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Interventions in Primary Care to Promote Breastfeeding: An Evidence Review for the U.S. Preventive Services Task Force

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Background: Evidence suggests that breastfeeding decreases the risk for many diseases in mothers and infants. It is therefore important to evaluate the effectiveness of breastfeeding interventions.

Purpose: To systematically review evidence for the effectiveness of primary care–initiated interventions to promote breastfeeding with respect to breastfeeding and child and maternal health outcomes.

Data Sources: Electronic searches of MEDLINE, the Cochrane Central Register of Controlled Trials, and CINAHL from September 2001 to February 2008 and references of selected articles, restricted to English-language publications.

Study Selection: Randomized, controlled trials of primary care–initiated interventions to promote breastfeeding, mainly in developed countries.

Data Extraction: Characteristics of interventions and comparators, study setting, study design, population characteristics, the proportion of infants continuing breastfeeding by different durations, and infant or maternal health outcomes were recorded.

Data Synthesis: Thirty-eight randomized, controlled trials (36 in developed countries) met eligibility criteria. In random-effects meta-analyses, breastfeeding promotion interventions in developed countries resulted in significantly increased rates of short- (1 to 3 months) and long-term (6 to 8 months) exclusive breastfeeding (rate ratios, 1.28 [95% CI, 1.11 to 1.48] and 1.44 [CI, 1.13 to 1.84], respectively). In subgroup analyses, combining pre- and postnatal breastfeeding interventions had a larger effect on increasing breastfeeding durations than either pre- or postnatal interventions alone. Furthermore, breastfeeding interventions with a component of lay support (such as peer support or peer counseling) were more effective than usual care in increasing the short-term breastfeeding rate.

Limitations: Meta-analyses were limited by clinical and methodological heterogeneity. Reliable estimates for the isolated effects of each component of multicomponent interventions could not be obtained.

Conclusion: Evidence suggests that breastfeeding interventions are more effective than usual care in increasing short- and long-term breastfeeding rates. Combined pre- and postnatal interventions and inclusion of lay support in a multicomponent intervention may be beneficial.

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Human milk is the natural nutrition for all infants. According to the American Academy of Pediatrics, it is the preferred choice of feeding for all infants (1). The goals of Healthy People 2010 for breastfeeding are an initiation rate of 75% and continuation rate of 50% at 6 months and 25% at 12 months after delivery (2). A survey of U.S. children in 2002 indicated that only 71% had ever been breastfed, and the percentage of infants who continue to be breastfed to some extent is 35% at 6 months and 16% at 12 months (3). Although the breastfeeding initiation rate is close to the goal set by Healthy People 2010, according to this survey, the breastfeeding continuation rates at 6 and 12 months fall short.

Evidence suggests that breastfeeding decreases risks for many diseases in infants and mothers. In children, breastfeeding has been associated with a reduction in the risk for acute otitis media, nonspecific gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, childhood leukemia, and the sudden infant death syndrome. In mothers, a history of lactation has been associated with a reduced risk for type 2 diabetes and breast and ovarian cancer (4). According to the American Academy of Pediatrics, 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, such as those implemented in pursuit of the Baby-Friendly Hospital Initiative (BFHI) designation (6, 7), and worksite lactation programs (8). Some of the other interventions implemented include peer-to-peer support, maternal education, and media marketing (9).

Our review is based on an evidence report (10) that was requested by the Center on Primary Care, Prevention, and Clinical Partnerships at the Agency for Healthcare Research and Quality, on behalf of the U.S. Preventive Services Task Force, to support the Task Force's update of its 2003 recommendations on counseling to promote breastfeeding (11). Together with the Tufts Evidence-based Practice Center, these agencies jointly developed an analytic framework for study questions to evaluate the available evidence to promote and

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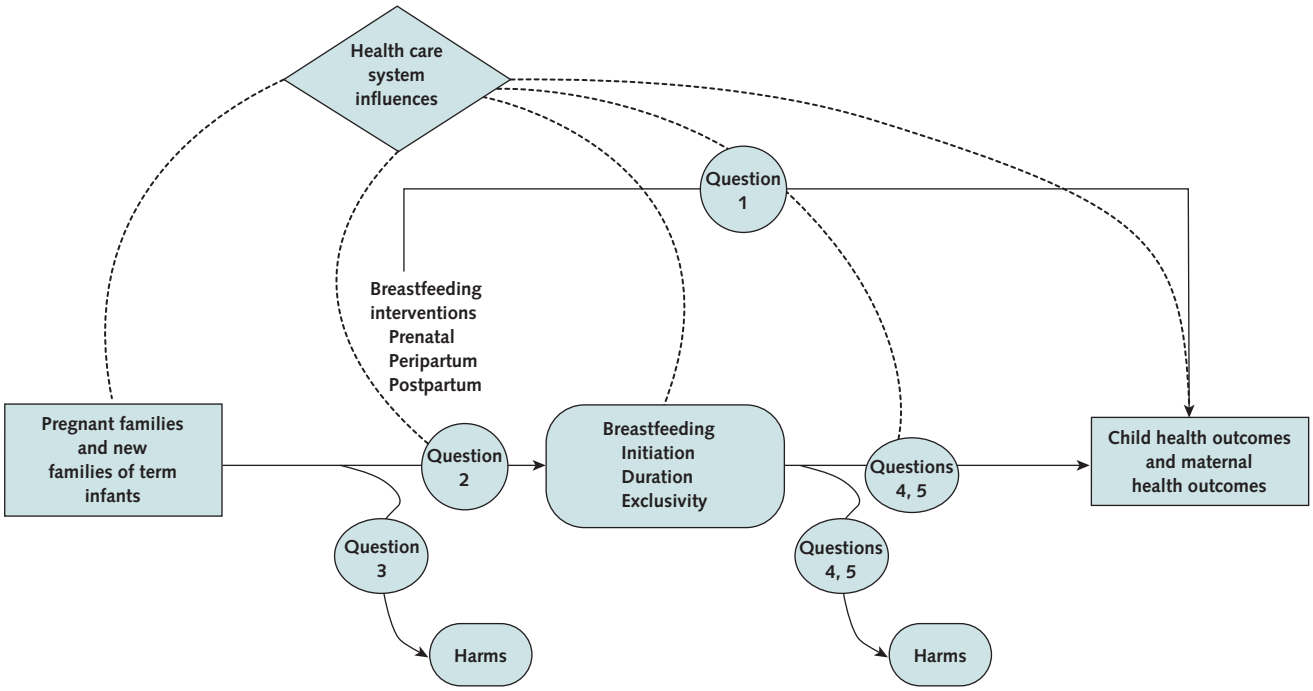
Figure 1. **Analytic framework and study questions.**



Question 1. What are the effects of interventions to promote and support breastfeeding, in terms of short- and long-term child and maternal health outcomes?
Question 2. What are the effects of prenatal, peripartum, and postpartum breastfeeding interventions on initiation, duration, and exclusivity of breastfeeding?
Question 3. Are there any harms from interventions to promote and support breastfeeding?
Question 4. What are the benefits and harms of breastfeeding on infants and children in terms of short- (e.g., otitis media, diarrhea) and long-term health outcomes (e.g., types 1 and 2 diabetes)?
Question 5. What are the benefits and harms of breastfeeding on mothers in terms of short- (e.g., postpartum depression, return to prepregnancy weight) and long-term health outcomes (e.g., osteoporosis, breast and ovarian cancer)?

Contextual Questions:
What are the effects of health care system influences on interventions to promote and support breastfeeding?

What are other potential benefits and harms related to interventions to promote and support breastfeeding and from breastfeeding itself?

support breastfeeding (**Figure 1**). Five linked key questions were proposed in the analytic framework:

1. What are the effects of breastfeeding interventions on child and maternal health outcomes?

2. What are the effects of 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 of breastfeeding on infant or child health outcomes?

5. What are the benefits and harms of breastfeeding on maternal health outcomes?

The contextual questions regarding the effectiveness of health care system influences on interventions to promote breastfeeding and the potential benefits and harms related to such interventions can be answered by synthesizing the available scientific evidence for each key question. To avoid redundant work, a joint decision was made to adopt results from our earlier Agency for Healthcare Research and Quality evidence report (4) to address questions 4 and 5 on the benefits and harms of breastfeeding for infants and mothers. **Table 1** (12–84) presents a synopsis of that report's findings on questions 4 and 5. We address only questions 1 to 3 in this article. Specifically, we examine the effects of primary care–initiated interventions to support or promote breastfeeding on child and maternal health outcomes and breastfeeding rates, as reported in randomized, controlled trials (RCTs) from developed countries. We also document reported harms from interventions to promote and support breastfeeding.

METHODS

Data Sources

This systematic review focuses on recent evidence (September 2001 to February 2008) and updates a previous systematic review (85) conducted for the U.S. Preventive Services Task Force to support its 2003 recommendation on counseling to promote breastfeeding (available at

(*continued on page 568*)

Table 1. **Findings from the Previous Systematic Review***

Outcomes Analyzed (References)	Breastfeeding Comparisons Analyzed	Results Summary†
Term infant outcomes		
Acute otitis media (12–16)	Any definition of breastfeeding duration vs. exclusive bottle feeding	Our meta-analysis of 5 cohort studies showed a significant risk reduction (pooled adjusted OR, 0.60 [95% CI, 0.46–0.78]) when any breastfeeding was compared with no breastfeeding. When exclusive breastfeeding for ≥3 mo was compared with exclusive bottle-feeding from 3 studies, the pooled adjusted OR was 0.50 (CI, 0.36–0.70).
Atopic dermatitis (17)	Exclusive breastfeeding for ≥3 mo vs. <3 mo	A previous meta-analysis of 18 cohort studies reported a reduced risk for atopic dermatitis (pooled adjusted OR, 0.58 [CI, 0.41–0.92]) in children with a family history of atopy.
Gastrointestinal infection (18)	Ever vs. never breastfed	A previous meta-analysis of 16 studies reported a reduced risk for nonspecific gastrointestinal infection. The pooled crude OR of 14 cohort studies for the development of gastrointestinal infection was 0.36 (CI, 0.32–0.41). The pooled crude OR of the 2 case–control studies was 0.54 (CI, 0.36–0.80).
Lower respiratory tract infection (19)	Exclusive breastfeeding for ≥4 mo vs. formula feeding	A previous meta-analysis of 7 cohort studies reported a reduced risk for hospitalization secondary to lower respiratory tract infection (pooled adjusted relative risk, 0.28 [CI, 0.14–0.54]) in infants age <1 y.
Childhood asthma (20–23)	Mixed or exclusive breastfeeding for ≥3 mo vs. never breastfed	Our updated meta-analysis of 15 cohort studies (12 studies were identified from a previous meta-analysis) showed a reduced risk for asthma in children age <10 years without a family history of asthma (pooled adjusted OR, 0.73 [CI, 0.59–0.92]) but conflicting results for children with a family history of asthma.
Cognitive development (24–31)	Any definition of breastfeeding duration vs. never breastfed	Eight primary studies published after 2000 qualified for inclusion. Many of these studies controlled for socioeconomic status and maternal education but not specifically for maternal intelligence. In 3 studies of full-term infants that adjusted analyses specifically for maternal intelligence, the results showed little or no evidence for an association between breastfeeding in infancy and cognitive performance in childhood.
Obesity (32, 33)	Ever vs. never breastfed	Reported in a previous meta-analysis of 7 cross-sectional and 2 cohort studies, the pooled adjusted OR for being overweight or obese was 0.76 (CI, 0.67–0.86). One previous meta-regression of 52 estimates from 14 studies (various study designs) found that each month of breastfeeding was associated with a 4% reduced risk (pooled unadjusted OR per month of breastfeeding, 0.96 [CI, 0.94–0.98]).
Risk for cardiovascular diseases (34–36)	Breastfed vs. formula-fed	Overall, no definitive conclusion could be drawn: Two previous meta-analyses of a total of 26 primary studies of various study designs found a small reduction of <1.5 mm Hg in systolic and ≤0.5 mm Hg in diastolic blood pressure among adults. In addition, 1 previous meta-analysis of 4 historical cohorts found little or no difference in all-cause and cardiovascular mortality.
Type 1 diabetes (37–44)	Breastfeeding for ≥3 mo vs. <3 mo	Two previous meta-analyses of a total of 17 case–control studies reported risk reduction for type 1 diabetes (pooled ORs, 0.81 [CI, 0.74–0.89] and 0.70 [CI, 0.56–0.87]). Five of 6 new case–control studies published after the meta-analyses reported similar results.
Type 2 diabetes (45)	Ever breastfed vs. formula-fed	A previous meta-analysis of 7 studies (various study designs) showed a reduced risk for type 2 diabetes in later life (pooled adjusted OR, 0.61 [CI, 0.44–0.85]). However, only 3 of the 7 studies provided information on important confounders, such as birthweight, parental diabetes, socioeconomic status, or maternal body size.
Childhood leukemia (46)	Any definition of breastfeeding duration vs. never breastfed	A previous meta-analysis of 14 case–control studies showed a significant reduced risk for acute lymphocytic leukemia with short-term (≤6 mo) and long-term (>6 mo) breastfeeding (pooled OR, 0.88 [CI, 0.80–0.96] and 0.76 [CI, 0.68–0.84], respectively).
Infant mortality (47)	Ever vs. never breastfed	One case–control 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 the sudden infant death syndrome or the risk for injury-related deaths.
The sudden infant death syndrome (48–53)	Ever vs. never breastfed	Our meta-analysis of 6 case–control studies showed a reduced risk for the sudden infant death syndrome (pooled crude OR, 0.41 [CI, 0.28–0.58]; pooled adjusted OR, 0.64 [CI, 0.51–0.81]).
Maternal outcomes		
Return to prepregnancy weight (54–56)	Any definition of breastfeeding duration	Three cohort studies reported <1-kg weight change from before pregnancy or first trimester to 1- to 2-year postpartum period in mothers who breastfed. These studies also showed that many factors other than breastfeeding had larger effects on weight retention.
Maternal type 2 diabetes (57)	Exclusive and total breastfeeding duration	One longitudinal cohort reported that each year of lifetime exclusive breastfeeding was associated with a hazard ratio for type 2 diabetes of 0.63 (CI, 0.54–0.73), whereas each year of total breastfeeding was associated with a hazard ratio of 0.76 (CI, 0.71–0.81), after controlling for age and parity.
Osteoporosis (58–63)	Lifetime breastfeeding duration	Results from 6 case–control studies in postmenopausal women showed little or no association between lifetime breastfeeding duration and the risk for hip, forearm, or vertebral fractures due to osteoporosis, after controlling for potential confounders.
Postpartum depression (64–69)	A history of short duration of breastfeeding or no breastfeeding	Three of 6 prospective cohort studies found an association between a history of short duration of breastfeeding or no breastfeeding and postpartum depression. None of the studies explicitly screened for depression at baseline before the initiation of breastfeeding or provided detailed data on breastfeeding. Thus, reverse causality is possible.

Continued on following page

Table 1—**Continued**

Outcomes Analyzed (References)	Breastfeeding Comparisons Analyzed	Results Summary†
Breast cancer (70–74)	Lifetime breastfeeding duration	The reduction in breast cancer risk was 4.3% for each year of breastfeeding in 1 previous meta-analysis combining 45 studies published through 2001, and 28% for ≥12 mo of breastfeeding in the other previous meta-analysis combining 23 studies published between 1980 and 1998. Findings from 3 new primary studies concurred with the findings from the earlier meta-analyses.
Ovarian cancer (75–84)	Lifetime breastfeeding duration vs. no breastfeeding	Our meta-analysis of 9 case–control studies showed a reduced risk for ovarian cancer for ever breastfeeding compared with never breastfeeding (pooled adjusted OR, 0.79 [CI, 0.68–0.91]). Subgroup analysis suggested that cumulative breastfeeding duration >12 mo was associated with a reduced risk for ovarian cancer (pooled adjusted OR, 0.72 [CI, 0.54–0.97]).

OR = odds ratio.
* See reference 4. Databases searched included MEDLINE, CINAHL, and the Cochrane Database of Systemic Reviews from 1966 to November 2005. Supplemental searches on selected outcomes were conducted through May 2006. Complete search strategy, eligibility criteria, and quality assessments were documented in the methods section (chapter 2) of the evidence report (4).
† The results summarized here were from primary studies and systematic reviews or meta-analyses that were rated quality A or B in the evidence report. The evidence tables are available in the evidence report (4).

www.ahrq.gov/clinic/uspstf/uspsbrfd.htm). We searched for English-language articles in MEDLINE, the Cochrane Central Register of Controlled Trials, and CINAHL from September 2001 to February 2008 by using such Medical Subject Heading terms and keywords as *breastfeeding, breast milk feeding, breast milk, human milk, nursing, breastfed, infant nutrition, lactating,* and *lactation.* We also reviewed reference lists of a related systematic review (86) for additional studies.

Study Selection

We included RCTs published from September 2001 to February 2008 that included any counseling or behavioral intervention initiated from a clinician's practice (office or hospital) to improve the breastfeeding initiation rate or duration of breastfeeding among healthy mothers or members of the mother–child support system (such as partners, grandparents, or friends) and their healthy term or near-term infants (≥35 weeks' gestation or ≥2500 g). We focused our review on studies conducted in developed countries; however, because of the widespread interest in the BFHI, we also included RCTs of the BFHI that were conducted in Brazil and Belarus.

We considered interventions conducted by various providers (lactation consultants, nurses, peer counselors, midwives, and physicians) in various settings (hospital, home, clinic, or elsewhere) to be eligible as long as they originated from a health care setting. We considered maternity services to be primary care for this review. We also included such health care system interventions as staff training. We excluded community- or peer-initiated interventions. Control comparisons were any usual prenatal, peripartum, or postpartum care, as defined in each study. Studies needed to report rates of breastfeeding initiation, duration of breastfeeding, or exclusivity of breastfeeding to be included. **Figure 2** shows our search and selection process.

Data Extraction and Quality Assessment

One investigator extracted data from each study, and another confirmed them. The extracted data included study setting, population, control, description of intervention (type, person, frequency, and duration), definitions of breastfeeding outcomes (initiation, exclusivity, and duration), definitions of health outcomes in both mothers and children (when provided), and analytic methods.

Classification of Breastfeeding Interventions

Breastfeeding interventions can include a combination of individual components, such as structured breastfeeding education or professional or lay support. We defined 3 categories of breastfeeding intervention: those that included a component of formal or structured breastfeeding education, those that included a component of either professional or lay breastfeeding support, or those that did not include the aforementioned components. The first 2 categories are not mutually exclusive. **Table 2** shows complete details.

Definitions

We classified breastfeeding regimens as exclusive or nonexclusive. Studies used different definitions of exclusive breastfeeding ("no supplement of any kind," "including water while breastfeeding," or "occasional formula is permissible while breastfeeding"); we adopted all of those definitions. We classified all other breastfeeding regimens (full, partial, mixed, or nonspecified) as nonexclusive.

We defined breastfeeding initiation as any breastfeeding at discharge or up to 2 weeks after delivery. We also defined a priori breastfeeding durations of 1 to 3 months as short-term, 4 to 5 months as intermediate-term, 6 to 8 months as long-term, and 9 or more months as prolonged. We categorized studies with breastfeeding durations shorter than 1 month as "no breastfeeding" in our meta-analyses.

Two investigators assessed the methodological quality of all eligible studies by using criteria developed by the U.S. Preventive Services Task Force (87). We assigned each article a quality rating of "good," "fair," or "poor." The criteria for quality assessment of primary studies included randomization techniques, allocation concealment, clear definitions of outcomes, intention-to-treat analysis,

and statistical methods. A third investigator reviewed studies for which the first 2 investigators gave discordant quality ratings. We reached final grades for those studies via consensus. We performed subgroup analyses to examine the effects of study quality on the meta-analysis results. We also based our qualitative conclusions on good- or fair-quality studies.

Data Synthesis and Analysis

We calculated the rates of breastfeeding initiation and short-term, intermediate-term, long-term, and prolonged breastfeeding for both the intervention and control groups in each study. We recorded the exclusivity of breastfeeding and did the same calculations for the exclusive breastfeeding rates.

Meta-analysis and Meta-regression

We used the rate ratio (relative risk) as the metric of choice to quantify the effectiveness of each breastfeeding promotion intervention. We used the DerSimonian and Laird model for random-effects meta-analysis (88) to obtain summary estimates across studies. We tested for heterogeneity by using the Cochran Q test, which follows a chi-square distribution to make inferences about the null hypothesis of homogeneity (considered significant at $P < 0.100$) and quantified its extent with I^2 (89, 90). The I^2 statistic ranges between 0% and 100% and quantifies the proportion of between-study variability that is attributed to heterogeneity rather than chance.

We used random-effects meta-regression (fitted with restricted maximum likelihood) to explore whether the effectiveness of breastfeeding interventions depends on breastfeeding duration, provided that at least 6 studies with relevant information were available (91, 92).

Subgroup Analyses

We performed subgroup analyses according to various study factors, such as study quality, timing of intervention (prenatal, postpartum, or combined prenatal and postpartum), and different components of breastfeeding interventions. We used a Z test to compare summary estimates between the subgroups.

We used Intercooled Stata, version 8.2 (Stata, College Station, Texas) for all analyses. All P values are 2-tailed and considered significant when less than 0.05 unless otherwise indicated.

Role of the Funding Source

The Agency for Healthcare Research and Quality and the U.S. Preventive Services Task Force helped formulate the initial study questions but did not participate in the literature search, determination of study eligibility criteria, data analysis or interpretation, or preparation of the manuscript.

Results

We identified 4877 abstracts in our search and evaluated a total of 147 full-text articles. Thirty-eight RCTs met our eligibility criteria: 32 parallel RCTs described in 33 publications (93–125), 4 clustered RCTs (126–129), and 2 quasi-RCTs described in 3 publications (130–132) (**Figure 2**). **Table 3** shows the 36 trials that were conducted in developed countries (Australia, Canada, Denmark, France, Italy, Japan, Netherlands, New Zealand, Scotland, Sweden, Singapore, United Kingdom, and United States). Two trials on BFHI were conducted in developing countries (Brazil and Belarus).

The interventions included system-level breastfeeding support (such as BFHI and training of health professionals), formal breastfeeding education, professional support (such as from lactation consultants, midwives, nurses, physicians, or other health professionals), lay support (such as peer support or counseling), motivational interviews, delayed or discouraged pacifier use, and skin-to-skin contact. Several components were of-

Table 2. **Interventions to Support or Promote Breastfeeding**

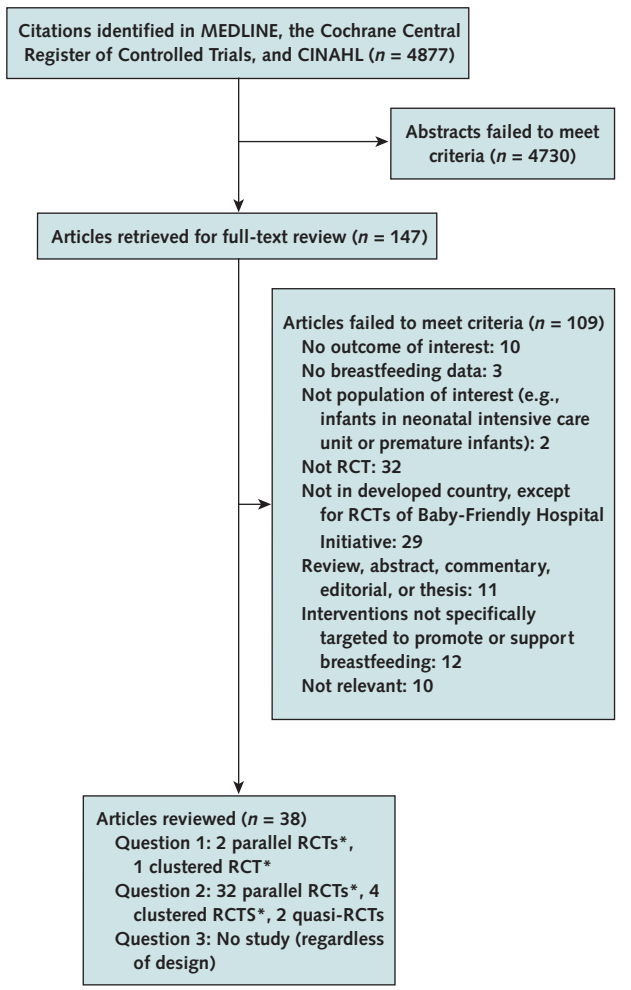
Intervention	Definition
Formal or structured breastfeeding education	Structured one-to-one or group education sessions or classes (e.g., curriculum or standard agenda) directed at mothers or other family members
Breastfeeding support	
Professional support	System-level: Baby-Friendly Hospital Initiative*; training of health professionals Individual-level: one-to-one support during hospital stay or outpatient visits; social support (e.g., home visits or telephone support) from health professionals
Lay support	Peer counseling; social support (e.g., home visits or telephone support) from peers
Other interventions	Examples include skin-to-skin contact†, pacifier use, and motivational interviews‡

* The Baby-Friendly Hospital Initiative promotes, protects, and supports breastfeeding through The Ten Steps to Successful Breastfeeding for Hospitals. The steps for the United States are: 1) maintain a written breastfeeding policy that is routinely communicated to all health care staff; 2) train all health care staff in skills necessary to implement this policy; 3) inform all pregnant women about the benefits and management of breastfeeding; 4) help mothers initiate breastfeeding within 1 hour of birth; 5) show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants; 6) give infants no food or drink other than breast milk, unless medically indicated; 7) practice "rooming in" (allowing mothers and infants to remain together 24 hours a day); 8) encourage unrestricted breastfeeding; 9) give no pacifiers or artificial nipples to breastfeeding infants; and 10) foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic (accessed at www.babyfriendlyusa.org/eng/10steps.html on 3 September 2008).

† After birth, the newborn is weighed and then immediately placed naked in a prone position between the mother's breasts until the mother chooses to stop the contact or the newborn seems to be ready for feeding.

‡ Motivational interviewing with the goal of decreasing ambivalence and resistance toward sustained breastfeeding.

Figure 2. **Study flow diagram.**



RCT = randomized, controlled trial.
* All RCTs for question 1 also included for question 2.

ten combined into a single, multifaceted breastfeeding intervention.

Eleven trials (29%) were of good quality, 14 trials (37%) were of fair quality, and 13 trials (34%) were of poor quality. The **Appendix Table** (available at www.annals.org) describes the criteria of quality assessment used to reach the overall quality rating for each RCT. **Table 3** summarizes the study characteristics.

Key Question 1

What are the effects of breastfeeding interventions on child and maternal health outcomes?

The effects of breastfeeding interventions on child health outcomes were reported in 3 RCTs published in 4 articles (93–95, 126). One of these RCTs also reported maternal health outcomes. One good-quality study (126), PROBIT (Promotion of Breastfeeding Intervention Trial), was conducted in Belarus, and 2 fair-quality studies (93–95) were conducted in low-income populations in the United States. We could not combine the results from these RCTs in a meta-analysis because the interventions were dissimilar.

The PROBIT study was a good-quality, cluster, multicenter RCT involving a total of 17 046 mother–infant pairs from urban and rural areas in Belarus. Infants in the intervention group (a modeled BFHI) had a significant reduction in the risk for 1 or more gastrointestinal infections (adjusted odds ratio, 0.60 [95% CI, 0.40 to 0.91]) and atopic dermatitis (adjusted odds ratio, 0.54 [CI, 0.31 to 0.95]) compared with those in the control group but had no significant reduction in respiratory tract infections (126). The 2 fair-quality RCTs, involving a total of 564 mother–infant pairs in low-income families in the United States, reported discordant results. The major drawbacks of these 2 RCTs were high rates of loss to follow-up or missing breastfeeding data. One study showed no significant differences between the 2 groups (hospital and home visits by 2 study lactation consultants vs. usual care) in the risk for gastrointestinal illnesses, respiratory tract diseases, or otitis media (94, 95), whereas the other study found that the risk for 1 or more diarrheal episodes during the study was decreased in the intervention group (home visits by trained breastfeeding peer counselors) compared with the control group (17.5% vs. 37.5%; $P = 0.02$) (93). The latter study also reported that mothers in the intervention group were less likely than those in the control group to have menses return at 3 months (47.6% vs. 66.7%; $P = 0.03$). Cessation of menstrual periods for the first few postpartum months during exclusive breastfeeding is a normal physiologic process.

Key Question 2

What are the effects of breastfeeding interventions on breastfeeding initiation, duration, and exclusivity?

Effects on Breastfeeding Initiation and Duration

We found substantial heterogeneity across eligible trials in the actual breastfeeding promotion interventions (including many different combinations of "intervention components") and their implementation, timing, and intensity (**Table 3**). Furthermore, the definition of "usual" or "routine" care varied substantially because of differences in background social support and health care systems in the various countries. The sociodemographic characteristics of the study populations also varied.

As shown in **Figure 3**, breastfeeding promotion interventions resulted in an increased rate of breastfeeding initiation (rate ratio, 1.04 [CI, 1.00 to 1.08]) and short-term breastfeeding (rate ratio, 1.10 [CI, 1.02 to 1.19]) compared with usual care, with significant statistical heterogeneity in both cases. It is questionable whether these trivial effects have any real-world effect. For short-term exclusive breastfeeding, the relative risk was 1.72 (CI, 1.00 to 2.97), again with evidence of statistical heterogeneity (**Figure 4**).

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Table 3. **Characteristics of Randomized, Controlled Trials**

Study, Year (Reference)	Design	Country	Patients, *n*	Population Characteristics	Intervention Components	Timing	Control	Outcomes	Quality*
Developed countries									
Anderson et al., 2005 (93)	Parallel	United States	182	Predominantly Latina and low-income, WIC	LS	Prenatal, peripartum, postnatal	BFHI†	Breastfeeding rates, maternal and child health	Fair
Bonuck et al., 2005 (94) and 2006 (95)	Parallel	United States	382	56% Medicaid, 39% foreign-born	Ed, PS-IL, provided nursing bras and pump	Prenatal, peripartum, postnatal	Usual prenatal care	Breastfeeding rates, maternal and child health	Fair
Carfoot et al., 2004 (96)‡	Parallel	United Kingdom	28	General (sparse demographic data)	Skin-to-skin contact	Postnatal	Routine care	Breastfeeding rates	Poor
Carfoot et al., 2005 (97)	Parallel	United Kingdom	201	General (sparse demographic data)	Skin-to-skin contact	Postnatal	Routine care	Breastfeeding rates	Fair
Chapman et al., 2004 (117)	Parallel	United States	219	Latino community from Puerto Rico, low-income, BFHI-accredited hospital	LS, provided electric breast pumps	Prenatal, peripartum, postnatal	Routine Ed	Breastfeeding rates	Fair
Dennis et al., 2002 (118)	Parallel	Canada	256	General, well-educated (>60% college education)	LS, telephone-based support	Postnatal	Conventional in-hospital and community postpartum support	Breastfeeding rates	Fair
Di Napoli et al., 2004 (124)	Parallel	Italy	605	General, well-educated	PS-IL, telephone-based support	Postnatal	No intervention	Breastfeeding rates	Fair
Ekström and Nissen, 2006 (130); Ekström et al., 2006 (131)	Quasi	Sweden	378	Large municipalities, well-educated	PS-SL§	Prenatal, peripartum	Usual care	Breastfeeding rates, absolute breastfeeding durations	Poor
Finch and Daniel, 2002 (99)	Parallel	United States	60	Low-income (urban WIC program), African-American and Hispanic, 25% ≥18 years old	Ed, incentives	Prenatal, peripartum	Usual prenatal care	Breastfeeding rates	Poor
Forster et al., 2004 (100)	Parallel	Australia	981	Low-income, culturally diverse, BFHI-accredited hospital	Ed‖	Prenatal, peripartum	BFHI¶	Breastfeeding rates, absolute breastfeeding durations	Fair
Gagnon et al., 2002 (119)	Parallel	Canada	586	General (living near the urban hospital)	PS-IL**, telephone-based support	Postnatal	Usual care in hospital and clinical follow-up	Breastfeeding rates, absolute breastfeeding durations	Fair
Graffy et al., 2004 (123)	Parallel	United Kingdom	720	General (urban areas)	PS-IL††	Prenatal, peripartum, postnatal	Usual care with no counselor contact	Breastfeeding rates	Good
Henderson et al., 2001 (101)	Parallel	Australia	160	2–3-d postpartum stay, well-educated	Ed	Postnatal	Usual postpartum care	Breastfeeding rates	Fair
Howard et al., 2003 (102)	Parallel	United States	700	Primarily white, well-educated, married, 77% employed	Delayed pacifier use (>4 wk)	Postnatal	Early pacifier use (2–5 d)	Absolute breastfeeding durations	Good
Kools et al., 2005 (129)	Cluster	Netherlands	781	General, well-educated	PS-IL‡‡	Prenatal, peripartum, postnatal	PS plus written material	Breastfeeding rates	Fair
Kramer et al., 2001 (103)	Parallel	Canada	281	Multicultural (67% English-speaking), well-educated, 76% employed	PS-IL, discouraged pacifier use	Postnatal	Pacifier use and PS	Breastfeeding rates	Good
Kronborg et al., 2007 (128)	Cluster	Denmark	1597	General, BFHI-accredited hospitals	PS-IL	Postnatal	Home visits by health visitors who did not have the training course	Breastfeeding rates	Fair
Labarere et al., 2003 (104)	Parallel	France	212	Employed, well-educated, prolonged maternity leave	Ed	Postnatal	Usual care in hospital	Breastfeeding rates	Good

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Table 3—**Continued**

Study, Year (Reference)	Design	Country	Patients, *n*	Population Characteristics	Intervention Components	Timing	Control	Outcomes	Quality*
Labarere et al., 2005 (105)	Parallel	France	231	Well-educated, employed, prolonged hospital stay	PS-SL§§	Postnatal	Usual care, including LS	Breastfeeding rates, absolute breastfeeding durations	Good
Lavender et al., 2005 (127)	Cluster	United Kingdom	742	Low-income, lack of social support	PS-SL‖ ‖	Prenatal, peripartum	Usual prenatal breastfeeding advice	Breastfeeding rates	Poor
Mattar et al., 2007 (114)	Parallel	Singapore	401	Low-income, less-educated	PS-IL¶¶, Ed materials (book and video)	Prenatal, peripartum	Routine prenatal care	Breastfeeding rates	Good
McKeever et al., 2002 (106)	Parallel	Canada	101	Metropolitan area, well-educated, about a 48-h postpartum stay	PS-IL	Postnatal	No home visits from lactation nurses	Breastfeeding rates	Poor
McLeod et al., 2004 (132)	Quasi	New Zealand	228	Maori, smokers	Ed***, PS-IL	Prenatal, peripartum, postnatal	Usual care for women who smoked	Breastfeeding rates	Poor
Mizuno et al., 2004 (107)	Parallel	Japan	60	Postpartum stay ≥4 d, infants not with mothers for 24 h and were fed formula	Skin-to-skin contact	Postnatal	Routine care	Breastfeeding rates, absolute breastfeeding durations	Fair
Moore and Anderson, 2007 (115)	Parallel	United States	21	General, well-educated	Skin-to-skin contact	Postnatal	Routine care	Breastfeeding rates	Poor
Muirhead et al., 2006 (108)	Parallel	Scotland	225	Some premature babies (5.3%) and babies in special care, few demographic data on the mothers	LS	Prenatal, peripartum, postnatal	Usual care†††	Breastfeeding rates	Fair
Noel-Weiss et al., 2006 (125)	Parallel	Canada	101	High family income, well-educated, 36% cesarean section, 68% received free formula	Ed	Prenatal, peripartum	Not described (no education)	Breastfeeding rates, absolute breastfeeding durations	Good
Pugh et al., 2002 (120)	Parallel	United States	41	Low-income, receiving financial medical assistance	PS-IL, LS	Postnatal	Usual care	Breastfeeding rates	Poor
Quinlivan et al., 2003 (121)	Parallel	Australia	136	Age <18 y	PS-IL	Postnatal	Routine postnatal support	Breastfeeding rates, absolute breastfeeding durations	Good
Ryser, 2004 (109)	Parallel	United States	54	Low-income (90% eligible for Medicaid)	Ed	Prenatal, peripartum	No intervention	Breastfeeding rates	Poor
Schlickau and Wilson, 2005 (110)	Parallel	United States	30	Hispanic women, emigrated from Mexico	Ed, commitment to breastfeed‡‡‡	Prenatal, peripartum	Usual care	Breastfeeding rates, absolute breastfeeding durations	Poor
Su et al., 2007 (116)	Parallel	Singapore	450	Low-income, less-educated	PS-IL§§§, printed materials	Prenatal, peripartum, postnatal	Usual care	Breastfeeding rates	Fair
Wallace et al., 2006 (111)	Parallel	United Kingdom	270	General (not BFHI-accredited hospital)	PS-SL‖ ‖ ‖	Postnatal	Usual postpartum care	Breastfeeding rates	Good
Wilhelm et al., 2006 (112)	Parallel	United States	73	Rural community	Motivational interview	Postnatal	Usual care¶¶¶	Breastfeeding rates, absolute breastfeeding durations	Poor
Winterburn et al., 2003 (122)	Parallel	United Kingdom	72	No data (women in a university hospital)	PS-IL, LS****	Prenatal, peripartum	Routine prenatal care	Breastfeeding rates	Poor
Wolfberg et al., 2004 (113)	Parallel	United States	59	Low-income, minority	Ed††††	Prenatal, peripartum	Control education (baby care and safety)	Breastfeeding rates	Poor

Table 3—**Continued**

Study, Year (Reference)	Design	Country	Patients, *n*	Population Characteristics	Intervention Components	Timing	Control	Outcomes	Quality*
Developing countries (for BFHI only)									
Coutinho et al., 2005 (98)	Parallel	Brazil	350	Low-income, 24-h hospital stay	PS-IL‡‡‡‡	Prenatal, peripartum, postnatal	BFHI (steps 4–9)§§§§	Breastfeeding rates	Good
Kramer et al., 2001 (126)	Cluster	Belarus	17 046	Prolonged postpartum stay; maternity leave	PS-SL‖ ‖ ‖ ‖	Prenatal, peripartum, postnatal	Usual care	Breastfeeding rates, maternal and child health	Good

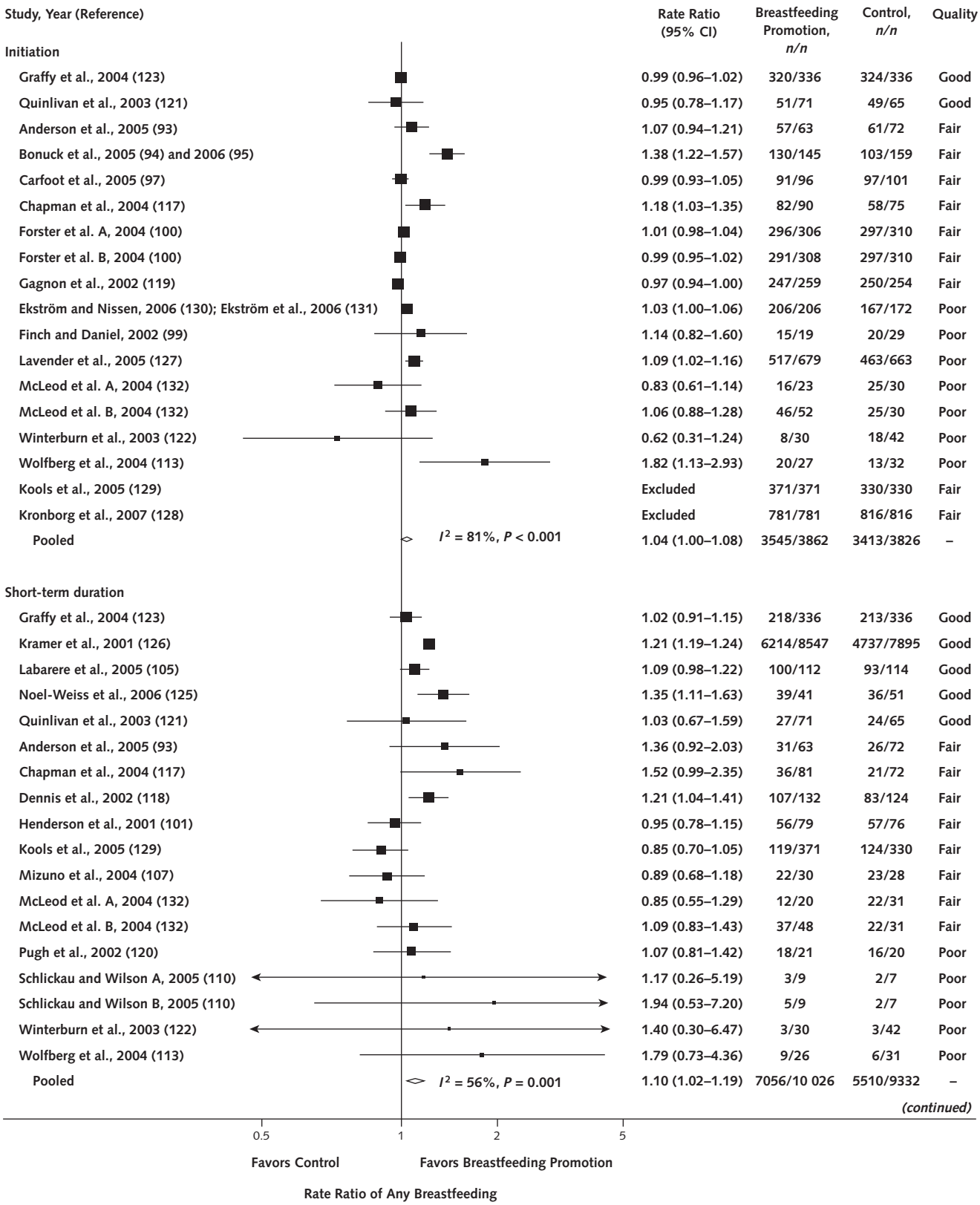
BHFI = Baby-Friendly Hospital Initiative; Ed = formal/structured breastfeeding education; LS = lay support; PS = professional support; PS-IL = professional support—individual level; PS-SL = professional support—system level; WIC = Women, Infants, and Children program.
* See **Appendix Table**, available at www.annals.org, for the detailed quality assessment.
† BFHI: breastfeeding warm line (telephone support), conventional breastfeeding education before birth, hands-on breastfeeding assistance, and education from the maternity ward nursing staff.
‡ Pilot study for reference 97.
§ Health professionals received a process-oriented program on breastfeeding counseling, including lectures on breastfeeding management and promotion, counseling skills, and personal breastfeeding experiences.
‖ Two intervention groups: practical skills or attitudes.
¶ Standard care included formal breastfeeding education, peer support, and postnatal home visits by midwives (BFHI-accredited hospital); the same control group was used to compare both intervention groups (practical skills or attitudes).
** Community follow-up (intervention group): telephone contact 48 hours after delivery and nurse contact in the home on day 3.
†† Trained, accredited counselors who visited once before birth, followed by telephone support or home visits if requested.
‡‡ Enhanced access to lactation consultants.
§§ 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.
‖ ‖ Education session (1 day, 9 a.m.–4 p.m.) to help midwives revise their knowledge of lactation management and educate women on basic lactation physiology and effective breastfeeding techniques.
¶¶ Two intervention groups: education materials (book and video) and individual counseling (1 session) or education materials (book and video) alone.
*** Two intervention groups: breastfeeding support only or breastfeeding support and smoking cessation.
††† Usual care included a community midwife for the first 10 days, health visitor after 10 days, breastfeeding support groups, and breastfeeding workshops.
‡‡‡ Two intervention groups: breastfeeding education or breastfeeding education plus commitment to breastfeed.
§§§ Two intervention groups: 1) 1-session video before birth, printed materials, or 15-minute counseling with lactation consultant or 2) counseling sessions after delivery (30 minutes each with lactation consultant) and printed materials.
‖ ‖ ‖ Midwives received a 4-hour workshop ("hands-off" approach to breastfeeding: advice about baby initiation of feeding, positioning, and attachment).
¶¶¶ Usual care included a lactation consultant troubleshooting problems during the hospital stay and at each visit by using the American Academy of Pediatrics' 2002 guide to breastfeeding.
**** Members of the intervention group were invited to choose a female confidante who could offer support with infant feeding, and the community midwife visited both mother and confidante together at home.
†††† Breastfeeding classes for expectant fathers taught by peer who was a father.
‡‡‡‡ BFHI step 10, postnatal home visits by professionals.
§§§§ BFHI step 4, skin-to-skin contact in delivery room and helped to breastfeed in delivery room; BFHI step 5, shown how to breastfeed (positioning and attachment); BFHI step 6, infant given only breast milk, given no water/tea, and given no other milk; BFHI step 7, roomed-in; BFHI step 8, advised to breastfeed on demand; BFHI step 9, advised not to give pacifiers and bottles; and BFHI step 10, postnatal home visits by professionals.
‖ ‖ ‖ ‖ Modeled BFHI.

When we excluded the 2 RCTs from developing countries (98, 126), the results for any breastfeeding initiation and short-term breastfeeding were no longer significant. However, intervention effects on short- and long-term exclusive breastfeeding were significant (rate ratios, 1.28 [CI, 1.11 to 1.48] and 1.44 [CI, 1.13 to 1.84], respectively), with evidence for statistically significant heterogeneity for short-term exclusive breastfeeding ($I^2 = 55\%$; $P = 0.006$).

Table 4 describes subgroup analyses performed according to the timing of breastfeeding promoting interventions (prenatal, postnatal, and combinations thereof). Overall, the direction of the effects favors breastfeeding promotion interventions over usual care and was statistically significant for some subgroups (**Table 4**). We found no clear pattern for the outcome of any breastfeeding with respect to intervention timing. However, for short-term exclusive breastfeeding, the summary point estimates of the corresponding rate ratios are larger for the combination of pre- and postnatal interventions ($P = 0.01$, Z test).

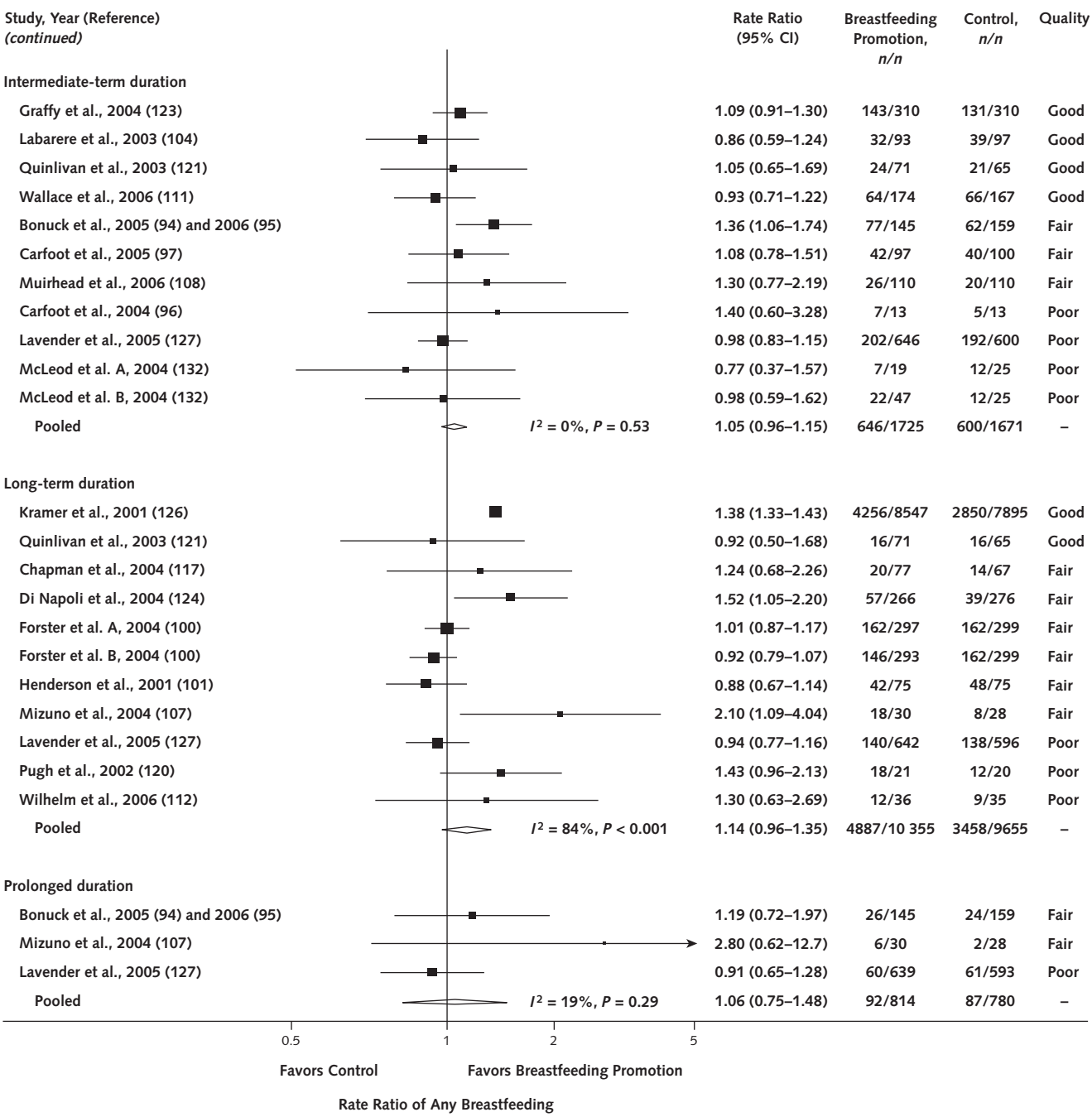
We performed subgroup analyses on the effects of different components of breastfeeding interventions on breastfeeding initiation, duration, and exclusivity compared with usual care. Again, multiple components were often combined into a single, multifaceted breastfeeding intervention. Our analyses compared only a specific component within a multifaceted intervention with usual care. Indirect comparison of the pooled effect sizes between different intervention components could be misleading, because other components in the intervention and control groups may not be the same across the different subgroups. Overall, we did not find that formal or structured breastfeeding education or individual-level professional support significantly affected the breastfeeding outcomes. We did find that lay support significantly increased the rate of any and exclusive breastfeeding in the short term by 22% (CI, 8% to 48%) and 65% (CI, 3% to 263%), respectively. Meta-regression suggested that larger effects (compared with usual care) were asso-

Figure 3. **Effectiveness of breastfeeding promotion on any breastfeeding initiation or durations, compared with usual care.**



(continued)

Figure 3—**Continued**



ciated with longer duration for any breastfeeding (P = 0.04) (**Table 5**).

Finally, the summary rate ratios of breastfeeding initiation and duration did not statistically significantly differ across RCTs of different quality grades (data not shown).

Differences in Absolute Breastfeeding Durations

Ten RCTs in 11 publications (100, 102, 105, 107, 110, 112, 119, 121, 125, 130, 131) reported the differences in the absolute breastfeeding duration between breastfeeding intervention and usual care groups. The follow-up durations ranged from 2 weeks to 1 year. We did not perform meta-analyses because the intervention components and units of analysis for the breastfeeding outcomes varied greatly across these trials. Seven of the 10 RCTs did not show a significant difference in absolute breastfeeding duration between the intervention and control groups. The other 3 RCTs, 2 of good qual-

Figure 4. **Effectiveness of breastfeeding promotion on exclusive breastfeeding initiation or durations, compared with usual care.**

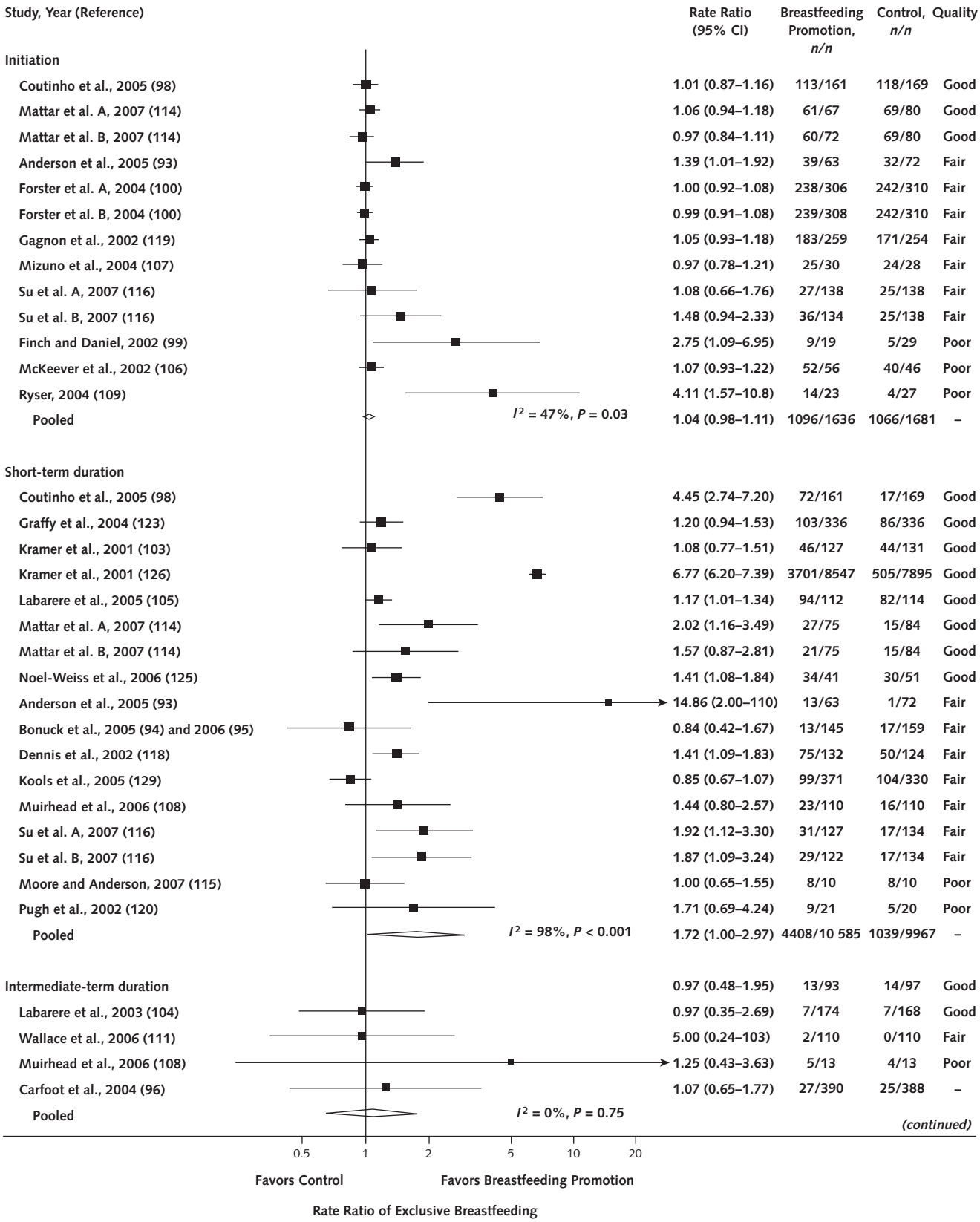
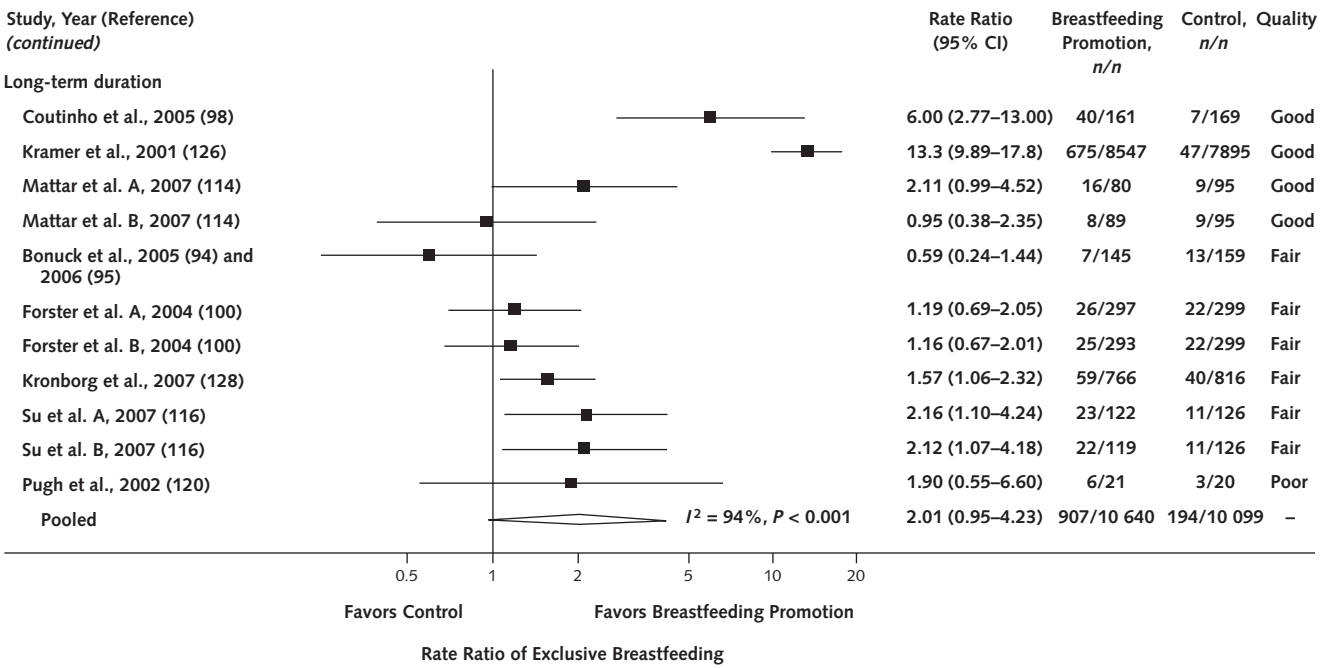


Figure 4—Continued



ity and 1 of fair quality, showed that delayed pacifier use (>4 weeks) was more effective than early pacifier use (within 2 to 5 days) (102) and system-level professional support (105) and postpartum skin-to-skin care (107) were more effective than usual care in increasing breastfeeding duration.

Interventions Involving Family Members

We identified 2 poor-quality RCTs involving family members in breastfeeding intervention. These 2 RCTs were graded poor quality because of incomplete reporting of trial protocol (for example, randomization and blinding) and nonrigorous definitions of breastfeeding outcomes. One study compared the effects of breastfeeding classes for expectant fathers to control group classes of baby care and safety on rates of any breastfeeding initiation and any breastfeeding at 2 months (113). This study found that more women whose partners attended the breastfeeding classes initiated breastfeeding than did women whose partners attended the control class (74% vs. 41%; $P = 0.02$). However, the rate of any breastfeeding at 2 months did not significantly differ between the intervention and control groups. The other study examined the role of a grandmother (maternal mother) or a close female confidante (sister or friend) of the mother's own choice in supporting breastfeeding (122). This study found no significant difference in breastfeeding initiation or duration between the breastfeeding promotion with a female confidante and the routine prenatal care without a female confidante.

Table 4. **Meta-analysis of Rate Ratios of Any or Exclusive Breastfeeding, by Timing of Breastfeeding Interventions**

Intervention Timing	Initiation		Short-Term		Intermediate-Term		Long-Term	
	Studies, *n*	Rate Ratio (95% CI)	Studies, *n*	Rate Ratio (95% CI)	Studies, *n*	Rate Ratio (95% CI)	Studies, *n*	Rate Ratio (95% CI)
Any breastfeeding								
Prenatal	7	1.03 (0.98–1.08)	5	1.37 (1.14–1.64)	1	0.98 (0.83–1.15)	3	0.96 (0.87–1.06)
Postpartum	3	0.97 (0.95–1.00)	6	1.07 (0.98–1.17)	5	0.98 (0.83–1.16)	6	1.25 (0.94–1.66)
Combined	6	1.09 (0.93–1.27)	7	1.09 (0.95–1.24)	5	1.15 (1.01–1.31)	2	1.38 (1.33–1.43)
Exclusive breastfeeding								
Prenatal	6	1.03 (0.93–1.14)	3	1.52 (1.22–1.90)	0	–	4	1.27 (0.92–1.75)
Postpartum	3	1.05 (0.96–1.13)	5	1.19 (1.07–1.33)	3	1.03 (0.62–1.70)	2	1.60 (1.10–2.32)
Combined	4	1.18 (0.94–1.47)	9	2.14 (0.95–4.81)	1	5.00 (0.24–102)	5	3.01 (0.93–9.77)

Table 5. **Subgroup Analysis of Specific Components of Multifaceted Breastfeeding Interventions***

Specific Intervention Component	Initiation		Short-Term		Intermediate-Term		Long-Term		*P* Value for Trend
	Studies, *n*	Rate Ratio (95% CI)	Studies, *n*	Rate Ratio (95% CI)	Studies, *n*	Rate Ratio (95% CI)	Studies, *n*	Rate Ratio (95% CI)	
Any breastfeeding									
Formal or structured education	7	1.09 (0.98–1.21)	7	1.11 (0.92–1.33)	4	1.04 (0.78–1.39)	3	0.95 (0.86–1.05)	0.39
System-level professional support	2	1.06 (0.95–1.17)	3	1.07 (0.92–1.26)	2	0.96 (0.84–1.11)	2	1.16 (0.80–1.68)	0.92
Individual-level professional support	9	1.04 (0.98–1.10)	9	1.06 (0.96–1.17)	6	1.08 (0.95–1.21)	5	1.23 (0.99–1.53)	0.20
Lay support	3	1.09 (0.92–1.28)	5	1.22 (1.08–1.37)	1	1.30 (0.77–2.19)	2	1.37 (0.98–1.91)	0.040
Exclusive breastfeeding									
Formal or structured education	4	1.09 (0.90–1.33)	3	1.16 (0.84–1.59)	1	0.97 (0.48–1.95)	3	1.05 (0.74–1.50)	0.28
System-level professional support	0	–	3	1.89 (0.41–8.79)	1	0.97 (0.35–2.69)	1	13.3 (9.89–17.8)	–
Individual-level professional support	7	1.04 (0.98–1.10)	11	1.79 (0.88–3.65)	0	–	9	2.27 (0.97–5.28)	0.060
Lay support	1	1.39 (1.01–1.92)	4	1.65 (1.03–2.63)	1	5.00 (0.24–102)	1	1.90 (0.55–6.60)	0.83

* Compared with usual care. Indirect comparison across different subgroups could be misleading.

Key Question 3

Are there harms from interventions to promote and support breastfeeding?

We did not identify any study specifically designed to examine harms from interventions to promote and support breastfeeding (regardless of design). None of the eligible RCTs reported harms from the breastfeeding interventions.

DISCUSSION

This systematic review summarizes the effects of primary care–initiated interventions to promote and support breastfeeding with respect to maternal and child health outcomes and breastfeeding outcomes. Although a large number of RCTs have been published since 2001, fewer than one third of them fulfilled most of our quality criteria and another one third had substantial methodological flaws (**Appendix Table**, available at www.annals.org). We also found great heterogeneity among the actual interventions as well as the background social support and health care systems that constituted usual or routine care across studies. Nonetheless, the RCTs reviewed in this report showed consistent findings. The evidence suggests that breastfeeding interventions can be more effective than usual care in increasing short- and long-term breastfeeding rates. Combined pre- and postnatal interventions and inclusion of layperson support in a multicomponent intervention may be beneficial. Observational data from our previous report (4) showed a relationship between breastfeeding and many beneficial child and maternal health outcomes (**Table 1**). In summary, only a few RCTs directly examined the effectiveness of breastfeeding interventions on child and maternal health outcomes. Thus, our conclusions about the value of breastfeeding interventions on health outcomes are largely based on an indirect chain of evidence.

Our review has several limitations, which stem mainly from methodological shortcomings of the primary studies and the multitude of possible breastfeeding promotion interventions. First, we found substantial clinical and methodological heterogeneity across studies, which make our summary effects difficult to interpret. This variability in interventions, definitions, and outcomes is not surprising. Breastfeeding schedules and habits are determined by cultural norms, personal desires, and a plethora of socioeconomic factors. To the extent possible, we performed subgroup and sensitivity analyses on factors that may explain the observed heterogeneity. Second, trials of breastfeeding interventions included several individual components. It is impossible to reliably distinguish "independent" effects for these components without performing head-to-head comparisons between them because the effects of individual components cannot be considered independent or additive. Finally, we did not use strict criteria to categorize "primary care–initiated" interventions. Whether a study was classified as primary care–initiated was entirely dependent on the clarity of reporting of the individual studies.

We did not find interventions with formal breastfeeding education or individual-level professional support to be effective in increasing the rates of breastfeeding initiation or duration. However, some evidence suggests that interventions with lay support may be effective in increasing the rates of short- and long-term breastfeeding. This conclusion, however, is based on findings from indirect comparisons of different studies. To further understand the role of lay versus professional support in breastfeeding promotion, future studies should directly compare them in the same population.

Only 2 fair-quality RCTs in developed countries directly examined the effects of breastfeeding interventions on child health outcomes. In both trials, the effects of interventions on rates of exclusive breastfeeding matched the corresponding effects on child outcomes. Specifically, 1 RCT reported an increased exclusive breastfeeding rate at 3 months and a lower risk for diarrheal diseases in the breastfeeding intervention group than in the control group (93). The other RCT 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 (94, 95). One may surmise from the above findings that the rate of exclusive breastfeeding may be an important determinant of certain health outcomes in infants. It is unclear whether differences in definitions of exclusive breastfeeding, health outcomes, and unknown factors that could interact with the intervention could also explain some of the different findings. However, these findings stressed the need to further examine the role of postnatal home support for breastfeeding from trained professionals or peer counselors.

Two good-quality RCTs conducted in developing countries (98, 126) provided good evidence that the BFHI is effective in increasing exclusive breastfeeding rates, at least up to 6 months after delivery. The PROBIT (126) also compared infants in the breastfeeding intervention group with those in the control group and showed a significant reduction in the risk for 1 or more gastrointestinal infections and atopic dermatitis. It is conceivable that a cluster randomized study similar to PROBIT in Belarus could be done in the United States, as the BFHI is not yet widely adopted; only 1.3% of the maternity units in this country are designated as baby-friendly (according to www.babyfriendly.org). Such a study is important to estimate the public health effect in a sociocultural environment that is not as breastfeeding-friendly as the one in Belarus. To assess the effectiveness of the complete BFHI, it is important to implement all 10 steps (**Table 2**); none of the studies conducted in developed countries did that.

More cluster RCTs with greater methodological rigor are needed to provide an understanding of the effectiveness of various breastfeeding interventions. Cluster RCTs allow random assignment of groups (such as families or primary care practices) rather than individuals. Cluster studies preempt exposures of intended interventions to nontargeted individuals, thus minimizing cross-contamination of interventions between groups. However, cluster RCTs are more complex to design, require more participants to obtain equivalent statistical power, and demand more complex analyses (133). In addition to proper randomization, the quality of the RCTs can be improved with clear and unbiased patient selection criteria, a common definition of exclusive breastfeeding, reliable collection of feeding data, definition of specific and quantifiable clinical outcomes of interest, and blinded assessments of the outcome. Any substantial differences in the degree of breastfeeding between the intervention and control groups as a result of the breastfeeding intervention will provide further opportunity to investigate any disparity in health outcomes between the 2 groups.

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Appendix Table. Quality Assessment of Randomized, Controlled Trials

Study, Year (Reference)	Design	Method of Randomization*	Allocation Concealment Adequate†	Intention-to-Treat Analysis	Outcome Assessors Blinded	Loss to Follow-up, %‡	Results Adjusted for Confounding	Groups Similar at Baseline	Recruitment Method Appropriate§	Statistical Analyses Appropriate‖	Overall Quality
Developed countries											
Anderson et al., 2005 (93)	Parallel	Assigned by the study field coordinator	No	Yes	Unclear	15	None	Yes	Yes	Yes	Fair
Bonuck et al., 2005 (94) and 2006 (95)	Parallel	Blocked and stratified according to center	Yes	Yes	No	21 (missing breastfeeding data)	Maternal age, ethnicity, Medicaid status, previous breastfeeding data	Yes	Yes	Yes	Fair
Carfoot et al., 2004 (96)‡	Parallel	Computer-generated randomization list, sequence of envelopes	No	No	No	7.1	None	Yes	Yes	No	Poor
Carfoot et al., 2005 (97)	Parallel	Computer-generated randomization list, sequence of envelopes	No	Yes	No	3.4	None	Yes	Yes	Yes	Fair
Chapman et al., 2004 (117)	Parallel	Computer software program	Unclear	Yes	No	25	None	No	Yes	Yes	Fair
Dennis et al., 2002 (118)	Parallel	Random number generated by a statistician	Yes	Unclear	Yes	1	None	No	Yes	No	Fair
Di Napoli et al., 2004 (124)	Parallel	Unclear	Unclear	Yes	No	10	Age, parental education, smoking, parity, participation in breastfeeding course, type of delivery	Yes	Yes	Yes	Fair
Ekström and Nissen, 2006 (130); Ekström et al., 2006 (131)	Quasi	Randomized pairwise; centers matched in pairs that were similar in size and had similar breastfeeding duration	Yes	No	Unclear	Unclear (can be as high as 33)	None	Yes	Yes	Yes	Poor
Finch and Daniel, 2002 (99)	Parallel	No	No	No	Unclear	37	None	Yes (presumed)	Unclear	Yes	Poor
Forster et al., 2004 (100)	Parallel	A computerized system of biased urn randomization	No	No	Unclear	7	Income, smoking before pregnancy, education	Yes	Yes	Yes	Fair
Gagnon et al., 2002 (119)	Parallel	Block randomization, using computer-generated blocks and stratified by parity	Unclear	Yes	Yes	15	None	Yes	Yes	Yes	Fair
Graffy et al., 2004 (123)	Parallel	Random permuted blocks by the statistical adviser	Yes	No	Yes	14	Decision about the feeding plan	Yes	Yes	Yes	Good
Henderson et al., 2001 (101)	Parallel	Computer-generated balanced blocks of 20	Yes	No	No	6.3	None	Yes	Yes	Yes	Fair
Howard et al., 2003 (102)	Parallel	Computer-generated balanced blocks of 20	Yes	Yes	Yes	2	All predictors with $P \leq 0.10$, including maternal race, previous births, and maternal education	Yes	Yes	Yes	Good
Kools et al., 2005 (129)	Cluster	Coin-flip for the center randomization, clusters matched by breastfeeding rates	Yes	Yes	Unclear	1.0	Variability of breastfeeding rates among the 10 centers	Yes	No	Yes	Fair
Kramer et al., 2001 (103)	Parallel	Computer-generated blocks of 4	Yes	No	Yes	8	Marital status, smoking	Yes	Yes	Yes	Good
Kronborg et al., 2007 (128)	Cluster	Computerized	Unclear	Unclear	No	~1.8	None	Yes	No	Yes	Fair
Labarere et al., 2003 (104)	Parallel	Computer-generated, random numbers in blocks of 8	Yes	Yes	Yes	9.5	None	Yes	Yes	Yes	Good

Continued on following page

Appendix Table—**Continued**

Study, Year (Reference)	Design	Method of Randomization*	Allocation Concealment Adequate†	Intention-to-Treat Analysis	Outcome Assessors Blinded	Loss to Follow-up, %‡	Results Adjusted for Confounding	Groups Similar at Baseline	Recruitment Method Appropriate§	Statistical Analyses Appropriate‖	Overall Quality
Labarere et al., 2005 (105)	Parallel	Random permuted blocks with a block size of 8	Yes	Yes	No	2	Age, education, white-collar worker, smoking, prenatal class attendance, primiparity, epidural anesthesia, infant birthweight and gestational age, breastfeeding <1 h after delivery, postpartum length of stay >4 d, expected breastfeeding duration >4 mo	Yes	Yes	Yes	Good
Lavender et al., 2005 (127)	Cluster	Wards were pair-matched; pairs were randomly allocated to the groups by a midwife, independent of the trial	Yes	Yes	Yes	5 to 7	None	Yes	Yes	Yes	Poor¶
Mattar et al., 2007 (114)	Parallel	Computer-generated list	Yes	Yes	No	10	Adjust for multiple comparisons	Yes	Yes	Yes	Good
McKeever et al., 2002 (106)	Parallel	Central randomization procedures	Unclear	No	No	26	None	Yes	Yes	Yes	Poor
McLeod et al., 2004 (132)	Quasi	Random number	No	Yes	No	60	Yes (although unclear what variables were adjusted for)	No	Yes	Yes	Poor
Mizuno et al., 2004 (107)	Parallel	Unclear**	Unclear	Unclear	No	10	Site of enrollment; age of infant at interview; maternal, paternal, and infant characteristics	Yes	Yes	Yes	Fair
Moore and Anderson, 2007 (115)	Parallel	Randomization with algorithm to adjust for maternal age, education, marital status, race, smoking, breastfeeding intention, infant sex, and health care provider	No	No	Yes	5	None	Yes	Yes	Yes	Poor††
Muirhead et al., 2006 (108)	Parallel	In a block of 10, separated for each of 4 strata (primigravidae, previous formula feeder, previously breastfed <6 wk, previously breastfed >6 wk)	Yes	Yes	No	2.3	None	Yes	Yes	Yes	Fair
Noel-Weiss et al., 2006 (125)	Parallel	Matching the sealed manila envelope with a sealed, sequentially numbered, opaque envelope containing the assignments	Yes	Yes	Yes	9	None	Yes	Yes	Yes	Good
Pugh et al., 2002 (120)	Parallel	Unclear	Unclear	Yes (no dropout)	Unclear	0	Yes (only on matching factors)	Yes	Yes	No	Poor
Quinlivan et al., 2003 (121)	Parallel	Computer-generated	Yes	Yes	Unclear	9.4	Age, social class, baseline knowledge, factors that were unbalanced between the 2 groups (ethnic origin, social isolation, involvement of the father, homelessness)	Yes (unbalanced factors between the 2 groups were adjusted for)	Yes	Yes	Good

Appendix Table—Continued

Study, Year (Reference)	Design	Method of Randomization*	Allocation Concealment Adequate†	Intention-to-Treat Analysis	Outcome Assessors Blinded	Loss to Follow-up, %‡	Results Adjusted for Confounding	Groups Similar at Baseline	Recruitment Method Appropriate§	Statistical Analyses Appropriate‖	Overall Quality
Ryser, 2004 (109)	Parallel	Participants select a sealed envelope	Unclear	Yes (no dropout)	No	0	No	Yes	Yes	No	Poor
Schlickau and Wilson, 2005 (110)	Parallel	Unclear	Unclear	No	Unclear	17	None	Unclear	Yes	Yes	Poor
Su et al., 2007 (116)	Parallel	Computer	No	Yes	Unclear	18	None	Yes	Yes	Yes	Fair
Wallace et al., 2006 (111)	Parallel	Telephone-balanced block and computer	Yes	Yes	Yes	6	None	Yes	Yes	Yes	Good
Wilhelm et al., 2006 (112)	Parallel	Random number	Unclear	No	No	3	Baseline breastfeeding self-efficacy, length of time before returning to work	No	No	Yes	Poor
Winterburn et al., 2003 (122)	Parallel	Unclear	Unclear	Unclear	Unclear	Unclear	None	Unclear	Yes	Yes	Poor
Wolfberg et al., 2004 (113)	Parallel	Unclear	No	No	Unclear	3	Breastfed previously, mother was breastfed as an infant, mother plans to breastfeed for first month, mother lives with father; mother's breastfeeding beliefs‡‡	Yes	Yes	Yes	Poor
Developing countries (for BFHI only)											
Coutinho et al., 2005 (98)	Parallel	Random-number table	Yes	Yes	Yes	6	None	Yes	Yes	Yes	Good
Kramer et al., 2001 (126)	Cluster	Random-number table	Unclear	Yes	Unclear	3	Birthweight, maternal age, previously breastfed infant for ≥3 mo, number of children in household, maternal smoking, family atopic history	Yes	Yes	Yes	Good

BFHI = Baby-Friendly Hospital Initiative.
* If cluster randomized, controlled trial (RCT), method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification, matching).
† 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.
‡ A good-quality RCT must have <20% loss to follow-up.
§ Appropriate consecutive or randomized.
‖ If cluster RCT, statistical methods used to compare groups for primary outcome indicating how clustering was taken into account; methods for additional analyses, such as subgroup analyses and adjusted analyses.
¶ Downgraded to poor quality because only 64.7% of women in intervention attended the workshop.
** Authors stated that it was not possible to randomize all sites because of constraints on willingness of different practices to provide different services and other reasons.
†† Downgraded to poor quality because the RCT was underpowered to detect differences.
‡‡ Mother's mother thinks that the baby should be breastfed, mother believes that her partner thinks her baby should be breastfed, or father would like the baby to be breastfed.