

REVIEW ARTICLE

## Effects of brief exposure to water, breast-milk substitutes, or other liquids on the success and duration of breastfeeding: A systematic review

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### Abstract

**Aim:** To systematically evaluate the effect of supplemental fluids or feedings during the first days of life on the overall breastfeeding duration and rate of exclusive breastfeeding among healthy infants. **Methods:** Medical subject headings and free-language terms were used to search the following electronic databases for studies relevant to breastfeeding: MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health (CINAHL), the Cochrane Library, and La Leche League. Only randomized, controlled trials (RCT) were considered for study inclusion. **Results:** Of 56 potentially relevant clinical trials identified, only one RCT (170 infants) met the inclusion criteria for this systematic review. In this study, formula feeding was significantly more frequent at 4 wk in the experimental group in which breastfeeding had been supplemented with 5% glucose *ad libitum* during the first 3 d of life ( $n = 83$ ) than in the exclusively breastfed control group ( $n = 87$ ) ( $p < 0.05$ ). At 16 wk (5 mo postpartum), the percentage of mothers who continued breastfeeding, either exclusively or partially, was significantly lower in the experimental group than in the control group ( $p < 0.01$ ).

**Conclusion:** There remains considerable uncertainty about the effect of brief exposure to water, breast-milk substitutes, or other liquids on the success and duration of breastfeeding.

**Key Words:** *Breastfed, breast-milk substitutes, prelacteal feedings*

### Introduction

Breastfeeding is recognized as the ideal way of feeding healthy infants. *Exclusive breastfeeding*, based on the WHO definition [1], refers to the practice of feeding only breast milk (including expressed breast milk) and allows the infant to receive vitamins, minerals and even medicine. Supplementary water, breast-milk substitutes, other liquids and solid foods are excluded. The term *predominant breastfeeding* applies if the infant's primary source of nourishment is breast milk. However, the infant may also receive water and water-based drinks, fruit juice, oral rehydration salt solutions, drop and syrup forms of vitamins, minerals and medicines, and ritual fluids such as herbal teas and ghee [2] (in limited quantities).

*Prelacteal feeding* refers to the feeding of infants water and water-based drinks (e.g., sweetened and flavoured water, teas, infusions) prior to their first breastfeed. Prelacteal feeds and supplements are used for a variety of reasons such as to improve hydration, reduce jaundice and prevent hypoglycaemia. This feeding strategy is also useful when an infant is unsettled, having difficulty attaching to the breast, or displaying apparent hunger after breastfeeding or when the mother is ill or tired. In some communities, prelacteal feedings are performed for ritualistic purposes [2].

In 1989, the World Health Organization (WHO) and UNICEF published guidelines intended to promote and support breastfeeding [3]. The subsequent WHO/United Nations Children's Fund Baby Friendly Hospital Initiative recommends that, unless

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medically indicated, one should avoid feeding infants food or drinks other than breast milk, which may delay onset of full milk production and/or cause early termination of breastfeeding and early weaning [4]. Although various studies have established a link between early weaning and prelacteal feedings/supplementation, most have been observational in design. Therefore, the primary objective of this study was to determine the effect of supplemental fluids or feedings during the first few days of life on the overall breastfeeding duration and rate of exclusive breastfeeding among healthy infants, via systematic review of relevant studies in electronic databases.

## Methods

### *Inclusion criteria*

Electronic databases (see "Search strategy") were systematically searched to identify studies appropriate for inclusion in this systematic review. Inclusion criteria were as follows.

*Types of studies.* Randomized, controlled trials (RCTs) comparing infants who were exclusively versus predominantly breastfed during their first few days of life.

*Types of participants.* Healthy, full-term infants (38–42 wk of gestation, birthweight >2500 g).

*Types of interventions.* Infants in the experimental groups received fluids such as water, water-based drinks, glucose solution, breast-milk substitutes (i.e., infant formula or food for special medical purposes), or other liquids delivered either by cup or bottle during the first days of life as prelacteal feeds or supplements. Infants in the control group were exclusively breastfed.

*Types of outcome measures.* Outcome measures in these studies included: 1) the proportion of exclusively breastfed infants at 6 mo of age; 2) the proportion of exclusively breastfed infants at other fixed time points between birth and 6 mo (as evaluated by the investigators); 3) the proportion of infants receiving any breast milk at fixed time points between birth and 6 mo (as evaluated by the investigators); 4) the proportion of infants still being breastfed at the end of their first year of life; 5) the overall duration of breastfeeding; 6) the proportion of infants receiving infant formula at time points between birth and 6 mo.

### *Search strategy*

The following electronic databases were systematically searched for relevant studies: MEDLINE (1966–April 2004), EMBASE (1980–December 2003), Cumulative Index to Nursing and Allied Health (CINAHL, 1982–April 2004), the Cochrane Database of Systematic Reviews (Issue 1, 2004) and the Cochrane Controlled Trials Register (Issue 1, 2004). The search strategy included use of a recognized filter for identifying controlled trials [5], which was combined with a topic-specific strategy.

The medical subject headings (MeSH) "breast feeding", "human milk" and "infant nutrition", as well as the free-language terms "breast-feeding", "breast feeding" or "breastfeeding" combined with "exclusive" or "exclusively", were used in the search. Furthermore, La Leche League International as well as reference lists from the original studies and review articles identified were screened, and key experts in the field were approached for unpublished material. No limit was imposed regarding the language of publication, but certain publication types (i.e., letters to the editor, abstracts, proceedings from scientific meetings) were excluded.

### *Methods of review*

*Included and excluded studies.* Titles and abstracts identified according to the above-described search strategy were screened independently by two reviewers (AH, MK). All potentially relevant articles were retained and the full text of these studies examined to determine which studies satisfied the inclusion criteria. Data extraction was carried out independently by the same reviewers, using standard data extraction forms. Studies reported in languages other than those familiar to the authors were translated. Discrepancies between the reviewers were resolved by discussion.

*Study quality.* Two reviewers (AH, HS) independently, but without being blinded to the authorship or journal, assessed the quality of studies that met the inclusion criteria. Use of the following strategies, associated with good-quality studies, was assessed: 1) allocation concealment, 2) blinding of investigators, participants, outcome assessors and data analysts (yes/no/not stated), 3) intention-to-treat analysis (yes/no), and 4) comprehensive follow-up.

Allocation concealment was considered adequate when the randomization method used did not allow the investigator or the participant to identify or influence the intervention group before the entry of eligible participants into the study. However, the quality of the allocation concealment was unclear

when randomization was used but no information about the method was available, and inadequate when inappropriate methods of randomization (e.g., alternate medical record numbers, unsealed envelopes) were used.

In regard to the intention-to-treat analysis, an answer of “yes” meant that the authors had specifically reported undertaking this type of analysis and/or that our own study confirmed this finding. Conversely, a “no” meant that authors did not report use of intention-to-treat analysis and/or that we could not confirm its use on study assessment. To evaluate the completeness of patient follow-up, we determined the percentage of participants excluded or lost to follow-up.

## Results

The search yielded 2859 citations. Most studies ( $n = 2801$ ) were excluded because they were not relevant to breastfeeding supplementation. Of the 58 potentially relevant remaining trials identified and/or screened for retrieval, only one by Martin-Calama et al. [6] met the inclusion criteria for this systematic review (see Table I). Thus, the remaining 57 studies were excluded [7–63]. Table II summarizes characteristics of the excluded trials, including the reasons for exclusion.

Although the investigation by Martin-Calama et al. [6] was a randomized study, they provided no information about the methods used. While the blinding of participants was not feasible, there was also no mention of the blinding of investigators, outcome assessors and data analysts. In addition, intention-to-treat analysis was not performed. In regard to study objectives, Martin-Calama et al. [6]

compared the effect of supplementing breastfeeding with 5% glucose water *ad libitum* (experimental group,  $n = 83$ ) during the first 3 d of life with the effect of exclusive breastfeeding (control group,  $n = 87$ ). Only two outcome measures of interest were studied: the proportion of infants receiving infant formula at time points between birth and 6 mo, and the proportion of infants receiving any breast milk at fixed time points between birth and 6 mo. At 4 wk, formula feeding was significantly more frequent in the experimental group compared with the control group (34% vs 18% (as estimated from the figure),  $p < 0.05$ ). At 16 wk (5 mo postpartum), phone interviews revealed that the percentage of mothers who had continued to breastfeed (either exclusively or partially) was significantly lower in the experimental group than in the control group (43% vs 67% (as estimated from the figure),  $p < 0.01$ ).

## Discussion

Based on this systematic review, considerable uncertainty remains about the effects of brief exposure to water, breast-milk substitutes, or other liquids on the success and duration of breastfeeding. No study has evaluated the effects of such exposure on the rate of exclusive breastfeeding at 6 mo or on the overall duration of breastfeeding.

Results from the only study that met our inclusion criteria (Martin-Calama et al. [6]) suggest that only brief exposure of breastfed infants to other liquids or foods would markedly reduce the success and duration of breastfeeding; however, this finding should be interpreted with caution. The unclear randomization and allocation concealment procedures in that study suggest that a selection bias was possible. That

Table I. Characteristics of included trial.

Study	Martin-Calama (1993) [6]
Methods	<i>Randomization</i> : stated, but no information on method used is available <i>Blinding</i> : investigators – not stated; participants – not feasible; outcome assessors – not stated; data analysts – not stated <i>Intention-to-treat</i> : no <i>Completeness of follow-up</i> : ten children (three from the exclusively breastfed group and seven from the glucose water-supplemented group) were excluded because of missing data or because it was impossible to ensure correct data transcription
Participants	Healthy mothers intending to breastfeed healthy term infants for $\geq 3$ mo, without medical indications for receiving glucose water
Interventions	Experimental group ( $n = 83$ ): 5% glucose water <i>ad libitum</i> from bottle, after breastfeeds, during the first 3 d of life Control group ( $n = 87$ ): exclusively breastfed
Outcomes	1) Total duration of breastfeeding (exclusive or partial) 2) Age of introduction of infant formula
Results	Introduction of formula at 4 wk (as calculated from a figure): 34% of infants in experimental group versus 18% in the control group, $p < 0.05$ Continuation of breastfeeding at 16 wk (as calculated from a figure): 43% of the infants in the experimental group versus 67% in the control group, $p < 0.01$
Allocation concealment	Unclear

Table II. Characteristics of the excluded studies.

Study	Ref.	Study design, purpose and/or reason(s) for exclusion
Aarts et al., 1999	7	Non-randomized, prospective study. Designed to relate BF patterns to thumb sucking and pacifier use
Al-Mazroui et al., 1997	8	Prospective cohort study. Designed to clarify patterns of BF and supplemental feeding and to identify factors affecting the initiation of BF
Arifeen et al., 2001	9	Prospective, observational study. Purpose was to describe BF practices and investigate the influence of exclusive BF during early infancy on the risk of infant deaths
Bannert and Lamme, 1995	12	RCT, without long-term follow-up (observation confined to the first 6 d of life). No exclusively breastfed control group
Benis, 2002	11	RCT. Explored relationship between regular pacifier use and early weaning from BF
Bergevin et al., 1983	10	RCT. Investigated effects of dispensing infant formula packs at hospital discharge on BF duration and choice of feeding method
Bliss, 1997	13	Prospective observational study. No early supplementation. Explored the effect of providing infant formula packs and breast pumps at hospital discharge on BF duration and choice of infant feeding method
Blomquist et al., 1994	14	Prospective observational study. Participants were healthy preterm and term newborns. Examined influence of feeding routines (including supplementary feedings) in a maternity ward on subsequent duration of BF
Brown et al., 1999	15	Retrospective study. Purpose was to identify the feeding methods at discharge of term babies after midwifery care supplemented either by cup or bottle while in the hospital
Cohen et al., 1994	16	RCT. Participants were 4-mo-old infants who were exclusively BF. The purpose was to determine the effects of age of introduction of complementary foods on infant breast-milk intake, total energy intake and growth
Cornblath and Reisner, 1971	17	Observational study. Participants were full-term and preterm newborns. Study was designed to compare blood glucose levels among infants and their clinical significance
Cronenwett et al., 1992	18	RCT. Designed to determine the effect of limited bottle use during the early postpartum weeks on BF outcomes
Dewey, 2000	19	Review article (but not a systematic review); not a clinical trial
Dewey, 1999	20	RCT. Participants were limited to low-birthweight (1500–2500 g) term infants. Purpose was to determine the effect of age of introduction of complementary foods on growth of low-birthweight, breastfed infants
Donma and Donma, 1999	21	Prospective, observational study. Designed to evaluate the influence of various feeding patterns (exclusive BF/formula-fed/mixed-fed) on the physical growth and mental development of infants during the first 6 mo of life
Dungy et al., 1997	22	RCT. Purpose was to determine the effect of hospital-supplied infant formula discharge packages on BF duration
Evans et al., 1986	23	RCT. Explored the effect of supplying commercial samples of breast-milk substitutes at discharge on subsequent BF practices
Feinstein et al., 1986	24	RCT. Purpose was to identify factors related to early termination of BF in an urban population, including the effects of supplying infant formula packs at hospital discharge
Folkens and Masuch, 1998	25	RCT, without follow-up (observation confined to the first 5 d of life). No exclusively breastfed control group
Frank et al., 1987	26	RCT. Examined the influence of BF counselling and supplying commercial packs of formula at discharge on later feeding practices
Gray-Donald et al., 1985	27	A quasi-experimental trial, which compared traditional supplementation (formula supplements used at the discretion of the nursing staff) with restricted nursery supplementation (formula supplements given for special indications—during the first 24 h after a caesarean delivery). Use of glucose water was unrestricted in both groups
Guthrie et al., 1985	28	Observational study. Explored the effect of supplying infant formula samples at discharge on later BF practices
Hall, 1978	29	Observational study. Examined the influence of teaching and nursing support on BF success
Hasan et al., 1991	30	Non-randomized, observational study. Investigated the influence of socio-cultural factors on infant nutritional status
Heath et al., 2002	31	Prospective cohort study designed to clarify infant feeding practices during the first year of life
Herrera, 1984	32	Non-randomized, prospective, observational study. Explored the effects of supplementation of BF on weight loss, serum bilirubin levels, the number of feedings/24 h and BF success.
Hill, 1997	33	Non-randomized, prospective, observational study. Participants were healthy term infants. Investigated the effects of beginning supplementation with manufactured formulas at week 2 (but not during the first days of life) on BF rates at 20 wk postpartum
Hornell et al., 2001	34	Descriptive, longitudinal, prospective study. Explored changes in the pattern and duration of BF associated with the introduction of solids and formula
Hossain et al., 1991	35	Non-randomized, prospective, cohort study. Examined effect of prelacteal feedings on BF and supplementation patterns, as well as the incidence of diarrhoea, during infancy
Howard et al., 1999	36	Prospective cohort study. Investigated effect of early pacifier use on BF duration
Howard et al., 2003	37	RCT. Explored effects of different supplementation methods (bottle-feeding/cup-feeding) and pacifier use on BF practices

Table II (Continued)

Study	Ref.	Study design, purpose and/or reason(s) for exclusion
de Jong et al., 1998	38	RCT. Investigated relationship between brief early exposure to cow's milk and the development of atopy during the first 2 y of life. Main outcome measures limited to development of allergic response (BF duration not assessed)
Kind et al., 1994	39	Non-randomized observational study. Explored effect of a change in nursing policy on BF success
Kuriniij, et al., 1984	40	Retrospective study. Designed to evaluate the influence of infant-feeding practices during the first postpartum month, social support and socio-demographic variables on BF duration
Kuriniij and Shiono, 1991	41	Non-randomized, prospective, cohort study. Explored the influence of maternal socio-demographic characteristics, commitment to breastfeeding and the effect of specific hospital procedures on early formula use
Ludvigsson et al., 2003	42	Cross-sectional retrospective analysis of BF patterns and determinants in Bolivia, including socio-economic, religious and ethnic characteristics
Lutter et al., 1997	43	Prospective observational study. Purpose was to determine the effectiveness of a hospital-based programme, which was designed to promote exclusive BF among low-income women
Marques et al., 2001	44	Non-randomized, longitudinal, observational study. Purpose was to identify BF practices from birth to 12 mo of age in urban Brazil and to identify factors associated with early weaning
Metaj et al., 2003	45	Non-randomized, observational, prospective study. Purpose was to compare the time until the first production of stool and urine between normal breastfed and formula-fed newborns
Michaelsen et al., 1994	46	RCT. Designed to evaluate: 1) the impact of various feeding patterns on growth during infants' first 9 mo of life, and 2) the influence of social and biological factors on BF duration. One limitation of this study is that infants in the exclusively BF group were allowed supplements consisting of water and camomile tea (but no milk or sugar); furthermore, three infants in the exclusively BF group received one or two meals of formula or solids per week
Mo-Suwan and Junjana, 1991	47	Non-randomized, observational study. Purpose was to evaluate growth every 2 wk, from birth until 6 mo of age, in healthy, full-term, breastfed infants
Nylander et al., 1991	48	Observational study. Evaluated the influence of an intervention designed to change feeding routines during the first week of life, i.e., promote more frequent BF, encourage early contact and feeding on demand, eliminate routine substitute feeds—on a variety of variables (e.g., BF rates, breast-milk volume, infant weights, use of formula and sugar solutions)
Perez-Escamilla, 1993	49	Not a clinical trial; retrospective analysis of BF patterns in nine Latin American and Caribbean countries between 1984 and 1988 based on data from demographic and health surveys
Perez-Escamilla et al., 1996	50	Not a clinical trial; retrospective analysis of the association between caesarean delivery and BF outcomes among Mexican women
Rosegger and Purstner, 1985	51	RCT, without follow-up (observation limited to the first 5 d of life). No exclusively breastfed control group included. Purpose was to explore effects of supplementation (with fully adapted milk substitute or calorie-free tea) during the first days of life on feeding behaviour and various physiological measurements
Rosegger, 1986	52	RCT, without follow-up (observation limited to the first 4 d of life). No exclusively breastfed control group included. Purpose was to explore effects of supplementation (with a fully adapted formula or 13% maltodextrine solution) on feeding behaviour and various physiological measurements
Sachdev et al., 1991	53	RCT. Designed to determine the need for water supplementation (to maintain water homeostasis) in healthy, exclusively breastfed infants during summer in a tropical country. While this study did not specifically evaluate the effect of early water supplementation on BF success/duration, the results suggest that this practice may reduce breast-milk intake
Salariya et al., 1978	54	Observational study. Explored influence of early initiation of BF and increased frequency of feedings on BF duration
Schubiger et al., 1997	55	RCT, but no exclusively breastfed control group included. Purpose was to clarify how both the restriction of supplemental feedings and the banning of bottles and pacifiers affects long-term BF practices. Involved comparison of bottle-feeding (with pacifier) versus cup- or spoon-feeding (without pacifier)
Schutzman et al., 1986	56	Observational study. Examined effect of early water supplementation on the establishment of lactation (arrival of milk in nursing mothers)
Sievers et al., 2002	57	Observational cohort study. No exclusively breastfed control group included. Investigated the effects of different types of supplemental feedings (supplementary neonatal formula or glucosaccharide solution) on BF duration
Simondon et al., 1996	58	RCT, which included a supplementation (intervention) group and a control group. Goal was to determine the effect of early, short-term supplementation on the weight and linear growth of infants in developing countries. Effect of supplementation on BF frequency/duration not directly assessed
Singh et al., 1997	59	Retrospective analysis of infant feeding and weaning practices in some semi-arid rural areas of Rajasthan.
Taylor et al., 1985	60	RCT, which included an intervention group (extra early contact) and a control group (regular contact). The purpose was to determine whether extra early physical contact between a mother and infant is associated with prolonged BF
Tonz and Schubiger, 1990	61	Prospective, observational study. Examined relationship between the prevalence of both BF and early supplementation (with food or fluid) and the incidence of atopic disease
de la Torre et al., 2001	62	Not a clinical trial. Review of early infant feeding practices used in Spain
Zhao et al., 2003	63	Cross-sectional study. Review of early infant feeding practices used in China

information about the duration of exclusive or partial breastfeeding was obtained via telephone interview further suggests the possibility of a reporting and/or recall bias. Other weaknesses of that RCT include the lack of analysis on an intention-to-treat basis, the absence of clear descriptions of exclusive and partial breastfeeding, and the relatively small sample size. It is therefore difficult to be certain whether the observed long-term effects of early liquid supplementation on the later success of breastfeeding would readily generalize to other situations.

While it is difficult to identify published studies, identifying unpublished studies represents an even greater challenge. The authors of this review have made every effort to avoid publication bias, including performing a comprehensive search using a range of databases. As only a limited number of experts in the field were contacted for unpublished material, publication bias cannot be ruled out. However, we believe that the risk of not having identified important, randomized, methodologically relevant trials is not high.

This systematic review was limited to RCTs. Other types of studies were excluded because they may have flaws, and selection bias is possible. However, findings in three non-RCTs [14,32,35] might be relevant to this discussion. In one prospective study ( $n=583$ ) conducted in a developed country, supplementary feedings (with donor milk or formula) in the maternity unit increased the risk of early cessation of breastfeeding in the intervention group compared with the control group (292/336 (87%) vs 102/156 (65%), respectively; OR: 3.5, 95% CI 2.3–5.5, adjusted OR 3.9, 95% CI 2–7) [14]. However, this study included both term and preterm infants. In another study involving 136 healthy term infants, only 39/73 (53%) infants in a supplemented group compared with 25/31 (81%) in an unsupplemented group were still being breastfed at 3 mo of age [32]. Like the other study, this study was conducted in a developed country. However, the interpretation of this study's results is hampered by the non-randomized design, poorly defined outcome measures and low response rate (only 104/136 (77%) of the infants' mothers responded to a questionnaire regarding breastfeeding). A third study conducted in Egypt explored the effect of prelacteal feeding on later breastfeeding rates. In this study, 89 of the 149 (60%) infants involved were prelacteally fed sugar-water, teas, or both. Compared with the other infants, the prelacteally fed infants were significantly less likely to be exclusively breastfed during the age periods of 0–3, 4–7 and 8–11 wk. However, this difference between groups was no longer present at older age periods (12–47 wk) [35].

As breastfeeding offers benefits to both infant and mother, it represents a key public health issue. Yet the

number of women initiating breastfeeding in many countries remains low. Although sensible, not-too-restrictive recommendations might increase breastfeeding rates, few current breastfeeding guidelines are evidence based. Our review is the first to systematically evaluate the effects of early supplementation on breastfeeding. We believe that our demonstration of clinical uncertainty about this issue is an important finding. As pointed out by Alderson and Roberts [64], clinical uncertainty is a prerequisite for the large-scale RCTs needed to evaluate the influence of such interventions; it also helps to clarify available treatment options and stimulate new and better research.

One could argue about whether supplements are actually needed in most circumstances. However, regardless of its utility, early supplementation is practised in many communities, and thus should be appropriately addressed in well-conducted RCTs. In addition to addressing outcomes studied here (breastfeeding success and duration), these trials should investigate other potential effects of supplemental feedings in early life. For example, exposure to formula can alter the gut microflora, which may affect gastrointestinal development and immune function [65]. There is also considerable debate about the effect of exposure to cow's milk proteins on the risk of diabetes [66].

In summary, this review clearly demonstrates the lack of adequate RCT evidence to support or refute the notion that brief exposure of breastfed infants to other liquids or feeds influences the success and/or duration of future breastfeeding. Thus, well-designed and conducted RCTs are needed to resolve this issue.

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