***Evidence Synthesis Number 66***

# Interventions in Primary Care to Promote Breastfeeding: A Systematic Review

**Prepared for:**
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

**Prepared by:**
Tufts-New England Medical Center Evidence-Based Practice Center
Boston, Massachusetts
under Contract No. 290-02-0022

**Investigators:**
Mei Chung, MPH, Project Leader
Stanley Ip, MD
Winifred Yu, MS, RD
Gowri Raman, MD
Thomas Trikalinos, MD, PhD
Deirdre DeVine, MLitt, Project Manager
Joseph Lau, MD, Principal Investigator

**AHRQ Publication No. 09-05126-EF-1**
**October 2008**

This report is based on research conducted by the Tufts-New England Medical Center Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-02-0022). The findings and conclusions in this document are those of the author(s), who are responsible for its content, and do not necessarily represent the views of AHRQ. No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

The information in this report is intended to help clinicians, employers, policymakers, and others make informed decisions about the provision of health care services. This report is intended as a reference and not as a substitute for clinical judgment.



**Suggested Citation:**
Chung M, Ip S, Yu W, Raman G, Trikalinos T, DeVine D, Lau J. Interventions in Primary Care to Promote Breastfeeding: A Systematic Review. Prepared for the Agency for Healthcare Research and Quality by the Tufts-New England Medical Center Evidence-based Practice Center, under Contract No. 290-02-0022. AHRQ Publication No. 08-05125-EF-1. Rockville, Maryland: Agency for Healthcare Research and Quality, October 2008. .

# Acknowledgments

This evidence report was funded by the Agency for Healthcare Research and Quality (AHRQ) for the U. S. Preventive Services Task Force (USPSTF), and the investigators acknowledge the contributions of David Meyer, MD, Medical Officer, AHRQ and Therese Miller, Dr.PH, Task Order Officer, AHRQ. Members of the USPSTF who served as leads for this project include, Thomas DeWitt, MD, Kimberly Gregory, MD, MPH, Carol Loveland-Cherry, PhD, RN, and Barbara Yawn, MD, MS. The investigators also thank the expert reviewers listed in Appendix E.

## Structured Abstract

**Context:** Breastfeeding decreases the risks of many diseases in mothers and infants. About 70 percent of US children have ever been breastfed. Thus, it is important to examine interventions that could promote and support breastfeeding in an effort to increase the breastfeeding rates and impact the public health.

**Objective:** To systematically review evidence for the effectiveness of primary care initiated interventions to promote and support breastfeeding.

**Data sources:** We searched MEDLINE, the Cochrane Controlled Trials Registry, CINAHL, and Cochrane Database of Systematic Reviews for articles from September, 2001 to January, 2007 using the MeSH terms and keywords, such as "breastfeeding", "breast milk feeding", "breast milk", "human milk", "nursing", "lactation", "counseling", and "health education". For additional studies, we also examined the bibliographies in existing systematic reviews.

**Study Selection:** We identified 21 RCTs, two clustered RCTs, two quasi-RCTs, four controlled, non-randomized studies, two before-and-after experimental studies (Baby Friendly Hospital Initiative (BFHI) only), four prospective observational studies with concurrent or historical (BFHI only) control, and one Cochrane systematic review. Seventeen studies were of good or fair internal validity according to US Preventive Services Task Force (USPSTF) criteria.

**Data Extraction**: Data elements were abstracted on to standardized forms and included information about the setting, study design, population characteristics, types of interventions, comparators, methods of analyses, loss to followup, breastfeeding outcomes in regards to initiation, duration, and exclusivity, and maternal or infant health outcomes. In addition to assessing the internal validity of the studies, we also assessed the applicability of the studies to the US primary care population.

**Data Synthesis**: Comparing breastfeeding interventions to the control (usual care): prenatal breastfeeding intervention increased the rate of any short-term breastfeeding (pooled RR: 1.39; 95%CI 1.16-1.67); combination of pre- and postnatal breastfeeding interventions increased both the rate of intermediate and long-term any breastfeeding (pooled RR: 1.15; 95%CI 1.00-1.32, 1.38; 95%CI 1.33-1.43, respectively); postnatal breastfeeding interventions increased the rate of exclusive short-term breastfeeding (pooled RR: 1.21; 95%CI 1.08-1.36); structured breastfeeding education with or without other components increased the rate of any breastfeeding initiation (pooled RR: 1.15; 95%CI 1.02-1.30); individual level professional support with or without other components significantly increased the rate of any intermediate breastfeeding (pooled RR: 1.12; 95%CI 1.02-1.30); lay support with or without other components increased the rate of any short- and long-term breastfeeding (pooled RR: 1.26; 95%CI 1.07-1.48, 1.38; 95%CI 1.00-1.92, respectively) and the rate of short-term exclusive breastfeeding duration (pooled RR: 1.66; 95%CI 1.05-2.56); and BFHI increased the exclusive breastfeeding rates at 3 (43.3% vs. 6.4% (P <0.001) and 6 (7.9% vs. 0.6% (P=0.01)) months. The BFHI study from Belarus found that infants in the intervention group had a significant reduction in the risk of one or more gastrointestinal infections (9.1% vs. 13.2%; adjusted OR 0.60; 95%CI 0.40-0.91) and atopic dermatitis (3.3% vs. 6.3%; adjusted OR 0.54; 95%CI 0.31-0.95), compared to the control group.

We did not identify any study that was designed to detect harms from interventions to promote and support breastfeeding.

**Conclusions**: The Baby Friendly Hospital Initiative is effective in promoting certain health outcomes in infants from Belarus. Whether those findings are applicable to United States primary care is unclear. Indirect evidence suggests that interventions with a component of lay support (e.g., peer support or peer counseling) are more effective than interventions with structured education or professional support in increasing both short- and long-term breastfeeding rate, compared to usual care. Prenatal combined with postnatal interventions are more effective than usual care in prolonging the duration of breastfeeding.

# Evidence Synthesis

## Contents

## Tables and Figures



## Appendixes

# Background

Human milk is the natural nutrition for all infants. According to the American Academy of Pediatrics (AAP), it is the preferred choice of feeding for all infants.[1] The goals of *Healthy People 2010* for breastfeeding are initiation rate of 75% and continuation of breastfeeding of 50% at 6 months and 25% at 12 months postpartum.[2] A survey of US children in 2002 indicated that 71% had ever been breastfed. The percentage of infants who continued to breastfeed to some extent are 35% at 6 months and 16% at 12 months.[3] Although the breastfeeding initiation rate from this survey is close to the goal of 75%, the breastfeeding continuation rates at 6 and 12 months are short of the goals set by that of *Healthy People 2010*.

Tufts-New England Medical Center Evidence-based Practice Center (Tufts-NEMC EPC) completed a review in 2006 examining the effects of breastfeeding on infant and maternal health outcomes in developed countries.[4] The Center on Primary Care, Prevention and Clinical Partnerships at the Agency for Healthcare Quality and Research (AHRQ), on behalf of the US Preventive Services Task Force (USPSTF), requested an additional related evidence report on the effectiveness of interventions to promote breastfeeding.

The topic, effectiveness of interventions to encourage and support breastfeeding, was last considered in 2003 by the USPSTF. The Task Force issued a B recommendation (fair evidence that the service improves important health outcomes) for structured education and behavioral counseling programs to promote breastfeeding, and an I recommendation (insufficient evidence to recommend for or against routinely providing the service) for other interventions. The present report will be used by the USPSTF to update its 2003 recommendation.

According to AAP, some of the obstacles to initiation and continuation of breastfeeding include insufficient prenatal education about breastfeeding, disruptive maternity care practices, and lack of family and broad societal support.[5] Effective interventions reported to date include changes in maternity care practices, like those implemented in pursuit of the *Baby Friendly Hospital Initiative*[6] designation,[7] and worksite lactation programs.[8] Some of the other interventions implemented include peer to peer support, maternal education and media marketing.[9]

This review focuses only on interventions that were initiated in a primary care setting. Any counseling or behavioral intervention initiated from a clinician's practice (office or hospital) to improve breastfeeding initiation, duration, or both will be considered. Interventions could be conducted by a variety of providers (lactation consultants, nurses, peer counselors, midwives or physicians) in a variety of settings (hospital, home, clinic, or elsewhere) as long as they originated from a health care setting. Health care system interventions, such as staff training, will also be included. However, community or peer initiated interventions is not part of this review.

To expand on the background behind the present review, the following is a brief summary of the 2003 evidence review[10] that supported the formulation of the 2003 recommendations.[11]

## Brief Summary the 2003 Evidence Review

*Effectiveness of structured breastfeeding education and behavioral counseling programs*

Structured breastfeeding education and behavioral counseling programs improve the rates of breastfeeding initiation, breastfeeding duration, or both. The most effective interventions used

brief, relatively directive health education combined with behaviorally-oriented skills training and problem-solving counseling.

### *Effectiveness of support from providers and peers*

- The independent effect of support alone on breastfeeding was modest.
- The combined effects of education and support significantly increased breastfeeding.

However, the effects of combined education and support on breastfeeding initiation and its continuation were not higher than the estimated effect of education alone.

No studies had evaluated whether advice by the women's primary obstetric provider or by the infant's primary pediatric provider in the course on in-hospital care or routine preventive visits was effective on its own in increasing breastfeeding rates.

### *Effectiveness of other breastfeeding education and support measures*

- Peer counselors are potentially a useful source of support and motivation for breastfeeding, though studies initiated from the clinical practice setting were judged to be of either poor quality or of limited generalizability due to the use of financial incentives.
- Written materials alone do not appear effective in increasing breastfeeding rates.
- Commercial discharge packs, in one good-quality Cochrane review of 9 randomized trials, were found to reduce exclusive breastfeeding.

#### *Adequacy of previous literature*

The 2003 review found that overall studies of breastfeeding interventions lacked scientific rigor. Intervention studies often lacked detail to assess similarity among similar interventions. The adequacy of reporting of information on educational interventions varied in the areas of:

- content of the session
- method of communicating the content,
- training of the individual to deliver the content
- total time spent in the educational session.

Across studies, it was difficult to assess the variability of routine care, which was the most common control group. For example, in certain communities it might be a standard practice to receive one home visitation and in others it might not.

Studies rated as poor quality by the USPSTF quality-rating system had results similar to those rated as good or fair. Many of these were non-randomized controlled trials that were rated poor due to baseline differences in the comparison groups, or randomized studies with inadequate randomization methods or lack of intention to treat analyses. Such flaws have been shown to be correlated with effect sizes in studies of obstetric interventions.[12] However, their impact in studies of clinic-based behavioral counseling is uncertain. Due to such uncertainty and the lack of statistically significant difference with and without poor-quality studies, all the studies were combined to display the mean differences and confidence boundaries. The 2003 review also noted that the lack of scientific rigor in the individual studies was a limitation for the strength of the findings in the meta-analysis.

*Evidence gaps*

There was insufficient evidence to recommend for or against the following interventions to promote breastfeeding:

- brief education and counseling by primary care providers
- peer counseling used alone and initiated in the clinical setting
- written materials, used alone or in combination with other interventions.

The 2003 review reported that breastfeeding intervention studies often combined interventions. None of the individual studies compared the combined intervention against each component separately. The meta-analysis also suggested that, in light of the results of the meta-regression to estimate the effects of education and support alone (results indicated that the combination of education plus support may be more effective than support alone for initiation and short-term duration of breastfeeding), there is a rationale for future intervention studies that compare combined education and support with education and support alone.

## USPSTF Recommendations (2003)

The USPSTF recommends structured breastfeeding education and behavioral counseling programs to promote breastfeeding[11]. **B recommendation.**

> *The USPSTF found fair evidence that programs combining breastfeeding education with behaviorally oriented counseling are associated with increased rates of breastfeeding initiation and its continuation for up to 3 months, although effects beyond 3 months are uncertain. Effective programs generally involved at least 1 extended session, followed structured protocols, and included practical, behavioral skills training and problem-solving in addition to didactic instruction.*
>
> *The USPSTF found fair evidence that providing ongoing support for patients, through in-person visits or telephone contacts with providers or counselors, increased the proportion of women continuing breastfeeding for up to 6 months. Such support, however, had a much smaller effect than educational programs on the initiation of breastfeeding and its continuation for up to 3 months. Too few studies have been conducted to determine whether the combination of education and support is more effective than education alone.*

The USPSTF found insufficient evidence to recommend for or against the following interventions to promote breastfeeding: brief education and counseling by primary care providers; peer counseling used alone and initiated in the clinical setting; and written materials, used alone or in combination with other interventions. **I recommendation.**

> *The USPSTF found no evidence for the effectiveness of counseling by primary care providers during routine visits and generally poor evidence to assess the effectiveness of peer counseling initiated from the clinical setting when used alone to promote breastfeeding in industrialized countries. The evidence for the effectiveness of written materials suggests no significant benefit when written materials are used alone and mixed evidence of incremental benefit when written materials are used in combination with other interventions.*

# Methods

This report will be used by the USPSTF to update its 2003 recommendation on counseling to promote breastfeeding. Tufts-NEMC EPC, the Center on Primary Care, Prevention and Clinical Partnerships at AHRQ, and the USPSTF jointly developed an analytic framework and a set of study inclusion/exclusion criteria that are suitable to meet the USPSTF objectives. In addition, we utilized results from a recently completed AHRQ evidence report (Number 153)[4] to answer two key questions.

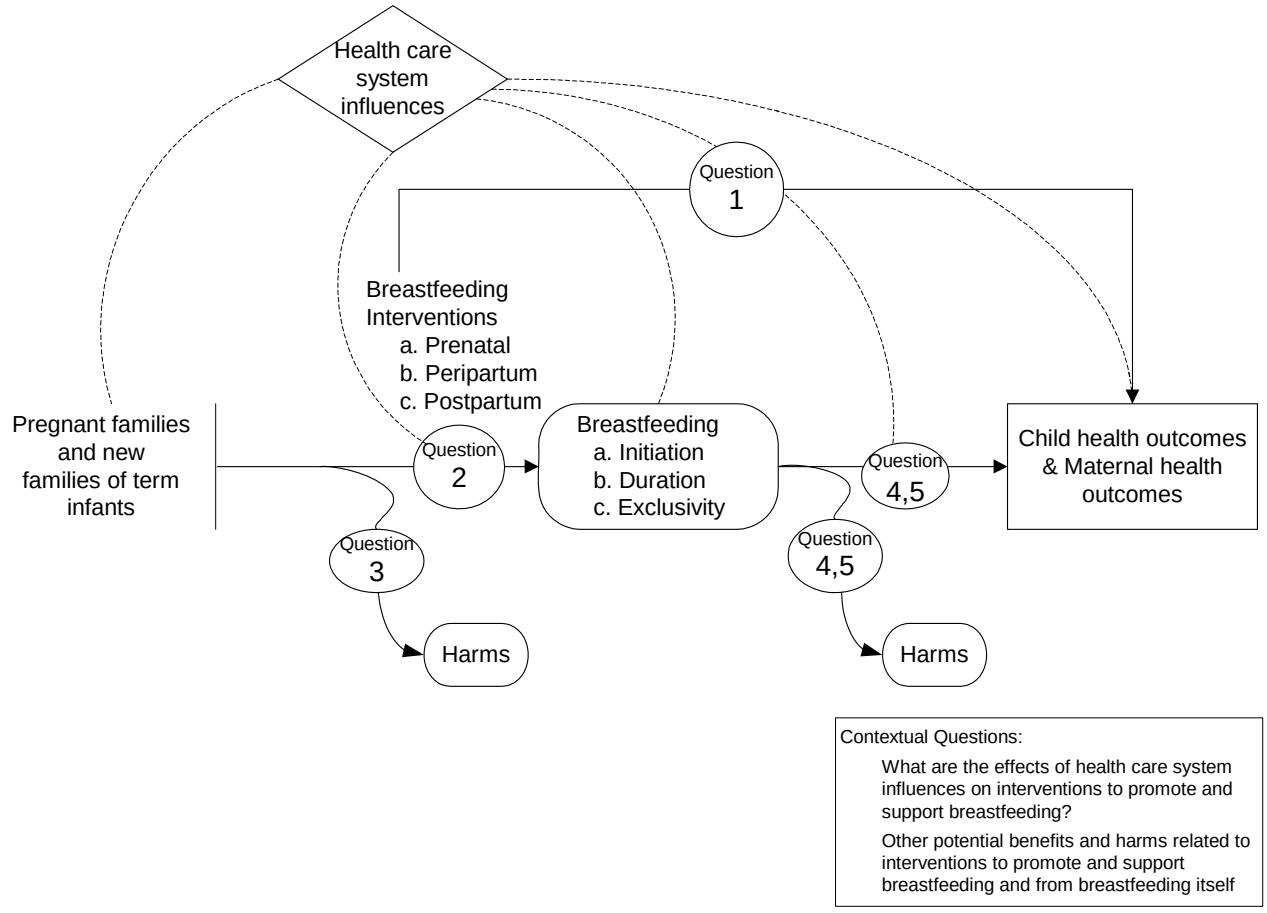



**Figure 1. Analytic framework for the effect of interventions to promote breastfeeding**

## Key Questions:

1. What are the effects of interventions to promote and support breastfeeding, in terms of short- and long-term child and maternal health outcomes?
2. What are the effects of a) prenatal, b) peripartum, and c) postpartum breastfeeding interventions on breastfeeding initiation, duration, and exclusivity?
3. Are there harms from interventions to promote and support breastfeeding?
4. What are the benefits and harms for infants and children in terms of short-term outcomes, such as infectious diseases (including otitis media and diarrhea), development, and

sudden infant death syndrome and infant mortality, and longer-term outcomes such as neoplastic diseases, autoimmune diseases (including type 1 diabetes), chronic diseases (including asthma, environmental allergies, type 2 diabetes, hypertension and hyperlipidemia), and obesity, compared among those who mostly breastfeed, mostly formula feed, and mixed feed; and how are these outcomes associated with duration of the type of feeding? Do the harms and benefits differ for any specific subpopulations based on socio-demographic factors?

5. What are the benefits and harms on maternal health short-term outcomes, such as post-partum depression, anemia, and return to pre-pregnancy weight, and long-term outcomes, such as breast and ovarian cancer and osteoporosis, compared among breastfeeding, formula feeding, and mixed feeding, and how are these associated with duration of the type of feeding? Do the harms and benefits differ for any specific subpopulations based on socio-demographic factors?

The answers to key questions 4 and 5 have been reviewed in our previous report. A summary of the findings from that report is provided in Appendix G. This report focuses on key questions 1 to 3 concerning the effectiveness of primary care initiated interventions to promote and support breastfeeding in the prenatal, peripartum, and postpartum periods. We focused our review on studies conducted in developed countries. However, because of the widespread interest in the Baby Friendly Hospital Initiative[1] (BFHI), randomized controlled trials (RCTs) of BFHI conducted in developing countries have also been included. Furthermore, because of the nature of the BFHI intervention, most of the observational studies on BFHI used a historical control for comparison. Thus, observational studies on BFHI using that study design have also been included.

**Definitions used in this report**

Definitions of "exclusive breastfeeding" varied widely in the literature. They ranged from "no supplement of any kind including water while breastfeeding" to "occasional formula is permissible while breastfeeding." We elected to accept all definitions of "exclusive breastfeeding" as provided by the different study authors, but we qualified our findings by the details regarding those definitions.

Other categories (full, partial, mixed, non-specified) of breastfeeding besides exclusive breastfeeding are classified as "any" breastfeeding.

We have also defined the following categories of breastfeeding durations. Breastfeeding initiation is any breastfeeding at discharge or before 2 weeks post delivery; 1 to 3 months of breastfeeding is short-term; 4 to 5 months is intermediate-term; 6 to 8 months is long-term; and 9 months or more is prolonged. Breastfeeding shorter than 1 month was considered together with the "no breastfeeding" category. These categories of breastfeeding duration were arbitrary but defined a priori.

[1] Written breastfeeding policy that is routinely communicated to all health care staff; train all health care staff in skills necessary to implement this policy; inform all pregnant women about the benefits and management of breastfeeding; help mothers initiate breastfeeding within one half-hour of birth; show mothers how to breastfeed and maintain lactation, even if they should be separated from their infants; give newborn infants no food or drink other than breast milk, unless medically indicated; practice rooming in - that is, allow mothers and infants to remain together 24 hours a day; encourage breastfeeding on demand; give no artificial teats or pacifiers to breastfeeding infants; foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic. (http://www.unicef.org/programme/breastfeeding/baby.htm)

Types of breastfeeding intervention were classified broadly into three major categories: breastfeeding education, breastfeeding support (professional and/or lay support), and all other interventions. Many of the breastfeeding interventions contain more than one component.

a. Formal/structured breastfeeding education directed at mothers and/or other family members:

Structured one-to-one or group education sessions or classes (e.g., curriculum or standard agenda)

b. Breastfeeding support

(1) Professional support:

- System level support – BFHI; training of health professionals
- Individual level support – one-to-one support during hospital stay or outpatient visits; social support (e.g., home visits or telephone support) from health professionals

(2) Lay support: peer counseling; social support (e.g., home visits or telephone support) from peers

c. Other interventions:

- Skin-to-skin care
- Pacifier use
- Motivational interview

**Overall Approach**

This report updates the previous systematic review[10] conducted for USPSTF, we focused our effort on primary studies published since Guise's search date of September 2001. We searched from January 2001 onward to ensure that all eligible studies have been accounted for. We elected not to systematically examine systematic reviews because all the other systematic reviews published since 2001 had search dates no later than 2002 except for one recent Cochrane review on support for breastfeeding mothers with a search date of November of 2005.[13] In consultation with AHRQ and the USPSTF, we decided to capitalize on this Cochrane systematic review by including the data from eight RCTs in developed countries reported in the review in our meta-analysis. However, we did not reassess the quality of these eight trials. To be as comprehensive as possible, we elected to summarize the primary studies not covered (either by exclusion or because they were not yet published at the time) in the Cochrane review.

**Study Selection**

We included RCTs and controlled but not randomized trials. For BFHI, we also included before and after experimental studies and prospective cohort studies with concurrent or historical controls. Any counseling or behavioral intervention initiated from a clinician's practice (office or hospital) to improve breastfeeding initiation, duration, or both were considered. Examples of interventions include physician counseling, peer-to-peer support, and hospital practices such as those outlined in the Baby-friendly Ten Steps. Only English language studies were included.

Inclusion criteria for the studies are as follow:

*Study Design*. RCTs, clustered RCTs, quasi-RCTs, controlled, non-randomized studies; for BFHI: we also included non-randomized before and after experimental studies and prospective cohort studies with concurrent or historical controls

*Population*. Healthy term or near-term infants (≥35 weeks gestation or ≥ 2,500 g) and their healthy mothers and members of the mother-child support system (such as partners, grandparents, or friends)

*Intervention*. Intervention must be primary care initiated, conducted, or referable (i.e., if the primary care does not offer that service, it should have the ability to refer the mother-infant pair or family to that service). Potential interventions include but are not limited to counseling, structured education, support, distribution of written materials, and adoption in whole or in part of Baby-friendly Ten Steps. Interventions may be stand alone or multi-component/multi-dimensional. They could be conducted by a variety of providers (lactation consultants, nurses, peer counselors, midwives, or physicians) in a variety of settings (hospital, home, clinic, or community) as long as they are linked with the health care system and the provision of primary care. Health care system interventions, such as staff training, were included (N.B., examples of non-primary care initiated interventions that were excluded from this review include mass-media campaigns, work site lactation programs, community interventions, and peer-to-peer support that do not interact with the health care system). For the purpose of this review, maternity services are considered primary care.

*Comparator*. Usual prenatal, peripartum, and/or postpartum care defined within each study for women in the control groups.

*Outcomes*. Studies must report rates of breastfeeding initiation, duration of breastfeeding, or exclusivity of breastfeeding. Maternal or infant health outcomes reported in these studies are also included. For adverse events associated with breastfeeding interventions, we reviewed both included and excluded studies conducted in developed countries.

**Search Strategy**

We searched Medline, the Cochrane Controlled Trials Registry, CINAHL, and Cochrane Database of Systematic Reviews for articles from September, 2001 to January, 2007 using the MeSH terms and keywords, such as “breastfeeding”, “breast milk feeding”, “breast milk”, “human milk”, “nursing”, “lactation”, “counseling”, and “health education”. We also examined the bibliographies in existing systematic reviews for additional studies.

**Data Extraction**

One reviewer initially screened abstracts for possible inclusion. This initial screening used very broad criteria to ensure that all potentially relevant abstracts were included (i.e., any human studies with any kind of interventions to promote or support breastfeeding were screened in). A second person reviewed all the potentially relevant abstracts using the formal study inclusion/exclusion criteria. The full papers of the eligible abstracts were retrieved and examined in detail. After full articles evaluation, data from qualified studies were abstracted (Appendix B). Items of interest extracted were: study setting, population, control, description of intervention (type, person, frequency, and duration), definitions of breastfeeding (initiation, exclusivity, and duration) outcomes, definitions of health outcomes (when provided) in both mothers and

children, and methods of analyses. We categorized interventions as multidimensional (as in Baby-friendly Ten Steps), individual or group education, in-person or telephone support, professional support or counseling, peer support or counseling, and miscellaneous category (written materials, rooming-in, early maternal contact, commercial discharge packets, and others).

**Quality and Applicability Assessment**

Two reviewers independently assessed the quality of published systematic reviews and controlled studies using criteria developed by the USPSTF.[14] Each paper was assigned a quality rating of "good", "fair", or "poor". The criteria of quality assessment for primary studies included the randomization techniques, clear definitions of outcomes, or intention to-treat analysis for RCTs and consideration for potential confounders in cohort studies. A third reviewer reviewed those studies in which the quality rating was discordant between the first two reviewers. Final grades in those studies were reached via consensus. We have also assessed the applicability (or external validity) of the study population to the United States primary care setting by examining the specific study conditions and population/sample characteristics. The overall assessment is categorized as either wide or narrow applicability.

**Data Synthesis**

Rates of breastfeeding initiation, short-term, intermediate-term, long-term, and prolonged breastfeeding were calculated for both the intervention and control groups in each study. The exclusivity of breastfeeding was recorded and the same calculations were performed for the exclusive breastfeeding rates. Moreover, the differences in the average duration of any or exclusive breastfeeding by the end of the study between the comparison groups were also calculated when the data are available.

The decision to combine studies in a meta-analysis and the subsequent selection of statistical methods can be challenging. Ideally, studies should only be combined if they are sufficiently homogeneous (i.e., comparable interventions, groupings, study designs, outcome measurements). In addition, the meta-analysis must be executed paying close attention to underlying assumptions and their attendant limitations. In this review, meta-analyses were performed, for RCTs and non-randomized but controlled studies to examine the effect of interventions on breastfeeding initiation, duration, and exclusivity. Although the studies in our meta-analyses are similar in design, they are still different in many respects: different combinations of intervention components and background social support, different health care systems defining "usual" or "routine" care, different timing and intensities of the interventions, and diverse study populations. Therefore, we also performed various subgroup analyses to analyze the heterogeneity across studies.

**Meta-analyses and Meta-regression**

To avoid multiple counting of the same study and subsequent improper weighting, we selected data from the longest duration of breastfeeding within each breastfeeding category to ensure one study enters the analysis only once. For example, if a study reported data on both 1- and 3-month breastfeeding rates, only the 3-month breastfeeding rate was selected for the analyses. We also included data from one recent Cochrane systematic review[13] that reported findings from RCTs conducted in developed countries. Data on breastfeeding initiation, duration, and exclusivity from those studies were abstracted from the review and incorporated into our

meta-analyses. Breastfeeding data reported in the Cochrane systematic review were verified. We used the data reported in the original publications in instances of inconsistencies.

We used the DerSimonian and Laird's random effects model for all meta-analyses.[15] We tested for heterogeneity using Cochran's Q and assessed its extent with $I^2$, which evaluates the proportion of between study variability that is attributed to heterogeneity rather than chance.[16, 17]

Subgroup analyses were performed to examine the impacts of study quality, the effects of timing of intervention (prenatal, postpartum, or combined prenatal and postpartum), and different components of breastfeeding interventions on breastfeeding initiation, duration, and exclusivity.

A random-effect meta-regression[18, 19] was performed to test the association between the effects of interventions and breastfeeding durations when at least six data points were available. A significant p-value indicated an increasing or decreasing trend for the effects of breastfeeding promotion, compared to the control, with an increasing or decreasing breastfeeding durations. We reported our results using rate ratios and 95% confidence intervals. Intercooled Stata 8.2 was used for the calculations and graphics.

# Results

## Search Results

Our search yielded 4,877 abstracts, of which 4,110 were rejected after initial screening using very broad inclusion/exclusion criteria. A second phase abstract screening using the formal criteria rejected additional 645 abstracts. One hundred seventy articles were retrieved for full text examination. The following studies met our inclusion/exclusion criteria: 21 RCTs,[20-40] two clustered RCTs,[41, 42] two quasi-RCTs in three publications,[43-45] four controlled, non-randomized studies in four publications[46-49, 63] two before-and-after experimental studies (BFHI only),[50, 51] four prospective observational studies with concurrent or historical control (BFHI only),[52-55], and one systematic review.[13] Eighteen studies were of good or fair quality; 18 studies were of poor quality. (Figure 2)

We also identified four studies (in five publications[56-60]) with interventions that did not explicitly aim to promote breastfeeding. Nevertheless, they reported breastfeeding, maternal, and/or infant health outcomes. These studies are summarized in appendix H, but they are not included in our analyses.

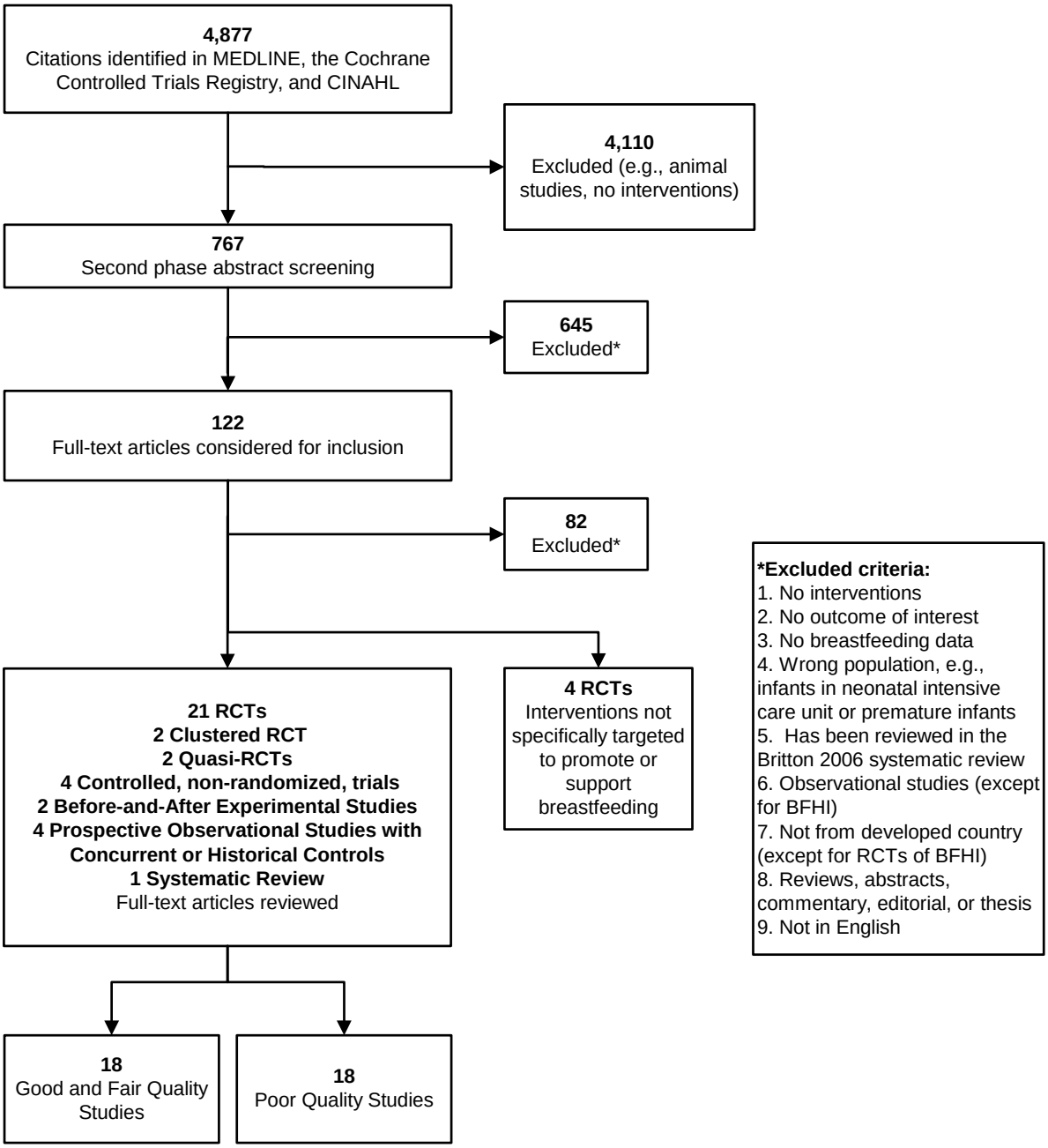



**Figure 2. Study Eligibility Flow Chart**

## Results by Key Questions

**1. What are the effects of interventions to promote and support breastfeeding, in terms of short- and long-term child and maternal health outcomes?**

Three randomized controlled trials (RCTs) in four publications,[20-22, 41] and one quasi-experimental study provided answers to this question.[48] One was rated good,[41] two were rated fair,[20-22] and one was rated poor quality.[48] One study was conducted in Belarus.[41]Three studies were conducted in low income populations in the United States.[20-22, 48] Results from the four studies could not be combined in a meta-analysis because the interventions were not comparable.

Kramer 2001 was a cluster RCT of 34 maternal hospitals and associated polyclinics with a total of 17,046 mother-infant pairs from urban and rural areas in the Republic of Belarus (PROBIT).[41] The intervention was modeled on the Baby-Friendly Initiative of the World Health Organization and United Nations Children's Fund, which emphasizes assistance with initiating and maintaining breastfeeding and lactation and postnatal breastfeeding support. Compared to infants in the control group, the study found that infants in the intervention group were more likely to be exclusively breastfed at 3 months (43.3% vs. 6.4%; P<0.001) and 6 months (7.9% vs. 0.6%; P=0.01), and had a significant reduction in the risk of one or more gastrointestinal infections (9.1% vs. 13.2%; adjusted OR 0.60; 95%CI 0.40-0.91) and atopic dermatitis (3.3% vs. 6.3%; adjusted OR 0.54; 95%CI 0.31-0.95), but no significant reduction in respiratory tract infection. This study was rated good quality. However, the applicability of this study to the US setting is uncertain. Belarus had a postpartum hospital stay of 6 to 7 days, an obligatory 3-year maternity leave policy, no day care, and formulas that could cost 20 percent of an average monthly salary.

Bonuck 2005 was an RCT with a total of 382 mother-infant pairs from a low income (57% Medicaid), largely Hispanic (57%) or African American (36%) population.[21, 22] The intervention was a series of hospital and home visits by two study lactation consultants. In addition to addressing issues specifically concerning breastfeeding, the study lactation consultants also helped the mothers to garner support from families, schools, workplaces, and health care providers. The study found that the ever breastfeeding rate at 5 months was higher in the intervention group compared to control (53% vs. 39%, $P < 0.028$). For the infants, there were no significant differences between the two groups in the risk of gastrointestinal illnesses, respiratory tract diseases, or otitis media. However, in a subgroup analysis of infants without Medicaid, infants of the intervention group had fewer otitis media related visits than control ($P \leq 0.03$). This study was rated fair quality because more than 20 percent of the breastfeeding data were missing.

Anderson 2005 was an RCT with a total of 182 mother-infant pairs from a low income and largely Hispanic (70%) population.[20] The intervention was visits by two trained breastfeeding peer counselors. The women were offered three prenatal home visits, daily in-hospital visits during postpartum hospitalization, and nine postpartum home visits. The study found that the exclusive breastfeeding rate at 3 months in the intervention group was 20.6 percent versus 1.4 percent in the control group (P=0.008). The study reported that mothers in the intervention group was less likely to have menses return at 3 months compared with control (47.6% vs. 66.7%, P=0.031). For the infants, the risk of one or more diarrheal episode during the study was lower in the intervention group compared with control (17.5% vs. 37.5%, P=0.015). This study was rated

fair quality because the allocation assignment was not properly concealed and it was unclear if the outcome assessors were blinded.

Pugh 2001 was a pilot "quasi-experimental" study with a total of 20 mother-infant pairs from low income, minority (40%) families.[48] The intervention was home visits by a breastfeeding support team consisting of a community health nurse and peer counselor. This team provided breastfeeding education and social support. It also provided instructions to decrease breast discomfort and fatigue. The intervention included a nurse visit during hospitalization and at least three home visits during weeks one, two, and four. In addition, peer counselors provided home visits and telephone support twice a week for the first 2 months, then weekly through the fifth month. The study found that 30 percent more women in the intervention group were breastfeeding at the fifth month compared with the control group. The study also found that the women in the intervention group had less fatigue at the fourth month (P=0.02) and less depressive and anxiety symptoms at the fifth month compared to control (P=NS). This study was rated poor quality because the details concerning the quasi-experimental design were not described.

**2. What are the effects of a) prenatal, b) peripartum, and c) postpartum breastfeeding interventions on breastfeeding initiation, duration, and exclusivity?**

A total of 25 RCTs in 26 publications[20-45] and four non-randomized controlled trials (non-RCTs) in five publications[46-49, 63] examined the effect of breastfeeding interventions on breastfeeding initiation, duration, and/or exclusivity. Twenty-seven trials were conducted in developed countries. Two trials on BFHI were conducted in developing countries. The interventions included BFHI, breastfeeding education, professional supports (e.g., lactation consultants, midwives, nurses, physicians, and other health professionals), lay supports (e.g., peer support or counseling), delayed/discourage pacifier use, and skin-to-skin care. Nine trials (31%) were of good quality, eight trials (28%) were of fair quality, and 12 trials (41%) were of poor quality. Table 1 summarized the study characteristics.

A recent Cochrane systematic review identified eight RCTs published after 2001 conducted in developed countries.[13] We elected to include data from these studies in our meta-analyses. However, we did not grade the quality or applicability of these RCTs. The quality was assumed to be of good or fair in our meta-analyses because only trials with a minimum of 75% followup were included in the Cochrane review.

**Table 1. Characteristics of studies categorized according to methodological quality and first author**

| Study, year Country | Design | Intervention components | Control | Population Characteristics | Timing, Duration of intervention | Follow-up Duration | Applic-ability | Quality |
|---|---|---|---|---|---|---|---|---|
| Coutinho 2005 Brazil | RCT | Postnatal home visits by professionals + BFHI (step 4-9) | BFHI (step 4-9) | Low income; 24 hr hospital stay | Peri- & Postpartum, 10 visits | 6 mo | N | Good |
| Howard 2005 US | RCT | Delayed pacifier use (>4 wk) | Early pacifier use (days 2-5) | - | Postpartum, in hospital | 1 yr | W | Good |
| Kramer 2001 Canada | RCT | Discourage pacifier use + Professional support | Pacifier to sooth the infant +Professional support | - | Postpartum, in hospital | 3 mo | W | Good |
| Kramer 2001 Belarus | Cluster RCT | BFHI (Modeled) | Standard care | Prolonged postpartum stay; maternity leave | Peri- & Postpartum, 18-hr course; 12 to 16 mo implement | 1 yr | N | Good |
| Lavender 2005 UK | Cluster RCT | Education session to midwives | Usual prenatal BF advice | - | Prenatal, single session 1 day | 1 yr | N | Good |
| Labarere 2003 France | RCT | Education | Usual care in hospital | Prolonged maternity leave | Postpartum, 30 min | 17 wk | N | Good |
| Labarere 2005 France | RCT | Training primary care physicians[a] | Usual care, including peer support | Prolonged hospital stay | Postpartum, 1 outpatient visit within 2 wk | 1 mo | N | Good |
| Noel-Weiss 2006 Canada | RCT | Education | Not described (no Education workshop) | Family income > $70,000 | Prenatal, 2.5 hr | 2 mo | N | Good |
| Wallace 2006 UK | RCT | Education workshop to midwives[b] | Usual postpartum care | - | Postpartum, 4 hr | 17 wk | W | Good |
| Anderson 2005 US | RCT | Lay support + BFHI | BFHI | Latina, low-income, WIC | Prenatal & Postpartum, prenatal home visits (2.6 hr) and in-hospital visits (2.2 hr) | 3 mo | W | Fair |
| Bonuck 2005;2006 US | RCT | Professional support, Education, provide nursing bras & pump | Usual prenatal care | 56% Medicaid | Prenatal & Postpartum, 2 prenatal meetings (60 min each), a postpartum hospital, and/or home visits (90 min) and telephone support | 1 yr | W | Fair |

**Table 1. Continued**

| Study, year Country | Design | Intervention components | Control | Population Characteristics | Timing, Duration of intervention | Follow-up Duration | Applic-ability | Quality |
|---|---|---|---|---|---|---|---|---|
| Carfoot 2005 UK | RCT | Skin-to-skin | Routine care | - | Postpartum, n/a | 4 mo | N | Fair |
| Forster 2004 Australia | RCT | Education (Practical Skills)<br>Education (Attitude) | Standard care[c] | - | Prenatal, 1.5 hr<br>Prenatal, 2 hr | 6 mo | N | Fair |
| Henderson 2001 Australia | RCT | Education | Usual postpartum care | - | Postpartum, 30 min | 6 mo | N | Fair |
| Mizuno 2004 Japan | RCT | Skin-to-skin | Routine care | - | Postpartum, n/a | 1 yr | N | Fair |
| Muirhead 2006 Scotland | RCT | Lay support | Usual support from midwife | Some premature babies (5.3%) and babies in special care (6.3%) | Prenatal & Postpartum, >1 prenatal visit, >every 2 d after returning home until day 28 | 4 mo | N | Fair |
| Pisacane 2005 Italy | Non-RCT[k] | Education + Leaflet | Childcare education + Leaflet | Married parents only | Prenatal, a 40-min session | 1 yr | N | Fair |
| Carfoot 2004[j] UK | RCT | Skin-to-skin | Routine care | - | Postpartum, n/a | 4 mo | N | Poor |
| Chertok 2006;2004 Israel | Non-RCT[d] | Professional support, Education, Early SSC | Routine care | Muslim or Jewish | Postpartum, 1 time Education & Professional support | 4 mo | N | Poor |
| Ekstrom 2006 Sweden | Quasi-RCT | Training health professionals[e] | Standard care, including prenatal family classes | 97% BF initiation rate in the control group | Prenatal, 7 sessions of training for health professionals | 9 mo | N | Poor |
| Finch 2002 US | RCT | Education + Incentives | Usual prenatal Education | Low income; WIC | Prenatal, nd | 2 mo | W | Poor |
| McKeever 2002 Canada | RCT | Professional support | No home visits | - | Postpartum, maximum of 3 home visits | 5 to 12 days | W | Poor |

**Table 1. Continued**

| Study, year Country | Design | Intervention components | Control | Population Characteristics | Timing, Duration of intervention | Follow-up Duration | Applic-ability | Quality |
|---|---|---|---|---|---|---|---|---|
| McLeod 2004 New Zealand | Quasi-RCT | Professional support, Education (BF support only)<br>Professional support, Education (BF support & smoking cessation) | Usual care for women who smoked[f] | Mori; Smokers | Prenatal & Postpartum, nd<br>Prenatal & Postpartum, nd | 4 mo | N | Poor |
| Pugh 2001 US | "Quasi experimental" | Lay support, Education, Professional support | Usual postpartum care | Low-income, mostly single women | Postpartum, 1 hospital visit; >3 home visits & telephone support | 5 mo | W | Poor |
| Reeve 2004 UK | Non-RCT[g] | Education | Routine prenatal care | - | Prenatal, 2 hr | 4 mo | N | Poor |
| Ryser 2004 US | RCT | Education (Best Start Program) | No intervention | Low income | Prenatal, 4 visits | 1 wk | N | Poor |
| Schlickau 2005 US | RCT | Education<br>Education + commitment-to-breastfeed | Usual care[h] | Hispanic women, emigrated from Mexico | Prenatal, 1 hr<br>Prenatal, 2 hr | 45 d | N | Poor |
| Wilhelm 2006 US | RCT | Motivational interview | Usual care | Rural community | Postpartum, nd | 6 mo | N | Poor |
| Wolfberg 2004 US | RCT | Education (taught by peer) | Control Education (baby care and safety) | Low-income, minority | Prenatal, 2 times; 2 hr each[i] | 2 mo | N | Poor |

FT, full term; n/a, not applicable; WIC, Women, Infants, and Children program; N, narrow; W, wide

[a] Pediatricians or family physicians, who had attended a 5-hour training program (breastfeeding-related knowledge and counseling skills) delivered in 2 parts in 1 month before the beginning of the study

[b] Midwives who received a 4-h workshop (hands off" approach to BF: advice about baby initiation of feeding, positioning and attachment)

[c] Including formal breastfeeding education, peer support and postnatal home visits by midwives; the same control group was used to compare both intervention groups (Practical Skills or Attitudes)

[d] Control group subjects were recruited between December 2000 through July 2001, while intervention group subjects were recruited from December 2001 to July 2002

[e] Health professionals received a process-oriented program on breastfeeding counseling, including lectures on breastfeeding management and promotion, counseling skills and personal breastfeeding experiences

[f] The same control group was used to compare both intervention groups (BF support only or BF support & smoking cessation)

[g] Non-random block allocation

[h] The same control group was used to compare both intervention groups (Education or Education + commitment-to-breastfeed)

[i] Two classes, 2-hour for each class and 2 weeks apart

[j] Pilot study of Carfoot 2005

[k] The fathers of the newborn were allocated to the study groups according to the date of birth of their infants in 2 time blocks: October to November 2002 (intervention group), and December 2002 and January 2003 (control group). This study was not included in the meta-analyses because it was identified after the submission of the final report.

## Meta-analyses of Breastfeeding Interventions on Rate of Breastfeeding Initiations, Durations, Compared to Usual Care

Studies comparing the effects of primary care initiated breastfeeding interventions to usual care are heterogeneous in many respects: different combinations of intervention components and background social support, different health care systems defining “usual” or “routine” care, different timing and intensities of the interventions, and diverse study populations.(Table 2) We did not find statistical heterogeneity among trials in three categories of breastfeeding (any intermediate, exclusive intermediate, and prolonged). There was significant statistical heterogeneity among trials in the remaining breastfeeding categories ($P<0.02$). Comparing the intervention to the control, our meta-analyses consistently showed an increased rate of any or exclusive breastfeeding initiation, short-, intermediate, and long-term breastfeeding, although most of these findings were not statistically significant. (Figures 3 and 4)

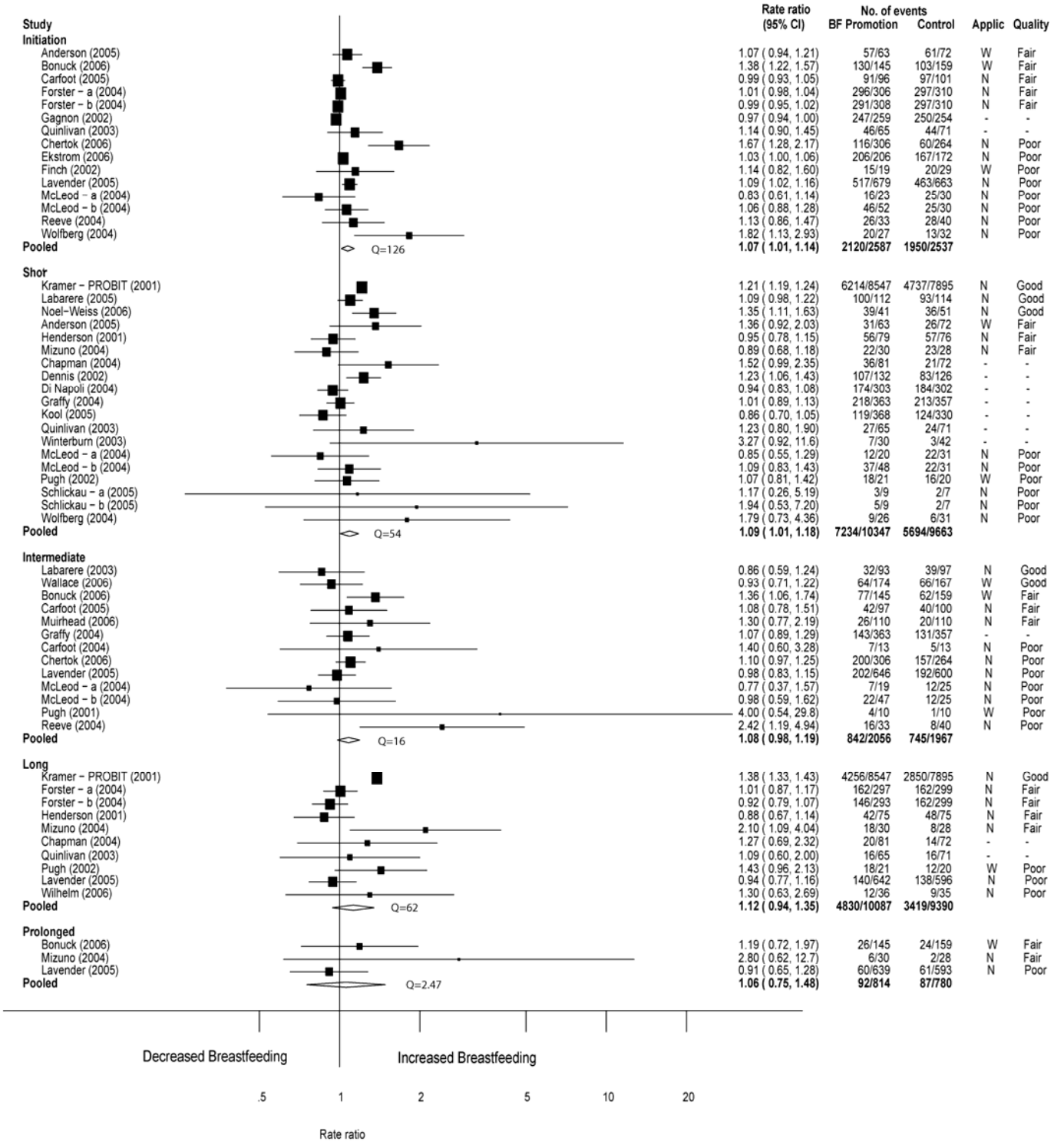



**Figure 3. Meta-analyses of the effect of primary care initiated breastfeeding interventions comparing to usual care on any breastfeeding initiation and durations**

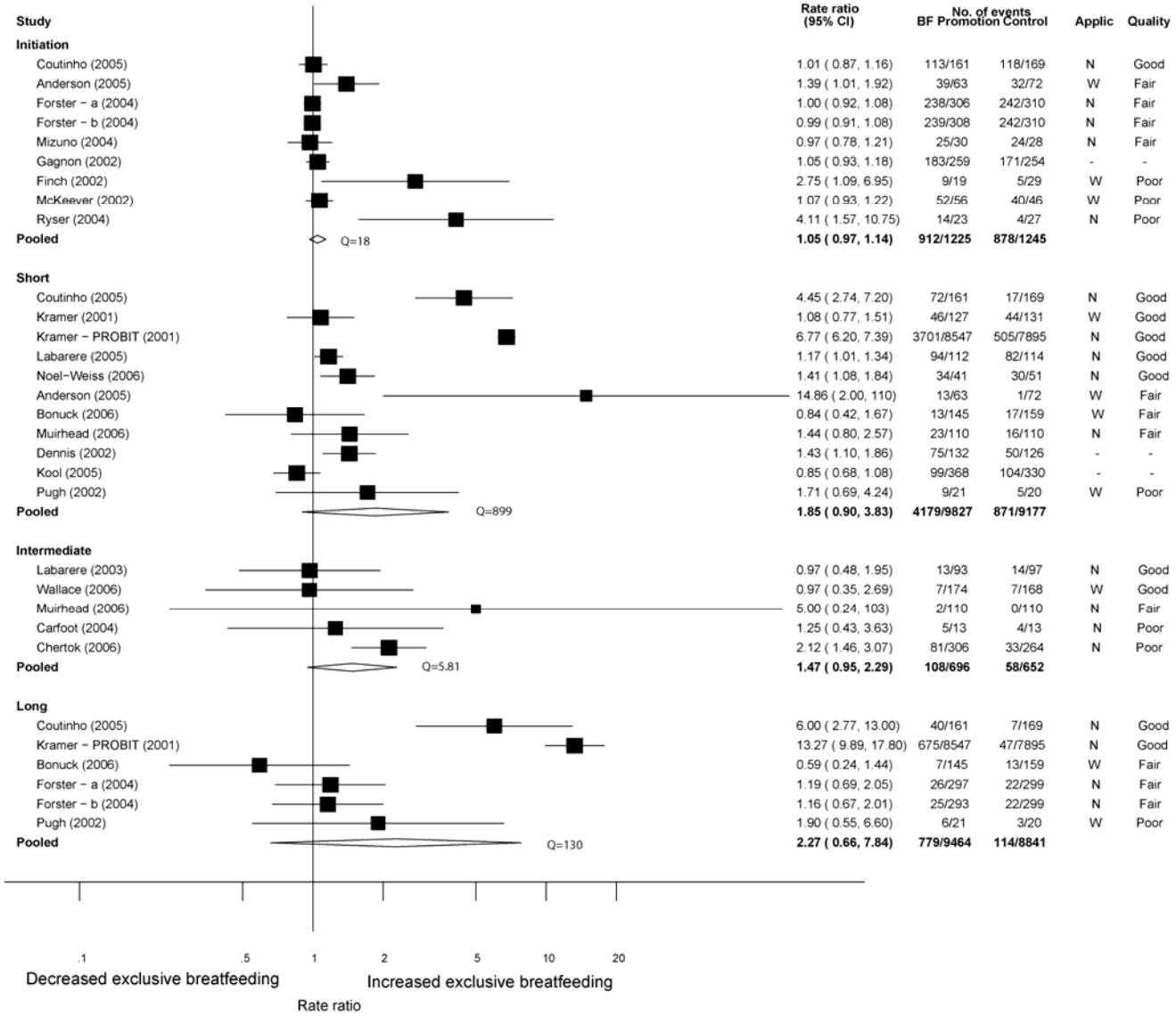



**Figure 4. Meta-analyses of the effect of primary care initiated breastfeeding interventions comparing to usual care on exclusive breastfeeding initiations and durations**

*The Impacts of Any versus Exclusive Breastfeeding (Table 2)*

Comparing breastfeeding interventions to the control, the pooled rate ratios of exclusive short-term and intermediate breastfeeding were larger than that of any short-term, and intermediate breastfeeding, respectively (P<0.10). Although not statistically significant, the pooled rate ratio of exclusive long-term breastfeeding was twice as large as that of any long-term breastfeeding.

**Table 2. Meta-analyses by exclusivity of breastfeeding**

| Breastfeeding Duration | Any | | | Exclusive | | | P any vs. exclusive* |
|---|---|---|---|---|---|---|---|
| | # Study | Pooled RR (95% CI) | $I^2$ | # Study | Pooled RR (95% CI) | $I^2$ | |
| Initiation | 15 | **1.07 (1.01, 1.14)** | 89% | 9 | 1.05 (0.97, 1.14) | 57% | 0.32 |
| Short | 19 | **1.09 (1.01, 1.18)** | 67% | 11 | 1.85 (0.90, 3.83) | 99% | **0.07** |
| Intermediate | 13 | 1.08 (0.98, 1.19) | 25% | 5 | 1.47 (0.95, 2.29) | 31% | **0.09** |
| Long | 10 | 1.12 (0.94, 1.35) | 85% | 6 | 2.27 (0.66, 7.84) | 96% | 0.14 |
| Prolonged | 3 | 1.06 (0.75, 1.48) | 19% | - | - | | |

*Z test

*The Impacts of Study Quality (Table 3)*

We performed subgroup analyses by study quality (good or fair versus poor) on the pooled rate ratios of any or exclusive breastfeeding initiation, short-, intermediate, and long-term breastfeeding. Overall, the impacts of study quality on the pooled rate ratios of breastfeeding initiation and durations were inconsistent. Comparing breastfeeding interventions to the control, the pooled rate ratios of any breastfeeding initiation and exclusive intermediate breastfeeding were larger in poor quality studies than the pooled rate ratios in good/fair quality studies (P=0.09 in the former and 0.02 in the latter). There were no other significant or borderline significant differences found.

**Table 3. Meta-analyses by quality of studies**

| Breast-feeding | Duration | Good/Fair Quality | | | Poor Quality | | | P good/fair vs. poor** |
|---|---|---|---|---|---|---|---|---|
| | | # Study | Pooled RR (95% CI) | $I^2$ | # Study | Pooled RR (95% CI) | $I^2$ | |
| Any | Initiation | 7 | 1.04 (0.98, 1.10) | 88% | 8 | **1.14 (1.00, 1.31)** | 88% | **0.09** |
| | Short | 14 | 1.07 (0.96, 1.19) | 74% | 5 | 1.07 (0.86, 1.32) | 0% | 0.50 |
| | Intermediate | 6 | 1.09 (0.95, 1.24) | 23% | 7 | 1.09 (0.91, 1.29) | 36% | 0.50 |
| | Long | 8 | 1.15 (0.94, 1.40) | 86% | 2 | 0.96 (0.79, 1.18) | 0% | 0.11 |
| | Prolonged | 2 | 1.34 (0.75, 2.41) | 10% | 1 | 0.91 (0.65, 1.28)* | - | |
| Exclusive | Initiation | 6 | 1.01 (0.96, 1.06) | 0% | 3 | 2.20 (0.56, 8.56) | 92% | 0.13 |
| | Short | 11 | 1.85 (0.90, 3.83) | 99% | - | - | - | - |
| | Intermediate | 3 | 1.03 (0.58, 1.77) | 0% | 2 | **2.00 (1.41, 2.84)** | 92% | **0.02** |
| | Long | 6 | 2.27 (0.66, 7.84) | 96% | - | - | | - |
| | Prolonged | - | - | - | - | - | | - |

*Result of single study
**Z test

*The Impacts of Timing of Breastfeeding Interventions (Table 4)*

We performed subgroup analyses by timing of breastfeeding interventions (prenatal, postpartum, or combined prenatal and postpartum) on the pooled rate ratios of any or exclusive breastfeeding initiation, short-, intermediate, and long-term breastfeeding. There were 18, 19, and 23 trials that examined the effects of prenatal, combination of pre- and postnatal, and postnatal breastfeeding interventions, respectively, on any breastfeeding initiation and durations.

The results suggest that prenatal breastfeeding interventions significantly increased the rate of any short-term breastfeeding compared to usual care (pooled RR: 1.39; 95%CI 1.16-1.67), while other timing of breastfeeding interventions did not change the outcome significantly. In addition, combination of pre- and postnatal breastfeeding interventions significantly increased both the rates of intermediate and long-term any breastfeeding compared to usual care (pooled RR: 1.15; 95%CI 1.00-1.32, 1.38; 95%CI 1.33-1.43, respectively), while other timing of breastfeeding interventions did not change the outcomes significantly. In interventions that had combined pre- and postnatal components, results from meta-regression suggest that larger effects (compared to control) were associated with longer breastfeeding durations (P<0.001). This association was not found in solely pre- or postnatal interventions.

There were seven, 12, and 12 trials that examined the effects of prenatal, combination of pre- and postnatal, and postnatal breastfeeding interventions, respectively, on exclusive breastfeeding initiation and durations. No significant differences in the outcomes were found between the timing of breastfeeding interventions, except that postnatal breastfeeding interventions significantly increased the rate of exclusive short-term breastfeeding compared to usual care (pooled RR: 1.21; 95%CI 1.08-1.36). In interventions that had only postnatal components, results from meta-regression suggest that larger effects (compared to control) were associated with longer exclusive breastfeeding durations (P<0.001). This association was not found for prenatal alone or combined pre- and postnatal breastfeeding interventions.

**Table 4. Subgroup analyses by timing of interventions**

| Timing of Intervention | Breastfeeding | Breastfeeding Duration | # Study | Pooled RR (95% CI) | P for trend** |
|---|---|---|---|---|---|
| Prenatal alone | Any | Initiation | 7 | 1.04 (0.99, 1.09) | 0.27 |
| | | Short | 5 | **1.39 (1.16, 1.67)** | |
| | | Intermediate | 2 | 1.44 (0.60, 3.47) | |
| | | Long | 3 | 0.96 (0.87, 1.06) | |
| | | Prolonged | 1 | 0.91 (0.65, 1.28)* | |
| Pre- and postnatal | | Initiation | 4 | 1.10 (0.91, 1.33) | <0.001 |
| | | Short | 7 | 1.03 (0.85, 1.26) | |
| | | Intermediate | 5 | **1.15 (1.00, 1.32)** | |
| | | Long | 2 | **1.38 (1.33, 1.43)** | |
| | | Prolonged | 1 | 1.19 (0.72, 1.97)* | |
| Postnatal alone | | Initiation | 4 | 1.13 (0.91, 1.39) | 0.33 |
| | | Short | 7 | 1.05 (0.95, 1.15) | |
| | | Intermediate | 6 | 1.06 (0.95, 1.17) | |
| | | Long | 5 | 1.23 (0.89, 1.68) | |
| | | Prolonged | 1 | 2.80 (0.62, 12.7)* | |
| Prenatal alone | Exclusive | Initiation | 4 | 1.09 (0.90, 1.33) | 0.35 |
| | | Short | 1 | 1.41 (1.08, 1.84)* | |
| | | Intermediate | - | - | |
| | | Long | 2 | 1.17 (0.80, 1.73) | |
| | | Prolonged | - | - | |
| Pre- and postnatal | | Initiation | 2 | 1.15 (0.83, 1.58) | 0.23 |
| | | Short | 6 | 2.52 (0.85, 7.47) | |
| | | Intermediate | 1 | 5.00 (0.24, 103) | |
| | | Long | 3 | 3.75 (0.66, 21) | |
| | | Prolonged | - | - | |
| Postnatal alone | | Initiation | 3 | 1.05 (0.96, 1.13) | <0.001 |
| | | Short | 4 | **1.21 (1.08, 1.36)** | |
| | | Intermediate | 4 | 1.41 (0.88, 2.27) | |
| | | Long | 1 | 1.90 (0.55, 6.60) | |
| | | Prolonged | - | - | |

*Result from single study

**Random-effect meta-regression based on individual studies

## Subgroup Analyses of Different Interventions

We performed subgroup analyses to examine the effects of different components of breastfeeding interventions on breastfeeding initiation, duration, and exclusivity. The interventions of interest have been classified into the following categories for the analyses: formal/structured breastfeeding education, professional support (system or individual level support), lay support, other breastfeeding interventions, and Baby Friendly Hospital Initiative (BFHI). The components of breastfeeding interventions are not mutually exclusive. In other words, if a trial had multiple components, this trial would appear in different subgroup analyses. BFHI is also considered one form of professional support. The detailed classification of the interventions is described in Table 1.

### Formal/Structured Breastfeeding Education (Table 5)

Formal/structured breastfeeding education with or without other components significantly increased the rate of any breastfeeding initiation compared to usual care (pooled RR: 1.15; 95%CI 1.02-1.30). However, there were no significant differences in the rate of exclusive breastfeeding initiation or durations between the breastfeeding education and usual care group.

**Table 5. Meta-analyses of breastfeeding education versus usual care**

| Intervention | Breastfeeding | Breastfeeding Duration | # Study | Pooled RR (95% CI) | P for trend |
|---|---|---|---|---|---|
| Education with or without other components | Any | Initiation | 9 | **1.15 (1.02, 1.30)** | 0.45 |
| | | Short | 7 | 1.11 (0.92, 1.33) | |
| | | Intermediate | 7 | 1.14 (0.93, 1.41) | |
| | | Long | 3 | 0.95 (0.86, 1.05) | |
| | | Prolonged | 1 | 1.19 (0.72, 1.97) | |
| Education with or without other components | Exclusive | Initiation | 4 | 1.09 (0.90, 1.33) | 0.15 |
| | | Short | 2 | 1.17 (0.67, 2.05) | |
| | | Intermediate | 2 | 1.52 (0.71, 3.24) | |
| | | Long | 3 | 1.05 (0.74, 1.50) | |
| | | Prolonged | - | - | |

*Result from single study
**Random-effect meta-regression on individual studies

### Professional Support (Table 6)

Professional support can be further broken down into two sub-categories: system level and individual level professional support. System level professional support includes training of health professional to increase breastfeeding promotion knowledge and skills, and BFHI. Individual level professional support includes all forms of one-to-one breastfeeding support or promotion during hospital stay or outpatient visits or social support after discharge (e.g., home visits or telephone support) from health professionals.

We identified five trials comparing system level professional support to usual care. The data on the effect of system level professional support compared to usual care were sparse: only less than three trials for each breastfeeding category. Our meta-analyses found no significant effect of system level professional support on breastfeeding initiation or duration compared to usual care. However, one study reported that BFHI significantly increased both short- and long-term exclusive breastfeeding.[41]

Individual level professional support with or without other components significantly increased the rate of any intermediate breastfeeding compared to usual care (pooled RR: 1.12; 95%CI 1.02-1.30). Our meta-analyses found no significant effect of individual level professional support on breastfeeding initiation or duration compared to usual care. However, one study reported that postnatal home visits by health professionals in addition to usual care (BFHI) significantly increased both short- and long-term exclusive breastfeeding.[25]

**Table 6. Meta-analyses of professional support versus usual care**

| Breastfeeding | | System-level support | | | Individual-level support with or without other components | | |
|---|---|---|---|---|---|---|---|
| | Duration | # Study | Pooled RR (95% CI) | P for trend** | # Study | Pooled RR (95% CI) | P for trend** |
| Any | Initiation | 2 | 1.06 (0.95, 1.17) | 0.92 | 6 | 1.15 (0.84, 1.57) | 0.59 |
| | Short | 3 | 0.96 (0.73, 1.26) | | 7 | 1.00 (0.92, 1.09) | |
| | Intermediate | 2 | 0.97 (0.84, 1.11) | | 6 | **1.12 (1.01, 1.25)** | |
| | Long | 2 | 1.16 (0.80, 1.68) | | 2 | 1.31 (0.95, 1.84) | |
| | Prolonged | 1 | 0.91 (0.65, 1.68)* | | 1 | 1.19 (0.72, 1.97)* | |
| Exclusive | Initiation | - | - | - | 3 | 1.04 (0.97, 1.12) | 0.23 |
| | Short | 3 | 1.89 (0.41, 8.80) | | 3 | 1.90 (0.63, 5.70) | |
| | Intermediate | 1 | 0.97 (0.35, 2.69)* | | 1 | 2.12 (1.46, 3.07)* | |
| | Long | 1 | 13.3 (9.9, 17.8)* | | 3 | 1.91 (0.42, 8.62) | |
| | Prolonged | - | - | | | | |

*Result from single study
**Random-effect meta-regression on individual studies

## Lay Support (Table 7)

Lay support with or without other components significantly increased the rate of any short- and long-term breastfeeding compared to usual care (pooled RR: 1.26; 95%CI 1.07-1.48, 1.38; 95%CI 1.00-1.92, respectively). Results from meta-regression suggest that larger effects (compared to control) were associated with longer exclusive breastfeeding durations (P=0.008).

Two of the five trials on the effects of lay support with or without other components were conducted in BFHI hospitals.[20, 61] The pooled rate ratio of any short-term breastfeeding from these two trials was 1.43 (95%CI 1.07, 1.92).

For outcomes of exclusive breastfeeding initiation and durations, meta-analysis was only performed for the effect of short-term exclusive breastfeeding. The result showed that lay support with or without other components significantly increased short-term exclusive breastfeeding duration (pooled RR: 1.66; 95%CI 1.05-2.56), compared to usual care.

**Table 7. Meta-analyses of lay support versus usual care**

| Intervention | Breastfeeding | Breastfeeding Duration | # Study | Pooled RR (95% CI) | P for trend** |
|---|---|---|---|---|---|
| Lay support with or without other components | Any | Initiation | 1 | 1.07 (0.94, 1.21)* | 0.008 |
| | | Short | 5 | **1.26 (1.07, 1.48)** | |
| | | Intermediate | 2 | 1.48 (0.73, 3.00) | |
| | | Long | 2 | **1.38 (1.00, 1.92)** | |
| | | Prolonged | - | - | |
| Lay support with or without other components | Exclusive | Initiation | 1 | 1.39 (1.01, 1.92)* | 0.83 |
| | | Short | 4 | **1.66 (1.05, 2.63)** | |
| | | Intermediate | 1 | 5.00 (0.24, 102)* | |
| | | Long | 1 | 1.90 (0.55, 6.60)* | |
| | | Prolonged | - | - | |

*Result of single study
**Random-effect meta-regression on individual studies

**Baby Friendly Hospital Initiative (Table 8; Appendix J)**

We identified two good quality RCTs,[25, 41] two poor quality experimental studies,[50, 51] and four poor quality observational studies.[52-55] The two good quality studies were the PROBIT study as detailed previously, and a trial in Brazil on a population with high poverty and infant mortality rates.[25] The PROBIT study compared an intervention based on BFHI with standard care, while the study in Brazil compared BFHI with home visits by health professionals to BFHI without home visits. Both studies found an increased exclusive breastfeeding rates at 3 and 6 months comparing intervention with control (Table 8). The PROBIT study also reported an increased ever breastfeeding rate at 12 months. The study from Brazil did not have 12 months data.

The two experimental studies were non-randomized before-after BFHI training design conducted in Italy[50] and Taiwan,[51] respectively. The study in Italy found a significant increase in exclusive breastfeeding rate at discharge, full breastfeeding rate at 3 months, and ever breastfeeding rate at 6 months, comparing intervention to control. The study in Taiwan found a significant increase in the exclusive breastfeeding rates at discharge, 2 weeks, 1 and 2 months postpartum, comparing intervention with control. Both studies were rated poor because of the study design.(Appendix J)

The other four observational studies were cohort studies comparing mother-infant pairs from hospitals with high breastfeeding promotion to mother-infant pairs from low breastfeeding promotion (assessed either by the number of steps fulfilling BFHI or a breastfeeding promotion index analogous to BFHI). (Appendix J) The study from the Czech Republic found that the durations of exclusive breastfeeding were comparable in both groups (3.9 months ± 1.92 SD in BFHI vs. 3.9 months ± 1.92 SD in others).[52] This study was rated poor because of the study design and the apparent lack of control for characteristics differences between groups. The study from Croatia reported an increase in general breastfeeding rates at 3 (66% vs. 30%, P<0.05), 6 (49% vs. 11%, P<0.05), 9 (35% vs. 6%, P<0.05), and 12 months (23% vs. 2%, P<0.05), comparing BFHI with postnatal support (1999-2000) to a historical cohort (1990-1993) without BFHI.[55] This study was rated poor because of the study design and large loss (57%) to followup. The study from Germany found an increased risk of short-term breastfeeding (<4 months full breastfeeding) in mother-infant pairs discharged from a hospital with low breastfeeding promotion index (adjusted OR: 1.24; 95%CI 0.99-1.55) compared to a hospital with high breastfeeding promotion index.[53] This study was rated poor because of the study design and low enrollment rate (45%). The study from Scotland found an increased odds ratio of breastfeeding at 1 week (adjusted OR 1.28, 95%CI 1.24-1.31) if an infant was born in a UK hospital with the BFHI standard award compared to an infant born in a hospital without BFHI accreditation.[54] This study was rated poor because of the study design and no details concerning breastfeeding were provided.

**Table 8. RCTs of Baby Friendly Hospital Initiative (BFHI)**

| Study Year Country | Population | Intervention (N) vs. Control (N) | Outcome | | | | Applic | Quality |
|---|---|---|---|---|---|---|---|---|
| | | | Initiation | Exclu BF at 3 mo | Exclu BF at 6 mo | Others | | |
| Kramer 2001 (Cluster RCT) Belarus | Urban and rural, >95% completed secondary education | Modeled BFHI (8847) vs. no BFHI (7895) | 100% vs. 100% | 43.3% vs. 6.4% (P <0.001) | 7.9% vs. 0.6% (P=0.01) | Ever BF at 12 mo 19.7% vs. 11.4% | Narrow | Good |
| Coutinho 2005 | Urban, widespread | BFHI with postnatal home | 70% vs. 70% | 45% (est.) vs. | 25% (est.) vs. | Aggregate exclu BF | Narrow | Good |

| Study Year Country | Population | Intervention (N) vs. Control (N) | Outcome | | | | Applic | Quality |
|---|---|---|---|---|---|---|---|---|
| | | | Initiation | Exclu BF at 3 mo | Exclu BF at 6 mo | Others | | |
| Brazil | poverty, 33% illiteracy rate | visits (175) vs. BFHI (175) only | | 10% (est.) | 4% (est.) | rate days (10-180) 45% vs. 13% (P<0.0001) | | |

## Differences in Absolute Breastfeeding Durations (Table 9)

Eight trials in nine publications reported the differences in the absolute breastfeeding duration comparing the breastfeeding intervention to usual care groups.[27, 29, 32, 34, 37, 39, 43, 44, 62] Three were good, two were fair, and three were poor quality. The followup durations ranged from 45 days to 1 year. We did not perform meta-analyses because the intervention components and outcome matrix varied greatly across these trials.

One good quality trial comparing delayed pacifier use to pacifier use within 2 to 5 days found an increase in any breastfeeding duration (adjusted HR 1.22, 95%CI 1.03-1.44).[29] Another good quality trial comparing system-level professional support to usual care also found a significant increase in any breastfeeding duration (adjusted HR: 1.40, 95%CI 1.03-1.92).[32] One fair quality trial showed that postpartum skin-to-skin care resulted in about a 2-months increase in breastfeeding duration, compared to usual care, at the end of 1-year followup.[34] There were no other trials that showed a significant difference in absolute breastfeeding durations between the intervention and the control groups.

**Table 9. The effects of primary care initiated breastfeeding interventions on absolute breastfeeding durations compared to usual care**

| Study, year Country | Intervention components | Outcome Definition | Dur of f/up | Units | Group | N | Final | SD | Diff | 95%CI or $P_{b/tw}$ | Quality |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Howard 2005 US | Delayed pacifier use (>4 wk) | Exclusive BF duration | 1 yr | day | BF promotion | 346 | 28[a] | | Adjusted HR: 1.09 | 0.94-1.27 | Good |
| | | | | | Control | 354 | 21 | | | | |
| Howard 2005 US | Delayed pacifier use (>4 wk) | Full BF duration | 1 yr | day | BF promotion | 346 | 52[a] | | Adjusted HR: 1.04 | 0.89-1.21 | Good |
| | | | | | Control | 354 | 49[a] | | | | |
| Howard 2005 US | Delayed pacifier use (>4 wk) | Ever BF duration | 1 yr | day | BF promotion | 346 | 163[a] | | Adjusted HR: 1.22 | 1.03-1.44 | Good |
| | | | | | Control | 354 | 140[a] | | | | |
| Labarere 2005 France | Training primary care physicians[e] | Any BF duration | 2 mo | Week | BF promotion | 112 | 18[a] | | HR: 1.40 | 1.03-1.92 | Good |
| | | | | | Control | 114 | 13[a] | | | | |
| Noel-Weiss 2006 Canada | Education | BF duration | 2 mo | day | BF promotion | 41 | 54 | 9.3 | | NS | Good |
| | | | | | Control | 51 | 47 | 17 | | | |
| Forster 2004 Australia | Education (Practical Skills) | Any BF duration | 6 mo | Week | BF promotion | 297 | 19 | 9.3 | 1 | NS | Fair |
| | | | | | Control | 299 | 18 | 9.7 | | | |
| Forster 2004 Australia | Education (Attitudes) | Any BF duration | 6 mo | Week | BF promotion | 293 | 17 | 10 | -1 | NS | Fair |
| | | | | | Control | 299 | 18 | 9.7 | | | |
| Mizuno 2004 Japan | Skin-to-skin | nd | 1 yr | Month | BF promotion | 30 | 6.7 | 3.7 | 1.9 | 0.016 | Fair |
| | | | | | Control | 28 | 4.8 | 2.5 | | | |
| Schlickau 2005 US | Education[d] | BF duration | 45 d | day | BF promotion | 9 | 23 | 16 | 6.3 | NS | Poor |
| | | | | | Control | 7 | 16 | 18 | | | |
| Schlickau 2005 US | Education + commitment-to-breastfeed[d] | BF duration | 45 d | day | BF promotion | 9 | 31 | 16 | 14.3 | NS | Poor |
| | | | | | Control | 7 | 17 | 18 | | | |
| Ekstrom 2006 Sweden | Professional support | Exclusive BF duration[b] | 9 mo | Month | BF promotion | nd | 3.9 | 2.2 | | NS | Poor |
| | | | | | Control | nd | 3.5 | 2.0 | | | |
| Ekstrom 2006 Sweden | Professional support | Exclusive & partial BF duration | 9 mo | Month | BF promotion | nd | 7.5 | 4.7 | | NS | Poor |
| | | | | | Control | nd | 7.0 | 4.5 | | | |
| Wilhelm 2006 US | Motivational interview | BF duration | 6 mo | day | BF promotion | 36 | 98 | 75 | Adjusted mean difference[c] = 12 | NS | Poor |
| | | | | | Control | 35 | 81 | 72 | | | |

P b/tw, p valued for the differences between the comparison groups; d, day(s); wk, week(s); mo, month(s); yr, year(s)
[a] Median
[b] including some babies received supplementary feeding with formula during the first week of life
[c] Adjusted for baseline breastfeeding self-efficacy and length of time before returning to work
[d] The same control group was used to compare both intervention groups (Education or Education + commitment-to-breastfeed)
[e] Pediatricians or family physicians, who had attended a 5-hour training program (breastfeeding-related knowledge and counseling skills) delivered in 2 parts in 1 month before the beginning of the study

## Interventions Involving Family Members

We identified only two studies involving family members in breastfeeding intervention, a RCT (poor quality) in United States and non-randomized but controlled trial (fair quality) in Italy of breastfeeding education involving expectant fathers.[40, 63]

Pisacane 2005 compared the effects of a face-to-face, 40-minute education session concerning the management of breastfeeding difficulties for expectant fathers to a control group that received education session on childcare on the rates of full or any breastfeeding initiation, as well as, full or any breastfeeding at 6 and 12 months.[63] The fathers of the newborns were allocated to the study groups according to the date of birth of their infants: those whose infants were born in October and November 2002 were assigned to the intervention group, and those whose infants were born in December 2002 and January 2003 were assigned the control group. A trained midwife conducted the breastfeeding education session. Another researcher conducted the control education session. The results showed no significant differences in the rates of full or any breastfeeding initiation. However, significantly more women whose husbands attended the breastfeeding education session were still fully breastfeeding at 6 months, compared to women whose husbands attended the control education session (25% vs. 15%, $P<0.05$). Any breastfeeding rate was also higher, but not statistically significant, in those women whose husbands attended the breastfeeding education session at 12 months (19% vs. 11%, $P=0.09$). This study was graded fair because no apparent adjustment was made to account for the fact that the two interventions took place during two different time periods.

Wolfberg 2004 compared the effects of breastfeeding classes for expectant fathers to control classes of baby care and safety on rates of any breastfeeding initiation and any breastfeeding at 2 months.[40] A peer classroom facilitator who was easygoing and engaging, knowledgeable without being overbearing, African-American, and who was a father himself gave the expectant fathers two prenatal breastfeeding classes (2 hours for each class and 2 weeks apart). The study found that more women whose partners attended the breastfeeding classes initiated breastfeeding than women whose partners attended the control classes (74% vs. 41%, $P=0.02$). Other characteristics were also associated with an increased incidence of breastfeeding initiation in the study, including mother's plan to breastfeed for the first month ($P=0.004$), baby's maternal grandmother's belief that the baby should be breastfed ($P=0.03$), mother's belief that her partner thinks her baby should be breastfed ($P=0.002$), and father's belief that the baby should be breastfed ($P=0.03$) There was no significant difference in the rate of any breastfeeding at 2 months between the intervention and the control groups. This study was graded poor because of low enrollment rate and the method of randomization and the blinding of outcome assessors were unclear.

**3. Are there harms from interventions to promote and support breastfeeding?**

We did not identify any study from our search that was designed specifically to examine harms from interventions to promote and support breastfeeding.

# Conclusion and Discussion

## Key Question 1

The PROBIT trial in Belarus provided good evidence that a system wide intervention to promote breastfeeding could affect certain health outcomes in infants (lower risk of gastrointestinal infections and atopic dermatitis). The study also found that infants in the intervention group (modeled Baby-Friendly Initiative) were more likely to be exclusively breastfed at 3 and 6 months, compared to the control. Whether the findings in Belarus are applicable to the United States are unclear, because the social milieu in Belarus is much more conducive (3-years obligatory maternity leave, no day care, expensive formula) to prolonged breastfeeding.

The two fair quality studies conducted in the United States focused on families from low income stratum, an important target of the interventions to promote breastfeeding because families from this stratum had lower breastfeeding rates compared with families from higher income stratum.[3] These studies focused on postnatal home support by trained peer counselors or lactation consultants. One study reported an increased exclusive breastfeeding rate at 3 months and a lower risk of diarrheal diseases in the intervention arm compared to control. The other study conducted in Bronx did not detect a significant difference in the exclusive breastfeeding rate at 3 months and also did not detect a difference in certain infant health outcomes between the intervention and control groups. One may surmise from the above studies that exclusive breastfeeding rate is an important determinant of certain health outcomes in infants. Studies that reported an increase in exclusive breastfeeding rate also reported a reduced risk of gastrointestinal infections or atopic dermatitis.

Whether possible differences in definitions of exclusive breastfeeding, health outcomes, and unknown factors that could interact with the intervention may also explain some of the different findings are unclear. Findings from one study stressed the need to further examine the role of postnatal home support for breastfeeding from trained professionals or peer counselors in affecting maternal mental health outcomes.

## Key Question 2

Studies comparing the effects of primary care initiated breastfeeding interventions to usual care on the rate of any or exclusive breastfeeding initiation, short-, intermediate, and long-breastfeeding are heterogeneous in many respects. Comparing the intervention to control, our meta-analyses showed a consistently increased rate of any or exclusive breastfeeding initiation, short-, intermediate, and long-term breastfeeding, although most of these findings were not statistically significant.

In our subgroup analyses, we found that breastfeeding interventions with a component of lay support (e.g., peer support or peer counseling) were more effective in increasing both short- and long-term breastfeeding, than interventions without lay support.

We examined possible sources of heterogeneity by conducting subgroup analyses on exclusivity of breastfeeding (any versus exclusive), quality of study (good or fair versus poor), and timing of intervention (prenatal, postpartum, or combined prenatal and postpartum). Comparing breastfeeding interventions to usual care, the sensitivity analyses showed that:

- The pooled rate ratios of exclusive short- and intermediate breastfeeding were larger than that of any short-, and intermediate breastfeeding, respectively.

- The impacts of study quality on the pooled rate ratios of breastfeeding initiation and durations were inconsistent.

- Timing of interventions had impacts on the pooled rate ratios of any or exclusive breastfeeding initiation and duration. Prenatal breastfeeding intervention significantly increased the rate of any short-term breastfeeding compared to usual care. In addition, combination of pre- and postnatal breastfeeding interventions significantly increased both the rate of any intermediate and long-term breastfeeding. Postnatal breastfeeding interventions significantly increased the rate of exclusive short-term breastfeeding.

Subgroup analyses were performed to examine the effects of different components of breastfeeding interventions on breastfeeding initiation, duration, and exclusivity. The interventions of interest were classified into the following categories: formal/structured breastfeeding education, professional support, lay support, and Baby Friendly Hospital Initiative (BFHI).

**Formal/structured breastfeeding education**

Compare to usual care, breastfeeding education (with or without other components) significantly increased the rate of any breastfeeding initiation (pooled RR: 1.15; 95%CI 1.02-1.30). There were no significant differences in the rate of exclusive breastfeeding initiation or durations between the breastfeeding education and usual care group.

**Professional support**

Four of the five trials comparing system level professional support to usual care did not find significant effects on breastfeeding initiation or durations. The fifth trial reported that BFHI significantly increased both short- and long-term exclusive breastfeeding comparing to usual care.

Individual level professional support with or without other components significantly increased the rate of any intermediate breastfeeding compared to usual care (pooled RR: 1.12; 95%CI 1.02-1.30).

**Lay support**

Lay support with or without other components significantly increased the rate of any short- and long-term breastfeeding compared to usual care (pooled RR: 1.26; 95%CI 1.07-1.48, 1.38; 95%CI 1.00-1.92, respectively). The effects of lay support also increased with breastfeeding durations (P=0.008). For outcomes of exclusive breastfeeding initiation and durations, the result showed that lay support with or without other components significantly increased short-term exclusive breastfeeding duration (pooled RR: 1.66; 95%CI 1.05-2.56), compared to usual care.

**Baby Friendly Hospital Initiative**

Both the PROBIT trial and the study in Brazil provided good evidence that BFHI is effective in increasing the exclusive breastfeeding rates, at least up to 6 months postpartum. The former study was conducted on a well-educated sample in a country with wide availability of basic health services and uncontaminated water supply, while the latter was conducted on a sample with widespread poverty, female illiteracy rate of around 33 percent, and an infant mortality rate of 76.5 per 1000 live births. Despite these differences, both studies reported increasing breastfeeding rates with BFHI. Furthermore, the study in Brazil illustrates the importance of

postnatal home visits to sustain the increased rates. This is especially important in a country where the typical postpartum stay was only 24 to 36 hours for women who had a normal vaginal delivery and 48 hours for those who had a caesarian section. Regardless of the applicability of these findings to a developed country like the United States, it should be noted that the first nine of the ten Baby Friendly steps take place in a hospital setting, but the tenth step concerning breastfeeding support during the post discharge period (i.e., foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic) is essential in ensuring long-term breastfeeding success.

**Interventions Involving Family Members**

One fair quality study showed the importance of fathers in breastfeeding success. More women whose husbands received breastfeeding education concerning management of breastfeeding difficulties were fully (exclusive and predominant) breastfeeding at 6 months than women whose husbands did not receive the education. The strengths of the study include the fact that all eligible married fathers were enrolled and there was no loss to followup at 12 months. However, the experimental and the control intervention did not take place during the same time periods. Also, the findings are applicable only to married couples as unmarried ones were excluded from the study. Nevertheless, this study points out the importance of involving fathers in ensuring the long-term success of breastfeeding.

# Limitations

This is a systematic review of primary care initiated interventions to promote and support breastfeeding. It is not always straightforward to determine if some of the interventions in the studies reviewed were indeed primary care initiated (e.g., some of the peer counseling interventions). We erred on the conservative side and included those studies in this review as long as there was a tangential hint that the health care system was involved. We included a Cochrane systematic review in this report but we did not reassess the individual studies within the review. Even though we have assessed the reporting quality of this systematic review, we cannot reliably know the validity of the reported summary data without knowing the details of the primary studies.

Studies included in our meta-analyses are heterogeneous in many aspects: different combinations of intervention components and background social support, different health care systems defining “usual” or “routine” care, different timing and intensities of the interventions, and diverse study populations. These sources of heterogeneity limited the validity and interpretability of the pooled estimates.

We performed subgroup analyses on formal/structured breastfeeding education, professional support, and lay support aiming to segregate the effects of different components of breastfeeding interventions. However, one should not interpret the observed effects as the “independent” effects of these intervention components on breastfeeding initiation and duration. This is because several components were often combined in the breastfeeding interventions. Our analyses only compared the interventions with a specific component to those without it. Other components in the intervention and the control groups may not be comparable in our meta-analyses. The previous meta-analyses attempted to examine the independent effects of different intervention components (education, support, or written materials) by using meta-regression.[10] However, we question the implicit assumption in this analysis that different intervention components are

independent. The lack of data precluded us from performing a more appropriate analysis by incorporating interaction terms in the regression model.

# Future Research

- It is conceivable that a cluster randomized study similar to the PROBIT study in Belarus could still be undertaken in this country, as Baby Friendly Hospital Initiative (BFHI) is not yet widely adopted (only 1.3% of the maternity units in this country is designated Baby Friendly (http://babyfriendly.org/, accessed 6-7-2007)). Such a study is important because the magnitude of effects measured from such an intervention is useful in assessing the public health impact in a socio-cultural environment that is not as breastfeeding friendly as the one in Belarus. It should also be noted that studies in the literature reported good success in improving the initiation rate of exclusive breastfeeding in hospitals that had achieved the Baby Friendly status, but those rates declined rapidly after discharge. Thus, if such a study is undertaken, step number ten of the BFHI ten steps, postdischarge breastfeeding support, must be designed carefully and implemented.

- For future studies on the effects of breastfeeding interventions, it may be preferable to focus on the rate of exclusive breastfeeding rather than the rate of any breastfeeding. The larger effects seen with exclusive breastfeeding compared with any breastfeeding in our meta-analyses suggested that the widely varying classifications of breastfeeding exposures in the any breastfeeding category might have biased the findings toward the null effect.

- Our results suggest that prenatal combined with postnatal interventions could be effective in prolonging the duration of breastfeeding. Future studies on particular interventions should take this possibility into account and emphasize interventions in both the prenatal and postnatal periods.

- In our overall analysis, we did not find that professional support was effective in increasing the rate of breastfeeding initiation or duration but we found that lay support was effective in increasing the rate of short- and long-term breastfeeding. It may be instructive to compare the two forms of support in a head-to-head trial to further understand the similarities and differences so that better breastfeeding support could be designed and implemented.

- One fair quality study on postpartum skin-to-skin intervention reported a 2 months increase in breastfeeding duration compared to usual care but the number of participants who received the intervention in the study was small (N=30). It would be desirable to confirm the effect of postpartum skin-to-skin intervention on breastfeeding duration in a larger trial.

- One fair quality study on prenatal breastfeeding education for expectant fathers reported a significant increased rate of full breastfeeding at 6 months compared to infants whose fathers did not receive such training. It would be important to conduct a head-to-head trial where the fathers were directly randomized to intervention or control. This will lend confidence to the effects reported. More studies involving other family members (e.g., grandparents, partners) will be of value to clarify the effects of interventions to promote and support breastfeeding.

## Addendum

The final report was submitted on 7-27-2007 to AHRQ. On 8-20-2007, we were alerted by David Meyers, M.D. of a 2005 study concerning fathers and breastfeeding success[63] that was not included in our report. We reviewed the study and found that it met our inclusion criteria. The final report was therefore revised to include this study but the overall meta-analysis was not re-conducted. An examination of our original literature search strategy including the terms "breastfeeding" and "controlled trials" did not reveal an apparent reason for the inadvertent omission of this study.

## Reference List


(1) *Pediatric Nutrition Handbook*. 5th ed. Elk Grove, IL: American Academy of Pediatrics; 2004.

(2) U.S.Department of Health and Human Services. *Healthy People 2010: Conference Edition*
*28*. Washington, DC: U.S. Government Printing Office; 2000.

(3) Li R, Darling N, Maurice E, Barker L, Grummer-Strawn LM. Breastfeeding rates in the United States by characteristics of the child, mother, or family: the 2002 National Immunization Survey. *Pediatrics* 2005 January;115(1):e31-e37.

(4) Ip S, Chung M, Raman G et al. Breastfeeding and Maternal and Infant Health Outcomes in Developed Countries. Rockville, MD: Agency for Healthcare Research and Quality; 2007 Apr 20. Report No.: 153.

(5) Gartner LM, Morton J, Lawrence RA et al. Breastfeeding and the use of human milk. *Pediatrics* 2005 February;115(2):496-506.

(6) World Health Organization. Baby-friendly hospital initiative (BFHI)
26. Geneva: World Health Organization; 2004.

(7) Philipp BL, Merewood A, Miller LW et al. Baby-friendly hospital initiative improves breastfeeding initiation rates in a US hospital setting
25. *Pediatrics* 2001 September;108(3):677-81.

(8) Cohen R, Mrtek MB. The impact of two corporate lactation programs on the incidence and duration of breast-feeding by employed mothers. *Am J Health Promot* 1994 July;8(6):436-41.

(9) Shealy KR, Li R, Benton-Davis S, Grummer-Strawn LM. The CDC Guide to Breastfeeding Interventions
27. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2005.

(10) Guise J, Palda V, Westhoff C, Chan B, Helfand M, Lieu T. The effectiveness of primary care based interventions to promote breastfeeding: a systematic evidence review and meta-analysis for the U.S. Preventive Services Task Force.
10050. *Agency for Healthcare Research and Quality* 2003;Available at: URL: www.preventiveservices.ahrq.gov.

(11) U.S.Preventive Services Task Force (USPSTF). Counseling to Promote Breastfeeding.
10053. *Guide to Clinical Preventive Services, 3rd Edition: Periodic Updates* 2003.

(12) Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials.[see comment]
10054. *JAMA* 1995 February 1;273(5):408-12.

(13) Britton C, McCormick FM, Renfrew MJ, Wade A, King SE. Support for breastfeeding mothers.[update of Cochrane Database Syst Rev. 2002;(1):CD001141; PMID: 11869593]. [Review] [131 refs]. *Cochrane Database of Systematic Reviews* 2007;(1):CD001141.

(14) Harris RP, Helfand M, Woolf SH et al. Current methods of the US Preventive Services Task Force: a review of the process
10052. *Am J Prev Med* 2001 April;20(3 Suppl):21-35.

(15) DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials* 1986 September;7(3):177-88.

(16) Higgins JP, Whitehead A, Turner RM, Omar RZ, Thompson SG. Meta-analysis of continuous outcome data from individual patients. *Stat Med* 2001 August 15;20(15):2219-41.

(17) Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003 September 6;327(7414):557-60.

(18) Berkey CS, Hoaglin DC, Mosteller F, Colditz GA. A random-effects regression model for meta-analysis. *Stat Med* 1995 February 28;14(4):395-411.

(19) Knapp G, Hartung J. Improved tests for a random effects meta-regression with a single covariate. *Stat Med* 2003 September 15;22(17):2693-710.

(20) Anderson AK, Damio G, Young S, Chapman DJ, Perez-Escamilla R. A randomized trial assessing the efficacy of peer counseling on exclusive breastfeeding in a predominantly Latina low-income community.[see comment]. *Archives of Pediatrics & Adolescent Medicine* 2005 September;159(9):836-41.

(21) Bonuck KA, Trombley M, Freeman K, McKee D. Randomized, controlled trial of a prenatal and postnatal lactation consultant intervention on duration and intensity of breastfeeding up to 12 months. *Pediatrics* 2005 December;116(6):1413-26.

(22) Bonuck KA, Freeman K, Trombley M. Randomized controlled trial of a prenatal and postnatal lactation consultant intervention on infant health care use. *Archives of Pediatrics & Adolescent Medicine* 2006 September;160(9):953-60.

(23) Carfoot S, Williamson PR, Dickson R. The value of a pilot study in breast-feeding research. *Midwifery* 2004 June;20(2):188-93.

(24) Carfoot S, Williamson P, Dickson R. A randomised controlled trial in the north of England examining the effects of skin-to-skin care on breast feeding.[see comment]. *Midwifery* 2005 March;21(1):71-9.

(25) Coutinho SB, de Lira PI, de Carvalho LM, Ashworth A. Comparison of the effect of two systems for the promotion of exclusive breastfeeding. *Lancet* 2005 September 24;366(9491):1094-100.

(26) Finch C, Daniel EL. Breastfeeding education program with incentives increases exclusive breastfeeding among urban WIC participants. *Journal of the American Dietetic Association* 2002 July;102(7):981-4.

(27) Forster D, McLachlan H, Lumley J, Beanland C, Waldenstrom U, Amir L. Two mid-pregnancy interventions to increase the initiation and duration of breastfeeding: a randomized controlled trial. *Birth* 2004 September;31(3):176-82.

(28) Henderson A, Stamp G, Pincombe J. Postpartum positioning and attachment education for increasing breastfeeding: a randomized trial. *Birth* 2001 December;28(4):236-42.

(29) Howard CR, Howard FM, Lanphear B et al. Randomized clinical trial of pacifier use and bottle-feeding or cupfeeding and their effect on breastfeeding. *Pediatrics* 2003 March;111(3):511-8.

(30) Kramer MS, Barr RG, Dagenais S et al. Pacifier use, early weaning, and cry/fuss behavior: a randomized controlled trial. *JAMA* 2001 July 18;286(3):322-6.

(31) Labarere J, Bellin V, Fourny M, Gagnaire JC, Francois P, Pons JC. Assessment of a structured in-hospital educational intervention addressing breastfeeding: a prospective randomised open trial. *BJOG: An International Journal of Obstetrics & Gynaecology* 2003 September;110(9):847-52.

(32) Labarere J, Gelbert-Baudino N, Ayral AS et al. Efficacy of breastfeeding support provided by trained clinicians during an early, routine, preventive visit: a prospective, randomized, open trial of 226 mother-infant pairs. *Pediatrics* 2005 February;115(2):e139-e146.

(33) McKeever P, Stevens B, Miller KL et al. Home versus hospital breastfeeding support for newborns: a randomized controlled trial. *Birth* 2002 December;29(4):258-65.

(34) Mizuno K, Mizuno N, Shinohara T, Noda M. Mother-infant skin-to-skin contact after delivery results in early recognition of own mother's milk odour.[see comment]. *Acta Paediatrica* 2004 December;93(12):1640-5.

(35) Muirhead PE, Butcher G, Rankin J, Munley A. The effect of a programme of organised and supervised peer support on the initiation and duration of breastfeeding: a randomised trial.[see comment]. *British Journal of General Practice* 2006 March;56(524):191-7.

(36) Ryser FG. Breastfeeding attitudes, intention, and initiation in low-income women: the effect of the best start program. *Journal of Human Lactation* 2004 August;20(3):300-5.

(37) Schlickau J, Wilson M. Development and testing of a prenatal breastfeeding education intervention for Hispanic women. *Journal of Perinatal Education*2005 Fall; 14(4):24-35.

(38) Wallace LM, Dunn OM, Alder EM, Inch S, Hills RK, Law SM. A randomised-controlled trial in England of a postnatal midwifery intervention on breast-feeding duration. *Midwifery* 2006 September;22(3):262-73.

(39) Wilhelm SL, Stepans MB, Hertzog M, Rodehorst TK, Gardner P. Motivational interviewing to promote sustained breastfeeding. *JOGNN - Journal of Obstetric, Gynecologic, & Neonatal Nursing* 2006 May;35(3):340-8.

(40) Wolfberg AJ, Michels KB, Shields W, O'Campo P, Bronner Y, Bienstock J. Dads as breastfeeding advocates: results from a randomized controlled trial of an educational intervention. *American Journal of Obstetrics & Gynecology* 2004 September;191(3):708-12.

(41) Kramer MS, Chalmers B, Hodnett ED et al. Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus 10046. *JAMA* 2001 January 24;285(4):413-20.

(42) Lavender T, Baker L, Smyth R, Collins S, Spofforth A, Dey P. Breastfeeding expectations versus reality: a cluster randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology* 2005 August;112(8):1047-53.

(43) Ekstrom A, Nissen E. A mother's feelings for her infant are strengthened by excellent breastfeeding counseling and continuity of care. *Pediatrics* 2006 August;118(2):e309-e314.

(44) Ekstrom A, Widstrom AM, Nissen E. Does continuity of care by well-trained breastfeeding counselors improve a mother's perception of support? *Birth* 2006 June;33(2):123-30.

(45) McLeod D, Pullon S, Benn C et al. Can support and education for smoking cessation and reduction be provided effectively by midwives within primary maternity care? *Midwifery* 2004 March;20(1):37-50.

(46) Chertok IR, Shoham-Vardi I, Hallak M. Four-month breastfeeding duration in postcesarean women of different cultures in the Israeli Negev. *Journal of Perinatal & Neonatal Nursing* 2004 April;18(2):145-60.

(47) Chertok IR. Breast-feeding initiation among post-Caesarean women of the Negev, Israel. *British Journal of Nursing* 2006 February 23;15(4):205-8.

(48) Pugh LC, Milligan RA, Brown LP. The breastfeeding support team for low-income, predominantly-minority women: a pilot intervention study. *Health Care for Women International* 2001 July;22(5):501-15.

(49) Reeve JR, Gull SE, Johnson MH, Hunter S, Streather M. A preliminary study on the use of experiential learning to support women's choices about infant feeding. *European Journal of Obstetrics, Gynecology, & Reproductive Biology* 2004 April 15;113(2):199-203.

(50) Cattaneo A, Buzzetti R. Effect on rates of breast feeding of training for the baby friendly hospital initiative. *BMJ* 2001 December 8;323(7325):1358-62.

(51) Gau ML. Evaluation of a lactation intervention program to encourage breastfeeding: a longitudinal study. *International Journal of Nursing Studies* 2004 May;41(4):425-35.

(52) Schneidrova D, Mullerova D, Janout V, Paulova M, Kudlova E. Impact of breast-feeding promotion on infant feeding in the Czech Republic. *Journal of Nutrition Education & Behavior* 2003 September;35(5):228-35.

(53) Dulon M, Kersting M, Bender R. Breastfeeding promotion in non-UNICEF-certified hospitals and long-term breastfeeding success in Germany.[see comment]. *Acta Paediatrica* 2003 June;92(6):653-8.

(54) Broadfoot M, Britten J, Tappin D, MacKenzie J. The Baby Friendly Hospital Initiative and breast feeding rates in Scotland. *Archives of Disease in Childhood Fetal and Neonatal Edition* 2005;2005 Mar; 90(2):F114-F116.

(55) Bosnjak AP, Batinica M, Hegedus-Jungvirth M, Grguri J, Bozikov J. The effect of baby friendly hospital initiative and postnatal support on breastfeeding rates--Croatian experience. *Collegium Antropologicum* 2004 June;28(1):235-43.

(56) Boulvain M, Perneger TV, Othenin-Girard V, Petrou S, Berner M, Irion O. Home-based versus hospital-based postnatal care: a randomised trial. *BJOG: An International Journal of Obstetrics & Gynaecology* 2004 August;111(8):807-13.

(57) Johnston BD, Huebner CE, Tyll LT, Barlow WE, Thompson RS. Expanding developmental and behavioral services for newborns in primary care; Effects on parental well-being, practice, and satisfaction. *American Journal of Preventive Medicine* 2004 May;26(4):356-66.

(58) Johnston BD, Huebner CE, Anderson ML, Tyll LT, Thompson RS. Healthy steps in an integrated delivery system: child and parent outcomes at 30 months. *Archives of Pediatrics & Adolescent Medicine* 2006 August;160(8):793-800.

(59) Minkovitz C, Strobino D, Hughart N, Scharfstein D, Guyer B, Healthy Steps Evaluation Team. Early effects of the healthy steps for young children program. *Archives of Pediatrics & Adolescent Medicine* 2001 April;155(4):470-9.

(60) O'Connor KO, Mowat DL, Scott HM, Carr PA, Dorland JL, Young Tai KF. A randomized trial of two public health nurse follow-up programs after early obstetrical discharge: an examination of breastfeeding rates, maternal confidence and utilization and costs of health services. *Canadian Journal of Public Health* 2003 March;Revue(2):98-103.

(61) Chapman DJ, Damio G, Young S, Perez-Escamilla R. Effectiveness of breastfeeding peer counseling in a low-income, predominantly Latina population: a randomized controlled trial. *Archives of Pediatrics & Adolescent Medicine* 2004 September;158(9):897-902.

(62) Noel-Weiss J, Rupp A, Cragg B, Bassett V, Woodend AK. Randomized controlled trial to determine effects of prenatal breastfeeding workshop on maternal breastfeeding self-efficacy and breastfeeding duration. *JOGNN - Journal of Obstetric, Gynecologic, & Neonatal Nursing* 2006 September;35(5):616-24.

(63) Pisacane A, Continisio GI, Aldinucci M, D'Amora S, Continisio P. A controlled trial of the father's role in breastfeeding promotion. *Pediatrics*. 2005;116:e494-e498.

# Appendix A. MEDLINE® Search Strategy

## Human and Animal Search
## 1950 to January week 5 2007

| # | Search History | Results |
|---|---|---|
| 1 | infant nutrition.mp. or exp MIlk, Human/ | 23820 |
| 2 | human milk.mp. | 5763 |
| 3 | (human adj2 milk).tw. | 6370 |
| 4 | breast milk.mp. | 5384 |
| 5 | breastmilk.mp. | 346 |
| 6 | breast feeding.mp. | 20338 |
| 7 | breastfeeding.mp. | 5655 |
| 8 | breastfeed$.mp. | 5808 |
| 9 | breast fed.mp. | 3641 |
| 10 | breastfed.mp. | 1514 |
| 11 | (breast adj2 fed).tw. | 3822 |
| 12 | exp lactation/ | 25946 |
| 13 | (lactating or lactation).mp. | 36065 |
| 14 | or/1-13 | 73052 |
| 15 | limit 14 to english language | 59770 |
| 16 | follow-up studies/ | 330722 |
| 17 | (follow-up or followup).tw. | 340787 |
| 18 | exp Case-Control Studies/ | 335140 |
| 19 | (case adj20 control).tw. | 45809 |
| 20 | exp Longitudinal studies/ | 549100 |
| 21 | longitudinal.tw. | 69276 |
| 22 | exp Cohort Studies/ | 595207 |
| 23 | cohort.tw. | 86811 |
| 24 | (random$ or rct).tw. | 358919 |
| 25 | exp randomized controlled trials/ | 46670 |
| 26 | exp random allocation/ | 56703 |
| 27 | exp double-blind method/ | 89226 |
| 28 | exp single-blind method/ | 10537 |
| 29 | randomized controlled trial.pt. | 228503 |
| 30 | clinical trial.pt. | 431474 |

| | | |
|---|---|---|
| 31 | controlled clinical trials/ | 3302 |
| 32 | (clin$ adj trial$).tw. | 102676 |
| 33 | ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).tw. | 85997 |
| 34 | exp PLACEBOS/ | 25721 |
| 35 | placebo$.tw. | 99472 |
| 36 | exp Research Design/ | 213290 |
| 37 | exp Evaluation Studies/ | 581017 |
| 38 | exp Prospective Studies/ | 214377 |
| 39 | exp Comparative Study/ | 0 |
| 40 | or/16-39 | 2082884 |
| 41 | 15 and 40 | 10598 |
| 42 | limit 41 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or overall or patient education handout or periodical index) | 368 |
| 43 | limit 41 to comment and (letter or editorial).pt. | 109 |
| 44 | 41 not (42 or 43) | 10230 |
| 45 | limit 44 to ("review" or "systematic review") [Limit not valid in: Ovid MEDLINE(R); records were retained] | 717 |
| 46 | limit 44 to yr="2001 - 2007" | 3915 |

# Appendix B. Data Abstraction Forms

## Evidence Table Template

| Author | | Year | | Ref ID | | UI | | Reviewer | |
|---|---|---|---|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized)<br>Cluster-RCT (subjects clustered within centers/areas were randomized)<br>Quasi-RCT (centers or caregivers were randomized) | | | | |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | | | |
| **Who implemented the BF promotion intervention?** | | | |
| **Comparator (Description)** | | | |
| **Inclusion Criteria** | | **Exclusion Criteria** | |
| **Other Population Description** | | **Setting** | |
| **Comments** | | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | | | | |
| **Mean Age** | | | | | |
| **Age Range** | **metric** | | | | |
| **Gestational Age:** | | | | | |
| **Range** | **metric:** | | | | |
| **Baseline SES Measure:** | | | | | |
| **Range** | **metric:** | | | | |
| **Duration of BF promotion** | | | | | |
| **Duration of Followup (after the intervention stopped)** | | | | | |
| **Comments:** | | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| **List the variables that were adjusted for:** | | | | | | | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | | | | | | | |
| **Comments** | | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR** | 95% CI** | P between | OR/RR** | 95% CI** | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **BF initiation rate** | | | | | | | | | | | | | |
| **BF > 3 mo rate** | | | | | | | | | | | | | |
| **BF > 6 mo rate** | | | | | | | | | | | | | |
| **Infant health outcomes**** | | | | | | | | | | | | | |
| **maternal health outcomes**** | | | | | | | | | | | | | |
| **Other outcome**** | | | | | | | | | | | | | |
| **AE: Other**** | | | | | | | | | | | | | |

** Duplicate one row per outcome. Replace "Other**" with actual Outcome and "OR/RR**" with actual metric and "95% CI**" with SE, if necessary

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD/SE** | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| **BF duration** | | **BF promotion** | | | | | | |
| | | **Control** | | | | | | |
| **Other**** | | **BF promotion** | | | | | | |
| | | **Control** | | | | | | |
| **Other**** | | **BF promotion** | | | | | | |
| | | **Control** | | | | | | |

** Replace "Other**" with actual Outcome and "SD/SE**" with actual metric

| **Results Comments** | |
|---|---|

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| | Factors reported in the study that one is ***likely*** to encounter in US primary care | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| | Factors reported in the study that one is ***unlikely*** to encounter in US primary care | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. All pre- and post-trials were rated C. |
| | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | |

## Evidence Table Template, Observational Studies

Author, year [UI#]

| Study characteristics | Study design and follow-up duration | Eligibility criteria | Breastfeeding promotion Intervention | Control Intervention |
|---|---|---|---|---|
| Mean age (range):<br>Mean GA (range):<br>Enrolled/Evaluate:<br>Location:<br>Sites: Single/Multi<br>Funding: | | | | |

| Outcome Definition | Statistical analyses and confounders adjusted | Results | Bias/limitations Comments |
|---|---|---|---|
| | | | |

| A: strong, B: moderate, C: weak | A | B | C |
|---|---|---|---|
| Selection | | | |
| Study design | | | |
| Confounder | | | |
| Blinding | | | |
| Data collection | | | |
| Withdraw and dropout | | | |
| Analyses | | | |
| Intervention integrity | | | |

Applicability

| | |
|---|---|
| **Study characteristics that one is likely to encounter in US primary care** | |
| **Study characteristics that may limit the applicability to a US primary care population** | |
| **Overall assessment of applicability to US primary care (wide or narrow)** | |

| Author | Anderson | Year | 2005 | UI | 16143742 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | US | N | January 2003 to July 2004 | Government |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Peer counseling: 3 prenatal home visits, 9 postpartum home visits, and daily in-hospital visits during postpartum hospitalization, from the assigned peer counselor. This is in addition to the routine breastfeeding support and education (BFHI). | | |
| **Who implemented the BF promotion intervention?** | Peer counselor, who had successfully breastfed a child for no less than 6 months and who had the motivation to help other mothers breastfeed their infants. An international board-certified lactation consultant trained these women over 2 weeks using the 40-hour WHO/US Children's Fund Breastfeeding Counseling Training Course and the Hispanic Health Council Breastfeeding Training Manual, while the exclusive breastfeeding component was handled by the study field coordinator. | | |
| **Comparator (Description)** | BFHI: breastfeeding warm line (telephone support), conventional breastfeeding education prenatal, hands-on breastfeeding assistance and education from the maternity ward nursing staff. | | |
| **Inclusion Criteria** | 18 years or older, GA of 32 weeks or younger, healthy and absence of any medical condition that is likely to impair successful breastfeeding.<br>Considering breastfeeding, planning deliver at the hospital, willing to stay in the study area for >3 months after delivery, living in a household.<br>Born at term (≥36 weeks gestation), with normal birth weight (≥ 2.5 kg), with no neonatal medical complications requiring treatment in the neonatal intensive care unit, and with Apgar scores at 1 and 5 minutes ≥6 | **Exclusion Criteria** | None |
| **Other Population Description** | 72% Hispanic; 18% Black<br>90% WIC participants | **Setting** | Hospital and home |
| **Comments** | Predominantly Latina low-income community | | |

| CHARACTERISTICS | | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|---|
| | | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | | 90 | | 92 | |
| **Mean Age** | | | | | | |
| **Age Range** | **metric** | <20<br>20-30<br>>30 | 9.5%<br>68.3%<br>22.2% | | 16.7%<br>66.7%<br>16.7% | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| Gestational Age: | | >=36 | | >=36 | |
| Range metric: | | | | | |
| Baseline SES Measure: | >High School education | 31.8% | | 31.9% | |
| Range metric: | | | | | |
| Duration of BF promotion | | 3 prenatal home visits, 9 postpartum home visits, and daily in-hospital visits during postpartum hospitalization. The mean total duration of the prenatal home visits and in-hospital visits was 2.6 hours and 2.2 hours, respectively. | | | |
| Duration of Followup (after the intervention stopped) | | 3 months postpartum | | 3 months postpartum | |
| Comments: | Baseline characteristics were reported for 135 women who completed the 3-month follow-up. 162 women were enrolled. The authors stated that there were no significant differences in the baseline characteristics between the completers and the dropouts. | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Assigned by the study field coordinator | N | Y | ND | 15 | N | Y | Y |

| | |
|---|---|
| List the variables that were adjusted for: | None |
| Were statistical analyses appropriate? [iv] (Y/N) | Y |
| Comments | Coverage by the peer counselors ranged from 56 (88.9%) of 63 for the prenatal home visits to 40 (63.5%) of 63 at week 6 postpartum. About 3% of mothers in the control group reported having received breastfeeding counseling from the existing hospital's peer counseling service during postpartum hospitalization at the maternity ward. 4 mothers in the intervention group declined to see the study peer counselor. |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RR (compared control to intervention group) | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| **BF initiation rate** | At hospital discharge | 63 | | 57 (91%) | 72 | | 61 (76%) | | | |
| **Exclusive BF initiation rate** | At hospital discharge | 63 | | 39 (59%) | 72 | | 32 (44%) | | | |
| **BF at 3 mo rate** | Self-report, phone follow-up | 63 | | 31 (49.2%) | 72 | | 26 (36.1%) | | | |
| **Exclusive BF at 3 mo rate** | No other food besides breastmilk (since birth recall) | 63 | | 13 (20.6%) | 72 | | 1 (1.4%) | | | |
| **Infant health outcomes** | Experiencing 1 or more diarrhea episodes during the study | 63 | | 11 (17.5% | 72 | | 27 (37.5%) | RR of diarrhea, compared control to intervention group = 2.15 | 1.16-3.97 | |
| **maternal health outcomes** | Menses return at 3 months postpartum | 63 | | 30 (47.6%) | 72 | | 48 (66.7%) | RR of menses return, compared control to intervention group = 1.4 | 1.03-1.90 | |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Predominantly Hispanic, low income | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | x | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| | **Study characteristics that may restrict the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Wide | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Unclear whether the outcome assessors were blinded; inappropriate allocation concealment;15% lost to follow-up | |

| Author | Bonuck | Year | 2005; 2006 (2 publications) | UI | 16322166; 6953019 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | US | Y - 2 community health center attached to one hospital | Aug 2000 – Nov 2002 | Government agencies |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Individualized, prenatal: first meeting for feeding intentions and benefits of breastfeeding; second meeting on how to initiate breastfeeding (latch-on, positioning, importance of early initiation, demand feeding) Individualized postnatal: Weekly near term telephone calls, Education and support for breastfeeding; provide nursing bras, manual or minielectric pump | | |
| **Who implemented the BF promotion intervention?** | Lactation consultants (LC) | | |
| **Comparator (Description)** | No contact with LCs, received standard of care; had prenatal care class that did not address infant feeding in detail | | |
| **Inclusion Criteria** | English or Spanish speaking; twin or singleton pregnancy; gestation before 24 weeks; intent to keep infant; with regular follow up until 12 mo | **Exclusion Criteria** | Any chronic medical illnesses or chronic therapy (HIV, gestational diabetes etc..) |
| **Other Population Description** | Study conducted in Bronx NY, the county with highest poverty rate and lowest median household income | **Setting** | 2 community health center |
| **Comments** | Moms into Learning about Kids (MILK) study; | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 188 | | 194 | |
| **Mean Age** | | 25.7 | | 24.84 | |
| **Age Range** | | ±6.38 | | ±5.86 | |
| **Gestational Age:** | | nd | | nd | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | High school education % | 58.5 | | 63.5 | |
| | Medicaid % | 53.7 | | 58.2 | |
| | | | | | |
| **Range metric:** | | | | | |

| CHARACTERISTICS | Breastfeeding promotion | | Control | |
|---|---|---|---|---|
| | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **Duration of BF promotion** | 2 prenatal meetings, a postpartum hospital visit, and/or home visits and telephone calls. Prenatal and home visits averaged 60 min; hospital visits averaged 90 min. | | | |
| **Duration of Followup (after the intervention stopped)** | 52 wks | | 52 wks | |
| **Comments:** | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Blocked and stratified according to center | Yes (sealed envelope) | Y | No (unblended) | 11% (for certain outcomes); 20.5% missing BF data | Y | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | Prenatal breastfeeding intentions; maternal age; ethnicity; Medicaid status; and previous breastfeeding |
| **Were statistical analyses appropriate? [iv] (Y/N)** | yes |
| **Comments** | Used backward stepwise regression model and logistic regression model |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **BF initiation rate** | Any BF at 2 wk | 145 | | 90% | 159 | | 65% | | | nd | | | |
| **BF at 3 mo rate** | Low versus high breastfeeding at 13 wk | Total (both groups) = 304 | | | | | | | | | 1.0 (intervention) Control 1.90 | 1.13-3.20 | <.05 |
| **BF rate up to week 20** | Any breastfeeding Up to week 20 | 145 | | 53.0% | 159 | | 39.3% | | | <0.028 | | | |
| **BF rate at 1 yr** | At the end of 12 mo | 145 | | 18% | 159 | | 15% | | | NS | | | |
| | Low versus high breastfeeding at 52 wk | Total (both groups) = 304 | | | | | | | | | Control = 2.50 | 1.48-4.21 | <.05 |
| **Exclusive breast feeding rates** | At 13 wks | 145 | | 9% | 159 | | 11% | | | NS | | | |
| | At 26 wk | 145 | | 5% | 159 | | 8% | | | NS | | | |
| **Infant health outcomes*** (visits with illness)** | Illness | 163 | | | 175 | | | ß -0.07 | -0.28 to 0.14 | NS | ß –0.06 | -0.29 to 0.17 | NS |
| | Breast-feeding sensitive illness | | | | | | | ß 0.01 | -0.20 to 0.23 | NS | ß 0.25 | -0.10 to 0.59 | NS |
| | GI illness | | | | | | | ß 0.03 | -0.10 to 0.16 | NS | ß 0.03 | -0.09 to 0.53 | NS |

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| | RS tract illness | | | | | | | ß –0.02 | -0.21 to 0.18 | NS | ß –0.02 | -0.21 to 0.18 | NS |
| | Otitis Media | | | | | | | ß 0.02 | -0.11 to 0.15 | NS | ß 0.20 | 0.0 to 0.39 | <.05 |

| APPLICABILITY | | QUALITY | |
|---|---|---|---|
| Hispanic, African-American, low income, 39% foreign born | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | x | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Wide | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | 20.5% missing BF data | |

Bosnjak, 2004 UI 15636080

| Study characteristics | Study design and follow-up duration | Eligibility criteria | Breastfeeding promotion Intervention | Control Intervention |
|---|---|---|---|---|
| Mean age (range): nd<br>Mean GA (range): nd<br>Enrolled/Evaluate: 7,414 / 7,208 @ 1mo; 7,139 @ 3 mo; 6,880 @ 6 mo<br>Location: Croatia<br>Sites: Multi<br>Funding: nd | Observational, retro- and prospective study of one county in Croatia; comparing no-intervention, BFHI, and BFHI+postnatal support.<br>Data on BF for no intervention and BFHI were collected retrospectively from medical records; BF data for BFHI+postnatal support were obtained from child health card at discharge, 1, 3, 6, 9, and 12 mo. | ND | BFHI (1994-98) or BFHI + postnatal support (1999-2000)<br><br>Not full BFHI because mothers received Happy Baby discharge packs. | No intervention (1990-93) |

| Outcome Definition | Statistical analyses and confounders adjusted | Results | Bias/limitations Comments |
|---|---|---|---|
| Ever BF: at least one meal of BF per day | Descriptive and chi2; no data on confounders | **Mean prevalence of BF**<br>* chi2, P < 0.05 | A: strong, B: moderate, C: weak |
| | | | Selection: B |
| | | | Study design: C |
| | | | Confounder: C |
| | | | Blinding: C |
| | | | Data collection: C |
| | | | Withdraw and dropout: C |
| | | | Analyses: C |
| | | | Large lost-to follow-up; no adjustment for confounders |

| Mean prevalence of BF | 1 mo | 3 mo | 6 mo* | 9 mo* | 11/12 mo* |
|---|---|---|---|---|---|
| No intervention (1990-93) | 1917/2818 (68%) | 856/2818 (30%) | 323/2818 (11%) | 173/2818 (6%) | 63/2818 (2%) |
| BFHI (1994-98) | 1967/2257 (87%) | 1212/2257 (54%) | 640/2257 (28%) | 332/2257 (15%) | 41/1179 (3%) |
| BFHI + postnatal support (1999-2000) | 1854/2133 (87%) | 1369/2064 (66%) | 891/1805 (49%) | 423/1214 (35%) | 210/921 (23%) |

**Applicability**

| | |
|---|---|
| **Study characteristics that one is likely to encounter in US primary care** | Given hospital discharge pack “Happy Baby”, use of visiting nurses |
| **Study characteristics that may limit the applicability to a US primary care population** | A highly selected sample from Croatia |
| **Overall assessment of applicability to US primary care (wide or narrow)** | Narrow |

| Author | Boulvain | Year | 2004 | UI | 15270928 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Switzerland | nd | 1998-2000 | Government |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Short hospital stay (24-48h, 2 d extra for c-section) with home care provided by midwife (number of visits determined by needs of the family) | | |
| **Who implemented the BF promotion intervention?** | nd | | |
| **Comparator (Description)** | Normal hospital stay (3 to 4 d after vaginal delivery, 2 d extra for c-section) | | |
| **Inclusion Criteria** | >37 wk gestation, low risk for complications or c-section | **Exclusion Criteria** | Strong preference for short or long hospital stay |
| **Other Population Description** | | **Setting** | Home or hospital |
| **Comments** | Some in the hospital-based group received midwife visits as well (1.7 visits as opposed to 4.8 visits in the short hospital stay group) | | |

| CHARACTERISTICS | | Home-based | | Hospital-based | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 228 | | 231 | |
| **Mean Age** | | 29 | | 29 | |
| **Age Range** | **metric** | | | | |
| **Gestational Age:** | | >37 | | >37 | |
| **Range** | **metric:** | | | | |
| **Baseline education ≤ 13 yr:** | | 115 | | 113 | |
| **Range** | **metric:** | | | | |
| **Duration of BF promotion** | | On average 4.8 visits | | | |
| **Duration of Followup (after the intervention stopped)** | | 6 mo | | | |
| **Comments:** | 1964/2324 eligible (85%) refused enrollment | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Random blocks | Y | Y | N | 0.5% | N | Y | Y |
| **List the variables that were adjusted for:** | | | | | | | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y | | | | | | |
| **Comments** | Home based vs. hospital based: nulliparity (60% vs 57%); smoking (25% vs 17%) | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | Home-based | | | Hospital-based | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **BF initiation rate** | | 227 | | 224 (99%) | 229 | | 223 (97%) | 1.01* | 0.99-1.04 | | | | |
| **BF rate at 1 mo** | | 224 | | 202 (90%) | 223 | | 194 (87%) | 1.04* | 0.97-1.11 | | | | |
| **BF rate at 6 mo** | | 220 | | 78 (35%) | 215 | | 78 (36%) | 0.98 | 0.76-1.3 | | | | |
| **EPDS > 12 at 28 days** | Edinburgh Postpartum Depression Scale | 228 | | 16 (7.4%) | 231 | | 21 (9.4%) | 0.79 | 0.42-1.5 | | | | |

* recalculated to reflect the ratio of BF initiation rate in home-based/hospital-based

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| **BF duration** | days | **home** | | | 127 | | | 0.42 |
| | | **hospital** | | | 121 | | | |
| **QOL – physical health** | SF-12 (No data on when the maternal quality of life data was collected) | **home** | 228 | | 46 | 7.9 | | NS |
| | | **hospital** | 231 | | 45 | 8.6 | | |
| **QOL – mental health** | SF-12 (No data on when the maternal quality of life data was collected) | **home** | 228 | | 47 | 10 | | NS |
| | | **hospital** | 231 | | 48 | 9.6 | | |
| **Results Comments** | Early discharge after c-section was not acceptable to many women, therefore, low compliance in this group (8%). Some women in home-based early discharge did not receive any midwife visits; while some hospital-based subjects did receive midwife visits. Even though ITT was done, unclear what proportion actually completed the protocol. | | | | | | | |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Middle income, low risk (for cesarean section and postnatal complications) mothers | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| 85% of eligible subjects refused enrollment; 97% BF initiation rate in the control group. | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Incomplete and inconsistent data reporting. No data on when the maternal quality of life data was collected. Maternal morbidity outcomes were only assessed once, so whether the groups were similar in terms of the morbidity profile was unclear. | |

Broadfoot, 2005 UI 2009109512 (Cinahl)

| Study characteristics | Study design and follow-up duration | Eligibility criteria | Breastfeeding promotion Interventions | Control Interventions |
|---|---|---|---|---|
| Mean age (range): nd<br>Mean GA (range): nd<br>Enrolled/Evaluate: 464,246 / 445,623<br>Location: Scotland<br>Sites: Multi<br>Funding: SPorting Aiding Medical Research for KidS | Observational study, prospective cohort with historical control analyzed with respect to progress towards BFHI status<br>Postal questionnaires between 3/2000 and 5/2001 to midwife at 33 maternity units with ≥ 50 births per year; collected BFHI status in the questionnaire; 1995-2000 data provided by BFHI; feeding status at 6-7 d collected by Guthrie dataset (check box for breast, bottle, or other feeding) | Excluded if born outside Scotland, <4 d or >30 d | WHO/UNICEF UK Baby Friendly Hospital Initiative standard award | No Baby Friendly accreditation |

| Outcome Definition | Statistical analyses and confounders adjusted | Results | Bias/limitations Comments |
|---|---|---|---|
| nd | Adjustment for deprivation category, maternal age, number of births at hospital, and year of birth | 445,623 records included (96%)<br>adjOR of BF at 7 d was 1.28 (95%CI 1.24 to 1.31) if born in hospitals with a UK BFHI standard award | A: strong, B: moderate, C: weak: A / B / C<br>Selection: / x /<br>Study design: / / x<br>Confounder: / x /<br>Blinding: / /<br>Data collection: / / x<br>Withdraw and dropout: x / /<br>Analyses: / x /<br>No details concerning BF |

**Applicability**

| | |
|---|---|
| **Study characteristics that one is likely to encounter in US primary care** | |
| **Study characteristics that may limit the applicability to a US primary care population** | BF status collected on Guthrie Inborn Errors Screening card at 7 d of age |
| **Overall assessment of applicability to US primary care (wide or narrow)** | Narrow |

| Author | Carfoot | Year | 2004 | UI | 15177863 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | United Kingdom | N | ND | North West regional Health Authority |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Skin-to-skin contact: after birth, newborn is weighed and then immediately placed between mother's breasts naked in a prone position until mother chooses to stop the contact or until newborn appears to be ready for feeding | | |
| **Who implemented the BF promotion intervention?** | Midwife | | |
| **Comparator (Description)** | Routine care: after birth, newborn is dried and clothed, and then given to either parent. Parent-newborn contact could be broken off due to baby weight measurement, dressing for the baby, or mother's perineum suturing | | |
| **Inclusion Criteria** | Healthy<br>Pregnant<br>Plan to breast-feed<br>Plan to deliver at Warrington Hospital<br>Fetus is at least 36 weeks old and is healthy<br>Provide informed consent | **Exclusion Criteria** | Requested to have or not to have skin-to-skin contact<br>Had previous multiple pregnancy<br>Expecting multiple pregnancy |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | This is a pilot study to see if a bigger study is feasible. The later trial is published: UI 15740818.<br>67% consent rate. Enrollment dependent on the availability of the clinical coordinator. | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 14 | | 14 | |
| **Mean Age** | | 31 | | 30 | |
| **Age Range** | **metric** | | | | |
| **Gestational Age:** | | ≥ 36 weeks | | ≥ 36 weeks | |
| **Range** | **metric:** | | | | |
| **Baseline SES Measure:** | | ND | | ND | |
| **Range** | **metric:** | | | | |
| **Duration of BF promotion** | | ND | | | |
| **Duration of Followup (after the intervention stopped)** | | 4 months | | 4 months | |
| **Comments:** | | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Computer-generated randomization list, sequence of envelops | N | N | N | 7.1% | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate? [iv] (Y/N)** | N/A |
| **Comments** | This is a pilot study, so no hypothesis testing. |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RD | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| Success of first BF | Breastfeeding Assessment Tool (BAT) score 8 or higher | 13 | | 13 (100%) | 13 | | 8 (62%) | | | Not done | | | |
| BF at 4 months | Exclusive BF | 13 | | 5 (36%) | 13 | | 4 (32%) | | | Not done | | | |
| BF at 4 months | Partial BF | 13 | | 2 (14%) | 13 | | 1 (8%) | | | Not done | | | |

| | |
|---|---|
| **Results Comments** | Clinical coordinator observed first feed. |

| APPLICABILITY | | | QUALITY | |
|---|---|---|---|---|
| | | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Small pilot study | | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | Outcome assessors were not blinded. Exclusivity of breastfeeding was not clearly defined. A pilot study, so no hypothesis testing. Small sample size. | |

| Author | Carfoot | Year | 2005 | UI | 15740818 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | United Kingdom | N | April 28 to September 1 2002 | North West regional Health Authority |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Skin-to-skin contact: after birth, newborn is weighed and then immediately placed between mother's breasts naked in a prone position until mother chooses to stop the contact or until newborn appears to be ready for feeding | | |
| **Who implemented the BF promotion intervention?** | Midwife | | |
| **Comparator (Description)** | Routine care: after birth, newborn is dried and clothed, and then given to either parent. Parent-newborn contact could be broken off due to baby weight measurement, dressing for the baby, or mother's perineum suturing | | |
| **Inclusion Criteria** | Healthy<br>Pregnant<br>Plan to breast-feed<br>Plan to deliver at Warrington Hospital<br>Fetus is at least 36 weeks old and is healthy<br>Provide informed consent | **Exclusion Criteria** | Requested to have or to not have skin-to-skin contact<br>Had previous multiple pregnancy<br>Expecting multiple pregnancy |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | 75% response rate | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 100 | | 101 | |
| **Mean Age** | | ND | | ND | |
| **Age Range** | **metric** | | | | |
| **Gestational Age:** | | ≥ 36 weeks | | ≥ 36 weeks | |
| **Range** | **metric:** | | | | |
| **Baseline SES Measure:** | | ND | | ND | |
| **Range** | **metric:** | | | | |
| **Duration of BF promotion** | | 45 minutes | | | |
| **Duration of Followup (after the intervention stopped)** | | 4 months | | 4 months | |
| **Comments:** | | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Computer-generated randomization list, sequence of envelops | N | Y | N | 3.4% | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RD | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| BF before discharge | Subsequent BF while at hospital | 96 | | 91 | 101 | | 97 | -1.2% | -8.1% 5.3% | |
| BF at 4 months | Exclusive or partial BF | 97 | | 42 | 100 | | 40 | 3.3% | -10.3% 16.7% | 0.64 |
| Success of first BF | Breastfeeding Assessment Tool (BAT) score 8 or higher | 98 | | 89 | 99 | | 82 | 8% | -1.6% 17.6% | 0.10 |

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| Mean time to first breastfeeding | minutes | **BF promotion** | 98 | | 46 | 22.2 | 1.3 (-5.1, 7.6 ) | 0.7 |
| | | **Control** | 99 | | 45 | 22.8 | | |
| Median duration of first feeding | minutes | **BF promotion** | 97 | | 40 | 95%CI: 32, 40 | 0 (-5, 5) | 0.99 |
| | | **Control** | 97 | | 35 | 95%CI: 33-40 | | |

| | |
|---|---|
| **Results Comments** | Research assistant revealed the treatment group and also observed the first breastfeeding (?). |

| APPLICABILITY | | QUALITY | |
|---|---|---|---|
| | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | **x** | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| First feed observed by research assistant, sparse demographic data | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Outcome assessors were not blinded. Exclusivity of breastfeeding was not clearly defined. | |

Cattaneo, 2001 UI 11739226

| Study characteristics | Study design and follow-up duration | Eligibility criteria | Breastfeeding promotion Interventions | Control Interventions |
|---|---|---|---|---|
| Mean age (range): Group 1 = 29.0 to 29.3; Group 2 = 30.0 to 31.0<br>Mean GA (range): nd<br>Enrolled/Evaluate: Group 1 = 1531/1219 @ 6 mo; Group 2 = 1055/962 @ 6 mo<br>Location: Italy<br>Sites: Multi<br>Funding: Government | Non-randomized before-after study; training hospital practice to use baby-friendly steps;<br>Training: UNICEF 18 h course with 2 h of WHO counseling course; Phase 1: baseline assessment of number of steps compliant with BFHI requirement, then training; Phase 2: after training; Phase 3: final assessment<br>Mothers interviewed at discharge, phone interviews at 3 and 6 mo<br>2 groups of hospitals; initiated training at different times. | 8 hospitals agreed to participate.<br><br>Infants with birth weight under 2000 g or a severe disease that required admission to the neonatal ward were excluded. | UNICEF BFHI training | Before BFHI training |

| Outcome Definition | Statistical analyses and confounders adjusted | Results | Bias/limitations Comments |
|---|---|---|---|
| Exclusive BF (no other foods or fluid)<br>Predominant BF (non-nutritive fluids allowed)<br>Full (exclusive and Predominant BF)<br>Complementary<br><br>BF data collected by 24h recall. | BF rates adjusted with direct standardization by parity, type of delivery, and birth weight; logistic regression | Before training: fulfilled 1-3 BFHI steps<br>After training: fulfilled 6-10 BFHI steps<br>Group 1 (crude rates):<br>Baseline exclusive BF at discharge: 212/518 (41%)<br>Final exclusive BF at discharge: 393/510 (77%)<br>Baseline exclusive BF at 3 mo: 101/506 (20%)<br>Final exclusive BF at 3 mo: 129/510 (25%)<br>Baseline exclusive BF at 6 mo: 3/485 (0.6%)<br>Final exclusive BF at 6 mo: 3/366 (0.8%)<br>Group 2 (crude rates):<br>Baseline exclusive BF at discharge: 105/464 (23%)<br>Final exclusive BF at discharge: 194/271 (72%)<br>Baseline exclusive BF at 3 mo: 69/471 (15%)<br>Final exclusive BF at 3 mo: 127/280 (45%)<br>Baseline exclusive BF at 6 mo: 4/454 (0.9%)<br>Final exclusive BF at 6 mo: 30/233 (13%)<br>Standardized rates do not differ significantly.<br>In both group, differences before and after training in exclusive BF at discharge, full BF at 3 mo, ever BF at 6 mo were significant (P<0.05) | A: strong, B: moderate, C: weak / A / B / C<br>Selection / / / x<br>Study design / / / x<br>Confounder / / x /<br>Blinding / / / x<br>Data collection / / x /<br>Withdraw and dropout / / / x<br>Analyses / / / x |

**Applicability**

| | |
|---|---|
| **Study characteristics that one is likely to encounter in US primary care** | Low number of BFHI-certified hospitals in Italy, comparable to US (1% vs. 1.3%, see www.babyfriendly.org), low infant mortality rate; large and small hospitals |
| **Study characteristics that may limit the applicability to a US primary care population** | |
| **Overall assessment of applicability to US primary care (wide or narrow)** | Wide |

| Author | Chertok | Year | 2006; 2004 (2 publications) | UI | 16603986; 15214252 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| Prospective Cohort with comparative group | Israel | N | 2000-2002 | Not stated |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Post-caesarean breastfeeding support, guidance, and education. Education covers benefits of early breastfeeding, benefits of exclusive breastfeeding, guidance on post-caesarean positioning, latching, and other infant feeding information.<br>For those with elective cesarean delivery, breastfeeding education is provided prior to delivery.<br>Newborn is placed with mother within first 4 hours of birth (immediately in recovery room if mother desires and not sedated) so that maternal-infant contact and/or breastfeeding is possible. | | |
| **Who implemented the BF promotion intervention?** | Certified lactation consultant and/or trained medical or nursing students | | |
| **Comparator (Description)** | Standard postpartum care, no mother-newborn interaction for at least first 2 hours after birth | | |
| **Inclusion Criteria** | Muslim or Jewish<br>Healthy mothers<br>Post-cesarean delivery without complication<br>Full term, singleton infants<br>Speaks either Arabic, English, Hebrew, or Russian | **Exclusion Criteria** | Premature or postmature infants<br>Infants with "apparent problems"<br>Mothers with compromised maternal health or complicated delivery |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | Recruited by interviewers on days when interviewers are present, so only 53.8% of eligible mothers were invited to participate<br>Overall refusal rate=8.6%<br>Control group subjects were recruited from December 2000 through July 2001, while intervention group subjects were recruited from December 2001 to July 2002. | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 306 | | 264 | |
| **Mean Age** | | See comments below | | See comments below | |
| **Age Range** | **metric** | | | | |
| **Gestational Age:** | | Full term – not specified | | Full term – not specified | |
| **Range** | **metric:** | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **Baseline SES Measure:** | Maternal education level (years) | See comments below | | See comments below | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | SSC, one-time education and breastfeeding support at hospital | | | |
| **Duration of Followup (after the intervention stopped)** | | 16 weeks postpartum | | 16 weeks postpartum | |
| **Comments:** | Age and education level are presented after stratified by ethnicity (Jewish or Muslim), not by treatment. The mean maternal age for all women was 30.5 years old, and mean education was 10.7 years. | | | | |

**QUALITY ISSUES**

| **Method of randomization[i]** | **Adequate allocation concealment[ii] (Y/N/nd)** | **Intention to treat? (Y/N)** | **Outcome assessors blinded? (Y/N)** | **Loss to followup (%)** | **Were the results adjusted? (Y/N)** | **Were groups similar at baseline? (Y/N)** | **Recruitment method appropriate[iii]? (Y/N)** |
|---|---|---|---|---|---|---|---|
| N | N | Y | N | 19% | Y | Y | ND |

| | |
|---|---|
| **List the variables that were adjusted for:** | Previous BF experience, postpartum smoking, BF education |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | Authors did not state how they choose what variables to adjust, but reported what variables are "significant" in the model. The adjusted results were not reported. |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| **Outcome** | **Definition** | **BF promotion** | | | **Control** | | | **Unadjusted** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **No. Analyzed** | | **No. Events** | **No. Analyzed** | | **No. Events** | **OR** | **95% CI** | **P between** |
| | | **Individual** | **Group** | | **Individual** | **Group** | | | | |
| **BF initiation rate** | Not defined | 306 | | 101+201=302 (98.69%) | 264 | | 88+154=242 (91.67%) | | | |
| **BF initiation rate** | Initiate BF within 0-4 hours after birth | 306 | | 29+87=116 (37.91%) | 264 | | 11+49=60 (22.72%) | | | |
| **Overall BF at 10 weeks** | Any amount of breastfeeding | 306 | | 132+94=226 (73.86%) | 264 | | 91+90=181 (68.56%) | | | |

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| **Exclusive BF at 10 weeks** | No nutritional food supplements or liquids except vitamin and mineral supplements within the past 24 hours | 306 | | 95+28=123 (40.20%) | 264 | | 51+19=70 (26.52%) | | | |
| **Overall BF at 16 weeks** | Any amount of breastfeeding | 306 | | 113+87=200 (65.36%) | 264 | | 67+90=157 (59.47%) | | | |
| **Exclusive BF at 16 weeks** | No nutritional food supplements or liquids except vitamin and mineral supplements within the past 24 hours | 306 | | 65+16=81 (26.47%) | 264 | | 29+4=33 (12.5%) | | | |

| | |
|---|---|
| **Results Comments** | Data are calculated by compiling data from different tables.<br>Results of BF initiation rates and BF within 0-4 hours are from Chertok 2006, while results of BF rates at 10 weeks and 16 weeks are from Chertok 2004. |

| APPLICABILITY | | QUALITY | |
|---|---|---|---|
| Healthy Jewish and Muslim women post-cesarean section | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Enrolled only 49% of eligible population, conducted in one hospital only in Israel | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | 19% lost to follow-up. Control group was recruited during different time periods. Adjusted results were not reported<br>Recruitment of subjects depended on availability of interviewer. | |

**Evidence table for Systematic Reviews of Breastfeeding Promotion**

| Author, Year Title | Britton, 2006 Support for breastfeeding mother |
|---|---|
| Literature search (Dates) | Medline (1966 to November 2005); Other databases searched? (yes); unpublished data used? (no) |
| Countries where primary studies conducted | No country restriction, including developed and developing countries<br>Included studies are from 14 countries: Canada, USA, UK, Brazil, Bangladesh, Australia, India, Nigeria, Italy, Iran, the Netherlands, Belarus, Mexico, and Sweden |
| Study eligibility / inclusion criteria | • Randomized or quasi-randomized controlled trials, with or without blinding, and with a minimum of 75% follow up<br>• Pregnant or postpartum women intending to breastfeed, or women breastfeeding their babies<br>• Postnatal and/or antenatal Intervention/support that was offered by either professional or volunteer to an individual or individuals which is supplementary to standard care with the purpose of facilitating continued breastfeeding<br>• Excluded studies with intervention that occur only in antenatal period<br>• Excluded studies with intervention that is only educational. |
| Study design [No. Of studies] | 34 trials were included |
| No. of subjects | 29,385 mother-baby pairs |
| Study population (definition in included studies) | Pregnant women who plan to breastfeed, or currently lactating women |
| Intervention/Exposure (definition in included studies) | Additional breastfeeding support by health professionals (medical personnel, nursing staff, allied health professionals), and/or lay people |
| Comparator (definition in included studies) | Routine maternity care at the time of studies |
| Outcomes (definition in included studies) | • Rate of partial or exclusive breastfeeding of various time points (2 weeks to 1 year after birth).<br>• Duration of breastfeeding<br>• Neonatal and infant morbidity<br>• Maternal satisfaction with care or feeding method |
| Heterogeneity assessments | There was heterogeneity in all groups of studies categorized by type of interventions as indicated by $I^2$ test |
| Quality assessments | 15 of the 34 included studies used adequate allocation concealment<br>Drop out rate<br>Statistical analysis used<br>Blinding<br>Intention to treat analysis |
| Publication bias assessments | No data |
| Statistical Analysis or meta-analytic methods | Random-effects models |
| Results | • Any breastfeeding support intervention increases breastfeeding duration up to 6 months (RR of stopping BF: 0.91, CI: 0.86-0.96).<br>• Any breastfeeding support intervention increases breastfeeding rate among areas with intermediate breastfeeding initiation rate (RR of stopping BF: 0.92, CI: 0.85-0.98), but not in areas with low or high breastfeeding initiation rates. |

| Author, Year Title | Britton, 2006 Support for breastfeeding mother |
|---|---|
| | • Professional breastfeeding support increases any breastfeeding at only 4 months (RR of stopping BF: 0.78, CI: 0.67-0.91), and increases exclusive breastfeeding up to 3 months.<br>• Lay support is effective in increasing any breastfeeding (RR of stopping BF: 0.86, CI: 0.76-0.98) and exclusive breastfeeding (RR of stopping BF: 0.72, CI: 0.57-0.90) before last study assessment<br>• Combined professional and lay support reduces breastfeeding termination (RR of stopping BF: 0.84, CI: 0.77-0.92).<br>• Face-to-face support is effective in decreasing breastfeeding termination (RR of stopping BF: 0.85, CI: 0.79-0.92) but telephone support is not (RR of stopping BF: 0.92, CI: 0.78-1.08).<br>• Postnatal support is effective in decreasing breastfeeding termination (RR of stopping BF: 0.89, CI: 0.84-0.96) but antenatal support is not (RR of stopping BF: 0.92, CI: 0.83-1.02).<br>• In three studies, recurrence of infant diarrhea is decreased (RR: 0.70, CI: 0.54-0.9). (comparing what groups?) |
| Author's interpretations of the results | All forms of support increases breastfeeding duration<br>Lay support and combined lay/professional support increase exclusive breastfeeding duration.<br>Recommend face-to-face support rather than telephone intervention |
| Quality | Fair |

| Author | Coutinho | Year | 2005 | UI | 16182897 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Brazil | Y | 2001 | Government |

| | | | | |
|---|---|---|---|---|
| **Type (Description) of BF promotion intervention** | BFHI plus 10 postnatal home visits by trained hospital staff | | | |
| **Who implemented the BF promotion intervention?** | Community health agents or recruited staff | | | |
| **Comparator (Description)** | BFHI only | | | |
| **Inclusion Criteria** | Singletons, ≥ 2500g | **Exclusion Criteria** | Serious disease in infants or mothers, planning to leave the area within 6 mo | |
| **Other Population Description** | Recruited from urban areas and 3 neighboring small towns | **Setting** | Hospital and home | |
| **Comments** | Usual stay is 24 h after vaginal delivery, and 48 h after c-section; strong traditions of giving water and tea from birth, and early introductions of milk and pacifiers | | | |

| CHARACTERISTICS | | BFHI + home visits | | BFHI (in hospital only) | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 175 | | 175 | |
| **Maternal age <20 y** | | 52% | | 64% | |
| **Age Range metric** | | | | | |
| **Gestational Age:** | | ≥ 2500g | | ≥ 2500g | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | <0.5 minimum wage | 107 | | 102 | |
| **Mother literate (yes)** | | 132 | | 131 | |
| **Duration of BF promotion** | | 10 visits | | | |
| **Duration of Followup (after the intervention stopped)** | | 6 mo | | 6 mo | |
| **Comments:** | | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Random number table | Y | Y | Y | 6% | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BFHI + home | | | BFHI (in hospital only) | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **Exclusive BF initiation rate** | Assessed in the maternity ward (day 1) | 161 | | 70% | 169 | | 70% | | | | | | |
| **Exclusive BF at 1 mo** | estimated from Fig 2 | | | 15% | | | 65% | | | | | | |
| **Exclusive BF at 3 mo** | estimated from Fig 2 | | | 45% | | | 10% | | | | | | |
| **Exclusive BF at 6 mo** | estimated from Fig 2 | | | 25% | | | 4% | | | | | | |
| **Aggregate exclusive BF rate days 10-180** | | | | 45% | | | 13% | | | <0.0001 | | | |

| Outcome | Definition | BFHI + home | | | BFHI (in hospital only) | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **Aggregate Ever BF rate days 10-180** | | | | 78% | | | 62% | | | <0.0001 | | | |
| **Results Comments** | Proportion of SES "better-off" mothers (P=0.02) and better-educated mothers (P=0.01) who breastfed exclusively at 1 mo were higher than "poorer" or less educated mothers. | | | | | | | | | | | | |

| APPLICABILITY | | QUALITY | |
|---|---|---|---|
| Usual postpartum stay is 24 h after vaginal delivery | **Study characteristics that one is likely to encounter in US primary care** | x | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Widespread poverty, high infant mortality rate, maternal illiteracy rate of ~30%, strong traditions of giving water and tea from birth | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |

Dulon, 2003 UI 12856972 (see also Kersting 2002, UI 12186663 for supplementary information)

| Study characteristics | Study design and follow-up duration | Eligibility criteria | Breastfeeding promotion Interventions | Control Interventions |
|---|---|---|---|---|
| Mean age (range):<br>91% ≥ 25<br>Mean GA (range):<br>≥ 37<br>Eligible/Enrolled mothers:<br>3,294/1,487<br>Location:<br>Germany<br>Sites: Multi<br>Funding:<br>government | Observational cohort, a prospective cohort; random sample of 360 hospitals in Germany were drawn; hospitals were rated by breastfeeding promotion index (low (≤ 5) or high (>5) using 10 indicators similar to Baby Friendly 10 steps); mother's full breastfeeding status was assessed at 4 months (only breast milk, no other foods except for vitamins or meds) | BW≥ 2,500 g; GA ≥ 37 wk; no admittance to NICU; familiar with German language; has phone at home | Hospitals with high breastfeeding promotion index (>5) | Hospitals with low breastfeeding promotion index (≤5) |

| Outcome Definition | Statistical analyses and confounders adjusted | Results | Bias/limitations Comments |
|---|---|---|---|
| Short-term: < 4 mo; long-term: ≥ 4 mo full BF<br><br>Full BF: exclusive and predominant BF (non-nutritive fluids allowed)<br><br>Women were prospectivel6y followed for the breastfeeding duration. | Age, education, area of upbringing (East vs. West Germany), breastfeeding promotion index, hospital size, geographic location of hospital (East vs. West Germany);<br>Bivariate associations between categorical variables analyzed using contingency tables, chi2 statistics and phi coefficient. Unit of analysis: mother | 17/360 hospitals and 1,487/3,294 mothers in final analysis;<br><br>Median breastfeeding promotion index was 5 index points (fulfilled 5 of 10 steps); 12 hospitals (6.8%) >7 index points; 1 hospital (0.6%) achieved the maximum of 10 index points<br><br>Adj OR of increased risk of short-term BF in a hospital with low BF promotion index: 1.24 (95%CI 0.99 – 1.55);<br>Associations of short-term BF with maternal age < 25, low education level (discrepancy between table 4 and text), and upbringing in East Germany, were stronger. | A: strong, B: moderate, C: weak / A / B / C<br>Selection / / x /<br>Study design / / / x<br>Confounder / / x /<br>Blinding / / x /<br>Data collection / / x /<br>Withdraw and dropout / / x /<br>Analyses / / x /<br>Low enrollment rate; self-selection bias |

**Applicability**

| | |
|---|---|
| **Study characteristics that one is likely to encounter in US primary care** | Large hospitals, low number of BFHI-certified hospitals in Germany, comparable to US (1.8% vs. 1.3%, see www.babyfriendly.org) |
| **Study characteristics that may limit the applicability to a US primary care population** | Typical postpartum stay of 5 days, BF interaction with specific geographic location (former East vs. West Germany) |
| **Overall assessment of applicability to US primary care (wide or narrow)** | Narrow |

| Author | Ekstrom | Year | 2006 | UI | 16732777 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| Quasi-RCT (centers or caregivers were randomized) | Sweden | Y | September 1999 to March 2000 (the intervention training) April 2000 and June 2002 (the follow-up period) | University |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Process-oriented program on breastfeeding counseling for health professionals and continuity in family classes through childbirth: lectures on breastfeeding management and promotion, counseling skills and personal breastfeeding experience | | |
| **Who implemented the BF promotion intervention?** | health professionals | | |
| **Comparator (Description)** | Standard routine care: family classes through the point of birth | | |
| **Inclusion Criteria** | Swedish-speaking mothers who gave birth to singleton, healthy, full-term babies delivered spontaneously, by vacuum extraction, or by cesarean section. | **Exclusion Criteria** | Mothers who had given birth to babies with life-threatening diseases or malformations |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 206 | | 172 | |
| **Mean Age** | | 26.6 | | 27.0 | |
| **Age Range metric** | | | | | |
| **Gestational Age:** | weeks | 40.4 | | 40.4 | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | High school<br>University | 37%<br>36% | | 41%<br>36% | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | "7 sessions" | | | |
| **Duration of Followup (after the intervention stopped)** | | 9 months postpartum | | 9 months postpartum | |
| **Comments:** | There were 2 control groups in the study. Data collection for control group A started before the intervention; that for control group B was collected simultaneously with data collection for the intervention group. Therefore, only control group B was reviewed for the purpose of our report. | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Randomized pairwise. Centers were matched in pairs that were similar in size and had similar figures of breastfeeding duration. | Y | N | ND | ND (can be as high as 33%) | N | Y | Y |
| **List the variables that were adjusted for:** | None | | | | | | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y | | | | | | |
| **Comments** | Incomplete reporting for breastfeeding outcomes. Based on the sample sizes reported for other outcomes, only 145 and 132 subjects provided 3-month follow-up data in the intervention and control group, respectively. Only 131 (64%) and 125 (73%) subjects provided 9-month follow-up data in intervention and control group, respectively. | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **BF initiation rate** | Not described | 206 | | 100% | 172 | | 97% | | | NS | | | |

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| **Exclusive BF duration** | breastmilk only but including some babies received supplementary feeding with formula during the first week of life (months) | **BF promotion** | ND | | 3.9 | 2.2 | | NS |
| | | **Control** | ND | | 3.5 | 2.0 | | |
| **Any BF duration** | Exclusive and partial breastfeeding | **BF promotion** | ND | | 7.5 | 4.7 | | NS |
| | | **Control** | ND | | 7.0 | 4.5 | | |
| **Results Comments** | The intervention group mothers perceived that they received better breastfeeding information and better breastfeeding support than control group mothers.<br>There was no significant difference in perceived emotional support at the antenatal clinic between intervention group mothers and control group mothers. | | | | | | | |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Large municipalities, majority had either high school or college education | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Very high background breastfeeding initiation rate (~100%) | **Study characteristics that may limit the applicability to a US primary care population** | x | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Incomplete reporting; differential rates of lost to followup between the intervention and the control groups; high lost to followup rates; unclear if the outcome assessors were blinded. | |

| Author | Finch | Year | 2002 | UI | 12146564 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | US | N | ND | ND |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Breastfeeding education with incentives for exclusive breastfeeding. Incentive marketing in the form of a truth or myth activity; followed by instruction and discussion accompanied by handouts. | | |
| **Who implemented the BF promotion intervention?** | A trained counselor | | |
| **Comparator (Description)** | Usual prenatal education regarding general benefits and barriers to breastfeeding. | | |
| **Inclusion Criteria** | Urban WIC participants who were English speaking, pregnant, and HIV negative | **Exclusion Criteria** | ND |
| **Other Population Description** | Poverty, primary African-American and Hispanic; 25% were 18 years old or younger | **Setting** | WIC |
| **Comments** | Women who exclusively breastfed, or did not receive formula, were eligible to receive a food package valued at more than $50 per month. Mothers who exclusively breastfed for >2 months were also eligible to receive a $25 mall gift certificate. These incentives were provided to both groups. | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 30 | | 30 | |
| **Mean Age** | | ~20 | | ~22 | |
| **Age Range metric** | | | | | |
| **Gestational Age:** | | ND | | ND | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | NY WIC program serving a mostly minority population with the highest poverty level in the city | 100% | | 100% | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | ND | | | |
| **Duration of Followup (after the intervention stopped)** | | 2 months postpartum | | | |
| **Comments:** | 11 participants were lost from the intervention group: 3 due to miscarriage or infant death, 1 due to relocating, the remaining lost due to not attending the intervention. | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| N | N | N | ND | 37% | N | Y (presumed) | ND |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Yes |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF education | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **BF initiation rate** (determined at WIC infant enrollment by interview plus medical documentation) | Exclusive | 19 | | 9 (47%) | 29 | | 5 (17%) | | | 0.025 | | | |
| | Partial | | | 6 (32%) | | | 15 (52%) | | | NS | | | |
| | None | | | 4 (21%) | | | 9 (31%) | | | NS | | | |

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | | No. Analyzed | | Final | Range | Net difference | P between |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Individual | Group | | | | |
| **BF duration** | Median breastfeeding duration at 2 months (weeks) | **BF education** | **Exclusive** | 9 | | 12 | 7-12 | N/A | 0.017 |
| | | | **Partial** | 6 | | 5 | 1-12 | | 0.088 |
| | | | **All subjects** | 19 | | 12 | 0-12 | | NS |
| | | **Control** | **Exclusive** | 5 | | 12 | 5-12 | | |
| | | | **Partial** | 15 | | 12 | 1-12 | | |
| | | | **All subjects** | 29 | | 5 | 0-12 | | |

| | |
|---|---|
| **Results Comments** | Most women in the study indicated they valued at least one of the incentives. In the intervention group, 16 of 18 (88%) listed at least one of the suggested incentives as having value compared with 23 of 29 (79%) control group participants. There were no significant differences in the types of incentives chosen. |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Primarily African-American and Hispanic; 25% were 18 years old or younger, urban WIC program participants | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| 37% in intervention did not complete study | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Wide | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Incomplete data reporting. High dropout rate in intervention group (37%). Subjects were followed for 2 months postpartum. However, median BF duration is more than 2 months. It is unclear how investigators obtained those data. | |

| Author | Forster | Year | 2004 | UI | 15330879 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Australia | N | May 1999 to August 2001 | Government and organization |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Intervention 1 (Practical Skills): Single session of 1.5 hours that focused on practical breastfeeding skills, such as the technique of attachment of the baby to the breast ("latching-on"). Partners were not included. Intervention 2 (Attitudes): Two 1-hour sessions that focused on changing attitudes to breastfeeding. Partners were encouraged to join. | | |
| **Who implemented the BF promotion intervention?** | Midwives and a community educator with specific training in childbirth education. Lactation consultant qualifications were not required. | | |
| **Comparator (Description)** | Control group: Women could access the standard care, which included formal breastfeeding education sessions; breastfeeding information as a component of standard childbirth education courses; lactation consultant support as necessary (inpatient and outpatient); peer support by means of community breastfeeding groups; optional attendance at a breastfeeding information evening; any videos or education on breastfeeding presented in the postnatal ward; 24-hour telephone counseling support; and a postnatal home visit by a domiciliary midwife. | | |
| **Inclusion Criteria** | Public patients; having a first child; between 16 and 24 weeks pregnant at time of recruitment; and able to speak, read, and write in English. | **Exclusion Criteria** | Physical problems that prevented breastfeeding, and choosing birth center or private obstetric care. |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | Recruitment was in the ultrasound department when women attended for their mid-trimester scan, at 18 to 20 weeks. | | |

| CHARACTERISTICS | | Breastfeeding promotion | | | Control | |
|---|---|---|---|---|---|---|
| | | Individual level | | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| | | Practical Skills | Attitudes | | | |
| **No. Enrolled** | | 327 | 327 | | 327 | |
| **Mean Age** | | 28.0 | 28.2 | | 28.7 | |
| **Age Range** **metric** | | | | | | |
| **Gestational Age:** | | ND | ND | | ND | |
| **metric:** **Range** | | | | | | |
| **Baseline SES Measure:** | Completed secondary school | 71.1% | 75.5% | | 78.7% | |
| | Pension/benefit primary family income | 14.6% | 16.0% | | 7.2% | |

| CHARACTERISTICS | Breastfeeding promotion | | | Control | |
|---|---|---|---|---|---|
| | Individual level | | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| | Practical Skills | Attitudes | | | |
| **Duration of BF promotion** | Single session of 1.5 hours | Two 1-hour sessions | | | |
| **Duration of Followup (after the intervention stopped)** | 6 months after birth | | | 6 months after birth | |
| **Comments:** | Of the women allocated to the intervention 1 (Practical Skill), 3 were not eligible to attend the class (1 miscarriage, 1 termination, and 1 birth before the class date). Attendance was 213/324 (66%).<br>Of the women allocated to the intervention 2 (Attitudes), 4 were not eligible to attend (births took place before class dates). Attendance was 190/323 (59%) at the first class and 132/323 (41%) at the second. | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| A computerized system of biased urn randomization | N | N | ND | 7% | Y | Y | Y |
| **List the variables that were adjusted for:** | Income, smoking before pregnancy, and education | | | | | | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Yes | | | | | | |
| **Comments** | Attendance of the interventions was low. | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF education | | | | Control (Standard Care) | | | Unadjusted / Adjusted (if noted) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | | No. Analyzed | | No. Events | OR | 95% CI | P between |
| | | Practical Skills | Attitudes | Practical Skills | Attitudes | Individual | Group | | | | |
| **BF initiation rate**<br><br>*Exclude baby not feeding yet | Interview 2-4 days after birth | 306 | 308 | | | 310 | | | | | |
| | - Breastmilk only (breastmilk is the only nutritional intake, either breast or expressed) | | | 238 (77.8%) | 239 (77.6%) | | | 242 (78.1%) | P/S* =0.98<br><br>A/S* =0.97 | 0.67-1.44<br><br>0.66-1.42 | NS<br><br>NS |
| | - Any breastmilk (mixed breastmilk and formula used) | | | 296 (96.7%) | 291 (94.5) | | | 297 (95.8%) | P/S* =1.30<br><br>A/S* =0.75 | 0.56-3.00<br><br>0.36-1.57 | NS<br><br>NS |
| | - Baby not feeding yet | | | 2 | 4 | 3 | | | | | |
| **BF > 3 mo rate** | | | | | | | | | | | |
| **BF > 6 mo rate** | 6-month interview<br><br>- Exclusive breastfeeding up to 6 mo | 297 | 293 | 26 (8.8%) | 25 (8.5%) | 299 | | 22 (7.4%) | P/S* =1.20<br><br>A/S* =1.17 | 0.67-2.18<br><br>0.66-2.13 | NS<br><br>NS |
| | - Breastmilk only (breastmilk is the only nutritional intake, either breast or expressed, although this may include solids, water or juice) | | | 107 (36.0%) | 99 (33.7%) | | | 105 (35.1%) | Adj P/S* =1.19<br><br>Adj A/S* =1.06 | 0.83-1.70<br><br>0.74-1.52 | NS<br><br>NS |

| Outcome | Definition | BF education | | | | Control (Standard Care) | | | Unadjusted / Adjusted (if noted) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | | No. Analyzed | | No. Events | OR | 95% CI | P between |
| | | Practical Skills | Attitudes | Practical Skills | Attitudes | Individual | Group | | | | |
| | - Any breastmilk (mixed breastmilk and formula used, and may include solids, water or juice) | | | 162 (54.5%) | 146 (49.8%) | | | 162 (54.2%) | Adj P/S* =1.26 | 0.88-1.79 | NS |
| | | | | | | | | | Adj A/S* =1.03 | 0.73-1.46 | NS |

*P/S compared Practical Skills group with standard care. A/S compared Attitudes group with standard care.

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| BF duration | Mean duration at 26 weeks (weeks) | Practical Skills | 297 | | 19 | 9.3 | +1 | NS |
| | | Attitudes | 293 | | 17 | 10.2 | -1 | NS |
| | | Control (standard care) | 299 | | 18 | 9.7 | | |

| | |
|---|---|
| **Results Comments** | The breastfeeding initiation rate was high in the study population (78% In the standard care group).<br>Breastfeeding duration comparisons using survival analysis confirmed that there were no significant differences among the groups (log-rank test, p=0.28) |

| APPLICABILITY | | QUALITY | |
|---|---|---|---|
| Low income, culturally diverse, subjects recruited from public health system | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | x | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| 95% breastfeeding initiation rate; BFHI accredited hospital | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Attendance of the interventions was low: <66% | |

Gau, 2004 [UI#15050853]

| Study characteristics | Study design and follow-up duration | Eligibility criteria | Breastfeeding promotion Intervention | Control Intervention |
|---|---|---|---|---|
| Mean age (range): 31 (16-45)<br>Mean GA (range): 38.8 (28-34)<br>Enrolled/Evaluate: 4,614 / nd<br>Location: Taiwan<br>Sites: Multi<br>Funding: government | Non-randomized pre-post design at 7 hospitals | Any breastfeeding women | Lactation intervention program (Baby Friendly 10 steps) in hospital (> 9 in BF promotion index (maximum of 10 points in the index)) | 7 hospitals comparable in the number of births and hospital accreditation, and volume.<br>2 hospitals withdrew from the study because their caseload in the maternity department decreased gradually to zero. |

| Outcome Definition | Statistical analyses and confounders adjusted | Results | Bias/limitations Comments |
|---|---|---|---|
| Breastfeeding initiation rate and duration: including exclusive breastfeeding and mixed breastfeeding.<br><br>Exclusive BF: only breast milk from the mother or a wet nurse, or expressed breast milk, and no other liquids or solids with the exception of drops or syrups consisting of vitamins, mineral supplements, or medicine.<br><br>Mixed BF: breast milk ingested along with formula milk (regardless of the number of feedings). | Repeated measure ANOVA, ANCOVA and Pearson correlation coefficients | See table below.<br><br>Exclusive breastfeeding rate of the BFHI group was higher than that of the control group in hospital, at 2 weeks, 1 and 2 months postpartum (p<0.001).<br>Mixed breastfeeding rate was higher in the control group than that of the experimental group in hospital, at 2 weeks, 1 and 2 months postpartum (p<0.001). However, the overall breastfeeding rate was lower in the Control group.<br><br>BF rates increased year by year (P<0.001) from 2000 to 2002. | See table below. |

| | | 2000 | | 2001 | | 2002 | |
|---|---|---|---|---|---|---|---|
| | | BFHI | Control | BFHI | Control | BFHI | Control |
| | n | 1339 | 380 | 1144 | 568 | 869 | 313 |
| Exclusive BF rates in hospital | % | 34 | 22 | 46 | 23 | 50 | 23 |
| Exclusive BF 2 mo rate | % | 6 | 5 | 8 | 3 | 12 | 0 |

| A: strong, B: moderate, C: weak | A | B | C |
|---|---|---|---|
| Selection | | | x |
| Study design | | | x |
| Confounder | | | x |
| Blinding | | | |
| Data collection | | x | |
| Withdraw and dropout | | | x |
| Analyses | | | x |

**Applicability**

| | |
|---|---|
| **Study characteristics that one is likely to encounter in US primary care** | High education, full-time career mothers, maternity leave ~7 wk, active promotion of formula |
| **Study characteristics that may limit the applicability to a US primary care population** | |
| **Overall assessment of applicability to US primary care (wide or narrow)** | Wide |

| Author | Henderson | Year | 2001 | UI | 11903211 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Australia | N | June to September 1999 | ND |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Postpartum positioning and attachment education: One-to one standardized education session lasting 30 minutes. Main focus of the intervention was the technique of self-positioning and self-attachment by the woman and the cues she could use to determine that her technique was correct. | | |
| **Who implemented the BF promotion intervention?** | The principle investigator (a doctoral student in the School of Nursing and Midwifery) | | |
| **Comparator (Description)** | Usual postpartum breastfeeding care | | |
| **Inclusion Criteria** | First-time, English-speaking mothers who planned to breastfeed and had a singleton, term infant with an Apgar score of 7 more at 5 minutes | **Exclusion Criteria** | ND |
| **Other Population Description** | Usual postpartum breastfeeding care | **Setting** | Hospital |
| **Comments** | Both groups received the usual breastfeeding care provided by the hospital midwives.<br>184 eligible women approached, 160 consented and were randomized. | | |

| CHARACTERISTICS | | Breastfeeding education | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 80 | | 80 | |
| **Mean Age** | | 27.6 | | 27.2 | |
| **Age Range metric** | SD | 5.6 | | 5.7 | |
| **Gestational Age:** | | term | | term | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | College/University Education | 47% | | 52% | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | One-to one standardized education session lasting 30 minutes | | | |
| **Duration of Followup (after the intervention stopped)** | | 6 months postpartum | | | |
| **Comments:** | High education level | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Computer-generated balanced blocks of 20 in individually sealed opaque envelopes | Y | N | N | 6.25 | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | The principle investigator conducted the intervention and was aware of group allocation. She also conducted the pain assessment in hospital. |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| **BF at 6 weeks** | Self-report | 79 | | 60 (76%) | 79 | | 65 (82%) | 0.92 | 0.79-1.08 | NS |
| **BF at 3 mo** | Self-report | 78 | | 56 (72%) | 76 | | 57 (75%) | 0.96 | 0.79-1.16 | NS |
| **BF at 6 mo** | Self-report | 75 | | 42 (56%) | 75 | | 48 (64%) | 0.88 | 0.67-1.14 | NS |
| **Nipple Pain** | In Hospital - Day 1 | 79 | | 4 (5%) | 80 | | 7 (8%) | | | NS |
| | - Day 2 | 78 | | 31 (39%) | 79 | | 49 (62%) | | | 0.004 |
| | - Day 3 | 76 | | 39 (51%) | 74 | | 50 (68%) | | | 0.04 |
| | Self-reported - 6 wk | 79 | | 21 (30%) | 79 | | 19 (25%) | | | NS |

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| | - 3 mo | 78 | | 14 (18%) | 76 | | 12 (16%) | | | NS |
| | - 6 mo | 75 | | 9 (12%) | 75 | | 13 (17%) | | | NS |
| **Nipple Trauma (such as redness, peeling, blistering, bruising, bleeding, cracking, and scabbing)** | Self-reported - 6 wk | 79 | | 14 (17%) | 79 | | 16 (20%) | | | NS |
| | - 3 mo | 78 | | 11 (14%) | 76 | | 10 (13%) | | | NS |
| | - 6 mo | 75 | | 8 (11%) | 75 | | 11 (15%) | | | NS |

| | |
|---|---|
| **Results Comments** | Higher incidence of nipple trauma was observed in both groups in the first few days in hospital (data not reported). |

| APPLICABILITY | | QUALITY | |
|---|---|---|---|
| Postpartum stay 2 to 3 d, >95% completed secondary education | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | x | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Background breastfeeding initiation rates higher; midwives provide in-home followup to women who gave birth in the public health system; midwives provide postpartum care | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Researcher aware of group allocation and also assessed one of the outcomes. | |

| Author | Howard | Year | 2003 | UI | 12612229 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | US | N | 1997-1998 | Government |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Delayed pacifier use (>4 wk) (RCT) | | |
| **Who implemented the BF promotion intervention?** | Research nurse | | |
| **Comparator (Description)** | Pacifier use (days 2-5) | | |
| **Inclusion Criteria** | Intend to BF ≥ 4 wk; undecided about pacifier use, healthy infant with GA ≥ 36 wk | **Exclusion Criteria** | |
| **Other Population Description** | | **Setting** | |
| **Comments** | Supplemental feeding (non-randomized, but assignment to cup vs bottle was randomized) was also studied, data not summarized here | | |

| CHARACTERISTICS | Breastfeeding promotion | | Control | |
|---|---|---|---|---|
| | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | 346 | | 354 | |
| **Mean Age** | 29 | | 29 | |
| **Age Range metric** | | | | |
| **Gestational Age:** | ≥ 36 | | ≥ 36 | |
| **Range metric:** | | | | |
| **Education:** | 14.4 yr | | 14.4 | |
| **Range metric:** | | | | |
| **Duration of BF promotion** | Instruction while in hospital | | | |
| **Duration of Followup (after the intervention stopped)** | 52 wk | | | |
| **Comments:** | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Opaque envelope, blocks of 20 | y | y | y | 2% | y | y | y |

| | |
|---|---|
| **List the variables that were adjusted for:** | Predictors (Maternal race, previous births, maternal education…and others) with P ≤ 0.10 were retained plus intervention variables ( cup vs bottle supplement, early vs delayed pacifier) |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | Unclear which predictors were retained in the final adjusted model |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | 95% CI | Adj HR of stop BF | 95% CI | P between |
|---|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | | |
| **Exclusive BF** | No liquid or solid food besides breast milk (day) | **Early pacifier** | 354 | | 21 | 17-27 | 1.09 | 0.94-1.27 | NS |
| | | **Delayed pacifier** | 346 | | 28 | 25-30 | | | |
| **Full BF** | Infrequent use of other liquids (day) | **Early pacifier** | 354 | | 52 | 42-60 | 1.04 | 0.89-1.21 | NS |
| | | **Delayed pacifier** | 346 | | 49 | 42-63 | | | |
| **Ever BF duration** | day | **Early pacifier** | 354 | | 140 | 120-157 | 1.22 | 1.03-1.44 | 0.02 |
| | | **Delayed pacifier** | 346 | | 163 | 140-180 | | | |

| APPLICABILITY | QUALITY |
|---|---|

| | | | |
|---|---|---|---|
| Primarily white, well-educated, married, 77% employed, wished to use or were undecided about pacifiers | **Study characteristics that one is likely to encounter in US primary care** | **x** | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Wide | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | |

Johnston, 2006 (6 mo data) UI 16894077; Johnston, 2004 (3 mo data) UI 15110063

| Study characteristics | Study design and follow-up duration | Eligibility criteria | Breastfeeding promotion Interventions | Control Interventions |
|---|---|---|---|---|
| Maternal age: 32.5 (HS), 30.9 (UC)<br>Mean GA (range): nd<br>Mean BW (range): nd<br>% Male: 52% (HS); 56% (UC)<br>Enrolled/Evaluate: 439/343<br>Location: US<br>Sites: Multi<br>Funding: Kaiser Foundation | Non-randomized comparative: usual care (UC) vs. Healthy Steps (HS), postnatal intervention, with or without PrePare (prenatal intervention); this was determined by randomization<br>Followup until 30 months by phone<br>Population from 5* outpatient clinics in a large HMO, subjects generally were well-educated, middle-income parents.<br>2 clinics were assigned UC; 3 clinics were assigned HS.<br>Enrollment between 7/1998 and 9/2000<br><br>*discrepancy between 2004 and 2006 papers, former reported 4 clinics, latter reported 5 clinics | <22 wk GA at enrollment, <45 yr, English speaking | Healthy Steps (HS), postnatal intervention, with or without PrePare (prenatal intervention) | Usual care |

<table>
<tr><th>Outcome Definition</th><th>Statistical analyses and confounders adjusted</th><th>Results</th><th>Bias/limitations Comments</th></tr>
<tr>
<td>BF initiation; any BF at 3 mo; any BF > 6 mo; total duration of BF</td>
<td>Baseline significant difference between maternal education (higher education 93% (HS) vs. 85% (UC)) and age (32.5 (HS) vs 30.9 (UC)).<br><br>For 6 mo: Maternal education, family income, status as a first-time parent<br>For 3 mo: maternal age, education, family income, paternal education, number of years in health plan, maternal race, child's actual age in weeks0</td>
<td>91 in usual care (UC); 232 in HS (HS)
<table>
<tr><th></th><th>HS (unadjusted)</th><th>UC (unadjusted)</th><th>Adjusted estimates (95%CI)</th></tr>
<tr><td>BF initiation</td><td>97%</td><td>91%</td><td>RR 1.06 (1.00 to 1.11)</td></tr>
<tr><td>BF at 3 mo</td><td>91%</td><td>76%</td><td>RR 1.14 (1.09 to 1.20)</td></tr>
<tr><td>Duration > 6 mo</td><td>82%</td><td>64%</td><td>RR 1.18 (1.11 to 1.26) P<0.05</td></tr>
<tr><td>Total duration</td><td>13.4 mo</td><td>11.2 mo</td><td>Adjusted β 1.30 (0.18 to 2.43)</td></tr>
</table>
No difference was found between the HS group without PrePare vs. HS with PrePare group (RCT part of the study).<br>Nonrespondents at 30 mo had less education and lower family incomes compared with respondents.<br>At 30 mo, 24% dropout in UC, 21% dropout in HS.<br>Mothers in intervention reported less mental health symptoms (14.2% vs. 17.5%, adj RR 0.61; 95%CI 0.49, 0.76), less depression (adj β: -0.59; 95%CI –0.98, -0.19), lower proportion with CES-D score > cutoff (6.6% vs. 12.5%; adj RR 0.42; 95%CI 0.25, 0.71)<br>Infants at 24 mo, language development did not differ between groups (combining ≥2 words, sometimes/often vs no; adj RR 1.02; 95%CI 0.94, 1.12).</td>
<td>
<table>
<tr><th>A: strong, B: moderate, C: weak</th><th>A</th><th>B</th><th>C</th></tr>
<tr><td>Selection</td><td></td><td>x</td><td></td></tr>
<tr><td>Study design</td><td></td><td></td><td>x</td></tr>
<tr><td>Confounder</td><td></td><td>x</td><td></td></tr>
<tr><td>Blinding</td><td></td><td></td><td>x</td></tr>
<tr><td>Data collection</td><td></td><td>x</td><td></td></tr>
<tr><td>Withdraw and dropout</td><td></td><td></td><td>x</td></tr>
<tr><td>Analyses</td><td></td><td>x</td><td></td></tr>
<tr><td>Intervention integrity</td><td></td><td>x</td><td></td></tr>
</table>
Unclear how the clinics got the initial assignments (HS vs. UC).
</td>
</tr>
</table>

<table>
<tr><th colspan="3">APPLICABILITY</th><th colspan="2">QUALITY</th></tr>
<tr><td colspan="2" rowspan="2">Large health maintenance organization, all subjects have prenatal care, well-educated, middle income</td><td rowspan="2">Study characteristics that one is likely to encounter in US primary care</td><td></td><td>A Good quality: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT.</td></tr>
<tr><td></td><td>B Fair quality: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study.</td></tr>
<tr><td colspan="2"></td><td>Study characteristics that may limit the applicability to a US primary care population</td><td>x</td><td>C Poor quality: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors.</td></tr>
<tr><td rowspan="2">Wide</td><td colspan="2" rowspan="2">Overall assessment of applicability to US primary care (wide or narrow)</td><td colspan="2">If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)</td></tr>
<tr><td colspan="2">Unclear how group assignments were made</td></tr>
</table>

| Author | Kramer | Year | 2001 | UI | 11242425 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| Cluster-RCT (subjects clustered within centers/areas were randomized) | Belarus | Y | 1996-1998 | Government, UNICEF, WHO |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Modeled on BFHI; chief obstetrician and chief pediatrician received the BFHI 18h course; full implementation required 12 to 16 mo | | |
| **Who implemented the BF promotion intervention?** | Chief obstetrician and chief pediatrician started the intervention | | |
| **Comparator (Description)** | Standard care | | |
| **Inclusion Criteria** | Intention to BF; healthy infant ≥ 37 wk, ≥ 2,500g, Apgar ≥ 5 | **Exclusion Criteria** | |
| **Other Population Description** | | **Setting** | |
| **Comments** | | | |

| CHARACTERISTICS | Breastfeeding promotion | | Control | |
|---|---|---|---|---|
| | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | 8,865 | 16 | 8,181 | 15 |
| **Mean Age** | 14% <20<br>81% 20-34<br>4.2% >=35 | | 13.5% <20<br>82.3% 20-34<br>4.5% >=35 | |
| **Age Range metric** | | | | |
| **% Male** | | | | |
| **Gestational Age:** | 39.4 | | 39.3 | |
| **Range metric:** | | | | |
| **Baseline SES Measure:** | | | | |
| **Range metric:** | | | | |
| **Duration of BF promotion** | | | | |
| **Duration of Followup (after the intervention stopped)** | 8,547 (12 mo) | | 7,895 (12 mo) | |
| **Comments:** | Original 34 sites; 2 refused to participate after randomization; 1 site excluded (falsified data) | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Random number table | N | Y | N | 3% | Y | Y | Y |
| **List the variables that were adjusted for:** | Birth weight, maternal age, history of BF previous infant ≥ 3 mo, number of children in household, maternal smoking, family atopic history | | | | | | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Yes. Stratification, multivariate modeling of group- and individual-level covariates | | | | | | |
| **Comments** | 20 charts were audited from each site: GI, respiratory tract infection, data on BF at 3 mo | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **Any BF at 3 mo** | | 8547 | | 72.7% | 7895 | | 60% | | | | 0.52 | 0.40-0.69 | |
| **Any BF at 6 mo** | | | | 49.8% | | | 36.1% | | | | 0.52 | 0.39-0.71 | |
| **Exclusive BF at 3 mo** | | | | 43.3% | | | 6.4% | | | P<0.001* | | | |
| **Exclusive BF at 6 mo** | | | | 7.9% | | | 0.6% | | | P=0.01* | | | |
| **Infant health outcomes** | ≥1 GI infection | | | 9.1% | | | 13.2% | | | | 0.60 | 0.40-0.91 | |
| | ≥2 respiratory infection | | | 39.2% | | | 39.4% | | | | 0.87 | 0.59-1.28 | |
| | Atopic dermatitis | | | 3.3% | | | 6.3% | | | | 0.54 | 0.31-0.95 | |

| | |
|---|---|
| **Results**<br>**Comments** | Weight in intervention group exceeded that of control through first 3 mo, then declined somewhat, and then the difference disappeared by 12 months (see UI 12165588)<br>*Unadjusted results because the GLIMMIX modes did not converge and could lead to unreliable estimates of adjusted ORs. Used unpaired t tests for estimates. |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Sanitary water supply, wide-availability of basic health services | **Study characteristics that one is likely to encounter in US primary care** | **x** | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Prolonged postpartum stay, prolonged maternity leave, no day care, and expensive formulas | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | |

| Author | Kramer | Year | 2001 | UI | 11466098 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Canada | N | 1998-1999 | Government |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Counseling intervention to discourage pacifier use. | | |
| **Who implemented the BF promotion intervention?** | Trained nurse | | |
| **Comparator (Description)** | Control intervention including pacifier to sooth the infant | | |
| **Inclusion Criteria** | Mom intend to BF ≥ 3 mo; ≥ 37wk; ≥ 2,500g | **Exclusion Criteria** | |
| **Other Population Description** | | **Setting** | In hospital and by phone |
| **Comments** | Both groups received usual counseling, including positioning, the importance of frequent feeding and feeding on demand, the avoidance of formula and other liquids, the management of sore nipples and breast engorgement, and provided the telephone numbers of persons and agencies whom the mother could call for answers to questions, help with difficulties, and general support | | |

| CHARACTERISTICS | | Discourage Pacifier use | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 140 | | 141 | |
| **Mean Age** | | 31.6 (SD4.5) | | 31.5 (SD3.2) | |
| **Age Range metric** | | | | | |
| **Gestational Age:** | | ≥ 37 wk | | ≥ 37 wk | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | Education (year) | 16.1 | | 16.0 | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | 45 min | | | |
| **Duration of Followup (after the intervention stopped)** | | 3 mo | | | |
| **Comments:** | | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Computer generated blocks of 4 | Y | N | Y | 8% | Y | Y (small baseline differences in marital status and smoking.) | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | Marital status, smoking |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | Discourage Pacifier use | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **Avoided pacifier use** | | 127 | | 38.6% | 131 | | 16% | 2.4 (RR) | 1.5-3.8 | | | | |
| **Stopped exclusive BF by 3 mo** | | 127 | | 63.8% | 131 | | 66.4% | 1.0 (RR) | 0.8-1.1 | | | | |
| **Weaning by age 3 mo** | | 127 | | 18.9% | 131 | | 18.3% | 1.0 (OR) | 0.6-1.9 | | 1.0 (OR) | 0.5-1.9 | |

| | |
|---|---|
| **Results Comments** | Observational analysis: 25% of infants with daily pacifier use vs. 12.9% of infants without daily pacifier use stopped BF by 3 mo. "Pacifier use is a marker of breastfeeding difficulties or reduced motivation to breastfeed, rather than a true cause of early weaning." |

| APPLICABILITY | | | QUALITY | |
|---|---|---|---|---|
| Multicultural (67% English speaking), well-educated, working mothers (76%) | | **Study characteristics that one is likely to encounter in US primary care** | **x** | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| | | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Wide | **Overall assessment of applicability to US primary care (wide or narrow)** | | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | | |

| Author | Labarere | Year | 2003 | UI | 14511968 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | France | N | October to late December 2001 | ND |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | One-to-one educational session (during hospital stay): feeding positions, importance of feeding on demand, avoidance of formula and pacifier, management of sore nipple and breast engorgement and opportunities for prolonging lactation after returning to work. | | |
| **Who implemented the BF promotion intervention?** | 3 midwives and 1 female intern of the maternity ward staff | | |
| **Comparator (Description)** | Usual care: usual verbal encouragement to maintain breastfeeding provided by the maternity staff. | | |
| **Inclusion Criteria** | In-hospital breastfeeding mothers, 18 years of age or older, speak French, were employed outside of the home parentally, and were delivered of a healthy singleton of >37 weeks of gestational age and of 2500 g birthweight. One mother per room. | **Exclusion Criteria** | Transferred to the intensive care unit, or infants died during the stay |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | In France, the paid maternity leave is 6 weeks before giving birth and 10 weeks after. On the birth of the 3rd child, the paid maternity leave is increased to 8 weeks before and 18 weeks after the birth. | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 106 | | 106 | |
| **Mean Age** | | 30.5 | | 30.9 | |
| **Age Range metric** | SD | 4.6 | | 4.2 | |
| **Gestational Age:** | | 39.9 | | 40.1 | |
| **Range metric:** | SD | 1.2 | | 1.2 | |
| **Baseline SES Measure:** | Partial/complete university education | 57% | | 60.8% | |
| | White collar | 88.2% | | 81.4% | |
| **Duration of BF promotion** | | 30 minutes | | | |
| **Duration of Followup (after the intervention stopped)** | | 17 weeks postpartum | | | |
| **Comments:** | This is open trial | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Computer-generated random numbers in blocks of eights | Y (sealed opaque envelopes opened after consent) | Y | Y | 9.5 | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **Self-reported breastfeeding at 17 weeks** | As receipt by the infant of any breast milk within the 24 hours preceding the completion of the questionnaire | 93 | | 32 (34.4%) | 97 | | 39 (40.2%) | 0.86 | 0.52-1.40 | | | | |
| **Self-reported exclusive breastfeeding at 17 weeks** | Giving maternal milk as the only food source since the birth, with no other liquids (other | 93 | | 13 (14.0%) | 97 | | 14 (14.4%) | 0.97 | 0.42-2.22 | | | | |

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| | than vitamins or medications) or food given | | | | | | | | | | | | |
| **Breastfeeding difficulties** | | 93 | | 41 (44.1%) | 97 | | 51 (52.6%) | 0.84 | 0.54-1.29 | | | | |

| | |
|---|---|
| **Results Comments** | |

| APPLICABILITY | | QUALITY | |
|---|---|---|---|
| Employed mothers, well-educated | **Study characteristics that one is likely to encounter in US primary care** | x | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| French law requires employers to allow mothers to breastfeed or express milk at work; subjects selected from one maternity ward in France | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Unclear if giving a handbook to the 4 professionals was sufficient to standardize the intervention. | |

| Author | Labarere | Year | 2005 | UI | 15687421 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | France | N | October 1, 2001 to May 31, 2002 | Government and university |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | A routine, preventive, outpatient visit in a primary care physician's office within 2 weeks after the birth, in addition to the usual predischarge and postdischarge support. | | |
| **Who implemented the BF promotion intervention?** | Pediatricians or family physicians, who had attended a 5-hour training program delivered in 2 parts in 1 month before the beginning of the study. The training program was intended to improve the physicians' breastfeeding-related knowledge and counseling skills. | | |
| **Comparator (Description)** | Usual postdischarge support: Verbal encouragement to maintain breastfeeding, provided by the maternity ward staff. Peer support group was also provided. | | |
| **Inclusion Criteria** | Mothers who had delivered a healthy singleton infant (GA ≥37 weeks) and were breastfeeding on the day of discharge | **Exclusion Criteria** | Infants admitted to a neonatal unit or mother was transferred to an intensive care unit, ≤18 years of age, living outside of the study area and its suburbs, refused or was unable to give consent, unable to speak French, or unlikely to complete follow-up due to psychosocial problems such a s homelessness. |
| **Other Population Description** | | **Setting** | Physician's office |
| **Comments** | Consecutive mother-infant pairs were screened and recruited on the day of discharge. | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 116 | | 115 | |
| **Mean Age** | | 29.3 | | 29.7 | |
| **Age Range metric** | year | >18 | | >18 | |
| **Gestational Age:** | weeks | 39.7 | | 39.8 | |
| **Range metric:** | SD | 1.3 | | 1.2 | |
| **Baseline SES Measure:** | >high school education | 75% | | 73% | |
| | White-collar worker | 79.3% | | 75.6% | |

| | | | |
|---|---|---|---|
| **Duration of BF promotion** | | 1 outpatient visit within 2 weeks after birth | |
| **Duration of Followup (after the intervention stopped)** | | 1 month | 1 month |
| **Comments:** | 72 mothers (79.3%) assigned to the intervention group and 8 mothers (7%) assigned to the control group attended the routine, preventive, outpatient visit (the intervention) | | |

**QUALITY ISSUES**

| **Method of randomization**[i] | **Adequate allocation concealment**[ii] **(Y/N/nd)** | **Intention to treat? (Y/N)** | **Outcome assessors blinded? (Y/N)** | **Loss to followup (%)** | **Were the results adjusted? (Y/N)** | **Were groups similar at baseline? (Y/N)** | **Recruitment method appropriate**[iii]**? (Y/N)** |
|---|---|---|---|---|---|---|---|
| Random permuted blocks with a block size of 8 | Y (numbered, sealed, opaque envelopes) | Y | N | 2 | Y | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate?** [iv] **(Y/N)** | Age, education more than high school graduate, white-collar worker, smoking history, prenatal class attendance, primiparity, epidural anesthesia, GA at delivery, infant birth weight, breastfed within 1 hr after birth, postpartum length of stay of >4 days, expected breastfeeding duration >4 months |
| **Comments** | Dependent variable of the multivariate analysis was exclusive breastfeeding at 4 weeks.<br>All other analyses were univariate. |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| **Outcome** | **Definition** | **BF promotion** | | | **Control** | | | **Unadjusted** | | | **Adjusted** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **No. Analyzed** | | **No. Events** | **No. Analyzed** | | **No. Events** | **HR** | **95% CI** | **P between** | **OR** | **95% CI** | **P between** |
| | | **Individual** | **Group** | | **Individual** | **Group** | | | | | | | |
| **Exclusive breastfeeding at 4 weeks** | Maternal milk as the only food source, with no other liquids (other than vitamin or medication) | 112 | | 94 (83.9) | 114 | | 82 (71.9) | 1.17 | 1.01-1.34 | 0.03 | 2.44 | 1.18-5.03 | |

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | HR | 95% CI | P between | OR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| | or food | | | | | | | | | | | | |
| **Any breastfeeding at 4 weeks** | Based on 24-hr recall | 112 | | 100 (89.3%) | 114 | | 93 (81.6%) | 1.09 | 0.98-1.22 | 0.10 | | | |
| **Reporting any breastfeeding difficulties** | | 112 | | 62 (55.3%) | 114 | | 83 (72.8%) | 0.76 | 0.62-0.93 | <0.01 | | | |

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Final (Median) | SD/SE | Hazard Ratio (95%CI) | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| **BF duration** | Any breastfeeding (weeks) | **BF promotion** | 112 | | 18 | | 1.40 (1.03-1.92) | 0.03 |
| | | **Control** | 114 | | 13 | | | |

| | |
|---|---|
| **Results Comments** | 8 mothers in control did attend routine preventive visits.<br>24 mothers in intervention did not attend routine preventive visits. |

| APPLICABILITY | | QUALITY | |
|---|---|---|---|
| Routine postnatal newborn care delivered by MD during the first 6 mo; majority had >high school education, white-collar worker | Factors reported in the study that one is ***likely*** to encounter in US primary care | x | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Postpartum stay ~5 d after normal vaginal delivery | Factors reported in the study that one is ***unlikely*** to encounter in US primary care | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |

| Author | Lavender | Year | 2005 | UI | 16045516 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| Cluster-RCT (subjects clustered within centers/areas were randomized) | UK | Y | July 1,1998 | Government |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Standard antenatal care plus a breastfeeding educational support session: To assist midwives to revise their knowledge of lactation management and to educate women on basic lactation physiology and effective breastfeeding techniques. One day intervention 9am to 4pm. | | |
| **Who implemented the BF promotion intervention?** | Midwives | | |
| **Comparator (Description)** | Standard antenatal care that included breastfeeding advice from attending midwives and information about hospital parent education classes | | |
| **Inclusion Criteria** | Women who were registered with a practice sited in one of the eight wards randomized. No fetal abnormality was detected at their 20-week ultrasound. Desire to breastfeed. | **Exclusion Criteria** | Ward with an outlying Underprivileged Area score (UPA) |
| **Other Population Description** | >90% White | **Setting** | Hospital |
| **Comments** | Of 1649 eligible women, 337 declined to participant: no difference in the 2 groups. | | |

| CHARACTERISTICS | | Breastfeeding education | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 679 | 4 | 633 | 4 |
| **Mean Age** | | 29.6 | | 29.7 | |
| **Age Range metric** | SD | 5.3 | | 5.4 | |
| **Gestational Age:** | | ND | | ND | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | Deprivation score | 20.8 | | 19.4 | |
| **Range metric:** | Mean | | | | |
| **Duration of BF promotion** | | Single session 1 day | | | |
| **Duration of Followup (after the intervention stopped)** | | 12 months | | | |
| **Comments:** | Of the 679 women allocated to the intervention arm, 439 (64.7%) attended the workshop; 5 women in the control arm also attended the workshop but were retained in their allocated group for analysis. | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Opaque sealed envelopes | Y | Y | Y (statistician was blinded) | 5 - 7 | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | Wards were pair matched base on UPA. Within each pair, one ward was randomly allocated to the intervention group and one to the control group by a midwife, independent of the trial |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF education | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **BF initiation rate** | Breastfeeding rate at discharge | 679 | | 517 | 633 | | 463 | 1.2 | 0.8-1.7 | NS | | | |
| **BF at 4 mo rate** | Note: 65 missing data | 646* | | 202 | 600* | | 192 | | | NS | | | |
| **Exclusive BF at 4 mo** | Total No. of event = 232 | | | | | | | 1.1 | 0.6-1.8 | NS | | | |
| **BF at 6 mo rate** | Note: 73 missing data | 642* | | 140 | 596* | | 138 | | | NS | | | |
| **BF at 12 mo rate** | Note: 80 missing data | 639* | | 60 | 593* | | 61 | | | NS | | | |

*Estimated from assuming equal number of missing data per group

| | |
|---|---|
| **Results Comments** | 42% and 44% women in the control and intervention group achieved their expected duration of breastfeeding, respectively (p=NS)<br>No difference between the 2 groups in the proportion of women who attended routine antenatal classes [136 (51.5%) vs. 147 (51.8%)] |

| APPLICABILITY | | | QUALITY | |
|---|---|---|---|---|
| Low income, lack of social support, difficulties of feeding in public, inconsistent advice from health professionals | **Study characteristics that one is likely to encounter in US primary care** | | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| 1/3 of the subjects did not get the intended intervention | **Study characteristics that may limit the applicability to a US primary care population** | | x | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | Only 64.7% of women in intervention attended the workshop. | |

| Author | McKeever | Year | 2002 | UI | 12431265 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Canada | N | 7/1999 to 12/2000 | Government |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Home visits from lactation nurses (maximum of 3 home visits) | | |
| **Who implemented the BF promotion intervention?** | Lactation nurses | | |
| **Comparator (Description)** | No lactation nurses visits | | |
| **Inclusion Criteria** | BF at discharge, ≥ 21 yr, ≥ 35 wk gestation and others | **Exclusion Criteria** | Did not speak English, C-section, postpartum complications, infant with hyperbilirubinemia and others |
| **Other Population Description** | | **Setting** | home |
| **Comments** | Outcomes assessed at 5 to 12 days postpartum | | |

| CHARACTERISTICS (Term Infant) | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 53 | | 48 | |
| **Mean Age** | | 32 (SD4.2) | | 33 (SD4.4) | |
| **Age Range metric** | | | | | |
| **Gestational Age:** | | ≥ 37 | | ≥ 37 | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | | ND | | | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | maximum of 3 home visits | | | |
| **Duration of Followup (after the intervention stopped)** | | Outcomes assessed at 5 to 12 days postpartum | | | |
| **Comments:** | | | | | |

| CHARACTERISTICS (Near-Term Infants 35-37 wk) | Breastfeeding promotion | | Control | |
|---|---|---|---|---|
| | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | 19 | | 18 | |

| | | | | | |
|---|---|---|---|---|---|
| **Mean Age** | | 32 (SD2.9) | | 32 (SD4.4) | |
| **Age Range metric** | | | | | |
| **Gestational Age:** | | ≥ 35 | | ≥ 35 | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | "well-educated" | ND | | | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | | | | |
| **Duration of Followup (after the intervention stopped)** | | Outcomes assessed at 5 to 12 days postpartum | | | |
| **Comments:** | | | | | |

**QUALITY ISSUES**

| **Method of randomization**[i] | **Adequate allocation concealment**[ii] **(Y/N/nd)** | **Intention to treat? (Y/N)** | **Outcome assessors blinded? (Y/N)** | **Loss to followup (%)** | **Were the results adjusted? (Y/N)** | **Were groups similar at baseline? (Y/N)** | **Recruitment method appropriate**[iii]**? (Y/N)** |
|---|---|---|---|---|---|---|---|
| Central | ND | N | N | 26% (term study); 27% (pre-term study) | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | |
| **Were statistical analyses appropriate?** [iv] **(Y/N)** | Y |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| **Outcome** | **Definition** | **BF promotion** | | | **Control** | | | **Unadjusted** | | | **Adjusted** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **No. Analyzed** | | **No.** | **No. Analyzed** | | **No.** | **OR/RR** | **95% CI** | **P between** | **OR/RR** | **95% CI** | **P between** |
| | | **Individual** | **Group** | **Events** | **Individual** | **Group** | **Events** | | | | | | |
| **Exclusive BF rate in past 24 h** | BF by breast and excluding supplementation | 41 | | 40 (98%) | 34 | | 30 (87%) | | | 0.01 | | | |

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **in term infants** | with expressed breast milk or formula | | | | | | | | | | | | |
| **Exclusive BF rate in past 24 h in near-term infants** | | 15 | | 12 (83%) | 12 | | 10 (87%) | | | 0.93 | | | |

| | |
|---|---|
| **Results Comments** | |

| APPLICABILITY | | QUALITY | |
|---|---|---|---|
| Metropolitan area, well-educated mothers, postpartum stay ~48h | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Mothers were not isolated (ie, had accessible family and friends to provide help if necessary) | **Study characteristics that may limit the applicability to a US primary care population** | x | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Wide | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Short followup, small sample size, large drop out, no adjustment | |

| Author | McLeod | Year | 2004 | UI | |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| Quasi-RCT (centers or caregivers were randomized) | New Zealand | Y | 1999-2000 | Government |

| | | | | |
|---|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Breastfeeding group: Midwife trained in BF education (a program of education and support for breastfeeding for women who smoked) provided care (observation of BF, information sheet)<br>Breastfeeding + smoking education: midwives received training to implement both the smoking education and breastfeeding education | | | |
| **Who implemented the BF promotion intervention?** | midwives | | | |
| **Comparator (Description)** | Usual care or smoking cessation group | | | |
| **Inclusion Criteria** | All midwives in selected localities in New Zealand (lower North Island), continue to practice for next 12 mo | **Exclusion Criteria** | | |
| **Other Population Description** | All women in this study were smokers | **Setting** | Prenatal and postnatal | |
| **Comments** | | | | |

| CHARACTERISTICS | | Control | BF support | Smoking cessation | combined |
|---|---|---|---|---|---|
| **No. Enrolled** | | 60 | 60 | 69 | 108 |
| **Mean Age** | | 24.9 | 26.1 | 27.3 | 25.1 |
| **Maori Ethnicity** | | 42% | 36% | 20% | 27% |
| **Gestational Age:** | | | | | |
| **Range metric:** | | | | | |
| **Tertiary education** | | 42% | 29% | 43% | 42% |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | | | | |
| **Duration of Followup (after the intervention stopped)** | | 4 mo postpartum | | | |
| **Comments:** | Clustering was not taken into account in these comparisons. | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Random number | N | Y | N | 164/275 (60%) | Y | N | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | unclear |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | Control | | | BF support | | | Smoking cessation | | | Combined | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Proportion | | Adj OR (95%CI) | Proportion | | Adj OR (95%CI) | Proportion | | Adj OR (95%CI) | Proportion | | Adj OR (95%CI) |
| **BF initiation rate** | At discharge | 25/30 | 83% | | 16/23 | 70% | | 35/42 | 83% | | 46/52 | 89% | |
| **BF at 6 wk rate** | | 22/31 | 71% | ref | 12/20 | 60% | 0.73 (0.18-2.84) | 23/34 | 68% | 0.74 (0.22-2.52) | 37/48 | 77% | 1.20 (0.36-4.04) |
| **BF at 4 mo rate** | | 12/25 | 48% | ref | 7/19 | 37% | 0.81 (0.18-3.58) | 14/28 | 50% | 0.73 (0.22-2.50) | 22/47 | 47% | 0.97(0.25-3.70) |

| | |
|---|---|
| **Results Comments** | BF outcome collected by postal questionnaire;<br>Women who had decreased or stopped smoking were more likely to BF fully at 6 wk (adj OR for cluster 4.46, 95%CI 1.55-12.85) |

| APPLICABILITY | | | QUALITY | |
|---|---|---|---|---|
| Smokers | | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Primary maternity care delivered by midwives alone, less often with a general practitioner or obstetrician; no fee for women attending a midwife or general practitioner; same provider provides ante-, intra- and post-natal care; | | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | Large drop out; did not take into account clustering in demographic comparisons | |

| Author | Minkovitz | Year | 2001 | Ref ID | | UI | 11296075 | Reviewer | SI |
|---|---|---|---|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized)<br>And non-randomized comparative | US | Y | 1996-1998 | Commonwealth Fund |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Healthy Steps Program for Young Children: well-child care emphasis on child development, home visits by Healthy Steps Specialist, phone info, written materials, parent groups, and others | | |
| **Who implemented the BF promotion intervention?** | Healthy Steps Specialists, Pediatricians, and Pediatric Nurse Practitioners | | |
| **Comparator (Description)** | No Healthy Steps intervention | | |
| **Inclusion Criteria** | | **Exclusion Criteria** | Mothers did not speak English or Spanish, too ill to make office visit within 4 wk, and others |
| **Other Population Description** | BF data only assessed in mothers who initiated BF | **Setting** | Hospital/clinic/home |
| **Comments** | Outcome data obtained via phone between 8 and 18 wks of age | | |

| CHARACTERISTICS | RCT | | Non-RCT | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| **No. Enrolled** | 1021 | 966 | 1610 | 1299 |
| **Mean Age** | 20-29 52%<br>≥ 30 33% | 20-30 51%<br>≥ 30 34% | 20-31 46%<br>≥ 30 42% | 20-32 54%<br>≥ 30 34% |
| **Birth weight <2500 g in total enrollment:** | 7.9% | 7.1% | 6.4% | 5.6% |
| **No. Enrolled who initiated BF** | 729 | 683 | 1297 | 971 |
| **Range metric:** | | | | |
| **Baseline education (<11 yr):** | 15% | 15% | 15% | 20% |
| **Range metric:** | | | | |
| **Duration of BF promotion** | | | | |
| **Duration of Followup (after the intervention stopped)** | Up to 18 wk | | | |
| **Comments:** | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| nd | nd | nd | N | 10% | Y | Y | Y |
| **List the variables that were adjusted for:** | | Site of enrollment, age of infant at interview, maternal, paternal, and infant characteristics | | | | | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | | Y | | | | | |
| **Comments** | Not possible to randomize all sites due to constraints on willingness of different practices to provide different services and other reasons | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Intervention | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | Individual | Initiated BF | | Individual | Initiated BF | | | | | | | |
| **Continue to BF between 2 and 4 mo (RCT)** | | 729 | 55.6% | | 683 | 54% | | | | 1.15 | 0.91-1.45 | |
| **Continue to BF between 2 and 4 mo (non-RCT)** | | 1297 | 57.1% | | 971 | 51.5% | | | ≤0.01 | 1.15 | 0.96-1.39 | |
| **BF > 6 mo rate** | | | | | | | | | | | | |
| **Infant health outcomes** | | | | | | | | | | | | |
| **maternal health outcomes** | | | | | | | | | | | | |
| **Other outcome** | | | | | | | | | | | | |
| **AE: Other** | | | | | | | | | | | | |

| APPLICABILITY | | | QUALITY | |
|---|---|---|---|---|
| Subjects drawn from group practices, hospitals, and health maintenance organizations; 33% Medicaid; 20% Hispanic; 24% African American | | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **x** | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| | | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Wide | **Overall assessment of applicability to US primary care (wide or narrow)** | | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | No details on breastfeeding; method of randomization not described | |

| Author | Mizuno | Year | 2004 | UI | 15841774 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Japan | N | February 1 2002 to March 31 2003 | Not stated |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Mother-newborn skin-to-skin contact from birth till newborn stop suckling. Then, there is no contact between mother and infant until 24 hours after birth. | | |
| **Who implemented the BF promotion intervention?** | Midwife | | |
| **Comparator (Description)** | Routine care: no contact between mother and infant until 24 hours after birth | | |
| **Inclusion Criteria** | Full term and healthy newborns | **Exclusion Criteria** | |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | Babies are excluded from analysis if developmental or growth abnormality is diagnosed during follow up. All infants are fed formula for the first 24 hours of life. | | |

| CHARACTERISTICS | Breastfeeding promotion | | Control | |
|---|---|---|---|---|
| | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | 30 | | 30 | |
| **Mean Age** | 31.8 | | 30.6 | |
| **Age Range metric** | | | | |
| **Gestational Age:** | 39.5 | | 39.5 | |
| **Range metric:** | | | | |
| **Baseline SES Measure:** | ND | | ND | |
| **Range metric:** | | | | |
| **Duration of BF promotion** | 1-time >50min contact | | | |
| **Duration of Followup (after the intervention stopped)** | 1 year | | 1 year | |
| **Comments:** | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Not specified | ND | N | Y | 3% | N | Y | N |
| **List the variables that were adjusted for:** | None | | | | | | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y | | | | | | |
| **Comments** | 2 infants from the control group were excluded from the analysis due to paternal consent withdrawal at 2 d of age and a diagnosis of melena neonatorum at 3 d of age | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **Exclusive BF rate** | at the time of discharge | 30 | | 25 (83%) | 28 | | 24 (86%) | | | | | | |
| **BF at 3 mo rate** | Estimated from figure | | | 72% | | | 82% | | | | | | |
| **BF at 6 mo rate** | Estimated from figure | | | 60% | | | 28% | | | | | | |
| **BF at 12 mo rate** | Estimated from figure | | | 20% | | | 7% | | | | | | |

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| **BF duration** | Not described (Months) | **BF promotion** | 30 | | 6.7 | 3.7 | 1.9 | 0.016 |
| | | **Control** | 28 | | 4.8 | 2.5 | | |

| | |
|---|---|
| **Results Comments** | Although the authors stated how “full”, “exclusive”, and “partial” breastfeeding were measured and defined in the method, it is unclear that what definition of “breastfeeding” of use in the analyses of breastfeeding duration |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | **x** | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Fathers not in the delivery room, postpartum stay ≥ 4 d, infants not with mothers for 24 h post delivery and was fed formula (hospital policy), midwives in attendance to help babies latch on at the initial breastfeeding | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Recruitment method was unclear. Breastfeeding definition in the analyses of breastfeeding duration was unclear. | |

| Author | Muirhead | Year | 2006 | UI | 165369859 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Scotland | N | July 1997 to March 2002 | Government |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Peer support plus normal breastfeeding support: Peer supporters visited participants at least once during the antenatal period. Peer support was available to women if they were breastfeeding on returning home from hospital after delivery and if the peer supporters were informed in time. After returning home from hospital, mothers were contacted by their peer supporters at least every 2 days or as often as required until day 28. | | |
| **Who implemented the BF promotion intervention?** | Peer supporters, experienced breastfeeding mothers known to the trial team and received training to gain the knowledge and skills necessary to provide appropriate support to women before and following childbirth. The training was initially 2 full days and 4 evening sessions with regular follow-up sessions where supporters presented case studies and reflected on their input. Each pair of peer supporters was given health professional supervision. | | |
| **Comparator (Description)** | Normal breastfeeding support: a community midwife for the first 10 days, health visitor after 10 days, breastfeeding support groups and breastfeeding workshops. | | |
| **Inclusion Criteria** | Women at 28 weeks of gestation from a general practice. | **Exclusion Criteria** | ND |
| **Other Population Description** | | **Setting** | Home |
| **Comments** | The authors stated that peer supporters had little or no contact with women in hospital, so that only hospital midwives helped mothers in both groups to initiate breastfeeding. | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 112 | | 113 | |
| **Mean Age** | | 28.5 | | 27.8 | |
| **Age Range metric** | | 17-43 | | 16-40 | |
| **Gestational Age:** | | ND | | ND | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | | ND | | ND | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | At least once during the antenatal period. At least every 2 days or as often as required until day 28 after mothers returned home. | | | |

| | | |
|---|---|---|
| **Duration of Followup (after the intervention stopped)** | 16 weeks postpartum | 16 weeks postpartum |
| **Comments:** | Based on the reasons that mothers gave for not breastfeeding initiation, there were some premature babies and babies in special care (5.3% and 6.25 respectively) | |

**QUALITY ISSUES**

| **Method of randomization**[i] | **Adequate allocation concealment**[ii] **(Y/N/nd)** | **Intention to treat? (Y/N)** | **Outcome assessors blinded? (Y/N)** | **Loss to followup (%)** | **Were the results adjusted? (Y/N)** | **Were groups similar at baseline? (Y/N)** | **Recruitment method appropriate**[iii]**? (Y/N)** |
|---|---|---|---|---|---|---|---|
| In a block of 10, separated for each of 4 strata (primagravidae, previous formula feeder, previously breastfed <6 weeks, previous breastfed >6 weeks). | Y | Y | N/A (self-administered questionnaire) | 2.3 | N | Y | Y |
| **List the variables that were adjusted for:** | None | | | | | | |
| **Were statistical analyses appropriate?** [iv] **(Y/N)** | Y | | | | | | |
| **Comments** | Based on the reported data, groups were similar at baseline, although limited baseline demographic data was reported. | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RD (%) | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| **BF initiation rate** | Not considered as an "outcome" (see comment) | | | | | | | | | |
| **Exclusive BF at 6 weeks** | No other feeding apart from breastfeeding | 110 | | 27 (24.1%) | 110 | | 24 (21.2%) | 2.9 | -8.1 to 13.8 | |
| **Exclusive BF at 8 weeks** | No other feeding apart from breastfeeding | 110 | | 23 (20%) | 110 | | 16 (14.2%) | 6.4 | -3.5 to 16.2 | |
| **BF at 16 weeks** | | 110 | | 26 (23.2%) | 110 | | 20 (17.7%) | 5.5 | -5.5 to 16.0 | |
| **Exclusive BF at 16 weeks** | No other feeding apart from breastfeeding | 110 | | 2 (1.8%) | 110 | | 0 | 1.8 | -0.7 to 4.2 | |
| **No formula by 16 weeks** | | 110 | | 16 (14.3%) | 110 | | 9 (8.0%) | 6.3 | -1.9 to 14.5 | |

| | |
|---|---|
| **Results Comments** | Based on the study design, the breastfeeding initiation rate was nothing or little to do with peer support intervention. Therefore, it is not included here as an "outcome".<br>31 (54.5%) and 60 (63.1%) if women in the intervention and control group initiated breastfeeding, respectively (p=NS)<br>Discrepancy noted: 97 (86% of intervention group) in Fig. 1 differed from 61 (54.5% of intervention group) in Tbl 2 received peer support. |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Population recruited from a general practice | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | x | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Normal BF support: community midwife for the first 10 d, health visitor after 10 d, BF support groups and workshops; little demographic data on the mothers | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Peer support only available for women in the intervention group, who initiated breastfeeding. | |

| Author | Noel-Weiss | Year | 2006 | UI | 16958717 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Canada | N | ND | ND |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Prenatal breastfeeding workshop based on the theory of self-efficacy and on adult learning principles | | |
| **Who implemented the BF promotion intervention?** | The researchers | | |
| **Comparator (Description)** | Not described (no workshop) | | |
| **Inclusion Criteria** | Nulliparous women expecting a single child, an uncomplicated birth, and planning to breastfeed.<br>Read and write in English and have a telephone. Mother-infant pair had to be discharged at the same time and be able to breastfeed without restriction. | **Exclusion Criteria** | None |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | Total = 101 | | | |
| **Mean Age** | | 30.2 | | | |
| **Age Range metric** | | 17 - 42 | | | |
| **Gestational Age:** | weeks | 39.77 | | | |
| **Range metric:** | weeks | 36 - 42 | | | |
| **Baseline SES Measure:** | | Family income >$70,000 | | | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | 2.5 hours | | | |
| **Duration of Followup (after the intervention stopped)** | | 8 weeks postpartum | | | |
| **Comments:** | 6 women (randomized to the intervention group did not attend the workshop.<br>High SES status | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Matching the sealed manila envelope with a sealed, sequentially numbered, opaque envelope containing the assignments | Y | Y | Y | 9 | N | Y | Y |
| **List the variables that were adjusted for:** | | N | | | | | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | | Y | | | | | |
| **Comments** | 2 dropped out for personal reasons, 2 did not remain in contact, and 6 had medical reasons for not remaining in the study. | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc. (ITT analyses)**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| **BF at 8 weeks** | Exclusive breastfeeding by breast | 47 | | 33 (70%) | 45 | | 26 (58%) | | | 0.135 |
| | Exclusive by breast/some EBM*** | 47 | | 1 (2%) | 45 | | 0 | | | |
| | Exclusive EBM* | 47 | | 0 | 45 | | 3 (7%) | | | |
| | Almost exclusive | 47 | | 0 | 45 | | 0 | | | |

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| | High (one or less bottle of formula daily) | 47 | | 2 (4%) | 45 | | 5 (11%) | | | |
| | Partial (>1 bottle of formula daily) | 47 | | 4 (9%) | 45 | | 1 (2%) | | | |
| | Token feeding (breastfeeding for comfort and not for nutritive reasons) | 47 | | 0 | 45 | | 0 | | | |
| | Bottle-feeding (weaned) | 47 | | 7 (15%) | 45 | | 10 (22%) | | | |

*** Exclusive by breast/some EBM = breastmilk by breast with no other liquids or solids except some bottles of EBM and possibly vitamins
*Exclusive EBM = all feeds are by bottle with EBM

**RESULTS: Breastfeeding rate etc. (Actual workshop attendance analyses)**

| Outcome | Definition | BF promotion attendance | | | Nonattendance | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| **BF at 8 weeks** | Exclusive breastfeeding by breast | 41 | | 32 (78%) | 51 | | 27 (53%) | | | 0.005 |
| | Exclusive by breast/some EBM*** | 41 | | 2 (1%) | 51 | | 0 | | | |
| | Exclusive EBM* | 41 | | 0 | 51 | | 3 (6%) | | | |
| | Almost exclusive | 41 | | 0 | 51 | | 0 | | | |
| | High (one or less bottle of formula daily) | 41 | | 2 (5%) | 51 | | 5 (10%) | | | |

| Outcome | Definition | BF promotion attendance | | | Nonattendance | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| | Partial (>1 bottle of formula daily) | 41 | | 4 (10%) | 51 | | 1 (2%) | | | |
| | Token feeding | 41 | | 0 | 51 | | 0 | | | |
| | Bottle-feeding (weaned) | 41 | | 2 (5%) | 51 | | 15 (29%) | | | |

**RESULTS: Continuous measures (ITT analyses)**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| **Number of days of breastfeeding at 8 weeks postpartum** | days | **BF promotion** | 47 | | 50.4 | 14.2 | | 0.34 |
| | | **Control** | 45 | | 49.9 | 14.5 | | |
| **Timing of first feeding** | hour | **BF promotion** | 47 | | 2.81 | 6.89 | | 0.106 |
| | | **Control** | 45 | | 5.44 | 8.54 | | |
| **Formula given in hospital** | Number of bottles | **BF promotion** | 47 | | 2.68 | 6.53 | | NS |
| | | **Control** | 45 | | 4.07 | 5.72 | | |

**RESULTS: Continuous measures (Actual workshop attendance analyses)**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| **Number of days of breastfeeding at 8 weeks postpartum** | days | **BF promotion** | 41 | | 54.0 | 9.3 | | 0.20 |
| | | **Control** | 51 | | 47.1 | 16.7 | | |
| **Timing of first feeding** | hour | **BF promotion** | 41 | | 2.95 | 7.37 | | NS |
| | | **Control** | 51 | | 5.02 | 8.1 | | |
| **Formula given in hospital** | Number of bottles | **BF promotion** | 41 | | 1.63 | 3.18 | | 0.15 |
| | | **Control** | 51 | | 4.75 | 7.51 | | |
| **Results Comments** | | | | | | | | |

<table>
<tr><th colspan="2">APPLICABILITY</th><th colspan="2">QUALITY</th></tr>
<tr><td rowspan="2">High income, majority completed secondary education, 36% had cesarean section, 68% received free formula</td><td rowspan="2">Study characteristics that one is likely to encounter in US primary care</td><td>x</td><td>A Good quality: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT.</td></tr>
<tr><td></td><td>B Fair quality: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study.</td></tr>
<tr><td>Subjects volunteered for the study; 87% intended to breastfeed before getting pregnant</td><td>Study characteristics that may limit the applicability to a US primary care population</td><td></td><td>C Poor quality: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors.</td></tr>
<tr><td>Narrow</td><td colspan="2">Overall assessment of applicability to US primary care (wide or narrow)</td><td colspan="2">If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)<br>Workshop conducted by the same person</td></tr>
</table>

| Author | O'Connor | Year | 2003 | UI | 12675164 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | Canada | Y (2 sites: A&B) | 1997-1999 | nd |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | 2 home visits post discharge (1st visit ASAP, 2nd visit within 10 d, some cases were delayed by a few days), thorough infant and postpartum assessment, referrals to other services if necessary | | |
| **Who implemented the BF promotion intervention?** | Public Health Nurse | | |
| **Comparator (Description)** | telephone call (but a home visit was made if a need was identified) | | |
| **Inclusion Criteria** | Primipara, singleton, vaginal delivery, discharged within 2 d, understand English, BF at time of discharge | **Exclusion Criteria** | |
| **Other Population Description** | ≥ 35 wk gestation | **Setting** | Selected from 2 tertiary care hospitals in Ontario, Canada |
| **Comments** | Telephone group also received home visit if necessary. | | |

| CHARACTERISTICS | | Home visit | | Telephone call | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 174 (A); 179 (B) | | 184 (A); 196 (B) | |
| **Mean Age** | | 26 (A); 28 (B) | | 28 (A); 27 (B) | |
| **Gestational age metric** | % 35-37 wk | 4% (A); 8% (B) | | 8% (A); 6% (B) | |
| **Baseline Health Measure:** | | | | | |
| **Range metric:** | | | | | |
| **Baseline education Measure: completed postsecondary** | | 62% (A); 67% (B) | | 63% (A); 68% (B) | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | 2 home visits | | | |
| **Duration of Followup (after the intervention stopped)** | | 6 mo | | | |
| **Comments:** | Site A and B were significantly different from each other in mothers' education and GA | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Random numbers | Y | Y | Y | 29% | Y | N | Y |
| **List the variables that were adjusted for:** | Duration of BF adjusted for site (A or B) and other significant variables in a Cox regression | | | | | | |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y | | | | | | |
| **Comments** | | | | | | | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Site | Home visit | | | Telephone | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| **BF initiation rate (BF at 2 wk)** | A | 149 | | 130 (87.2%) | 167 | | 147 (87%) | | | |
| | B | 157 | | 141 (89.9%) | 165 | | 145 (87.9%) | | | |
| **BF at 4 wk** | A | 129 | | 122 (94.6%) | 146 | | 130 (89%) | | | |
| | B | 140 | | 133 (95%) | 143 | | 136 (95.1%) | | | |
| **BF at 6 mo rate** | A | 118 | | 69 (58.5%) | 129 | | 69 (53.5%) | | | |
| | B | 129 | | 77 (59.7%) | 133 | | 80 (60.2%) | | | |
| **Total number of infants with health problems (up to 4 weeks postpartum)** | A | 167 | | 92 (55.1%) | 175 | | 86 (49.1%) | | | NS |
| | B | 169 | | 86 (50.9) | 185 | | 110 (59.5%) | | | NS |
| **Results Comments** | Cox regression revealed no significant difference between Home visit and Telephone Screen (P=0.22). Does not appear that the Home visit is specifically targeted at BF support. | | | | | | | | | |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Low risk family that can be discharged within 2 d | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | x | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Mothers restricted to those who are fluent in the main language of the community where they live | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Wide | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | 29% lost-to-followup at 6 month | |

| Author | Pisacane | Year | 2005 | UI | 16199676 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| Nonrandomized, but Controlled Trial (subjects allocated to one of the two blocks of time) | Italy | N | October 1, 2002 to January 31, 2003 | nd |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Fathers received a face-to-face, 40-min session about infant feeding and the difficulties sometimes associated with breastfeeding, such as fear of milk insufficiency; transitional lactation crisis, return to outside employment; and problems such as breast engorgement, mastitis, sore and inverted nipples, and breast refusal. They were taught how problems with lactation can occur and how it is possible to prevent and manage them. A leaflet with the main points of the session was provided to the fathers. | | |
| **Who implemented the BF promotion intervention?** | A midwife who was trained through the WHO-UNICEF 40-hour training course | | |
| **Comparator (Description)** | Fathers received a face-to-face 40-min training session about child care, such as accident prevention and vaccination, but discussion was focused on the health benefits of breast milk rather than the management of breastfeeding. A leaflet with the main points of the session was provided to the fathers. | | |
| **Inclusion Criteria** | All mother and father pairs of healthy, term, normal birth weight infants | **Exclusion Criteria** | Unmarried women, mothers who had decided to bottle feed, and parents whose infants were admitted to the ICU |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 140 | | 140 | |
| **Mean Age** | | nd | | nd | |
| **Age Range metric** | | 4% <20, 84% 20-35, 11% >35 | | 3% <20, 83% 20-35, 14% >35 | |
| **Gestational Age:** | | Term | | Term | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | Father's education >8 yr<br>Mother's education >8 yr | 54%<br>61% | | 53%<br>60% | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | 40 min | | | |

| | | |
|---|---|---|
| **Duration of Followup (after the intervention stopped)** | 12 mo | |
| **Comments:** | During the 2 time blocks of the study period, 194 and 191 normal birth weight infants were born, respectively. The first consecutive 140 families who met the recruitment criteria were enrolled during each block of time. All of the families who were enrolled agreed to participate in the interview and in the training session. | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| N/a | nd | N | Y | 0 | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | The fathers of the newborn were allocated to the study groups according to the date of birth of their infants: those whose infants born in October and November were assigned to the intervention group and those whose infants were born in December and January constituted the control group. No modification in the care provided to the mothers and to the newborn was planned or implemented during the study period. |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| **BF initiation rate** | At discharge from the hospital | 140 | | | 140 | | | | | |
| | - Full | | | 127 (91%) | | | 124 (89%) | 1.02 | 0.9-1.1 | NS |
| | - Complementary | | | 7 (5%) | | | 5 (4%) | 1.4 | 0.46-4.3 | NS |
| | - Bottle | | | 6 (4%) | | | 11 (8%) | 0.5 | 0.2-1.4 | NS |
| **BF at 6 mo rate** | Full (exclusive+predominant) | | | 35 (25%) | | | 21 (15%) | 1.67 | 1.02-2.71 | <0.05 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Complementary (any consumption of breast milk after the introduction) | | | 40 (33%) | | | 41 (34%) | 0.98 | 0.68-1.39 | NS |
| **BF at 12 mo rate** | Complementary | | | 27 (19%) | | | 16 (11%) | | | 0.09 |
| **Full BF at 6 mo rate** | Among mothers who reported breastfeeding problems | 96 | | 23 (24%) | 89 | | 4 (4.5%) | | | <0.001 |
| | Among mothers who didn't report breastfeeding problems | 44 | | 12 (27%) | 51 | | 17 (33%) | | | NS |
| **Results Comments** | 69% and 64% of the mothers in the intervention and control group respectively reported problems and difficulties with lactation, but the type of problems and the frequency of breastfeeding interruption were significantly different between the groups.<br>- Perceived milk insufficiency and giving up breastfeeding due to problems with lactation were significantly more frequent among the mothers of the control group<br>- Significantly more mothers in the intervention group reported to have received support and relevant help with infant feeding from their partners. | | | | | | | | | |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Married parents | Factors reported in the study that one is ***likely*** to encounter in US primary care | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | **x** | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Exclusion of unmarried parents (an important subgroup in US) | Factors reported in the study that one is ***unlikely*** to encounter in US primary care | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | No apparent adjustment was made to account for the fact that the two interventions took place in two different time periods. | |

| Author | Pugh | Year | 2001 | UI | 11508101 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| "Quasi experimental" | US | Y | ND | University |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Breastfeeding Support Team (BST): Traditional educational support for breastfeeding, emphasized ways to decrease breast discomfort using positioning to decrease fatigue, and provided social support. This included a nurse visit during hospitalization and at least 3 home visits (during weeks 1, 2, and 4). Peer counselor also visited and provided telephone support twice weekly through week 8 and weekly through month 5. | | |
| **Who implemented the BF promotion intervention?** | A community health nurse and peer counselor | | |
| **Comparator (Description)** | Usual care: 1 hospital visit by a lactation consultant and up to 2 nurse home visits for infant assessment and care. | | |
| **Inclusion Criteria** | Women in the 2 study hospitals; receiving medical assistance low-income) | **Exclusion Criteria** | ND |
| **Other Population Description** | 100% low-income, 40% minority (30% African-American, 5% Latino-American, 5% other), 60% single, mostly young women | **Setting** | Hospital and home |
| **Comments** | This is a pilot study. Response rate 80%.<br>Both groups received usual care. | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 10 | | 10 | |
| **Mean Age** | | 23.8 | | 24.9 | |
| **Age Range metric** | | | | | |
| **Gestational Age:** | | 39.1 | | 39.9 | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | Education (years) | 12.1 | | 12.5 | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | a nurse visit during hospitalization, >3 home visits; routine peer counselor visited and telephone supports | | | |
| **Duration of Followup (after the intervention stopped)** | | 5 months | | 5 months | |
| **Comments:** | | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Not described | N/A | N | N | 0 | Y (only on matching factors) | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | Women were matched on type of delivery, previous breastfeeding experience, and race. |
| **Were statistical analyses appropriate? [iv] (Y/N)** | N (no statistical method was described) |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | RD | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **BF at 5 mo rate** | Not described | 10 | | 4 (40%) | 10 | | 1 (10%) | | | ND | | | |

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Baseline | Final | SD | Net difference | P between |
|---|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | | |
| **Maternal depressive symptoms** | CES-D* (ranged 0-60) | **BF promotion** | 10 | | 13.3 | 5.9 | 9.1 | ND | ND |
| | | **Control** | 10 | | 12.8 | 12.6 | 17.2 | | |
| **Maternal fatigue** | Three dimension scales of fatigue: tiredness, decreased concentration, and a physical feeling of fatigue (ranged 0-300) | **BF promotion** | 10 | | 143.1 | 18.8 | 28.2 | ND | ND |
| | | **Control** | 10 | | 125.8 | 43.5 | 43.6 | | |
| **Maternal Anxiety** | Speilberger State Trait Anxiety Inventory (ranged 20-60) | **BF promotion** | 10 | | 29.2 | 30.8 | 10.1 | ND | ND |
| | | **Control** | 10 | | 31.8 | 35.3 | 16.2 | | |

*CES-D, Center for Epidemiologic Study-Depressive Symptomatology Scale

| | |
|---|---|
| **Results Comments** | Unclear if breastfeeding rates from birth to less than 5 months were collected. |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Low income, 40% minority, primarily young single women, large metropolitan community | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Wide | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Method of "quasi-experimental" was not described. Outcomes were all self-reported, so cannot blind women to the group assignments. Exclusivity of breastfeeding was unclear. Small sample size. | |

| Author | Reeve | Year | 2004 | UI | 15063960 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| Non-RCT | UK | N | March to July 1999 | ND |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Routine care plus a breastfeeding seminar: brainstorming, discussion of individual selection, investigation of strategies, and role-play. "Experiential learning" model. | | |
| **Who implemented the BF promotion intervention?** | The primary investigator (MD) | | |
| **Comparator (Description)** | Routine care: routine antenatal provision for receiving information about infant feeding. Parentcraft classes provided by district midwives and breastfeeding workshops offered within the hospital setting are available for those wanting to breastfeed. | | |
| **Inclusion Criteria** | All primiparous women attending antenatal clinic at a hospital for their 32 weeks check, during a 5-month period | **Exclusion Criteria** | ND |
| **Other Population Description** | | **Setting** | Hospital |
| **Comments** | 181 women approached and 73 agreed to participate | | |

| CHARACTERISTICS | | Breastfeeding education | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 33 | | 40 | |
| **Mean Age** | | ND | | ND | |
| **Age Range metric** | <20 years old | 6.1% | | 12.5% | |
| **Gestational Age:** | | ND | | ND | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | Professional | 51.5% | | 50.0% | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | 2 hours | | | |
| **Duration of Followup (after the intervention stopped)** | | 4 months postpartum | | | |
| **Comments:** | | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| N/A | N/A | N | ND | 0 | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Yes |
| **Comments** | Non-random block allocation: Women were assigned to intervention and control groups before being approached based on the time of their appointment: those attending the clinic during a six week period in April-May 1999 were assigned to intervention group; those attending afterwards or before were assigned to the control group. |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF education | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **BF initiation rate** | Breastfeeding on day one (self-report) | 33 | | 26 (78.8%) | 40 | | 28 (72.5%) | | | NS | | | |
| **BF at 4 mo rate** | Breastfeeding at 4 months (self-report) | 33 | | 16 (48.5%) | 40 | | 8 (20%) | | | 0.0099 | | | |

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD/SE | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| **BF duration** | | **BF promotion** | | | | | | |
| | | **Control** | | | | | | |
| **Results Comments** | High breastfeeding initiation rate in both groups. | | | | | | | |

| APPLICABILITY | | | QUALITY | |
|---|---|---|---|---|
| | **Study characteristics that one is likely to encounter in US primary care** | | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| 60% of eligible subjects did not enroll in the study, small number of subjects selected from 1 hospital | **Study characteristics that may limit the applicability to a US primary care population** | | x | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | "Breastfeeding" was self-reported and exclusivity was not defined. Non-randomized design although no statistically significant difference in baseline characteristics and SES (likely the study was not power to detect those differences). Unclear whether or not the outcome assessor was blinded. | |

| Author | Ryser | Year | 2004 | UI | 15296584 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | US | N | nd | University |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Best Start Program (education intervention): assess subjects' perceptions of BF; acknowledgement and reassurance; targeted educational messages; presented in 4 prenatal visits | | |
| **Who implemented the BF promotion intervention?** | researcher | | |
| **Comparator (Description)** | No intervention | | |
| **Inclusion Criteria** | ≥ 18 yr; English speaking, gestation early enough to allow 4 contacts; low income, intention to bottle feed or undecided | **Exclusion Criteria** | Intend to BF |
| **Other Population Description** | Sample from one physician's office | **Setting** | physician's office |
| **Comments** | | | |

| CHARACTERISTICS | | Best Start | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 26 | | 28 | |
| **Mean Age** | | 25.3 ± 5.6 | | 22.6 ± 4.6 | |
| **Age Range metric** | | 18-40 | | 18-36 | |
| **Gestational Age:** | | nd | | nd | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | | low income | | low income | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | 4 prenatal visits | | | |
| **Duration of Followup (after the intervention stopped)** | | BF assessed via phone within 1 wk post delivery | | | |
| **Comments:** | | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Subjects select a sealed envelope | nd | N | N | 0* | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | nd |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | ?Discrepancy in text: "All 54 completed the study." But only 53 had data on BF initiation. |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | |
| **Exclusive BF initiation rate** | No formula, 1-week postpartum telephone f/up | 23 | | 14 (61%) | 27 | | 4 (15%) | | | P<0.01 |

| APPLICABILITY | | | QUALITY | |
|---|---|---|---|---|
| Low income (90% eligible for Medicaid), | | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias.<br>Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Subjects recruited from one physician's practice, "nonprobability" sample | | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | Unadjusted results, small sample, non-blinded | |

| Author | Schlickau | Year | 2005 | UI | ? |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | US | N | ND | ND |

| | | | | |
|---|---|---|---|---|
| **Type (Description) of BF promotion intervention** | 1st level: Prenatal breastfeeding education (PBE)- enhance knowledge, increase perception of benefits, and decrease perception of barriers to breastfeeding.<br>2nd level: PBE plus commitment-to-breastfeed (PBE-CB)- a session involving the PBE intervention in which a selected group of participants formulated a specific plan for breastfeeding and committed to breastfeed for a certain length of time. | | | |
| **Who implemented the BF promotion intervention?** | The researchers | | | |
| **Comparator (Description)** | Usual care | | | |
| **Inclusion Criteria** | Low-risk, primigravid Hispanic women in their 3rd trimester who received care at the clinic. Normal breast and nipple exam, stable family and not planning to work outside the home for 6 months. | **Exclusion Criteria** | ND | |
| **Other Population Description** | 85% emigrated from Mexico within the last 7 years; all preferred to speak Spanish rather than English. | **Setting** | Hospital | |
| **Comments** | Health Promotion Model was chosen to guide to development of the intervention.<br>Participants were referred to the researcher by the clinic's staff.<br>2nd level of the intervention was administered to those who had completed the 1st level during a previous clinic visit and who had been randomized to the Level 2 group at the time of enrollment.<br>This is a pilot study. 32 women approached, 30 were recruited. | | | |

| CHARACTERISTICS | | Breastfeeding education | | | Control | |
|---|---|---|---|---|---|---|
| | | Individual level | | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi- RCT) |
| | | PBE | PBE-CB | | | |
| **No. Enrolled** | | 10 | 10 | | 10 | |
| **Mean Age** | | 22 | | | | |
| **Age metric Range** | | 16-45 | | | | |
| **Gestational Age:** | | ND | | | | |
| **metric: Range** | | | | | | |
| **Baseline SES Measure:** | | ND | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **metric: Range** | | | | | | |
| **Duration of BF promotion** | | PBE: 1 hr<br>PBE+CB: 2 hrs | | | | |
| **Duration of Followup (after the intervention stopped)** | | 45 days | | | 45 days | |
| **Comments:** | | | | | | |

**QUALITY ISSUES**

| **Method of randomization**[i] | **Adequate allocation concealment**[ii] **(Y/N/nd)** | **Intention to treat? (Y/N)** | **Outcome assessors blinded? (Y/N)** | **Loss to followup (%)** | **Were the results adjusted? (Y/N)** | **Were groups similar at baseline? (Y/N)** | **Recruitment method appropriate**[iii]**? (Y/N)** |
|---|---|---|---|---|---|---|---|
| N | ND | N | ND | 17 | N | ND | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate?** [iv] **(Y/N)** | Y |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| **Outcome** | **Definition** | **BF promotion** | | | | **Control** | | | **Unadjusted** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **No. Analyzed** | | **No. Events** | | **No. Analyzed** | | **No. Events** | **OR/RR** | **95% CI** | **P between** |
| | | **PBE** | **PBE+ CB** | **PBE** | **PBE+ CB** | **Individual** | **Group** | | | | |
| **BF by 45 days** | By 45 days | 9 | 9 | 33% | 56% | 7 | 29% | | | | ND |

**RESULTS: Continuous measures**

| **Outcome** | **Definition (units)** | **Group** | **No. Analyzed** | | **Final** | **SD** | **Net difference** | **P between** |
|---|---|---|---|---|---|---|---|---|
| | | | **Individual** | **Group** | | | | |
| **BF duration** | days | **PBE** | 9 | | 23.1 | 15.9 | 6.3 | NS |
| | | **PBE+CB** | 9 | | 31.1 | 16.2 | 14.3 | NS |
| | | **Control** | 7 | | 16.9 | 18.2 | | |
| | | | | | | | | |

| | |
|---|---|
| **Results Comments** | This is a pilot study. Underpowered. |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Primigravid, low-risk, Hispanic women, immigrants | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Small convenience sample | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Method of randomization not described. More controls were lost to follow-up. Total lost to follow-up 17%. Short follow-up period. Exclusivity of breastfeeding was unclear. Unclear whether the outcome assessors were blinded. | |

Schniedrova 2003 UI 14521822

| Study characteristics | Study design and follow-up duration | Eligibility criteria | Breastfeeding promotion Intervention | Control Intervention |
|---|---|---|---|---|
| Mean age (range):<br>Mean GA (range):<br>Term<br>Enrolled/Evaluate::<br>1,104 / 1,019<br>Location: Czech Republic<br>Sites: Multi: 9 sites<br>Funding: government | Prospective study at 2 time points comparing infants from Baby Friendly hospitals with other hospitals; first questionnaire: 36 questions: education, marital status, decision on infant feeding, prenatal preparation, birth, breastfeeding support in the hospital, infant feeding practices at discharge; followup questionnaire at 6 mo: 51 questions; mothers randomly selected | Term, ≥ 2500 g; no postnatal complications, no multiple births | Hospitals with Baby-friendly hospital award | Other hospitals |

| Outcome Definition | Statistical analyses and confounders adjusted | Results | Bias/limitations Comments |
|---|---|---|---|
| Feeding modes, duration of exclusive BF<br><br>Exclusive BF, supplemented BF, formula | ANOVA, F test, chi2;<br>Method of randomization not reported; did not report control for characteristics differences between hospitals (baby-friendly vs. others) | 1,104 mothers completed initial interview;<br>1,109 mothers completed 6 mo interview;<br>5 Baby-friendly hospitals (625 mothers), 4 others (479 mothers)<br>93.5% of infants were BF exclusively at discharge;<br>23.1% of infants were BF exclusively at 6 mo;<br>Duration of exclusive BF in both groups were comparable:<br>Baby-friendly: 3.9 mo ± 1.92 SD<br>Others: 3.90 mo ± 1.84 SD<br>Actual numbers of the two groups at 6 mo was not reported. | A: strong, B: moderate, C: weak / A / B / C<br>Selection / / x /<br>Study design / / / x<br>Confounder / / / x<br>Blinding / / / x<br>Data collection / / / x<br>Withdraw and dropout / x / /<br>Analyses / / / x |

**Applicability**

| | |
|---|---|
| **Study characteristics that one is likely to encounter in US primary care** | Samples selected from large cities; pediatricians not trained in lactation management and counseling |
| **Study characteristics that may limit the applicability to a US primary care population** | 56% of the maternity units in the study had the Baby Friendly status |
| **Overall assessment of applicability to US primary care (wide or narrow)** | Narrow |

| Author | Wallace | Year | 2006 | UI | |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | England | Y | 2001-2002 | Government |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | "hands off" approach to BF: advice about baby initiation of feeding, positioning and attachment | | |
| **Who implemented the BF promotion intervention?** | Midwives who received a 4-h workshop | | |
| **Comparator (Description)** | Usual care delivered by midwives who did not receive the 4-h workshop | | |
| **Inclusion Criteria** | Intend to BF, primiparous, GA>37wk, able to sit out of bed at time of first feed | **Exclusion Criteria** | c-section under general anesthesia |
| **Other Population Description** | | **Setting** | Hospital (not BFHI accredited) |
| **Comments** | | | |

| CHARACTERISTICS | Breastfeeding promotion | | Control | |
|---|---|---|---|---|
| | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | 188 | | 182 | |
| **Mean Age** | <20 5%<br>20-29 50%<br>30-39 43% | | <20 6%<br>20-30 52%<br>30-39 40% | |
| **Age Range metric** | | | | |
| **Gestational Age:** | >37wk | | >37wk | |
| **Range metric:** | | | | |
| **Baseline SES Measure:** | | | | |
| **Range metric:** | | | | |
| **Duration of BF promotion** | Initial feeding only | | | |
| **Duration of Followup (after the intervention stopped)** | 17 wk postpartum | | | |
| **Comments:** | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Telephone balanced block and computer | Y | Y | Y | 6% | N | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | None |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | No. Events | No. Analyzed | | No. Events | OR/ RR | 95% CI | P between | OR/ RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **Exclusive BF rate at 17 wk** | Breast milk and non-nutritive water feed | 174 | | 7 (4%) | 168 | | 7 (4.2%) | | | NS | | | |
| **Ever BF rate at 17 wk** | | 173 | | 64 (37%) | 167 | | 66 (40%) | | | NS | | | |

| APPLICABILITY | | | QUALITY | |
|---|---|---|---|---|
| Hospitals did not have BFHI accreditation, postnatal care managed by midwives | | **Study characteristics that one is likely to encounter in US primary care** | x | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| | | **Study characteristics that may limit the applicability to a US primary care population** | | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| wide | **Overall assessment of applicability to US primary care (wide or narrow)** | | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | | |

| Author | Wilhelm | Year | 2006 | UI | 16700683 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | US | Yes | nd | Private |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Motivational Interviewing (initial session at days 2 to 4, then at 2 and 6 wk as outpatient) with goal of decreasing ambivalence and resistance toward sustained breastfeeding. | | |
| **Who implemented the BF promotion intervention?** | Research nurse | | |
| **Comparator (Description)** | Usual care: a lactation consultant troubleshooting problems during the hospital stay and at each visit using the AAP's (2002) guide to breastfeeding | | |
| **Inclusion Criteria** | primiparous BF mothers | **Exclusion Criteria** | NICU, <37 wk GA, <2500 g, bilirubin 15 mg/dL |
| **Other Population Description** | Rural community | **Setting** | hospital |
| **Comments** | Convenience sample | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 37 | | 36 | |
| **Mean Age** | | 25 | | | |
| **Age Range metric** | SD | 4.5 | | | |
| **Gestational Age:** | | 39.3 | | | |
| **Range metric:** | SD | 1.1 | | | |
| **Baseline SES Measure:** | <high school | 6.8% | | | |
| | >$40,000 | 45.8% | | | |
| **Duration of BF promotion** | | nd | | | |
| **Duration of Followup (after the intervention stopped)** | | 6 mo | | 6 mo | |
| **Comments:** | Intervention group has higher BF self-efficacy scores (P=0.001); paper did not report baseline data stratified by intervention and control; mean age = 25 (SD 4.5); mean GA = 39.3 wk (SD 1.1) | | | | |

**QUALITY ISSUES**

| Method of randomization[i] | Adequate allocation concealment[ii] (Y/N/nd) | Intention to treat? (Y/N) | Outcome assessors blinded? (Y/N) | Loss to followup (%) | Were the results adjusted? (Y/N) | Were groups similar at baseline? (Y/N) | Recruitment method appropriate[iii]? (Y/N) |
|---|---|---|---|---|---|---|---|
| Random number | nd | N | N | 3% | Y | N | N |

| | |
|---|---|
| **List the variables that were adjusted for:** | Baseline BF self-efficacy, length of time before returning to work |
| **Were statistical analyses appropriate? [iv] (Y/N)** | Y |
| **Comments** | Motivational Interviewing trained nurse administered intervention; non-motivational trained nurse administered control |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| Outcome | Definition | BF promotion | | | Control | | | Unadjusted | | | Adjusted | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | No. Analyzed | | Events | No. Analyzed | | Events | OR/RR | 95% CI | P between | OR/RR | 95% CI | P between |
| | | Individual | Group | | Individual | Group | | | | | | | |
| **BF at 6 mo rate** | | 36 | | 32% | 35 | | 25% | | | | | | |

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Final | SD | Net difference | P between |
|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | |
| **BF duration** | days | **BF promotion** | 36 | | 98.1 | 75.2 | Adjusted mean difference = 12 | NS |
| | | **Control** | 35 | | 80.7 | 71.9 | | |
| **Results Comments** | One site reported the practice of motivational interviewing might not have been consistent because the formal training was too complex. | | | | | | | |

| APPLICABILITY | | | QUALITY | |
|---|---|---|---|---|
| Rural community | | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Convenience sample | | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | | Convenience sample, inadequate reporting of results | |

| Author | Wolfberg | Year | 2004 | UI | 15467529 |
|---|---|---|---|---|---|

| Study Design (from perspective of BF intervention) | Country | Multicenter? (Y/N) | Calendar Years of study | Funding Source |
|---|---|---|---|---|
| RCT (subjects were randomized) | US | N | March 2001 to August 2002 | Government |

| | | | |
|---|---|---|---|
| **Type (Description) of BF promotion intervention** | Breastfeeding classes for expectant fathers: Every 2 weeks in a group of 4 to 12. Nondidactic, informal environment, and use of a variety of teaching media. Core information was designed to educate the expectant fathers that breast milk is the best nutritional choice for their child and to help them develop the skill that are necessary to communicate that to their partner. | | |
| **Who implemented the BF promotion intervention?** | A peer classroom facilitator: easygoing and engaging, knowledgeable without being overbearing, black, and who was a father himself<br>Expected fathers | | |
| **Comparator (Description)** | Control class (baby care and safety): Topics included car seat use, fire safety, lead-exposure prevention, sleeping positions, and bath safety, taught by the same facilitator. Similar media were used. | | |
| **Inclusion Criteria** | Partner of the women who sought prenatal care in the hospital | **Exclusion Criteria** | See comments |
| **Other Population Description** | Expectant fathers. 80% Black | **Setting** | Hospital |
| **Comments** | 567 pregnant women were approached and 59 couples completed the trial. Attrition reasons: refusal (24%), loss to follow-up during the prenatal period (36%), the mothers lack of involvement with the father of her pregnancy (8%), the fathers' refusal to participate (11%), and the fathers' failure to attend the study class after enrolling for the study (9%).<br>Women who were excluded from the study were more likely to receive welfare (36% vs. 19%) and were less likely to be employed (38% vs. 61%) than the women in the study | | |

| CHARACTERISTICS | | Breastfeeding promotion | | Control | |
|---|---|---|---|---|---|
| | | Individual level | Group level (if cluster or quasi-RCT) | Individual level | Group level (if cluster or quasi-RCT) |
| **No. Enrolled** | | 27 | | 32 | |
| **Mean Age** | | ND | | ND | |
| **Age Range metric** | | | | | |
| **Gestational Age:** | | ND | | ND | |
| **Range metric:** | | | | | |
| **Baseline SES Measure:** | < a high school education<br>- fathers<br>- mothers | <br>22%<br>30% | | <br>27%<br>25% | |
| | Employed<br>- fathers<br>- mothers | <br>85%<br>59% | | <br>70%<br>63% | |

| | | | | | |
|---|---|---|---|---|---|
| | Mothers enrolled in WIC program | 78% | | 81% | |
| **Range metric:** | | | | | |
| **Duration of BF promotion** | | 2 classes, 2-hour for each class and 2 weeks apart | | | |
| **Duration of Followup (after the intervention stopped)** | | 8 weeks | | 8 weeks | |
| **Comments:** | Low-income, minority | | | | |

**QUALITY ISSUES**

| **Method of randomization**[i] | **Adequate allocation concealment**[ii] **(Y/N/nd)** | **Intention to treat? (Y/N)** | **Outcome assessors blinded? (Y/N)** | **Loss to followup (%)** | **Were the results adjusted? (Y/N)** | **Were groups similar at baseline? (Y/N)** | **Recruitment method appropriate**[iii]**? (Y/N)** |
|---|---|---|---|---|---|---|---|
| ND | N | N | ND | 3% | Y | Y | Y |

| | |
|---|---|
| **List the variables that were adjusted for:** | Mother breastfed previously, mother were breastfed as an infant, mother plans to breastfeed for first month, mother lives with father, mother's mother thinks baby should be breastfed, mother believes her partner thinks her baby should be breastfed, or father would like baby to be breastfed |
| **Were statistical analyses appropriate?** [iv] **(Y/N)** | Y |
| **Comments** | Power calculation was performed: 230 women were needed to detect a 50% increase in breastfeeding duration with a power of 0.8. Therefore, this study is clearly underpowered. |

[i] If cluster RCT, method used to generate the random allocation sequence, including details of any restriction (eg blocking, stratification, matching)
[ii] If cluster RCT, method used to implement the random allocation sequence, specifying that allocation was based on clusters rather than individuals and clarifying whether the sequence was concealed until interventions were assigned
[iii] Appropriate consecutive or randomized
[iv] If cluster RCT, Statistical methods used to compare groups for primary outcome(s) indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses

**RESULTS: Breastfeeding rate etc.**

| **Outcome** | **Definition** | **BF education classes** | | | **Control** | | | **Unadjusted** | | | **Adjusted** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **No. Analyzed** | | **No. Events** | **No. Analyzed** | | **No. Events** | **OR/RR** | **95% CI** | **P between** | **OR/RR** | **95% CI** | **P between** |
| | | **Individual** | **Group** | | **Individual** | **Group** | | | | | | | |
| **BF initiation rate** | Self-report by the mothers | 27 | | 20 (74%) | 32 | | 13 (41%) | | | 0.02 | | | |
| **BF at 8 weeks** | Self-report by the mothers | 26 | | 9 (35%) | 31 | | 6 (19%) | | | 0.13 | | | |

**RESULTS: Continuous measures**

| Outcome | Definition (units) | Group | No. Analyzed | | Baseline | Final | Change | P Within | Net Change | P between |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Individual | Group | | | | | | |
| **BF duration** | | **BF promotion** | | | | | | | | |
| | | **Control** | | | | | | | | |

| | |
|---|---|
| **Results Comments** | The following paternal characteristics are associated with an increased incidence of breastfeeding initiation in the study: mother plans to breastfeed for first month (p=0.004), the baby's maternal grandmother's belief that the baby should be breastfed (p=0.03), mother believed her partner thinks her baby should be breastfed (p=0.002), and father's belief that the baby should be breastfed (p=0.03) |

| **APPLICABILITY** | | **QUALITY** | |
|---|---|---|---|
| Low-income, minority, expectant fathers | **Study characteristics that one is likely to encounter in US primary care** | | **A Good quality**: Prospective, no obvious biases or reporting errors, <20% dropout, complete reporting of data. Must be RCT or cluster RCT. |
| | | | **B Fair quality**: Problems with study/paper unlikely to cause major bias. Must be RCT, cluster RCT, or non-randomized, controlled study. |
| Highly selected sample; ~90% of eligible subjects did not participate | **Study characteristics that may limit the applicability to a US primary care population** | **x** | **C Poor quality**: Prospective or retrospective. Cannot exclude possible significant biases. Poor methods, incomplete data, reporting errors. |
| Narrow | **Overall assessment of applicability to US primary care (wide or narrow)** | **If Quality is rated B or C, what are the limiting factors? (i.e., incomplete data, errors in analysis, definitions not clear, poor follow-up, dropouts)** | |
| | | Method of randomization was unclear. No data on the blinding of outcome assessors. Exclusivity of breastfeeding was unclear. | |

# Appendix D. List of Excluded Studies

Breastfeeding in the WHO Multicentre Growth Reference Study. Acta Paediatr Suppl 2006;450:16-26. **No control group**

Banderali G, Riva E, Scaglioni S, et al. Monitoring breastfeeding rates in Italy. Acta Paediatrica Suppl 2003 Sep;91(441):6-8. **Retrospective design**

Banks JW. Ka'nistenhsera. Teiakotihsnie's. A Native community rekindles the tradition of breastfeeding.[erratum appears in AWHONN Lifelines. 2003 Dec-2004 Jan;7(6):493]. AWHONN Lifelines 2003 Aug;7(4):340-7. **Review**

Barlow A, Varipatis-Baker E, Speakman K, et al. Home-visiting intervention to improve child care among American Indian adolescent mothers: a randomized trial. Arch Pediar & Adolesc Med 2006 Nov;160(11):1101-7. **No interventions**

Bartington S, Griffiths LJ, Tate AR, et al. Are breastfeeding rates higher among mothers delivering in Baby Friendly accredited
materrnity units in the UK? Int J Epidemiol 2006 Oct;35(5):1178-86. **Retrospective design**

Battersby S. The Worldly Wise project. A different approach to breastfeeding support. Practising Midwife 2001 Jun;4(6):30-1. **No outcome of interest**

Beake S, McCourt C, Rowan C, et al. Evaluation of the use of health care assistants to support disadvantaged women
breastfeeding in the community. Maternal & Child Nutr 2005 Jan;1(1):32-43. **Historical control**

Benis MM. Are pacifiers associated with early weaning from breastfeeding? Adv Neonatal Care 2002 Oct;2(5):259-66. **Review**

Binns CW, Scott JA. Using pacifiers: what are breastfeeding mothers doing? Breastfeeding Review 2002 Jul;10(2):21-5. **Review**

Black MM, Siegel EH, Abel Y, et al. Home and videotape intervention delays early complementary feeding among adolescent mothers. Pediatrics 2001 May;107(5):E67. **No comparative breastfeeding outcome**

Britten J, Hoddinott P, McInnes R. Breastfeeding peer support: health service programmes in Scotland. Br J of Midwifery 1916;2006 Jan; 14(1):12-4. **No outcome of interest**

Caddy R. The Reading breastfeeding drop-in centre. Practising Midwife 2002 Nov;5(10):18-22. **Observational** study; BF rate not reported

Campbell MK, Carbone E, Honess-Morreale L, et al. Randomized trial of a tailored nutrition education CD-ROM program for women receiving food assistance. J Nutrition Ed and Behavior ;2004 Mar-Apr; 36(2):58-66. **No interventions**

Chapman D, Damio G, Young S, et al. Association of degree and timing of exposure to breasfeeding peer counseling services with breastfeeding duration. Advances in Experimental Med & Biol 2004;554:303-6. **In Britton 2006 systematic review**

Chapman DJ. Randomized trial evaluating a unique lactation consultant intervention. J Hum Lactation ;2006 Aug; 22(3):362-3. **Editorial**

Chapman DJ, Young S, Ferris AM, et al. Impact of breast pumping on lactogenesis stage II after cesarean delivery: a randomized clinical trial. Pediatrics 2001 Jun;107(6):E94. **Abstract**

Chapman DJ, Damio G, Perez-Escamilla R. Differential response to breastfeeding peer counseling within a low-income, predominantly Latina population. J Hum Lactation 2004 Nov;20(4):389-96. **In Britton 2006 systematic review**

Chapman DJ, Damio G, Young S, et al. Effectiveness of breastfeeding peer counseling in a low-income, predominantly Latina population: a randomized controlled trial. Arch Pediatr & Adolesc Med 2004 Sep;158(9):897-902. **In Britton 2006 systematic review**

Chatterji P, Brooks-Gunn J. WIC participation, breastfeeding practicess, and well-child care among unmarried, low-income mothers. Am J Public Health 2004 Aug;94(8):1324-7. **Observational study**

De KM, Blais R, Joubert P, et al. Comparing women's assessment of midwifery and medical care in Quebec, Canada. J Midwifery & Women's Health 2001 Mar;46(2):60-7. **No outcome of interest**

Dennis CL. Breastfeeding peer support: maternal and volunteer perceptions from a randomized controlled trial. Birth 2002 Sep;29(3):169-76. **In Britton 2006 systematic review**

Dennis CL, Hodnett E, Gallop R, et al. The effect of peer support on breast-feeding duration among primiparous women: a randomized controlled trial.[see comment]. CMAJ 2002 Jan 8;166(1):21-8. **In Britton 2006 systematic review**

Di NA, Di LD, Fortes C, et al. Home breastfeeding support by health professionals: findings of a randomized controlled trial in a population of Italian women. Acta Paediatrica 2004 Aug;93(8):1108-14. **In Britton 2006 systematic review**

Downie J, Rakic V, Juliff D. Enhancing the ability of nurses and midwives to promote breastfeeding: a longitudinal study. Birth Issues ;2002; 11(2/3):53-9. **No interventions**

Durand M, Labarere J, Brunet E, et al. Evaluation of a training program for healthcare professionals about breast-feeding. Eur J of Obstetr Gynecol, & Reprod Biol 2003 Feb 10;106(2):134-8. **Historical control**

Dykes F. 'Supply' and 'demand': breastfeeding as labour. Soc Sci & Med ;2005 May; 60(10):2283-93. **No outcome of interest**

Escobar GJ, Braveman PA, Ackerson L, et al. A randomized comparison of home visits and hospital-based group follow-up visits after early postpartum discharge. Pediatrics 2001 Sep;108(3):719-27. **No outcome of interest**

Fallon AB, Hegney D, O'Brien M, et al. An evaluation of a telephone-based postnatal support intervention for infant feeding in a regional Australian city. Birth 2005 Dec;32(4):291-8. **Historical control**

Finigan V. Providing breastfeeding support to ethnically diverse groups of mothers. Professional Nurse 2003 May;18(9):524-8. **No control group**

Gagnon AJ, Dougherty G, Jimenez V, et al. Randomized trial of postpartum care after hospital discharge. Pediatrics 2002 Jun;109(6):1074-80. **In Britton 2006 systematic review**

Gilchrist D, Woods B, Binns CW, et al. Breastfeeding and health promotion: the experience of Aboriginal and non-Aboriginal mothers. Health Promotion J Au s;2004 Dec; 15(3):226-30. **Observational study**

Gonzalez KA, Meinzen-Derr J, Burke BL, et al. Evaluation of a lactation support service in a children's hospital neonatal intensive care unit. J oum Lact 2003 Aug;19(3):286-92. **Neonatal ICU**

Gorbe E, Kohalmi B, Gaal G, et al. The relationship between pacifier use, bottle feeding and breast feeding. J Maternal-Fetal & Neonatal Med 2002 Aug;12(2):127-31. **Observational study**

Graffy J, Taylor J, Willliams A, et al. Randomised controlled trial of support from volunteer counsellors for mothers considering breast feeding.[see comment]. BMJ 2004 Jan 3;328(7430):26. **In Britton 2006 systematic review**

Graffy J, Taylor J. What information, advice, and support do women want with breastfeeding? Birth 2005 Sep;32(3):179-86. **In Britton 2006 systematic review**

Heath AL, Tuttle CR, Simons MS, et al. A longitudinal study of breastfeeding and weaning practices during the first year of life in Dunedin, New Zealand. J Am Diet Assoc 2002 Jul;102(7):937-43. **Observational study**

Hedges S, Simmes D, Martinez A, et al. A home visitation program welcomes home first-time moms and their infants. Home Healthcare Nurse 2005 May;23(5):286-9. **No concurrent control**

Hoddinot P, Chalmers M, Pill R. One-to-one or group-based peer support for breastfeeding? Women's perceptions of a breastfeeding peer coaching intervention. Birth ;2006 Jun; 33(2):139-46. **Survey**

Hoddinott P, Lee AJ, Pill R. Effectiveness of a breastfeeding peer coaching intervention in rural Scotland. Birth ;2006 Mar; 33(1):27-36**. Before-after study**

Hofvander Y. Breastfeeding and the Baby Friendly Hospitals Initiative (BFHI): organization, response and outcome in Sweden and other countries. Acta Paediatrica 2005 Aug;94(8):1012-6. **Review**

Hogan M, Westcott C, Griffiths M. Randomized, controlled trial of division of tongue-tie in infants with feeding problems.[see comment]. J Paediatr & Child Health 2005 May;41(5-6):246-50. **No comparative Bf outcome**

Inch S, Law S, Wallace L. Hands off! The Breastfeeding Best Start Project (2). Practising Midwife 2003 Dec;6(11):24-5. **No outcome of interest**

Ingram J, Johnson D. A feasibility study of an intervention to enhance family support for breast feeding in a deprived area in Bristol, UK. Midwifery ;2004 Dec; 20(4):367-79. **No interventions**

Ingram J, Johnson D, Greenwood R. Breastfeeding in Bristol: teaching good positioning, and support from fathers and families. Midwifery 2002 Jun;18(2):87-101. **Historical control**

Kanng N, Song Y, Hyun TH, et al. Evaluation of the breastfeeding intervention program in a Korean community health center. Int J Nursing Studies ;2005 May; 42(4):409-13. **Historical control**

Kersting M, Dulon M. Assessment of breast-feeding promotion in hospitals and follow-up survey of mother-infant pairs in Germany: the SuSe Study. Public Health Nutr 2002 Aug;5(4):547-52. **No interventions**

Khoury AJ, Mitra AK, Hinton A, et al. An innovative video succeeds in addressing barriers to breastfeeding among low-income women. J Hum Lact ;2002 May; 18(2):125-31. **No outcome of interest**

Khoury AJ, Hinton A, Mitra AK, et al. Improving breastfeeding knowledge, attitudes, and practices of WIC clinic staff. Public Health Reports 2002 Sep;117(5):453-62. **No outcome of interest**

Kluka, S. M. A randomized controlled trial to test the effect of an antenatal educational intervention on breastfeeding duration among primiparous women. **Thesis/Dissertation**

Kools EJ, Thijs C, Kester AD, et al. A breast-feeding promotion and suppot program a randomized trial in The Netherlands. Preventive Medi2005 Jan;40(1):60-70. **In Britton 2006 systematic review**

Kovach AC. A 5-year follow-up study of hospital breastfeeding policies in the Philadelphia area: a comparison with the ten stepss. J Hum Lact 2002 May;18(2):144-54. **Cross-sectional survey**

Kramer MS, Guo T, Platt RW, et al. Breastfeeding and infant growth: biology or bias?[see comment]. Pediatrics 2002 Aug;110(2:Pt 1):t-7. **Observational study**

Mamiro PR, Van CJ, Roberfroid D, et al. Nutritional problems of infants in Kilosa district, rural Tanzania, and appropriate interventions. Mededelingen (Rijksuniversiteit Te Gent 2001;Fakulteit(4):291-4. **No interventions**

Martens PJ. Increasing breastfeeding initiation and duration at a community level: an evaluation of Sagkeeng First Nation's community health nurse and peer counselor programs. J Hum Lact 2002 Aug;18(3):236-46. **Descriptive, retrospective study**

Memmott MM, Bonuck KA. Mother's reactions to a skills-based breastfeeding promotion intervention. Maternal & Child Nutri 2006 Jan;2(1):40-50. **Duplicate publication (MILK study)**

Merewood A, Chamberlain LB, Cook JT, et al. The effect of peer counselors on breastfeeding rates in the neonatal intensive care unit: results of a randomized controlled trial. Arch Pediatr & Adolesc Med 2006 Jul;160(7):681-5. **Premature infants only**

Merten S, Dratva J, ckermann-Liebrich U. Do baby-friendly hospitals influence breastfeeding duration on a national level? Pediatrics 2005 Nov;116(5):e702-e708. **Retrospective study**

Mikiel-Kostyra K, Mazur J, Boltruszko I. Effect of early skin-to-skin contact after delivery on duration of breastfeeding: a prospective cohort study.[see comment]. Acta Paediatrica 2002;91(12):1301-6. **Observational study**

Philipp BL, Merewood A, Miller LW, et al. Baby-friendly hospital initiative improves breastfeeding initiation rates in a US hospital setting.[see comment]. Pediatrics 2001 Sep;108(3):677-81. **Retrospective study**

Philipp BL, Malone KL, Cimo S, et al. Sustained breastfeeding rates at eding rates at a US baby-friendly hospital. Pediatrics 2003 Sep;112(3:Pt 1):t-6. **Retrospective study**

Pugh LC, Milligan RA, Frick KD, et al. Breastfeeding duration, costs, and benefits of a support program for low-income breastfeeding women. Birth 2002 Jun;29(2):95-100. **In Britton 2006 systematic review**

Quinlivan JA, Box H, Evans SF. Postnatal home visits in teenage mothers: a randomised controlled trial. Lancet 2003 Mar 15;361(9361):893-900. **In Britton 2006 systematic review**

Radford A. Baby friendly education standards. Aiming to improve breastfeeding training. Practising Midwife 2003 Jan;6(1):32-3. **Communication**

Rowe-Murray HJ, Fisher JR. Baby friendly hospital practices: cesarean section is a persistent barrier to early initiation of breastfeeding. Birth 2002 Jun;29(2):124-31. **No interventions**

Schlickau, J. M. Prenatal breastfeeding education: an intervention for pregnant immigrant Hispanic women. **Thesis/Dissertation**

Shaw R, Wallace L, Cook M, et al. Perceptions of the Breastfeeding Best Start psing Midwife 2004 Jan;7(1):20-4. **No outcome of interest**

Sheehan D, Watt S, Krueger P, et al. The impact of a new universal postpartum program on breastfeeding outcomes. J Hum Lact;2006 Nov; 22(4):398-408. **No concurrent control**

Siddell E, Marinelli K, Froman RD, et al. Evaluation of an educational intervention on breastfeeding for NICU nurses. J Hum Lact ;2003 Aug; 19(3):293-302. **No interventions**

Simmer K. Telephone-based peer support increased the duration of breastfeeding in primiparous mothers. ACP Journal Club;2002 Sep-Oct; 137(2):68. **Commentary**

Sisk JE, Greer AL, Wojtowycz M, et al. Implementing evidence-based practice: evaluation of an opinion leader strategy to improve breast-feeding rates. Am J Obstetr & Gynecol 2004 Feb;190(2):413-21. **Actual BF rate not measured**

Stevens B, Guerriere D, McKeever P, et al. Economics of home vs. hospital breastfeeding support for newborns. J Adv Nursing 2006 Jan;53(2):233-43. **No relevant outcome**

Stremler J, Lovera D. Insight from a breastfeeding peer suppoding peer support pilot program for husbands and fathers of Texas WIC pacipants. J of Hum Lact 2004 Nov;20(4):417-22. **Historical control**

Taveras EM, Capra AM, Braveman PA, et al. Clinician support and psychosocial risk factors associated with breastinuation. Pediatrics 2003 Jul;112(1:Pt 1):t-15. **Retrospective study**

Vittoz JP, Labarere J, Castell M, et al. Effect of a training program for maternity ward professionals on duration of breastfeeding. Birth 2004 Dec;31(4):302-7. **Historical control**

Vogel AM, Hutchison BL, Mitchell EA. The impact of pacifier use on breastfeeding: a prospective cohort study. J Paediatr & Child Health 2001 Feb;37(1):58-63. **Observational study**

Wagner CL, Hulsey TC, Southgate WM, et al. Breastfeeding rates at an urban medical university after initiation of an educational program. Southern Med J 2002 Aug;95(8):909-13. **Historical control**

Walker ML. Telephone based peer support increased duration of breast feeding in primiparous mothers. Evidence-Based Nursing ;2002 Jul; 5(3):75. **Abstract**

Wallace H, Clarke S. Tongue tie division in infants with breast feeding difficulties. Int J Pediatr Otorhinolaryngol 2006 Jul;70(7):1257-61. **No interventions**

Watt RG, McGlone P, Russell JJ, et al. The process of establishing, implementing and maintaining a social support infant feeding programme. Public Health Nutrition 2006 Sep;9(6):714-21. **No interventions**

Winterburn S, Jiwa M, Thompson J. Maternal grandmothers and support for breastfeeding. J Comm Nursing 2006 Sep;2003 Dec; 17(12):4. **In Britton 2006 systematic review**

Woods A, Dykes F, Bramwell R. An intervention study using a breastfeeding positioning and attachment tool. Clinical Effectiveness in Nursing ;2002 Sep-Dec; 6(3-4):134-42. **Historical control**

Zuckerman B, Parker S, Kaplan-Sanoff M, et al. Healthy Steps: a case study of innovation in pediatric practice. Pediatrics 2004 Sep;114(3):820-6. **Observational study**

# Appendix E. Peer Reviewers

The peer reviewer comments on a preliminary draft of this report were considered by the EPC in preparation of this final report. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers. The authors gratefully acknowledge the peer reviewers.

Lori Feldman-Winter, MD, MPH
Robert Wood Johnson Medical School
University of Medicine and Dentistry of New Jersey
Camden, NJ

Pamela D. Hill, PhD, RN
College of Nursing
University of Illinois at Chicago
Director, Quad Cities Regional Program
Moline, Illinois

Ardythe L. Morrow, PhD, MSc
Center for Epidemiology and Biostatistics
Cincinnati Children's Hospital Medical Center
Cincinnati, Ohio

# Appendix G.

## A Summary of Breastfeeding and Maternal and Term-infant Health Outcomes in Developed Countries

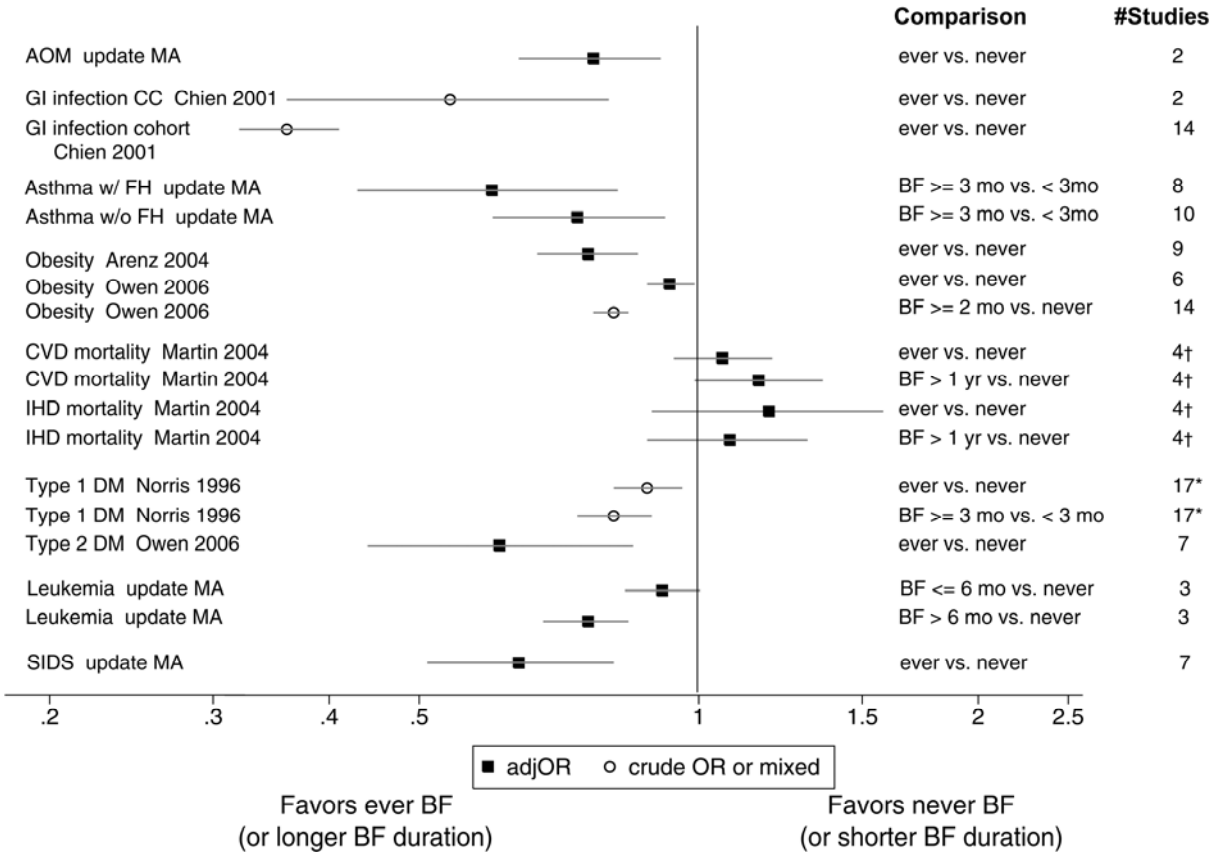
## (Abridged from Evidence Report No. 153: available at http://www.ahrq.gov/clinic/tp/brfouttp.htm)

Nineteen outcomes were analyzed in this review. We screened over 9,000 abstracts. Thirty-two primary studies on infant health outcomes, 43 primary studies on maternal health outcomes, and 28 systematic reviews or meta-analyses that covered approximately 400 individual studies were included.

The association studies of breastfeeding and health outcomes mostly presented results as odds ratios. To facilitate interpretation of the odds ratio, we chose to present these data as a reduction in relative risk, estimated as "(1 – odds ratio) x 100%", along with the corresponding 95% confidence interval (CI).

We present three overall summary figures below to give the reader a quick overview of the results from the meta-analyses included in this report on the association of breastfeeding with health outcomes. Outcomes that did not have meta-analyses are not listed in these figures. Figure 1 shows term infant health outcomes expressed as odds ratios or risk ratios comparing the different feeding groups; Figure 2 shows the association between exclusive breastfeeding and term infant health outcomes; and Figure 3 shows maternal health outcomes expressed as odds ratios or risk ratios comparing the different feeding groups.

**Figure 1. The relationship between breastfeeding and health outcomes in term infants - meta-analysis results**

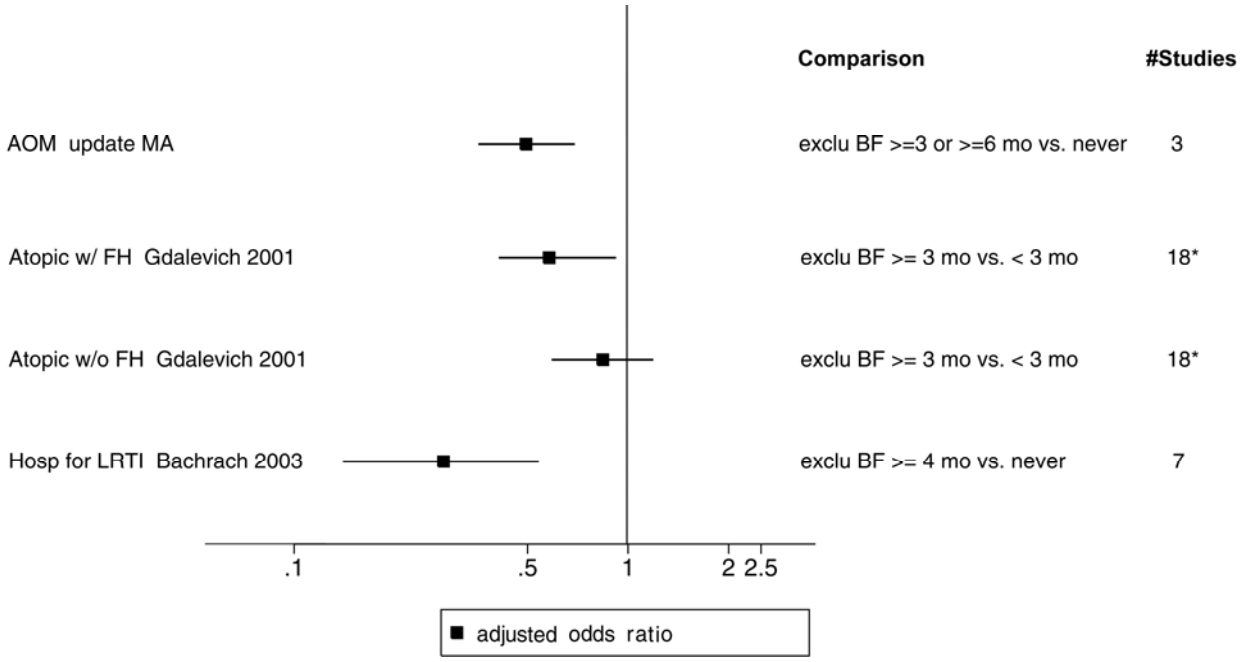



Legend: MA, meta-analysis; AOM, acute otitis media; GI, gastrointestinal; CC, case-control studies; FH, family history; CVD, cardiovascular disease; IHD, ischemic heart disease; DM, diabetes; adj, adjusted

*17 studies in total were included in Norris 1996 meta-analyses. The number of studies per comparison was not reported.

†Four historical cohort studies reported data on the relationship between breastfeeding and both CVD and IHD mortality.

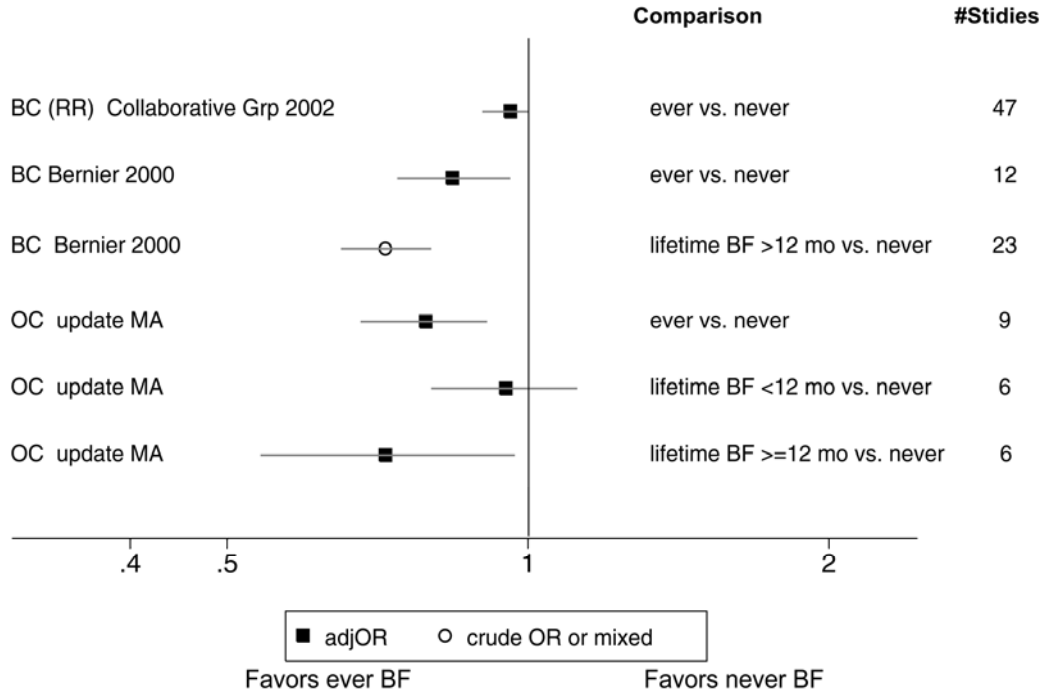
**Figure 2. The relationship between exclusive breastfeeding and health outcomes in term infants - meta-analysis results**




Legend: MA, meta-analysis; AOM, acute otitis media; FH, family history; Hosp, hospitalization; exclu, exclusive; LRTI, lower respiratory track infection

*18 studies in total were included in Gdalevich 2001 meta-analyses. The number of studies per comparison was not reported.

**Figure 3. The relationship between breastfeeding and maternal outcomes - meta-analysis results**




Legend: MA, meta-analysis; BC, breast cancer; RR, relative risk; OC, ovarian cancer; adj, adjusted

## Term Infant Outcomes

**Acute Otitis Media.** Our meta-analysis of five cohort studies (with 6 comparisons)[1-5] of good and moderate methodological quality showed that breastfeeding was associated with a significant reduction in the risk of acute otitis media. Comparing ever breastfeeding with exclusive bottle-feeding, the pooled adjusted odds ratio of AOM was 0.77 (95%CI 0.64 - 0.91). When comparing exclusive breastfeeding with exclusive bottle-feeding, either for more than 3 or 6 months duration, the pooled odds ratio was 0.50 (95%CI 0.36 - 0.70). These results were adjusted for potential confounders like parental smoking and use of day care.

**Atopic Dermatitis.** One good quality meta-analysis of 18 prospective cohort studies on full term infants reported an odds ratio of 0.58 (95%CI 0.41 - 0.92) in the risk of atopic dermatitis in children with a family history of atopy and exclusively breastfed for at least 3 months compared with those who were breastfed for less than 3 months.[6] The meta-analysis did not distinguish between atopic dermatitis of infancy (under 2 years of age) and persistent or new atopic dermatitis at older ages. It has been postulated that the diagnosis of atopic dermatitis in patients younger than 2 years of age could be attributed to infectious etiologies, which may be prevented by breastfeeding. However, a stratified analysis by duration of followup found the summary odds ratio in the group with less than 2 years of followup was 0.74 (95%CI 0.61 – 0.90), whereas the summary odds ratio in the group with 2 or more years of followup was 0.78 (95%CI 0.62 – 0.99).

**Gastrointestinal Infections.** For non-specific gastroenteritis, one systematic review identified three primary studies that controlled for potential confounders (eg, maternal education,

parity, family living standards).[7] These studies reported that there was a reduction in the risk of non-specific gastrointestinal infections during the first year of life in breastfed infants from developed countries. But a summary adjusted estimate taking into account potential confounders could not be determined because the studies did not provide usable quantitative data. However, a recent case-control study from England that took into account the role of potential confounders reported that infants who were currently breastfeeding had a reduced risk of non-specific gastroenteritis compared with infants who were currently not breastfeeding (OR 0.36, 95% CI 0.18 to 0.74, P=0.005). The result was adjusted for age, sex, social class, contact with person in and outside household, and other factors. This study also reported that the protective effect of breastfeeding did not persist beyond 2 months after cessation of breastfeeding.[8]

**Lower Respiratory Tract Diseases.** A good quality meta-analysis of seven studies reported an overall risk reduction (summary relative risk 0.28, 95% CI 0.14 - 0.54) of hospitalization secondary to lower respiratory tract diseases in infants less than 1 year of age who were exclusively breastfed for 4 months or more compared with those who were formula-fed. [9] The results remained consistent after adjustment for potential confounders like smoking and socioeconomic status.

**Asthma.** A well-performed meta-analysis from 2001 concluded that breastfeeding was associated with a reduction in the risk of developing asthma.[10] This association was stronger in those subjects with a positive family history. However, three new primary studies.[11-13] and one followup study[14] reported conflicting results. We updated the meta-analysis with three of the studies.[11,12,14] Our analysis showed that breastfeeding for at least 3 months was associated with a reduced risk of asthma (OR 0.73, 95%CI 0.59 – 0.92) in those subjects without a family history of asthma compared with those who were not breastfed. This association was also found in subjects under 10 years of age with a positive family history of asthma. It is unclear whether this association changes for older children. It should also be noted that the fourth study,[13] which did not qualify for inclusion in our new meta-analyses, reported an increase in asthma risk with increased duration of breastfeeding in those subjects with a maternal history of asthma.

**Cognitive Development**. One well-performed sibling analysis[15] and three prospective cohort studies[15-17] of full-term infants, all conducted in developed countries, adjusted their analyses specifically for maternal intelligence. The studies found little or no evidence for an association between breastfeeding in infancy and cognitive performance in childhood. Most of the published studies adjusted their analyses for socioeconomic status and maternal education but not specifically for maternal intelligence. For those studies that reported a significant effect after specific adjustment for maternal intelligence, residual confounding from other factors such as different home environments cannot be ruled out.

**Obesity.** Findings from three systematic reviews and meta-analyses of good and moderate methodological quality suggest that a history of breastfeeding is associated with a reduction in the risk of obesity in later life.[18-20] The pooled adjusted odds ratio of overweight/obesity comparing ever breastfeeders to never breastfeeders was 0.76 (95%CI 0.67-0.86) and 0.93 (95%CI: 0.88–0.99) in Arenz 2004[18] and Owen 2005[20] meta-analysis, respectively. In Harder 2005[19] meta-analysis, duration of breastfeeding was significantly negatively related to the unadjusted risk of overweight (regression coefficient: 0.94, 95%CI 0.89 - 0.98), and each month of breastfeeding was found to be associated with a four percent decrease in risk (unadjusted OR 0.96/month of breastfeeding, 95%CI 0.94 - 0.98). However, the results from Harder 2005 meta-analysis employed techniques that required the use of crude odds ratios from the primary studies for its summary estimates. Therefore, those estimates may not be accurate because potential confounders could not be accounted for in the analysis. As demonstrated in the sensitivity analyses in both Arenz 2004 and Owen 2005, the magnitude of effects was reduced when more confounders were adjusted for in the analyses. The observed association between breastfeeding and a reduced risk of obesity could also reflect selective reporting and/or publication bias.

**Risk of Cardiovascular Diseases.** Results from two moderate quality meta-analyses concluded that there was a small reduction of less than 1.5 mm Hg in systolic blood pressures and no more than 0.5 mm Hg in diastolic blood pressures among adults who were breastfed in their infancy compared with those who were formula-fed.[21,22] The association weakened after stratification by study size, suggesting the possibility of bias in the smaller studies.

One meta-analysis of cohort and case-control studies reported that there was a reduction in total and LDL cholesterol levels by 7.0 mg/dL and 7.7 mg/dL, respectively, in adults who were breastfed during infancy compared with those who were not.[23] However, these findings were based on data from adults with a wide age range. The analysis did not segregate the data according to gender and potential confounders were not explicitly analyzed. Detailed information (eg, fasting or non-fasting) on the collection of specimen for cholesterol testing was not included. Because of these deficiencies, the correct characterization of a relationship between breastfeeding and adult cholesterol levels cannot be determined at this time.

One meta-analysis found little or no difference in all-cause and cardiovascular mortality between adults who were breastfed during infancy and those who were not.[24] There were possible biases and limitations in the studies reviewed, however. Presence of statistical heterogeneity across studies suggests that it may not have been appropriate to combine estimates from individual studies into one summary estimate. Because of these reasons, no definitive conclusion could be drawn regarding the relationship between a history of breastfeeding and cardiovascular mortality.

**Type 1 Diabetes**. Two meta-analyses of moderate methodological quality reported statistically significant odds ratios of 1.23 (95%CI 1.12 - 1.35)[25] and 1.43 (95%CI 1.15 - 1.77),[26] respectively, for the risk of type 1 diabetes in subjects exposed to less than 3 months compared with more than 3 months of breastfeeding. In addition, findings from five[27-31] of six[27-32] studies published since the meta-analyses reported similar results. Since case-control studies are prone to recall biases, Norris and Scott compared the odds ratios in studies relied on long-term recall to assess infant diet with studies that did not.[25] The results showed that studies using existing infant records to determine breastfeeding initiation and duration failed to show the associations reported in the studies relying on long-term recall for their exposure data. This suggests that subjects with type 1 diabetes were more likely to report shorter duration of breastfeeding than control subjects.

**Type 2 Diabetes.** Results from a high-quality systematic review and meta-analysis[33] of seven studies[34-40] suggest that breastfeeding is associated with a lower risk of type 2 diabetes in later life, compared with formula feeding. Comparing subjects who were ever breastfed to those who were formula-fed, the pooled adjusted odds ratio of type 2 diabetes in later life was 0.61 (95%CI 0.44-0.85). Three studies provided information on important confounders like birth weight, parental diabetes, socioeconomic status, or maternal body size.[34,37,40] Even though these three studies found that adjustment did not alter the crude estimate, we cannot be completely confident that potential confounding by birth weight and maternal factors has been ruled out for the overall pooled estimate.

**Childhood Leukemia.** The published studies on childhood acute lymphocytic leukemia (ALL) were equivocal; a good quality meta-analysis[41] reported a moderate protective effect from breastfeeding and the other good quality systematic review[42] reached the opposite conclusion. We conducted a meta-analysis including only good and fair quality case-control studies identified in the systematic review, since the meta-analysis did not provide methodological quality grading of primary studies. We combined socioeconomic status-adjusted odds ratios of ALL in relation to short- (≤ 6 months) and long- (> 6 months) term breastfeeding from UKCCS[43], CCG study,[44] and Dockerty 1999.[45] One study was excluded from the analysis because the duration of breastfeeding was not reported.[46] The results from our meta-analysis suggest that long-term breastfeeding is associated with a reduction in the risk of ALL (OR 0.81; 95%CI 0.71 - 0.91).

**Infant Mortality.** One study of moderate methodological quality evaluated the relationship between breastfeeding and infant mortality.[47] The study reported a protective effect of breastfeeding in reducing infant mortality after controlling for some of the potential confounders. However, in subgroup analyses of the study, the only statistically significant association reported was between "never breastfed" and Sudden Infant Death Syndrome (SIDS) or the risk of injury-related deaths. Because of the limited data in this area, the relationship between breastfeeding and infant mortality in developed countries remains unclear.

**Sudden Infant Death Syndrome (SIDS).** Results from the previously published meta-analysis of case-control studies concluded that an overall crude risk of SIDS was twice as great for formula-fed infants compared with breastfed infants.[48] The conclusion may be biased because the reported association was not adjusted for potential confounders.

Findings from the four studies published subsequent to the meta-analysis in developed countries concurred with the findings from the meta-analysis.[49-53] All studies reported autopsy-confirmed diagnoses of SIDS and adjusted for potential confounders. However, the definitions of breastfeeding exposure and the time intervals accepted for defining SIDS varied across studies.

We elected to conduct our own meta-analysis using only studies that provided an objective definition of SIDS (autopsy confirmed SIDS among infants 1 week to 1 year of age), clear reporting of breastfeeding data, and outcomes adjusted for important confounders or risk factors (eg, sleeping positions, maternal smoking, and socioeconomic status). Four studies included in the previously published meta-analysis[54-57] and two studies published since 1997 met the eligibility criteria.[51,53] The results from our meta-analysis found that ever breastfeeding was associated with a reduction in both crude and adjusted risk of SIDS (crude OR 0.41; 95%CI (0.28, 0.58), and adjusted OR 0.64; 95%CI (0.51, 0.81), respectively); both estimates were statistically significant with a reduction in SIDS for the ever breastfed infants.

## Maternal Outcomes

**Return to Pre-pregnancy Weight.** Three moderate quality prospective cohort studies reported less than 1 kg weight change from pre-pregnancy or first trimester to 1 to 2 year postpartum period in mothers who breastfed.[58-60] Results from four moderate quality prospective cohort studies (in five publications)[61-65] showed that the effects of breastfeeding on postpartum weight loss were unclear. Results from all seven studies consistently showed that many factors other than breastfeeding had larger effects on weight retention or postpartum weight loss. Methodological challenges in these studies included the accurate measurement of weight change, adequate control for numerous covariables including the amount of pregnancy weight gain, and quantifying accurately the exclusivity and the duration of breastfeeding.

**Maternal Type 2 Diabetes.** Two large cohorts from a high quality longitudinal study of 150,000 parous women in the United States examined the relationship between breastfeeding and the risk of maternal type 2 diabetes.[66] In parous women without a history of gestational diabetes, each additional year of breastfeeding was associated with a 4 percent (95% CI 1% to 9%) reduced risk of developing type 2 diabetes in the first cohort and a 12 percent (95% CI 6% to 18%) reduced risk in the second cohort. In women with a history of gestational diabetes, breastfeeding had no significant effect on the already increased risk of diabetes. Because only nurses were included in the cohorts, generalization of findings to the rest of the population must be done with care.

**Osteoporosis.** There is little or no evidence from six moderate quality case-control studies for an association between lifetime breastfeeding duration and the risk of fractures due to osteoporosis.[67-72] In two[73,74] of three[73-75] moderate or good quality prospective cohort studies using bone mineral density as a surrogate for osteoporosis, lactation does not appear to have an effect on long-term changes in bone mineral densities. The third study found a small decrease in the

bone mineral contents in the distal radius with increased duration of breastfeeding (correlation coefficient = -0.34, P = 0.015), but no significant changes in bone mineral contents in the femoral neck or the trochanter.[75]

**Postpartum Depression.** Four prospective cohort studies of moderate methodological quality reported on the relationship between a history of breastfeeding and postpartum depression.[76-79] None of the studies explicitly screened for depression at baseline before the initiation of breastfeeding and none of them provided detailed data on breastfeeding. Three of the four studies found an association between a history of short duration of breastfeeding or not breastfeeding with postpartum depression.[77-79] The results were adjusted for socio-demographic and obstetric variables. More investigation will be needed to determine the nature of this association. It is plausible that postpartum depression led to early cessation of breastfeeding, as opposed to breastfeeding altering the risk of depression. Both effects might occur concurrently.

**Breast Cancer.** Two meta-analyses of moderate methodological quality concluded that there was a reduction of breast cancer risk in women who breastfed their infants.[80,81] The reduction in breast cancer risk was 4.3 percent for each year of breastfeeding in one meta-analysis[81] and 28 percent for 12 or more months of lifetime breastfeeding in the other.[80] In addition, one[80] of the two meta-analyses and another systematic review[82] reported decreased risk of breast cancer primarily in premenopausal women. Findings from primary studies published after the meta-analyses concurred with the findings from the earlier meta-analyses. These findings suggest that there is an association between breastfeeding and a reduced risk of breast cancer.

**Ovarian Cancer.** We reviewed 15 case-control studies[83-99] that examined the relationship between breastfeeding and the risk of ovarian cancer, and performed meta-analyses in nine studies[83,85,87-90,93-95,99] that adjusted for potential confounders. The overall result from the nine studies showed an association between breastfeeding and a 21 percent (95% CI 9% to 32%) reduction in the risk of ovarian cancer, compared to never breastfeeding. Because not all the studies reported similar comparisons of breastfeeding durations, we had to estimate the comparable risks in five studies.[85,87-90,99] Excluding these five studies from the meta-analysis results in loss of statistical significance for this association.

There was indirect evidence for a dose-response relationship between breastfeeding and a reduced risk of ovarian cancer. Breastfeeding of more than 12 months (cumulative duration) was associated with a reduced risk of ovarian cancer, compared to never breastfeeding. However, it must be noted that the 12 months cutoff was arbitrary, and the odds ratios were estimated in half of these studies.

References


1. Alho OP, Laara, Oja H. How should relative risk estimates for acute otitis media in children aged less than 2 years be perceived? J Clin Epidemiol 1996;49(1):9-14.

2. Duffy LC, Faden H, Wasielewski R, et al. Exclusive breastfeeding protects against bacterial colonization and day care exposure to otitis media. Pediatrics 1997;100(4):E7.

3. Duncan B, Ey J, Holberg CJ, et al. Exclusive breast-feeding for at least 4 months protects against otitis media.[see comment]. Pediatrics 1993;91(5):867-72.

4. Scariati PD, Grummer-Strawn LM, Fein SB. A longitudinal analysis of infant morbidity and the extent of breastfeeding in the United States. Pediatrics 1997;99(6):E5.

5. Teele DW, Klein JO, Rosner B. Epidemiology of otitis media during the first seven years of life in children in greater Boston: a prospective, cohort study. J Infect Dis 1989;160(1):83-94.

6. Gdalevich M, Mimouni D, David M, et al. Breast-feeding and the onset of atopic dermatitis in childhood: a systematic review and meta-analysis of prospective studies. J Am Acad Dermatol 2001;45(4):520-7.

7. Chien PF, Howie PW. Breast milk and the risk of opportunistic infection in infancy in industrialized and non-industrialized settings. [Review] [75 refs]. Adv Nutr Res 2001;10:69-104.

8. Quigley MA, Cumberland P, Cowden JM, et al. How protective is breast feeding against diarrhoeal disease in infants in 1990s England? A case-control study. Arch Dis Child 2006;91(3):245-50.

9. Bachrach VR, Schwarz E, Bachrach LR. Breastfeeding and the risk of hospitalization for respiratory disease in infancy: a meta-analysis. Arch Pediatr Adolesc Med 2003;157(3):237-43.

10. Gdalevich M, Mimouni D, Mimouni M. Breast-feeding and the risk of bronchial asthma in childhood: a systematic review with meta-analysis of prospective studies. J Pediatr 2001;139(2):261-6.

11. Burgess SW, Dakin CJ, O'Callaghan MJ. Breastfeeding does not increase the risk of asthma at 14 years. Pediatrics 2006;117(4):e787-e792.

12. Kull I, Almqvist C, Lilja G, et al. Breast-feeding reduces the risk of asthma during the first 4 years of life.[see comment]. J Allergy Clin Immunol 2004;114(4):755-60.

13. Sears MR, Greene JM, Willan AR, et al. Long-term relation between breastfeeding and development of atopy and asthma in children and young adults: a longitudinal study.[see comment]. Lancet 2002;360(9337):901-7.

14. Wright AL, Holberg CJ, Taussig LM, et al. Factors influencing the relation of infant feeding to asthma and recurrent wheeze in childhood.[see comment]. Thorax 2001;56(3):192-7.

15. Der G, Batty D, Deary IJ. Effect of breast feeding on intelligence in children: prospective study, sibling pairs analysis, and meta-analysis. BMJ 2006.

16. Angelsen NK, Vik T, Jacobsen G, et al. Breast feeding and cognitive development at age 1 and 5 years. Arch Dis Child 2001;85(3):183-8.

17. Gomez-Sanchiz M, Canete R, Rodero I, et al. Influence of breast-feeding and parental intelligence on cognitive development in the 24-month-old child. Clin Pediatr (Phila) 2004;43(8):753-61.

18. Arenz S, Ruckerl R, Koletzko B, et al. Breast-feeding and childhood obesity--a systematic review. [Review] [51 refs]. Int J Obes Relat Metab Disord 2004;28(10):1247-56.

19. Harder T, Bergmann R, Kallischnigg G, et al. Duration of breastfeeding and risk of overweight: a meta-analysis. Am J Epidemiol 2005;162(5):397-403.

20. Owen CG, Martin RM, Whincup PH, et al. Effect of infant feeding on the risk of obesity across the life course: a quantitative review of published evidence. Pediatrics 2005;115(5):1367-77.

21. Martin RM, Gunnell D, Smith GD. Breastfeeding in infancy and blood pressure in later life: systematic review and meta-analysis. Am J Epidemiol 2005;161(1):15-26.

22. Owen CG, Whincup PH, Gilg JA, et al. Effect of breast feeding in infancy on blood pressure in later life: systematic review and meta-analysis. [Review] [26 refs]. BMJ 2003;327(7425):1189-95.

23. Owen CG, Whincup PH, Odoki K, et al. Infant feeding and blood cholesterol: a study in adolescents and a systematic review.[see comment]. [Review] [88 refs]. Pediatrics 2002;110(3):597-608.

24. Martin RM, Davey SG, Mangtani P, et al. Breastfeeding and cardiovascular mortality: the Boyd Orr cohort and a systematic review with meta-analysis. [Review] [25 refs]. Eur Heart J 2004;25(9):778-86.

25. Norris JM, Scott FW. A meta-analysis of infant diet and insulin-dependent diabetes mellitus: do biases play a role? Epidemiology 1996;7(1):87-92.

26. Gerstein HC. Cow's milk exposure and type I diabetes mellitus. A critical overview of the clinical literature. Diabetes Care 1994;17(1):13-9.

27. EURODIAS S. Rapid early growth is associated with increased risk of childhood type 1 diabetes in various European populations. Diabetes Care 2002;25(10):1755-60.

28. Jones ME, Swerdlow AJ, Gill LE, et al. Pre-natal and early life risk factors for childhood onset diabetes mellitus: a record linkage study. Int J Epidemiol 1998;27(3):444-9.

29. McKinney PA, Parslow R, Gurney KA, et al. Perinatal and neonatal determinants of childhood type 1 diabetes. A case-control study in Yorkshire, U.K. Diabetes Care 1999;22(6):928-32.

30. Tai TY, Wang CY, Lin LL, et al. A case-control study on risk factors for Type 1 diabetes in Taipei City. Diabetes Res Clin Pract 1998;42(3):197-203.

31. Visalli N, Sebastiani L, Adorisio E, et al. Environmental risk factors for type 1 diabetes in Rome and province. Arch Dis Child 2003;88(8):695-8.

32. Meloni T, Marinaro AM, Mannazzu MC, et al. IDDM and early infant feeding. Sardinian case-control study. Diabetes Care 1997;(3):340-2.

33. Owen CG, Martin RM, Whincup PH, et al. Does breastfeeding influence risk of type 2 diabetes in later life? A quantitative analysis of published evidence. Am J Clin Nutr 2006;84(5):1043-54.

34. Fall CH, Osmond C, Barker DJ, et al. Fetal and infant growth and cardiovascular risk factors in women. BMJ 1995;310(6977):428-32.

35. Martin RM, Ebrahim S, Griffin M, et al. Breastfeeding and atherosclerosis: intima-media thickness and plaques at 65-year follow-up of the Boyd Orr cohort. Arterioscler Thromb Vasc Biol 2005;25(7):1482-8.

36. Martin RM, Ben-Shlomo Y, Gunnell D, et al. Breast feeding and cardiovascular disease risk factors, incidence, and mortality: the Caerphilly study. J Epidemiol Community Health 2005;59(2):121-9.

37. Pettitt D, Decourten M, Nelson R , et al. Lower prevalence of NIDDM in breast-fed Pima-Indians. Diabetes 44. 1995. A6

38. Ravelli AC, van der Meulen JH, Osmond C, et al. Infant feeding and adult glucose tolerance, lipid profile, blood pressure, and obesity. Arch Dis Child 2000;82(3):248-52.

39. Rich-Edwards JW, Stampfer MJ, Manson JE, et al. Breastfeeding during infancy and the risk of cardiovascular disease in adulthood. Epidemiology 2004;15(5):550-6.

40. Young TK, Martens PJ, Taback SP, et al. Type 2 diabetes mellitus in children: prenatal and early infancy risk factors among native canadians. Arch Pediatr Adolesc Med 2002;156(7):651-5.

41. Kwan ML, Buffler PA, Abrams B, et al. Breastfeeding and the risk of childhood leukemia: a meta-analysis. Public Health Rep 2004;119(6):521-35.

42. Guise JM, Austin D, Morris CD. Review of case-control studies related to breastfeeding and reduced risk of childhood leukemia. Pediatrics 2005;116(5):e724-e731.

43. Beral VaUCCSI. Breastfeeding and childhood cancer. Br J Cancer 2001;85(11):1685-94.

44. Shu XO, Linet MS, Steinbuch M, et al. Breast-feeding and risk of childhood acute leukemia. J Natl Cancer Inst 1999;91(20):1765-72.

45. Dockerty JD, Skegg DC, Elwood JM, et al. Infections, vaccinations, and the risk of childhood leukaemia. Br J Cancer 1999;80(9):1483-9.

46. Rosenbaum PF, Buck GM, Brecher ML. Early child-care and preschool experiences and the risk of childhood acute lymphoblastic leukemia. Am J Epidemiol 2000;152(12):1136-44.

47. Chen A, Rogan WJ. Breastfeeding and the risk of postneonatal death in the United States. Pediatrics 2004;113(5):e435-e439.

48. McVea KL, Turner PD, Peppler DK. The role of breastfeeding in sudden infant death syndrome. J Hum Lact 2000;16(1):13-20.

49. Findeisen M, Vennemann M, Brinkmann B, et al. German study on sudden infant death (GeSID): design, epidemiological and pathological profile. Int J Legal Med 2004;118(3):163-9.

50. Hauck FR, Herman SM, Donovan M, et al. Sleep environment and the risk of sudden infant death syndrome in an urban population: the Chicago Infant Mortality Study. Pediatrics 2003;111(5 Part 2):1207-14.

51. Mitchell EA, Tuohy PG, Brunt JM, et al. Risk factors for sudden infant death syndrome following the prevention campaign in New Zealand: a prospective study. Pediatrics 1997;100(5):835-40.

52. Schellscheidt J, Ott A, Jorch G. Epidemiological features of sudden infant death after a German intervention campaign in 1992. Eur J Pediatr 1997;156(8):655-60.

53. Vennemann MM, Findeisen M, ButterfassBahloul T, et al. Modifiable risk factors for SIDS in Germany: results of GeSID. Acta Paediatrica 2005;94(6):655-60.

54. Wennergren G, Alm B, Oyen N, et al. The decline in the incidence of SIDS in Scandinavia and its relation to risk-intervention campaigns. Nordic Epidemiological SIDS Study. Acta Paediatrica 1997;86(9):963-8.

55. Brooke H, Gibson A, Tappin D, et al. Case-control study of sudden infant death syndrome in Scotland, 1992-5.[see comment]. BMJ 1997;314(7093):1516-20.

56. Mitchell EA, Taylor BJ, Ford RP, et al. Four modifiable and other major risk factors for cot death: the New Zealand study.[see comment]. J Paediatr Child Health 1992;28:Suppl-8.

57. Fleming PJ, Blair PS, Bacon C, et al. Environment of infants during sleep and risk of the sudden infant death syndrome: results of 1993-5 case-control study for confidential inquiry into stillbirths and deaths in infancy. Confidential Enquiry into Stillbirths and Deaths Regional Coordinators and Researchers.[see comment]. BMJ 1996;313(7051):191-5.

58. Sichieri R, Field AE, Rich-Edwards J, et al. Prospective assessment of exclusive breastfeeding in relation to weight change in women. Int J Obes Relat Metab Disord 2003;27(7):815-20.

59. Janney CA, Zhang D, Sowers M. Lactation and weight retention. Am J Clin Nutr 1997;66(5):1116-24.

60. Olson CM, Strawderman MS, Hinton PS, et al. Gestational weight gain and postpartum behaviors associated with weight change from early pregnancy to 1 y postpartum. Int J Obes Relat Metab Disord 2003;27(1):117-27.

61. Ohlin A, Rossner S. Maternal body weight development after pregnancy. Int J Obes 1990;14(2):159-73.

62. Ohlin A, Rossner S. Factors related to body weight changes during and after pregnancy: the Stockholm Pregnancy and Weight Development Study. Obes Res 1996;4(3):271-6.

63. Brewer MM, Bates MR, Vannoy LP. Postpartum changes in maternal weight and body fat depots in lactating vs nonlactating women. Am J Clin Nutr 1989;49(2):259-65.

64. Walker L, Freeland-Graves JH, Milani T, et al. Weight and behavioral and psychosocial factors among ethnically diverse, low-income women after childbirth: II. Trends and correlates. Women Health 2004;40(2):19-34.

65. Haiek LN, Kramer MS, Ciampi A, et al. Postpartum weight loss and infant feeding. J Am Board Fam Pract 2001;14(2):85-94.

66. Stuebe AM, Rich-Edwards JW, Willett WC, et al. Duration of lactation and incidence of type 2 diabetes. JAMA 2005;294(20):2601-10.

67. Alderman BW, Weiss NS, Daling JR, et al. Reproductive history and postmenopausal risk of hip and forearm fracture. Am J Epidemiol 1986;124(2):262-7.

68. Chan HH, Lau EM, Woo J, et al. Dietary calcium intake, physical activity and the risk of vertebral fracture in Chinese. Osteoporos Int 1996;6(3):228-32.

69. Cumming RG, Klineberg RJ. Breastfeeding and other reproductive factors and the risk of hip fractures in elderly women.[erratum appears in Int J Epidemiol 1993 Oct;22(5):962]. Int J Epidemiol 1993;22(4):684-91.

70. Hoffman S, Grisso JA, Kelsey JL, et al. Parity, lactation and hip fracture. Osteoporos Int 1993;3(4):171-6.

71. Kreiger N, Kelsey JL, Holford TR, et al. An epidemiologic study of hip fracture in postmenopausal women. Am J Epidemiol 1982;116(1):141-8.

72. Michaelsson K, Baron JA, Farahmand BY, et al. Influence of parity and lactation on hip fracture risk. Am J Epidemiol 2001;153(12):1166-72.

73. Matsushita H, Kurabayashi T, Tomita M, et al. The effect of multiple pregnancies on lumbar bone mineral density in Japanese women. Calcif Tissue Int 2002;71(1):10-3.

74. Sowers MR, Clark MK, Hollis B, et al. Radial bone mineral density in pre- and perimenopausal women: a prospective study of rates and risk factors for loss. J Bone Miner Res 1992;7(6):647-57.

75. Uusi-Rasi K, Sievanen H, Pasanen M, et al. Association of physical activity and calcium intake with the maintenance of bone mass in premenopausal women. Osteoporos Int 2002;13(3):211-7.

76. Chaudron LH, Klein MH, Remington P, et al. Predictors, prodromes and incidence of postpartum depression. J Psychosom Obstet Gynaecol 2001;22(2):103-12.

77. Henderson JJ, Evans SF, Straton JA, et al. Impact of postnatal depression on breastfeeding duration.[erratum appears in Birth. 2004 Mar;31(1):76]. Birth 2003;30(3):175-80.

78. Warner R, Appleby L, Whitton A, et al. Demographic and obstetric risk factors for postnatal psychiatric morbidity. Br J Psychiatry 1996;168(5):607-11.

79. Cooper PJ, Murray L, Stein A. Psychosocial factors associated with the early termination of breast-feeding. J Psychosom Res 1993;37(2):171-6.

80. Bernier MO, PluBureau G, Bossard N, et al. Breastfeeding and risk of breast cancer: a metaanalysis of published studies. Hum Reprod Update 2000;6(4):374-86.

81. Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and breastfeeding: collaborative reanalysis of individual data from 47 epidemiological studies in 30 countries, including 50302 women with breast cancer and 96973 women without the disease.[see comment][comment]. [Review] [68 refs]. Lancet 2002;360(9328):187-95.

82. Lipworth L, Bailey LR, Trichopoulos D. History of breast-feeding in relation to breast cancer risk: a review of the epidemiologic literature.[see comment]. [Review] [43 refs]. J Natl Cancer Inst 2000;92(4):302-12.

83. Chiaffarino F, Pelucchi C, Negri E, et al. Breastfeeding and the risk of epithelial ovarian cancer in an Italian population. Gynecol Oncol 2005;98(2):304-8.

84. Cramer DW, Hutchison GB, Welch WR, et al. Determinants of ovarian cancer risk. I. Reproductive experiences and family history. J Natl Cancer Inst 1983;71(4):711-6.

85. Greggi S, Parazzini F, Paratore MP, et al. Risk factors for ovarian cancer in central Italy. Gynecol Oncol 2000;79(1):50-4.

86. Gwinn ML, Lee NC, Rhodes PH, et al. Pregnancy, breast feeding, and oral contraceptives and the risk of epithelial ovarian cancer. J Clin Epidemiol 1990;43(6):559-68.

87. Hartge P, Schiffman MH, Hoover R, et al. A case-control study of epithelial ovarian cancer. Am J Obstet Gynecol 1989;161(1):10-6.

88. Modugno F, Ness RB, Wheeler JE. Reproductive risk factors for epithelial ovarian cancer according to histologic type and invasiveness. Ann Epidemiol 2001;2001 Nov; 11(8):568-74.

89. Ness RB, Grisso JA, Cottreau C, et al. Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer.[see comment]. Epidemiology 2000;11(2):111-7.

90. Riman T, Dickman PW, Nilsson S, et al. Risk factors for invasive epithelial ovarian cancer: results from a Swedish case-control study. Am J Epidemiol 2002;156(4):363-73.

91. Risch HA, Weiss NS, Lyon JL, et al. Events of reproductive life and the incidence of epithelial ovarian cancer. American Journal of Epidemiology 1983;117(2):128-39.

92. Risch HA, Marrett LD, Howe GR. Parity, contraception, infertility, and the risk of epithelial ovarian cancer. Am J Epidemiol 1994;140(7):585-97.

93. Siskind V, Green A, Bain C, et al. Breastfeeding, menopause, and epithelial ovarian cancer. Epidemiology 1997;8(2):188-91.

94. Titus-Ernstoff L, Perez K, Cramer DW, et al. Menstrual and reproductive factors in relation to ovarian cancer risk. Br J Cancer 2001;84(5):714-21.

95. Tung KH, Goodman MT, Wu AH, et al. Reproductive factors and epithelial ovarian cancer risk by histologic type: a multiethnic case-control study. Am J Epidemiol 2003;158(7):629-38.

96. Tung KH, Wilkens LR, Wu AH, et al. Effect of anovulation factors on pre- and postmenopausal ovarian cancer risk: revisiting the incessant ovulation hypothesis. Am J Epidemiol 2005;161(4):321-9.

97. West RO. Epidemiologic study of malignancies of the ovaries. Cancer 1966;19(7):1001-7.

98. Wynder EL, Dodo H, Barber HR. Epidemiology of cancer of the ovary. Cancer 1969;23(2):352-70.

99. Yen ML, Yen BL, Bai CH, et al. Risk factors for ovarian cancer in Taiwan: a case-control study in a low-incidence population. Gynecol Oncol 2003;89(2):318-24.

# Appendix H. Studies not specifically targeting promotion of breastfeeding that reported breastfeeding, maternal, or infant health outcomes

**Studies not specifically targeting promotion of breastfeeding that reported breastfeeding, maternal, or infant health outcomes**

| Study/Country N in intervention vs. control | Population | Intervention /Control | Outcome: Intervention vs. control | | | Quality/Applicability/Comments |
|---|---|---|---|---|---|---|
| | | | Breastfeeding | Maternal | Infant | |
| *Randomized Controlled Trials* | | | | | | |
| O'Connor 2003<br><br>Canada<br><br>353 vs. 380 | Low risk mothers, could be discharged within 2 d postpartum | 2 home visits vs. telephone call | BF rate at 6 mo: 59% vs. 54% (site A); 60% vs. 60% (site B) (NS) | | Total no. of health problems at 4 wk: 55% vs. 49% (site A); 51% vs. 60% (site B) (NS) | Fair<br>Wide<br><br>>20% loss to followup at 6 mo compared to enrollment |
| Boulvain 2004<br>Switzerland<br><br>228 vs. 231 | Middle income | Short stay (1-2d) with home care vs. normal hospital stay (3-4d) | BF rate at 6 mo: 35% vs. 36% (NS) | Fewer problems with BF at 4 wk (RR 0.64; 95%CI 0.47, 0.87); no difference in depression score at 4 wk (RR 0.79; 95%CI 0.42, 1.5); no diff in SF-12 physical and mental (P=0.42, 0.44) | Readmission rate to hospital first 6 mo: (12% vs. 5%; RR 2.6; 95%CI 1.3, 5.1) | Poor<br>Wide<br><br>Incomplete and inconsistent data reporting; no baseline maternal morbidity data |
| Minkovitz 2001<br>US<br>729 vs. 683 | 33% Medicaid, 20% Hispanic, 24% African Americans | Healthy Steps vs. no Healthy Steps | Continue to BF between 2 and 4 mo: 55.6% vs. 54% (adj RR 1.15, 95%CI 0.91, 1.45) | | | Fair<br>Wide<br>No details on breastfeeding |
| *Non-randomized comparative study* | | | | | | |
| Johnston 2004 2006<br><br>US<br>232 vs.91 | Well-educated, middle-income | Healthy Steps (with or without prenatal intervention) vs. Usual Care | BF at 3 mo: 91% vs. 76% (RR 1.14; 5%CI1.09, 1.20) Duration >6 mo 82%vs. 64% (P<0.05) | At 3 mo, less mental health symptoms (14.2% vs. 17.5%, adj RR 0.61, 95%CI 0.49, 0.76); less depression (adj β: -0.59; 95%CI –0.98, -0.19), lower proportion with | At 24 mo, language development did not differ between groups. (combining ≥2 words, sometimes/often vs no; adj RR 1.02; 95%CI 0.94, 1.12) | Poor<br>Wide<br><br>Unclear how group assignments were made |

| Study/Country N in intervention vs. control | Population | Intervention /Control | Outcome: Intervention vs. control | | | Quality/Applicability/Comments |
|---|---|---|---|---|---|---|
| | | | Breastfeeding | Maternal | Infant | |
| | | | | CES-D score > cutoff (6.6% vs. 12.5%; adj RR 0.42; 95%CI 0.25, 0.71) | | |

# Appendix J. Before-and-After Experimental Studies and Prospective Observational Studies with Concurrent or Historical Controls on Baby Friendly Hospital Initiative

**Before-and-After Experimental Studies and Prospective Observational Studies with Concurrent or Historical Controls on Baby Friendly Hospital Initiative**

<table>
<tr><th>Study, year<br>Country<br>Design</th><th>Mother's Age (yr)<br>Baby's GA (wk)</th><th>Outcome Definition</th><th>Results</th><th>Applic</th><th>Quality</th></tr>
<tr><td colspan="6">Experimental studies</td></tr>
<tr><td>Cattaneo 2001<br>Italy<br><br>Non-randomized, before-after study</td><td>Group 1<br>Age: 29<br>GA/BW: ≥ 2000 g<br><br>Group 2<br>Age: 30<br>GA/BW: ≥ 2000 g</td><td>Exclusive BF: no other foods or fluid<br><br>Full BF: exclusive and predominant BF (non-nutritive fluids allowed)</td><td>
<table>
<tr><th></th><th></th><th colspan="2">Exclusive BF at discharge</th><th colspan="2">Exclusive BF at 3 mo</th><th colspan="2">Exclusive BF at 6 mo</th></tr>
<tr><th></th><th></th><th>Before</th><th>After</th><th>Before</th><th>After</th><th>Before</th><th>After</th></tr>
<tr><td>Group 1</td><td>n</td><td>518</td><td>510</td><td>506</td><td>510</td><td>485</td><td>366</td></tr>
<tr><td></td><td></td><td>41%</td><td>77%</td><td>20%</td><td>25%</td><td>1%</td><td>1%</td></tr>
<tr><td>Group 2</td><td>n</td><td>464</td><td>271</td><td>471</td><td>280</td><td>454</td><td>233</td></tr>
<tr><td></td><td></td><td>23%</td><td>72%</td><td>15%</td><td>45%</td><td>1%</td><td>13%</td></tr>
</table>
BF rates adjusted with direct standardization by parity, type of delivery, and birth weight did not differ significantly.<br>In both group, differences before and after training in exclusive BF at discharge, full BF at 3 mo, ever BF at 6 mo were significant (P<0.05)</td><td>Wide</td><td>Poor</td></tr>
<tr><td>Gau 2004<br>Taiwan<br><br>Non-randomized, before-after study</td><td>Age: 31<br>GA/BW: 38.8</td><td>Exclusive BF: only breast milk from the mother or a wet nurse, or expressed breast milk, and no other liquids or solids</td><td>
<table>
<tr><th></th><th colspan="2">2000</th><th colspan="2">2001</th><th colspan="2">2002</th></tr>
<tr><th></th><th>BFHI</th><th>Control</th><th>BFHI</th><th>Control</th><th>BFHI</th><th>Control</th></tr>
<tr><td>n</td><td>1339</td><td>380</td><td>1144</td><td>568</td><td>869</td><td>313</td></tr>
<tr><td>Exclusive BF rates in hospital</td><td>34%</td><td>22%</td><td>46%</td><td>23%</td><td>50%</td><td>23%</td></tr>
<tr><td>Exclusive BF 2 mo rate</td><td>6%</td><td>5%</td><td>8%</td><td>3%</td><td>12%</td><td>0%</td></tr>
</table>
Exclusive breastfeeding rate of the BFHI group was higher than that of the control group in hospital, at 2 weeks, 1 and 2 months postpartum (p<0.001).<br>BF rates increased year by year (P<0.001) from 2000 to 2002.</td><td>Wide</td><td>Poor</td></tr>
<tr><td colspan="6">Observational studies</td></tr>
</table>

| Study, year Country Design | Mother's Age (yr) Baby's GA (wk) | Outcome Definition | Results | Applic | Quality |
|---|---|---|---|---|---|
| Dulon 2003 Germany<br><br>Prospective cohort | Age: 91% ≥ 25 GA/BW: ≥ 37 | Full BF: exclusive and predominant BF (non-nutritive fluids allowed) | <table><tr><th></th><th colspan="5">Prevalence of Full BF</th></tr><tr><th></th><th>At birth</th><th>At discharge (5 day)</th><th>2 mo</th><th>4 mo</th><th>6 mo</th></tr><tr><td>Low BF promotion index (≤5) n=814</td><td>91.3%</td><td>79.7%</td><td>59.2%</td><td>42.1%</td><td>10.8%</td></tr><tr><td>High BF promotion index (>5) n=673</td><td>90.0%</td><td>76.8%</td><td>60.9%</td><td>49.5%</td><td>15.7%</td></tr></table>Increased risk of short-term BF in a hospital with low BF promotion index (adjusted OR: 1.24; 95%CI 0.99, 1.55) after controlling for age, education, area of upbringing, hospital size, and geographic location of hospital.<br>Associations of short-term BF with maternal age < 25, low education level, and upbringing in East Germany, were stronger. | Narrow | Poor |

**Appendix J. Continued**

| Study, year Country Design | Mother's Age (yr) Baby's GA (wk) | Outcome Definition | Results | Applic | Quality |
|---|---|---|---|---|---|
| Schniedrova 2003 Czech Republic<br><br>Prospective cohort | M: 91% ≥ 25 B: Term, ≥ 2500 g | Ever BF | Duration of exclusive BF in both groups were comparable:<br>BFHI hospitals: 3.9 mo ± 1.92 SD<br>Other hospitals: 3.90 mo ± 1.84 SD<br>93.5% of infants were BF exclusively at discharge; 23.1% of infants were BF exclusively at 6 mo. No difference in feeding modes between BFHI and other hospitals. | Narrow | Poor |
| Bosnjak 2004 Croatia<br><br>Retro- & Prospective cohort | nd | Ever BF: at least one meal of BF per day | <table><tr><th></th><th></th><th colspan="5">Prevalence of any BF</th></tr><tr><th></th><th></th><th>1 mo</th><th>3 mo</th><th>6 mo</th><th>9 mo</th><th>11 or 12 mo</th></tr><tr><td rowspan="2">No intervention (1990-93)</td><td>n</td><td>2818</td><td>2818</td><td>2818</td><td>2818</td><td>2818</td></tr><tr><td></td><td>68%</td><td>30%</td><td>11%</td><td>6%</td><td>2%</td></tr><tr><td rowspan="2">BFHI (1994-98)</td><td>n</td><td>2257</td><td>2257</td><td>2257</td><td>2257</td><td>1179</td></tr><tr><td></td><td>87%</td><td>54%</td><td>28%</td><td>15%</td><td>3%</td></tr><tr><td rowspan="2">BFHI + postnatal support (1999-2000)</td><td>n</td><td>2133</td><td>2064</td><td>1805</td><td>1214</td><td>921</td></tr><tr><td></td><td>87%</td><td>66%</td><td>49%</td><td>35%</td><td>23%</td></tr><tr><td colspan="2">P between groups</td><td>NS</td><td><0.05</td><td><0.05</td><td><0.05</td><td><0.05</td></tr></table>Not full BFHI because mothers received Happy Baby discharge packs. | Narrow | Poor |

| Study, year Country Design | Mother's Age (yr) Baby's GA (wk) | Outcome Definition | Results | **Applic** | Quality |
|---|---|---|---|---|---|
| Broadfoot 2005 Scotland<br><br>Prospective cohort | nd | nd | <table><tr><td></td><td>UK standard award</td><td>No accreditation</td></tr><tr><td>n</td><td>39,340</td><td>289,453</td></tr><tr><td>BF at 7 days</td><td>49.4%</td><td>42.0%</td></tr></table>After controlling for deprivation category, maternal age, number of births at hospital, and year of birth, the adjusted odds ratio of BF at 7 day was 1.28 (95%CI 1.24 to 1.31), compared babies born in hospitals with a UK BFHI standard award to those born in hospitals with no Baby Friendly accreditation. | Narrow | Poor |