleroderma, +ve cocaine screen), control 1 (+ve cocaine screen) Comment: high risk of bias due to incomplete outcome data.
Incomplete outcome data addressed? 6 months post discharge	No	Missing outcome data n=15 (15%) (experimental 9, control 6) • Died 1: experimental • Infant clinical conditions 4: experimental 2 (chronic lung disease, congenital heart defect) ; control 2 (NEC, subglottic stenosis) • Transfer to another hospital 2: 1 in each group • Protocol violation 5: experimental 3,

		control 2 • Maternal conditions 3: experimental 2 (scleroderma, +ve cocaine screen), control 1 (+ve cocaine screen) Comment: high risk of bias due to incomplete outcome data.

Mosley 2001

Methods	Randomised controlled trial, pilot study. Study duration - 3 months.
Participants	Single centre, Special Care Baby Unit, District General Hospital, England. Inclusion criteria: gestational age at birth 32 to 37 weeks, mother wishes to breast feed, no congenital abnormality, no maternal preference for cup or bottle, had not been fed by cup or bottle. Sample size 16 randomised (8 experimental, 8 control), 14 included in analysis 6 (experimental), 8 (control).
Interventions	Experimental: supplementary feeds given by cup. Control: supplementary feeds given by bottle.
Outcomes	Prevalence exclusive breastfeeding on discharge home
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Quote: "there were 10 instructions to cup feed and ten to bottle feed. These details were then put in the envelopes, shuffled thoroughly and then the envelopes were numbered sequentially".
Allocation concealment?	Yes	Quote: "midwife/nurse responsible was asked to select a sealed, numbered, opaque envelope, which contained information on the feeding method to be adopted".
Blinding? All outcomes	No	Not possible to blind intervention. No information provided on blinding of outcome assessors.
Incomplete outcome data addressed? On discharge home	Yes	Missing outcome data n=2 (13%) (experimental 2, control 0). • Protocol violation (Quote: "excluded from the study prior to its start ....had

Mosley 2001 (*Continued*)

		been given a supplementary feed") Comment: Although difference in proportion of incomplete outcome data across groups (25% experimental, 0% control) the sample size is so small we are unable to assess the impact of missing data sensibly. Low risk of bias due to incomplete outcome data.

Rocha 2002

Methods	Randomised controlled trial, stratified by weight (500 - 999g, 1000 -1499g, 1500 - 1699g). Study duration - 18 months, August 1998 to February 2000.
Participants	Single Centre, NICU, University Hospital, Brazil. Inclusion criteria: gestational age at birth 32-34 weeks (experimental: mean 32.7 weeks, SD 1.8, range not reported; control: mean 32.5 weeks, SD 2, range not reported) and birth weight <1700g (experimental: mean 1276g, SD 283g; control: mean 1262g, SD 270g), mothers wished to breast feed, clinically stable, not initially on parenteral nutrition. Sample size 83 randomised (46 experimental, 37 control), 78 included in analysis. Number randomised to each group 44 (experimental/cup), 34 (control/bottle).
Interventions	Infants in both groups fed by orogastric tube until 1600g. Experimental: supplements or complements given by cup according to the recommendations of Kuehl 1997 and Lang 1994a. Not offered a dummy. Control: supplements or complements given by bottle.
Outcomes	breastfeeding prevalence on discharge, first follow up visit and 3 months post discharge. Weight gain (calculated as the difference between weight at the beginning of the intervention and weight at the end of 1 week during feeding observation). Length of feeding time (one week after beginning oral feeds). Oxygen saturation.
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Quote: ". controlled experimental study with stratified randomisation." "Within each stratum, the infants were randomly assigned to 1 of 2 feeding groups by drawing lots."
Allocation concealment?	Unclear	Quote: "Infants were randomly assigned to 1 of 2 feeding groups by drawing lots." Comment: The mechanism for drawing of lots not reported, therefore unclear if allocation concealed.

Rocha 2002 (*Continued*)

Blinding? All outcomes	No	Blinding of intervention not possible. Blinding of outcome assessment not reported.
Incomplete outcome data addressed? On discharge home	Yes	Missing outcome data n=5 (6%) (experimental 2, control 3). • Control 3: (gastro-oesophageal reflux, bronchopulmonary dysplasia, maternal cocaine use) • Experimental 2 (protocol violation, bronchopulmonary dysplasia) Comment: Low risk of bias due to incomplete outcome data. Small difference in proportion of missing data across groups, although protocol violations only in experimental group (4% experimental, 8% control). Overall small proportion of missing data (6%).
Incomplete outcome data addressed? 3 months post discharge	Yes	Missing outcome data n=5 (6%) (experimental 2, control 3). • Control 3: (gastro-oesophageal reflux, bronchopulmonary dysplasia, maternal cocaine use) • Experimental 2 (protocol violation, bronchopulmonary dysplasia) Comment: Low risk of bias due to incomplete outcome data. Small difference in proportion of missing data across groups, although protocol violations only in experimental group (4% experimental, 8% control). Overall small proportion of missing data (6%).

DATA AND ANALYSES

Comparison 1. Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 No breastfeeding or only partial breastfeeding at discharge	4	455	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.41, 0.96]
1.1 Breastfeeding + Cup vs. Breastfeeding + Bottle	3	371	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.61, 0.91]
1.2 Breastfeeding + Tube vs. Breastfeeding + Bottle	1	84	Risk Ratio (M-H, Random, 95% CI)	0.22 [0.10, 0.53]
2 No breastfeeding or only partial breastfeeding at 3 months post discharge	1	84	Risk Ratio (M-H, Fixed, 95% CI)	0.59 [0.40, 0.87]
3 No breastfeeding or only partial breastfeeding at 6 months post discharge	1	84	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.48, 0.89]
4 No breastfeeding at all at discharge	4	519	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.56, 0.97]
4.1 Breastfeeding + Cup vs. Breastfeeding + Bottle	3	435	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.62, 1.09]
4.2 Breastfeeding + Tube vs. Breastfeeding + Bottle	1	84	Risk Ratio (M-H, Fixed, 95% CI)	0.30 [0.11, 0.83]
5 No breastfeeding at all at 3 months post discharge	3	444	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.71, 0.96]
5.1 Breastfeeding + Cup vs. Breastfeeding + Bottle	2	361	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.76, 1.03]
5.2 Breastfeeding + Tube vs. Breastfeeding + Bottle	1	83	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.23, 0.90]
6 No breastfeeding at all at 6 months post discharge	2	364	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.73, 0.96]
6.1 Breastfeeding + Cup vs. Breastfeeding + Bottle	1	281	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.78, 1.05]
6.2 Breastfeeding + Tube vs. Breastfeeding + Bottle	1	83	Risk Ratio (M-H, Fixed, 95% CI)	0.61 [0.41, 0.91]
7 Days to reach full sucking feeds	2	332	Mean Difference (IV, Fixed, 95% CI)	7.18 [2.30, 12.07]
8 Daily weight gain	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
8.1 Measured from birth to discharge home	1	293	Mean Difference (IV, Fixed, 95% CI)	-0.09 [-0.77, 0.59]
8.2 Measured for one week after commencing oral feeds	1	78	Mean Difference (IV, Fixed, 95% CI)	-0.60 [-3.21, 2.01]
9 Length of hospital stay	2	385	Mean Difference (IV, Fixed, 95% CI)	6.63 [1.85, 11.41]
9.1 Breastfeeding + Cup vs. Breastfeeding + Bottle	1	301	Mean Difference (IV, Fixed, 95% CI)	10.08 [3.87, 16.29]
9.2 Breastfeeding + Tube vs. Breastfeeding + Bottle	1	84	Mean Difference (IV, Fixed, 95% CI)	1.60 [-5.89, 9.09]

10 Duration of supplementary feed	1	Mean Difference (IV, Fixed, 95% CI)		Subtotals only

Analysis 1.1. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 1 No breastfeeding or only partial breastfeeding at discharge.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 1 No breastfeeding or only partial breastfeeding at discharge

Study or subgroup	BF + avoid bottle n/N	BF + bottle n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Breastfeeding + Cup vs. Breastfeeding + Bottle					
Collins 2004	59/151	80/152		40.9 %	0.74 [0.58, 0.95]
Gilks 2004	17/27	23/27		37.0 %	0.74 [0.53, 1.03]
Mosley 2001	2/6	2/8		5.8 %	1.33 [0.26, 6.94]
Subtotal (95% CI)	**184**	**187**		**83.7 %**	**0.75 [0.61, 0.91]**
Total events: 78 (BF + avoid bottle), 105 (BF + bottle)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.48, df = 2 (P = 0.79); I^2 =0.0%					
Test for overall effect: Z = 2.89 (P = 0.0039)					
2 Breastfeeding + Tube vs. Breastfeeding + Bottle					
Kliethermes 1999	5/38	27/46		16.3 %	0.22 [0.10, 0.53]
Subtotal (95% CI)	**38**	**46**		**16.3 %**	**0.22 [0.10, 0.53]**
Total events: 5 (BF + avoid bottle), 27 (BF + bottle)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.44 (P = 0.00058)					
Total (95% CI)	**222**	**233**		**100.0 %**	**0.63 [0.41, 0.96]**
Total events: 83 (BF + avoid bottle), 132 (BF + bottle)					
Heterogeneity: Tau^2 = 0.10; Chi^2 = 8.36, df = 3 (P = 0.04); I^2 =64%					
Test for overall effect: Z = 2.13 (P = 0.033)					

Analysis 1.2. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 2 No breastfeeding or only partial breastfeeding at 3 months post discharge.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 2 No breastfeeding or only partial breastfeeding at 3 months post discharge

Study or subgroup	BF + avoid bottle n/N	BF + bottle n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Kliethermes 1999	17/38	35/46		100.0 %	0.59 [0.40, 0.87]
Total (95% CI)	**38**	**46**		**100.0 %**	**0.59 [0.40, 0.87]**

Total events: 17 (BF + avoid bottle), 35 (BF + bottle)

Heterogeneity: not applicable

Test for overall effect: Z = 2.68 (P = 0.0074)

Analysis 1.3. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 3 No breastfeeding or only partial breastfeeding at 6 months post discharge.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 3 No breastfeeding or only partial breastfeeding at 6 months post discharge

Study or subgroup	BF + avoid bottle n/N	BF + bottle n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Kliethermes 1999	21/38	39/46		100.0 %	0.65 [0.48, 0.89]
Total (95% CI)	**38**	**46**		**100.0 %**	**0.65 [0.48, 0.89]**

Total events: 21 (BF + avoid bottle), 39 (BF + bottle)

Heterogeneity: not applicable

Test for overall effect: Z = 2.70 (P = 0.0070)

Analysis 1.4. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 4 No breastfeeding at all at discharge.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 4 No breastfeeding at all at discharge

Study or subgroup	BF + avoid bottle n/N	BF + bottle n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Breastfeeding + Cup vs. Breastfeeding + Bottle					
Collins 2004	39/151	49/152		56.6 %	0.80 [0.56, 1.14]
Gilks 2004	13/27	15/27		17.4 %	0.87 [0.52, 1.45]
Rocha 2002	8/44	7/34		9.2 %	0.88 [0.36, 2.19]
Subtotal (95% CI)	**222**	**213**		**83.2 %**	**0.82 [0.62, 1.09]**
Total events: 60 (BF + avoid bottle), 71 (BF + bottle)					
Heterogeneity: Chi² = 0.08, df = 2 (P = 0.96); I² =0.0%					
Test for overall effect: Z = 1.34 (P = 0.18)					
2 Breastfeeding + Tube vs. Breastfeeding + Bottle					
Kliethermes 1999	4/38	16/46		16.8 %	0.30 [0.11, 0.83]
Subtotal (95% CI)	**38**	**46**		**16.8 %**	**0.30 [0.11, 0.83]**
Total events: 4 (BF + avoid bottle), 16 (BF + bottle)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.32 (P = 0.020)					
Total (95% CI)	**260**	**259**		**100.0 %**	**0.74 [0.56, 0.97]**
Total events: 64 (BF + avoid bottle), 87 (BF + bottle)					
Heterogeneity: Chi² = 3.74, df = 3 (P = 0.29); I² =20%					
Test for overall effect: Z = 2.21 (P = 0.027)					

Analysis 1.5. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 5 No breastfeeding at all at 3 months post discharge.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 5 No breastfeeding at all at 3 months post discharge

Study or subgroup	BF + avoid bottle n/N	BF + bottle n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Breastfeeding + Cup vs. Breastfeeding + Bottle					
Collins 2004	83/144	89/139		63.6 %	0.90 [0.75, 1.09]
Rocha 2002	31/44	29/34		23.0 %	0.83 [0.65, 1.05]
Subtotal (95% CI)	**188**	**173**		**86.5 %**	**0.88 [0.76, 1.03]**
Total events: 114 (BF + avoid bottle), 118 (BF + bottle)					
Heterogeneity: Chi^2 = 0.33, df = 1 (P = 0.56); I^2 =0.0%					
Test for overall effect: Z = 1.64 (P = 0.10)					
2 Breastfeeding + Tube vs. Breastfeeding + Bottle					
Kliethermes 1999	8/38	21/45		13.5 %	0.45 [0.23, 0.90]
Subtotal (95% CI)	**38**	**45**		**13.5 %**	**0.45 [0.23, 0.90]**
Total events: 8 (BF + avoid bottle), 21 (BF + bottle)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.26 (P = 0.024)					
Total (95% CI)	**226**	**218**		**100.0 %**	**0.82 [0.71, 0.96]**
Total events: 122 (BF + avoid bottle), 139 (BF + bottle)					
Heterogeneity: Chi^2 = 3.80, df = 2 (P = 0.15); I^2 =47%					
Test for overall effect: Z = 2.51 (P = 0.012)					

Analysis 1.6. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 6 No breastfeeding at all at 6 months post discharge.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 6 No breastfeeding at all at 6 months post discharge

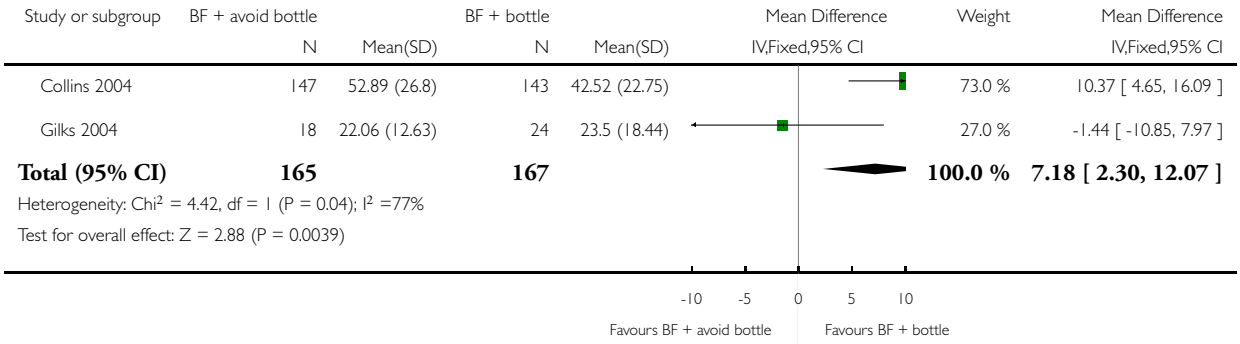
Study or subgroup	BF + avoid bottle n/N	BF + bottle n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Breastfeeding + Cup vs. Breastfeeding + Bottle					
Collins 2004	98/142	106/139		78.0 %	0.90 [0.78, 1.05]
Subtotal (95% CI)	**142**	**139**		**78.0 %**	**0.90 [0.78, 1.05]**
Total events: 98 (BF + avoid bottle), 106 (BF + bottle)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.36 (P = 0.17)					
2 Breastfeeding + Tube vs. Breastfeeding + Bottle					
Kliethermes 1999	17/38	33/45		22.0 %	0.61 [0.41, 0.91]
Subtotal (95% CI)	**38**	**45**		**22.0 %**	**0.61 [0.41, 0.91]**
Total events: 17 (BF + avoid bottle), 33 (BF + bottle)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.45 (P = 0.014)					
Total (95% CI)	**180**	**184**		**100.0 %**	**0.84 [0.73, 0.96]**
Total events: 115 (BF + avoid bottle), 139 (BF + bottle)					
Heterogeneity: Chi^2 = 3.55, df = 1 (P = 0.06); I^2 =72%					
Test for overall effect: Z = 2.47 (P = 0.013)					

Analysis 1.7. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 7 Days to reach full sucking feeds.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 7 Days to reach full sucking feeds

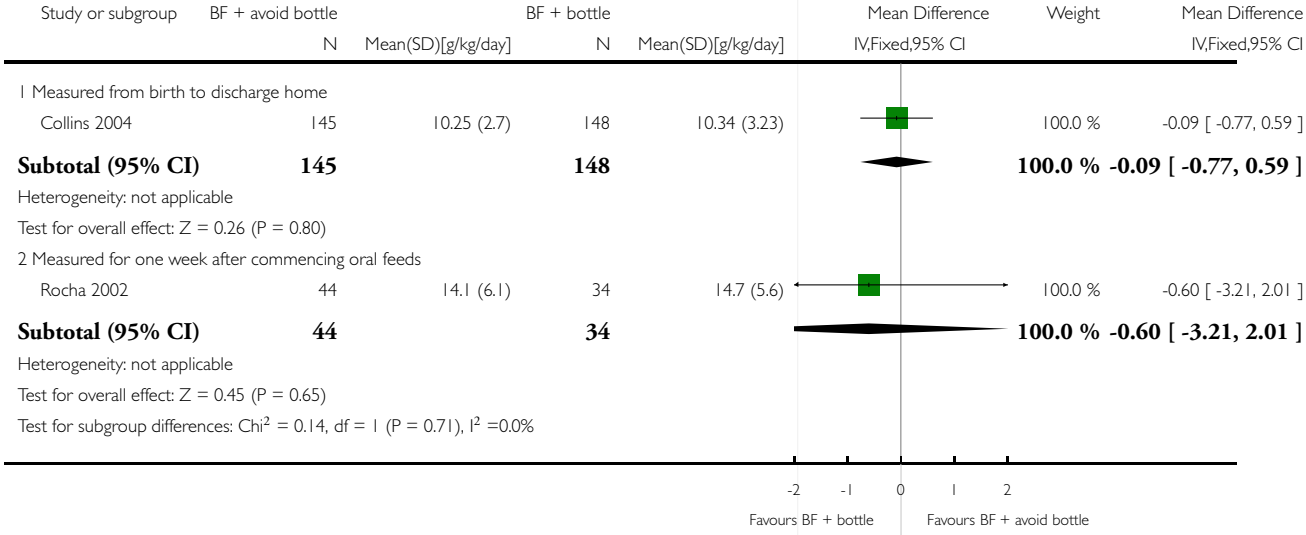


Analysis 1.8. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 8 Daily weight gain.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 8 Daily weight gain

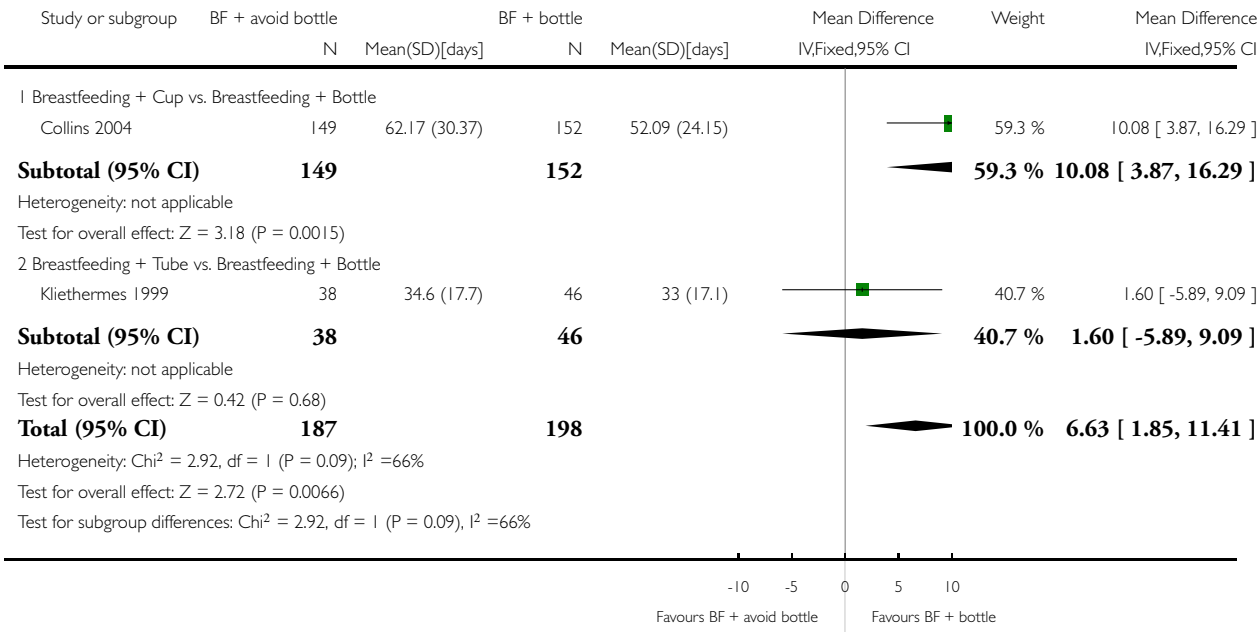


Analysis 1.9. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 9 Length of hospital stay.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 9 Length of hospital stay

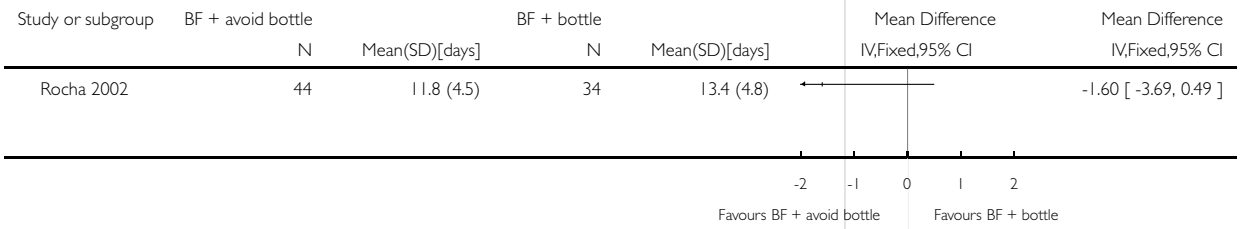


Analysis 1.10. Comparison 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials), Outcome 10 Duration of supplementary feed.

Review: Avoidance of bottles during the establishment of breast feeds in preterm infants

Comparison: 1 Breastfeeding with supplemental feeds by other than bottle versus breastfeeding with supplemental feeds by bottles (all trials)

Outcome: 10 Duration of supplementary feed



HISTORY

Protocol first published: Issue 2, 2005

Review first published: Issue 4, 2008

CONTRIBUTIONS OF AUTHORS

C Collins wrote the protocol, searched for studies, extracted data, analysed data, wrote review.

J Gillis contributed to protocol, extracted data and commented on drafts of the review.

M Makrides contributed to protocol and commented on drafts of the review.

A McPhee contributed to protocol and commented on drafts of the review.

DECLARATIONS OF INTEREST

CT Collins and AJ McPhee were investigators responsible for one of the studies included in this review (Collins 2004). J Gillis is a clinical nurse in the Special Care Baby Unit where one of the included studies was undertaken (Collins 2004). CT Collins undertook a systematic review on this same topic as part of her PhD thesis (Collins 2004).

SOURCES OF SUPPORT

Internal sources

- Women's and Children's Health Research Institute, Adelaide, South Australia, Australia.
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External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Breast Feeding; *Cooking and Eating Utensils; *Infant, Premature; Bottle Feeding [*utilization]; Enteral Nutrition [methods]; Infant, Newborn; Infant Formula [administration & dosage]; Length of Stay; Milk, Human; Sucking Behavior

MeSH check words

Female; Humans