Randomized, Controlled Trial of a Prenatal and Postnatal Lactation Consultant Intervention on Duration and Intensity of Breastfeeding up to 12 Months

Karen A. Bonuck, PhD*; Michelle Trombley, BA*; Katherine Freeman, DrPH*; and Diane McKee, MD‡

ABSTRACT. Objective. To determine whether an individualized, prenatal and postnatal, lactation consultant intervention resulted in increased cumulative intensity of breastfeeding up to 52 weeks.

Design. The randomized, nonblinded, controlled trial recruited women from prenatal care. Baseline prenatal interviews covered demographic data and breastfeeding experience, intention, and knowledge. Interviews at 1, 2, 3, 4, 6, 8, 10, and 12 months after birth collected data on weekly feeding patterns, infant illness, and infant health care use.

Setting. Two community health centers serving low-income, primarily Hispanic and/or black women.

Participants. The analytic sample included 304 women (intervention: n = 145; control: n = 159) with ≥1 postnatal interview.

Intervention. Study lactation consultants attempted 2 prenatal meetings, a postpartum hospital visit, and/or home visits and telephone calls. Control subjects received the standard of care.

Outcome Measures. Cumulative breastfeeding intensity at 13 and 52 weeks, based on self-reports of weekly feeding, on a 7-level scale.

Results. The intervention group was more likely to breastfeed through week 20 (53.0% vs 39.3%). Exclusive breastfeeding rates were low and did not differ according to group. In multivariate analyses, control subjects had lower breastfeeding intensity at 13 weeks (odds ratio [OR]: 1.90; 95% confidence interval [CI]: 1.13–3.20) and 52 weeks (OR: 2.50; 95% CI: 1.48–4.21). US-born control subjects had lowest breastfeeding intensity at 13 weeks (OR: 2.50; 95% CI: 1.48–4.21) and 52 weeks (OR: 2.50; 95% CI: 1.13–3.20) and 52

Conclusions. This “best-practices” intervention was effective in increasing breastfeeding duration and intensity. Breastfeeding promotion should focus on US-born women and exclusive breastfeeding. Pediatrics 2005;116: 1413–1426; randomized, controlled trial, breastfeeding duration, intensity of breastfeeding, exclusive breastfeeding, lactation consultant.

ABBREVIATIONS. WIC, Supplemental Nutrition Program for Women, Infants, and Children; OR, odds ratio; CI, confidence interval; MILK, Moms Into Learning about Kids; LC, lactation consultant; RA, research assistant.

The American Academy of Pediatrics recommends exclusive breastfeeding for 6 months and continuation of partial breastfeeding for ≥12 months.¹ The unique composition of breast milk has essential nutrients that are absorbed more readily than cow’s milk or infant formula into the infant’s bloodstream. Breast milk confers increased immune function and is associated with the growth of human tissues, especially the brain.² In the first 1 year of life, in particular, breastfeeding is associated with significantly fewer cases of otitis media,³–⁷ respiratory infections,⁸–¹² and gastrointestinal illnesses.¹²–¹⁵

Healthy People 2010 set a goal that 75% of infants be breastfed in the early postpartum period, with continued breastfeeding to 6 months for 50%,¹⁶ Breastfeeding rates are generally higher among older women, women of greater income and education, and women who are not black.¹⁷,¹⁸ From 1990 to 2001 there were dramatic increases in any breastfeeding to 69.5% (from 52%) in the hospital and 32.5% (from 18%) at 6 months. Exclusive breastfeeding during this period increased to 46.3% (from 43.5%) in the hospital and 17.2% (from 10.4%) at 6 months. The greatest initiation gains were among women who were black, younger (<20 years of age), high school educated or less, and receiving Supplemental Nutrition Program for Women, Infants, and Children (WIC) benefits. At 6 months, exclusivity was lower among black versus white non-Hispanic and Hispanic women (10.7% vs 18.7% and 16.2%, respectively), younger women (10.3% for women <20 years of age vs 22% for women ≥35 years of age), and women lacking a college degree (24% for college vs 12.7% for high school).¹⁹ Recently published 2002 National Immunization Survey data found similar results; Li et al¹⁸ recommended that strenuous public health efforts target non-Hispanic black women and socioeconomically disadvantaged groups.

A US Preventive Services Task Force meta-analysis found that combined education, counseling, and problem-solving were most effective for promoting breastfeeding in the first 3 months, whereas ongoing support through in-person visits or telephone contacts increased duration to 6 months.²⁰ Brief, small-

From the Departments of *Epidemiology and Population Health and ‡Family and Community Medicine, Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, New York. Accepted for publication May 5, 2005. doi:10.1542/peds.2005-0435

No conflict of interest declared.

Reprint requests to (K.A.B.) Department of Epidemiology and Population Health, Montefiore Medical Center/Albert Einstein College of Medicine, 111 E 210th St, Bronx, NY 10467. E-mail: kbonuck@montefiore.org

PEDIATRICS (ISSN 0031 4005). Copyright © 2005 by the American Academy of Pediatrics.
scale interventions and those without face-to-face interactions were generally ineffective, according to a systematic review. Hands-on assistance with breastfeeding techniques, demand feeding, and postnatal support are essential postpartum factors, according to several reviews of controlled clinical trials. Women value being shown how to feed their infants, rather than being told how to, as found in our previous work and by others. Support offered by trained volunteers had no effect in a large, randomized, clinical trial of women intending to breastfeed, underscoring the value of offering postnatal support routinely, compared with on demand.

Although the literature is replete with breastfeeding-promotion intervention studies, few are good-quality, randomized, controlled trials of best practices. In preparing its meta-analysis, the US Preventive Services Task Force systematically reviewed studies of counseling or behavioral interventions originating from clinicians’ practices. Eligible studies included physician, nurse, lactation consultant (LC), or peer counselor interventions occurring in the clinic, hospital, or home or elsewhere. An exhaustive search of 1996–2001 articles yielded just 22 randomized, controlled trials, only 1 of which was judged to be of good quality. Of these 22 studies, just 7 included follow-up monitoring for ≥4 months, only 8 included both educational and supportive elements, and just 2 provided both prepartum and postpartum interventions.

We conducted a randomized, nonblinded, controlled trial of a breastfeeding-promotion intervention, compared with standard care, in community health centers where women received their prenatal and postpartum care. The intervention combined several best-practice interventions; it offered professional, one-on-one, skills-based, prenatal and postnatal education and support routinely. Intention to breastfeed at prenatal baseline was assessed in both groups. Weekly breastfeeding outcomes up to 12 months were assessed in both groups with a standardized tool that measured 7 levels of breastfeeding, ranging from exclusive to none. The study was conducted in the Bronx, New York, the US county with the highest poverty rate and lowest median household income. Nearly one half (48%) of the Bronx population is Hispanic; just 15% of residents identified themselves as non-Hispanic white in the 2000 US Census.

METHODS

Recruitment and Eligibility

The Moms Into Learning about Kids (MILK) study was a randomized, controlled trial of a multicomponent breastfeeding-promotion intervention. Breastfeeding, infant health, and infant health care utilization outcomes were tracked up to 12 months. This article reports on breastfeeding outcomes. Prenatal care patients at 2 hospital-affiliated health centers in the Bronx, New York, were recruited from August 2000 through November 2002. At 1 site, a research assistant (RA) bilingual in English and Spanish recruited directly from the center’s mandatory prenatal class. At the other center, social work staff members recruited interested participants and passed contact information onto another bilingual MILK RA.

Eligibility criteria included the following: English or Spanish speaking, twin or singleton pregnancy, intent to keep the infant, plans to remain in the center and its affiliated hospital system for prenatal and infant care up to 12 months, ≥2 contact telephone numbers, and gestation before 24 weeks (to allow sufficient time to deliver the 2-part prenatal intervention). Exclusion criteria included HIV-positive status, chronic therapy with medications incompatible with breastfeeding, and pregestational diabetes mellitus; diabetic prenatal patients were referred to a high-risk site for care. Although they are not generally considered contraindications, women with human T-cell leukemia virus-1, breast reduction surgery, or hepatitis B or C were excluded, given some controversy that might have predisposed affected women and their health care providers against breastfeeding.

All study materials were translated professionally into Spanish. These translations were checked for cultural concordance with local dialects by native Spanish-speaking study staff members. The study was approved by the medial center’s institutional review board for the protection of human subjects.

Randomization and Referral for Intervention

After consent, eligible women who agreed to participate were assigned randomly to the intervention or control group, with an undisclosed blocking factor and stratification according to center. The project’s biostatistical office generated and maintained a list of random codes for subjects, corresponding to the intervention and control assignment groups. A page with the subject’s identification number, treatment assignment, and administrative information (eg, date assigned) was generated for each subject. Each page was secured in a sealed envelope and labeled externally with the subject’s number, name, and study information. A series of envelopes were given to the RA at the site, with instructions to open the envelopes in sequence and to assign the women to the corresponding intervention or control group.

After intervention group participants completed the baseline interview, the MILK RA referred them to the study LC. The RA shared basic demographic and contact information but did not discuss the breastfeeding intentions, knowledge, or attitudes assessed at the baseline interview. The LC then sought to arrange a first meeting with the participant, either at the center during an upcoming visit or at her home.

Trial Enrollment

As shown in Fig 1 (MILK Trial enrollment flow chart), a total of 382 women (385 mother/infant dyads, with 3 sets of twins) were assigned randomly in the study (intervention: n = 188; control: n = 194). Of these, 21 mother/infant dyads were excluded at contact for postnatal follow-up monitoring (intervention: n = 15; control: n = 6). Exclusions included mothers of twins (a decision was made after data collection was complete to exclude them from analyses; intervention: n = 2; control: n = 1), women who chose to withdraw from the study (intervention: n = 3; control: n = 2), and women who miscarried or terminated their pregnancy (intervention: n = 8; control: n = 2) after baseline assessment. Among the remaining eligible women, 30 from each group (17% of the intervention group and 16% of the control group) were lost to all follow-up monitoring. The outcomes sample represents 79.6% of
all those assigned randomly and 83.5% of eligible women after exclusions. Data were not collected for women who were approached but did not enroll.

Therefore, a total of 304 women (intervention: n = 145; control: n = 159) with ≥1 postnatal follow-up data point were included in the final analysis (outcomes sample). The mean lengths of follow-up periods for the outcomes sample were 41 weeks (SD: 16.3 weeks) for the intervention group and 44 weeks (SD: 13.9 weeks) for the control group. At 13 weeks, follow-up data were available for 90% of the outcomes sample intervention group and 92% of the outcomes sample control group. Follow-up rates decreased but remained comparable between the intervention and control groups at 26 weeks (79% vs 87%), 39 weeks (70% vs 79%), 48 weeks (63% vs 67%), and 52 weeks (52% vs 59%). We compared participants who were retained with those who were lost to follow-up monitoring at those times, both within and across treatment groups in terms of age, education, foreign birth, race/ethnicity, marriage/partner status, Medicaid, parity, prior breastfeeding experience, and infant feeding intention at baseline. None of these differences was statistically significant (data not shown).

Data Collection
Data collection consisted of 1 prenatal baseline interview covering demographic data, previous breastfeeding experience, feeding intention, and breastfeeding knowledge and 8 telephone interviews, at 1, 2, 3, 4, 6, 8, 10, and 12 months after birth, to assess infant feeding. The 1-month follow-up interview collected detailed data about the immediate postpartum experience, including infant feeding in the hospital and during the first week, the infant’s health, and health care use. Interviews at months 2, 3, 4, 6, 8, 10, and 12 were briefer and focused primarily on weekly feeding, infant health care, and health care use.

At the site where a MILK RA recruited directly from the prenatal class, the RA attempted to complete the baseline interview just after recruitment or at the next prenatal visit. At the site that relied on social work referrals, interested participants were met at their next prenatal visit. Participants were given gift cards for $20.00 after completion of the baseline interview, $40.00 after completion of follow-up interviews at 1, 2, 3, and 4 months, and $55.00 after completion of the remaining interviews.

Blinding
Neither the RA collecting breastfeeding outcome data nor the study LCs providing the intervention were blinded with respect to treatment group. However, the study protocol prohibited any discussion or sharing of feeding data between the study RAs and the study LCs.

Power Analysis
The power analysis was based on the following assumptions: 29% of mothers without the intervention would initiate breastfeeding, compared with twice that proportion in the intervention group. With these assumptions, 52 women per group, or 104 women total at each center, were needed to detect a difference of $55.00 after completion of the remaining interviews.

Differences between women assigned to the intervention group and free of charge, to facilitate breastfeeding. Study LCs also provided manual (Spring Express manual breast pump system; Medela, McHenry, IL) or minielectric (Medela) breast pumps to women, free of charge, in certain circumstances. Women who were separated from their infants because of work or college travel were given minielectric pumps. Women who were not separated from their infants for long periods but wanted the freedom to go out for several hours were given a manual pump.

The general policy of the study LCs was to discourage the use of breast pumps in favor of nursing for women who were in continual proximity to their infants.

The 2 study LCs maintained detailed activity logs for the women assigned to them. These logs recorded the dates and sites (eg, clinic, home, or hospital) of all attempted and actual contacts and telephone calls, duration of contact (minutes), supplies delivered, and content of contact.

Control group women had no contact with the study LCs. Control subjects received the health center standard of care. At one site this included a mandatory prenatal care class, which did not address infant feeding in any detail. At the other site, there was no routine prenatal education. Neither site followed an established protocol for breastfeeding education or support or offered a private lactation space. Participants enrolled in WIC had the opportunity to visit a breastfeeding coordinator at the WIC site, although such use was not assessed specifically. Given the study population’s diversity, it would be difficult to characterize a community “standard” with respect to breastfeeding.

Assessment of Breastfeeding Outcomes
Breastfeeding was measured through maternal self-report. At each follow-up interview, participants reported breastfeeding status for each week since their last interview or since hospital discharge (at the first follow-up interview). Breastfeeding status was assessed with the Index of Breastfeeding Status, a measure that has been used by several investigators.31-34

Breastfeeding Status is a 7-level ordinal scale that measures the percentage of breast milk an infant receives, compared with the total amount of feedings. These 7 levels are mutually exclusive (level 1, 100% breast milk; level 2, ≥80% breast milk combined with <20% artificial milk or solids; level 3, 50–80% breast milk and the rest artificial milk or solids [ie, 2–5 of every 10 feedings are not breast milk]; level 4, 50% breast milk and 50% artificial milk or solids; level 5, 20–50% breast milk and the rest artificial milk or solids [5–8 of every 10 feedings are not breast milk]; level 6, ≤20% breast milk combined with ≥80% artificial milk or solids; level 7, 100% artificial milk or solids [includes weaned]). Exclusive breastfeeding is defined as level 1. Exclusive formula feeding is defined as level 7. Analyses that report majority (≥50%) breastfeeding include levels 1 to 4. When data are presented as breastfeeding levels for ease of presentation, levels 2 and 3 are combined, as are levels 5 and 6. For our study, exclusive breastfeeding was defined as no artificial milk or solids. Intake of water, liquids other than artificial milk, and vitamin drops was not assessed. The next section describes how these data were used to construct a measure of breastfeeding intensity.

Statistical Analyses
We compared participants who were assigned randomly and included in the final analyses (outcomes sample) with participants who were assigned and not included in the final analyses, both within and across treatment groups. The outcomes sample was composed of women with ≥1 postnatal follow-up data point. Differences between women assigned to the intervention group
and women assigned to the control group were tested for significance with \( t \) tests (for maternal age), \( \chi^2 \) tests for dichotomous outcomes, and the Mantel-Haenszel test for trend for breastfeeding intention, a trichotomous ordinal variable. Descriptive statistics are shown as mean (SD) or number (percentage).

All remaining data descriptions and analyses were based on the outcomes sample of 304 women. Unadjusted differences between the intervention and control groups were tested for significance as described above. A comparison of baseline data from the 2 sites found no significant differences for the 60 baseline variables assessed, except that foreign birth was somewhat collinear with site. Therefore, with data for the 2 sites pooled, multivariate analyses controlled for foreign birth.

We created a breastfeeding intensity score over 52 weeks by summing weekly scores (range of 1–7, with 7 being exclusive formula feeding). For subjects with missing values before a given week, we imputed the treatment group’s median value for that week. Similarly, for subjects with missing values later than a given week, we imputed the treatment group’s subsequent weekly median values. The sum of weekly intensity scores was derived for each subject through week 13 (TOTAL13) and through week 52 (TOTAL52), with minimum to maximum ranges of 13 to 91 and 52 to 364, respectively.

Bivariate associations between each total intensity score and variables related to breastfeeding were assessed with Wilcoxon rank sum tests for dichotomous variables and Spearman rank correlations for continuous variables. These variables included Medicaid status, breastfeeding intention at baseline, logarithm of age, age squared (to assess for a nonlinear effect of age), education, marital status, race/ethnicity, country of origin (US mainland versus other), prior breastfeeding, and recruitment site. Variables with associations yielding \( P \) values of < .20 were used in initial multivariate models. Models were analyzed with and without (for ease of interpretation) transformations of scale for non-normally distributed variables, with backward stepwise multiple regression. There were no interaction terms in initial models. With data from all subjects regardless of treatment group, covariates with associations of \( P < .05 \) were retained in subsequent multivariate models, to assess the significance of the intervention. Initial models were divided into those with (baseline parity of \( \geq 1 \)) and without (entire sample) the prior breastfeeding variable.

We examined race/ethnicity and country of origin interactions with treatment group, given our prior findings and interest in determining whether specific subpopulations benefited differentially from the intervention. This effect modification was significant according to country of origin but not race/ethnicity. Unadjusted TOTAL13 and TOTAL52 scores are presented for both the entire sample and subjects with baseline parity of \( \geq 1 \), stratified according to treatment group and country of origin. Differences according to treatment group and country of origin were analyzed with analysis of variance, with Duncan multiple comparisons.

Lastly, both TOTAL13 and TOTAL52 were dichotomized at their medians. Logistic regression models were derived with the dichotomized intensity scores as outcomes and the set of significant covariates, the treatment group, and the interaction between treatment group and country of origin as independent factors. Odds ratios (ORs) and 95% confidence intervals (CIs) are presented.

All significance testing was based on 2-tailed tests, with \( P < .05 \) denoting significance. Analyses used an intention-to-treat model.

Client tracking data were entered and maintained centrally by study staff members, in an administrative database. Baseline and follow-up interviews were scanned with Teleform Elite 8.0 software (Cardiff Software, Bozeman, MT). Data were then transferred to SAS software, version 8.2 (SAS Institute, Cary, NC), for analysis.

### RESULTS

#### Baseline Characteristics

Baseline characteristics are shown in Table 1. There were no significant differences between women included in the final analysis of outcomes and those assigned randomly but not included in the final analysis, within or across treatment groups. Unless otherwise specified, all remaining results are reported for the outcomes sample.

The mean age of mothers was 25 years (SD: 6.23 years). 61.5% had a high school degree, 51.5% were married or living with a partner, and nearly 40% were foreign born. The sample was primarily Hispanic (57%) and black (36%). The majority (57%) of women were receiving Medicaid. Nearly two thirds (63%) had other children, and 70% reported prior breastfeeding experience. Breastfeeding intentions were as follows: breast milk only, 30%; combined breast milk and formula, 49%; exclusive formula feeding, 9%.

Twenty-six women completed the Spanish-language version of the baseline instrument. Some

### TABLE 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Values</th>
<th>Percentage (No.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td></td>
<td>Assigned* (n = 188)</td>
<td>Outcomes† (n = 145)</td>
</tr>
<tr>
<td>High school</td>
<td>Yes</td>
<td>58.5 (110)</td>
</tr>
<tr>
<td>Married/partner</td>
<td>Yes</td>
<td>50.3 (94)</td>
</tr>
<tr>
<td>Foreign born</td>
<td>Yes</td>
<td>44.1 (83)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td>Black</td>
<td>35.6 (67)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>54.8 (103)</td>
<td>56.6 (82)</td>
</tr>
<tr>
<td>Other</td>
<td>9.6 (18)</td>
<td>7.6 (11)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>Yes</td>
<td>53.7 (101)</td>
</tr>
<tr>
<td>Parity</td>
<td>Other children</td>
<td>59.9 (109)</td>
</tr>
<tr>
<td>Breastfed before</td>
<td>Yes</td>
<td>67.9 (74)</td>
</tr>
<tr>
<td>Intentions</td>
<td>Only breast milk</td>
<td>33.0 (62)</td>
</tr>
<tr>
<td>Other</td>
<td>47.3 (89)</td>
<td>47.4 (92)</td>
</tr>
<tr>
<td>Only formula</td>
<td>8.5 (16)</td>
<td>10.3 (20)</td>
</tr>
<tr>
<td>Do not know</td>
<td>11.2 (21)</td>
<td>13.4 (26)</td>
</tr>
</tbody>
</table>

For each variable shown, both within-group differences and between-group differences among those assigned randomly versus those in the outcomes data were tested for significance with \( \chi^2 \) tests. None of these associations was significant at the .05 level.

* “Assigned” includes all women assigned randomly in the study.
† “Outcomes” includes mother/infant dyads included in the outcome data in the remaining tables. The following mother/infant dyads were excluded from outcome analyses: women who lost the fetus (n = 9), lost custody were separated from the infant (n = 1), changed their minds (n = 5), or had twin births (n = 3) or for whom no breastfeeding outcome data were obtained (n = 60).
women completed both English and Spanish versions of study instruments throughout the study.

**Birth and Postpartum Experiences**

Detailed data about the birth and immediate postpartum experience were obtained at the 1-month follow-up interview (Table 2). There were no significant differences between the groups in any of the variables related to birth or infant morbidity, eg, delivery time, infant discharged with mother, birth type, low birth weight, time in NICU, or maternal perception of newborn health problems. The health centers’ affiliated hospital was the delivery site for 85% of births.

At the 1-month follow-up interview, we also obtained data about when women considered their feeding choice, prenatal care providers, and hospital practices pertaining to feeding and onset of breastfeeding. Again, there were no significant differences between groups. Two thirds (67%) of women had first thought about their feeding choice by the end of the first trimester. However, less than one half (43%) reported receiving advice about breastfeeding from their prenatal care providers. Eighty-four percent “roomed in” with their infants. Hospital staff members asked 73% of women if they wanted to breastfeed immediately after the birth. Although more women in the intervention group (62%) attempted to breastfeed in the first 4 hours, compared with control women in the intervention group (52%), this difference was not significant. There was no association between maternal perception of newborn health problems and either breastfeeding within the first 4 hours after birth or any subsequent breastfeeding at 2, 4, or 13 weeks (data not shown).

**TABLE 2. Birth and Postpartum Experiences**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Values</th>
<th>Intervention (No.)</th>
<th>Control (No.)</th>
<th>Sample (No.)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study hospital (n = 301; missing: n = 3)</td>
<td>Yes</td>
<td>84.0 (121)</td>
<td>85.4 (134)</td>
<td>84.7 (255)</td>
<td>.750</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>16.0 (23)</td>
<td>14.6 (23)</td>
<td>15.3 (46)</td>
<td>.830</td>
</tr>
<tr>
<td>Delivery time (n = 257; missing: n = 47)</td>
<td>Day</td>
<td>53.3 (65)</td>
<td>42.2 (57)</td>
<td>47.5 (122)</td>
<td>.076</td>
</tr>
<tr>
<td></td>
<td>Night</td>
<td>46.7 (57)</td>
<td>57.8 (78)</td>
<td>52.5 (135)</td>
<td>.262</td>
</tr>
<tr>
<td>Left hospital with mother (n = 301; missing: n = 3)</td>
<td>Yes</td>
<td>86.1 (124)</td>
<td>86.6 (136)</td>
<td>86.4 (260)</td>
<td>.862</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>13.9 (20)</td>
<td>13.4 (21)</td>
<td>13.6 (41)</td>
<td>.904</td>
</tr>
<tr>
<td>Birth type (n = 301; missing: n = 3)</td>
<td>Vaginal</td>
<td>81.3 (117)</td>
<td>77.7 (122)</td>
<td>79.4 (239)</td>
<td>.448</td>
</tr>
<tr>
<td></td>
<td>Cesarean</td>
<td>18.8 (27)</td>
<td>22.3 (35)</td>
<td>20.6 (62)</td>
<td>.245</td>
</tr>
<tr>
<td>Birth weight (n = 301; missing: n = 3)</td>
<td>Low birth weight</td>
<td>8.3 (12)</td>
<td>7.6 (12)</td>
<td>8.0 (24)</td>
<td>.825</td>
</tr>
<tr>
<td></td>
<td>Normal weight</td>
<td>91.7 (132)</td>
<td>92.4 (145)</td>
<td>92.0 (277)</td>
<td>.277</td>
</tr>
<tr>
<td>NICU (n = 301; missing: n = 3)</td>
<td>Yes</td>
<td>14.6 (21)</td>
<td>12.1 (19)</td>
<td>13.3 (40)</td>
<td>.526</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>85.4 (123)</td>
<td>87.9 (138)</td>
<td>86.7 (261)</td>
<td>.323</td>
</tr>
<tr>
<td>Newborn health problems (n = 301; missing: n = 3)</td>
<td>Yes</td>
<td>25.0 (36)</td>
<td>24.8 (39)</td>
<td>24.9 (75)</td>
<td>.975</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>75.0 (108)</td>
<td>75.2 (118)</td>
<td>75.1 (226)</td>
<td>.226</td>
</tr>
<tr>
<td>Roomed in (n = 301; missing: n = 3)</td>
<td>Yes</td>
<td>83.3 (120)</td>
<td>84.1 (132)</td>
<td>83.7 (252)</td>
<td>.862</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>16.7 (24)</td>
<td>15.9 (25)</td>
<td>16.3 (49)</td>
<td>.345</td>
</tr>
<tr>
<td>First breastfeeding attempt (n = 263; missing: n = 41)</td>
<td>0–4 h</td>
<td>61.7 (82)</td>
<td>52.3 (68)</td>
<td>57.0 (150)</td>
<td>.126</td>
</tr>
<tr>
<td></td>
<td>&gt;4 h</td>
<td>38.2 (51)</td>
<td>47.7 (62)</td>
<td>43.0 (113)</td>
<td>.323</td>
</tr>
<tr>
<td>Advised on breastfeeding by prenatal care provider (n = 301; missing: n = 3)</td>
<td>Yes</td>
<td>43.1 (62)</td>
<td>43.3 (68)</td>
<td>43.2 (130)</td>
<td>.964</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>56.9 (82)</td>
<td>56.7 (89)</td>
<td>56.8 (171)</td>
<td>.435</td>
</tr>
<tr>
<td>Asked if wanted to nurse in delivery room by hospital staff (n = 290; missing: n = 14)</td>
<td>Yes</td>
<td>72.9 (97)</td>
<td>73.9 (116)</td>
<td>73.4 (213)</td>
<td>.855</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>27.1 (36)</td>
<td>26.1 (41)</td>
<td>26.6 (77)</td>
<td>.777</td>
</tr>
<tr>
<td>When first considered how to feed infant (n = 299; missing: n = 5)</td>
<td>Before pregnancy</td>
<td>21.7 (31)</td>
<td>18.6 (29)</td>
<td>20.1 (60)</td>
<td>.956</td>
</tr>
<tr>
<td></td>
<td>First trimester</td>
<td>48.3 (69)</td>
<td>46.2 (72)</td>
<td>47.2 (141)</td>
<td>.762</td>
</tr>
<tr>
<td></td>
<td>Later</td>
<td>30.1 (43)</td>
<td>35.3 (55)</td>
<td>32.8 (98)</td>
<td>.245</td>
</tr>
</tbody>
</table>

* For each variable shown, both within-group differences and between-group differences for the assigned group versus the outcomes sample were tested for significance with χ² tests. None of these associations was significant at the .05 level.
tric pumps and 12 manual pumps) were given out. A few women required the use of a supplemental nursing system (n = 3) to induce lactation (data not shown).

Weekly Breastfeeding Outcomes

Any Breastfeeding

Figure 2 presents data on any breastfeeding and ≥50% breastfeeding, according to treatment group, for selected weekly intervals up to 52 weeks. At 2 weeks, nearly 90% of the intervention group was breastfeeding, compared with 65% of the control group. The steepest decline in breastfeeding occurred between 2 and 6 weeks, when rates decreased by 15% and 10% in the intervention and control groups, respectively. The intervention group was significantly more likely to breastfeed at each week up to and including week 20 (53.0% vs 39.3%; P = .028), with the exception of week 18. At 21 weeks (~5 months), 51.7% of the intervention group was still breastfeeding. At the end of 12 months, 18% of the intervention group and 15% of the control group continued to breastfeed.

Breastfeeding of ≥50%

Significantly more women in the intervention group gave ≥50% breast milk feedings in the first 1 week after birth (69% vs 47%; P < .001). More than one half of the intervention group gave their infants ≥50% breast milk through the first 6 weeks after birth. Group differences remained significant for

![Chart showing breastfeeding outcomes](chart.png)

Fig 2. Any and ≥50% breastfeeding, according to treatment group. Breastfeeding of ≥50% was significant up to and including week 9 (P < .03). Any breastfeeding was significant up to and including week 20 (P < .028), except for week 18.
Breastfeeding Intensity in Weeks 1 to 52

Figure 3 presents descriptive, unadjusted, weekly feeding data for the intervention group (Fig 3A) and the control group (Fig 3B). Data are shown for 5 levels of breastfeeding intensity, reduced from 7, ie, exclusive breastfeeding, more breast milk than formula, equal breast milk and formula, less breast milk than formula, or exclusive formula feeding. Exclusive breastfeeding rates, which peaked at 2 weeks (intervention: 20%; control: 19%), decreased at 6 weeks (intervention: 15%; control: 16%), and continued to decline at 13 weeks (intervention: 9%; control: 11%), 26 weeks (intervention: 5%; control: 8%), and 52 weeks (intervention: 6%; control: 5%), were not significantly different at any of the 52 weeks observed (data not shown).

Table 4 presents unadjusted TOTAL13 and TOTAL52 scores stratified according to treatment group and country of origin. Separate scores are shown for participants according to parity (total sample vs parity of =1 at baseline) to permit inclusion of the variable for prior breastfeeding. US-born control subjects had significantly higher scores than did the foreign-born control, foreign-born intervention, or US-born intervention groups (P < .05). No other treatment groups, according to country of origin, differed significantly from one another. Higher 52-week scores for all groups indicated the progression to greater formula feeding.

We performed multiple logistic regression analysis of the dichotomized median breastfeeding intensity scores, stratified according to week and parity. Results shown in Table 5 include the interaction between treatment group and country of origin. Effects of the remaining covariates were essentially unchanged in a logistic regression model excluding this interaction. Thus, Table 5 presents only the treatment group effect from that model. ORs adjusted for significant covariates, 95% CIs, and estimated $R^2$ values are presented for the 4 models. The OR indicates the “risk” of low versus high levels of breastfeeding, compared with the reference category.

The intervention’s effect was modified significantly by country of origin in multivariate analysis. US-born control subjects had significantly greater risk of low breastfeeding at 13 weeks in both the entire sample (OR: 5.22; 95% CI: 2.43–11.22) and the subsample (OR: 7.66; 95% CI: 2.75–21.36), compared with the foreign-born women in the intervention group. Similar results were found at 52 weeks. Among the foreign-born women, there was no significant difference between the intervention group and the control group, neither of which differed from US-born women in the intervention group. Therefore, the intervention reduced the risk of low breastfeeding among US-born women to the levels found in foreign-born women.

In analyses without the interaction term, control subjects had greater risk of low breastfeeding levels, across the 4 models. ORs were greater at 52 weeks for both the entire sample (OR: 2.50; 95% CI: 1.48–4.21) and the subsample (OR: 4.47; 95% CI: 2.13–9.36), compared with 13 weeks for both the entire sample (OR: 1.90; 95% CI: 1.13–3.20) and the subsample (OR: 3.71; 95% CI: 1.81–7.59). As noted above, estimates for covariates were essentially unchanged from the model excluding the interaction between treatment group and country of origin.

With respect to other significant covariates, women intending to formula feed exclusively at baseline had significantly greater risk of low breastfeeding at 13 weeks in the entire sample (OR: 10.51; 95% CI: 2.97–37.15), compared with women intending exclusive breastfeeding, with similar results in the other 3 models. Intent to combine formula and breastfeeding was not associated significantly with risk of low breastfeeding in 3 of the 4 models. Women who were undecided about their feeding choice had a greater risk of low breastfeeding at 13 and 52 weeks in the entire sample but not in the subsample with parity of =1. Older age, both dichotomized at 24 years and as a continuous variable, was associated with reduced risk of low breastfeeding. Black women had significantly reduced risk of low breastfeeding at 13 weeks (OR: 0.44; 95% CI: 0.24–0.79) and 52 weeks (OR: 0.37; 95% CI: 0.20–0.67), compared with a Hispanic reference group. Among women with other children, not having breastfed a previous child was significant at 52 weeks (OR: 2.91; 95% CI: 1.24–6.83) but not 13 weeks.

DISCUSSION

We performed a randomized, controlled trial of an individualized, LC, prenatal and postnatal, breastfeeding-promotion intervention modeled on best practices found in the literature. At 3 and 12 months, control subjects receiving standard care in urban primary care health centers had 90% and 150% increased risk of low breastfeeding, respectively, compared with the intervention group. The intervention group achieved the Healthy People 2000 goal of 50% continued breastfeeding up to 5 or 6 months but did not sustain this level at 6 months, which is the Healthy People 2010 goal. By comparison, the control subjects’ 6-month breastfeeding rate of 33% matched national survey data from one source exactly and approximated the rate from another national data source (36%). Unfortunately, we observed similar rates of exclusive breastfeeding in the 2 groups, which suggests that the intervention was not effective in helping women to breastfeed exclusively. Exclusive breastfeeding, which peaked at 20% at 2 weeks in our study, was proposed as a Healthy People 2010 goal in the mid-course review.

Our most striking finding was the strength with which country of origin modified the effect of treatment group. Our previous work on feeding intentions and other work on breastfeeding initiation and ever breastfeeding found that foreign-born women in the United States are predisposed to breastfeed, compared with their native-born counterparts. In this study, US-born women were 5 to 8 times as likely to have low breastfeeding intensity, depending on observation period and parity, compared with the foreign-born control, foreign-born in-

Downloaded from http://pediatrics.aappublications.org/ by guest on March 12, 2018
tervention, and US-born intervention groups. In fact, the mean breastfeeding intensity scores for the latter 3 groups did not differ significantly from one another. Therefore, our intervention was highly effective in raising the breastfeeding level of US-born women to that of foreign-born women, whose scores did not differ according to treatment group.

In contrast to the aforementioned results, race/ethnicity did not modify the effect of treatment group significantly. That is, the intervention was no more effective among one racial/ethnic group than another. Furthermore, in sharp contrast to recent national studies, black women were 50% to 60% more likely to have a high intensity of breastfeeding, compared with a reference group of women who identified themselves as Hispanic. Presumably, this finding is related to demographic distributions in the study’s locale, ie, New York City. New York City experienced a 41% increase in the West Indian population between 1990 and 2000, nearly all of whom identify themselves as black. West Indians represented 25% of the black population of New York City in 2000. Compared with the United States, West Indian nations have considerably higher rates of any and exclusive breastfeeding and longer duration of breastfeeding. Presumably, in areas with high concentrations of immigrant groups from countries where breastfeeding is the standard, there is likely to be both greater acceptance of breastfeeding and informal support.

Fig 3. Feeding mixture in weeks 1 to 26 for the intervention group (A) and the control group (B).
In findings similar to ours, Celi et al\textsuperscript{40} found that foreign-born women were more likely to initiate breastfeeding than US-born women (OR: 3.2; 95\% CI: 2.0–5.2), in multivariate analyses controlling for race/ethnicity. In addition, they found no material difference in initiation rates among US-born white, black, and Hispanic women.\textsuperscript{40} Those data and ours differ from analyses of the National Survey of Family Growth, which found that black women were 60\% less likely to have ever breastfed than were nonblack women, even after controlling for country of origin. Foreign-born women were 75\% more likely than US-born women to have ever breastfed in that study.\textsuperscript{41}

The studies cited above were based on observational data. They are unable to predict who would derive the most benefit from an intensive intervention, such as the one tested in this study. Our findings with regard to country of origin and race/ethnicity are valuable for targeting future interventions. National data consistently place non-Hispanic black women at greatest risk for not initiating or limiting breastfeeding\textsuperscript{18,19,41} We posit that race/ethnicity may matter less than cultural background in determining who would benefit most from future interventions.

Our findings with regard to baseline feeding intentions underscore the importance of prenatal counseling to increase knowledge about the benefits of breastfeeding (and risks of not doing so) and to identify and to overcome perceived barriers to breastfeeding. Compared with women who intended to breastfeed their new infants exclusively, women who intended only formula feeding were 10 to 14 times more likely, depending on observation period and parity, to have low breastfeeding intensity. Concerns about pain and breastfeeding in public and an unsupportive work environment can be potential barriers to breastfeeding, particularly among low-income women.\textsuperscript{48,49} Individualized counseling, such as that provided by the study LCs, can help women strategize about how best to address these potential barriers.

Data on breastfeeding duration and amount were used to derive both short-term (13 weeks, ie, 3 months) and long-term (52 weeks) measures of breastfeeding intensity. These outcome measures, which represent cumulative rather than prevalent feeding patterns, contrast with how data on breastfeeding generally are collected and presented. Compared with the intervention group, control subjects had increased odds of low breastfeeding of 90\% at 13 weeks and 150\% at 52 weeks. Although intervention contacts were concentrated in the early postpartum period, cumulative data show how effects persisted over the long term.

In our study, differences in breastfeeding outcomes cannot be attributed to differences in the birth and immediate postpartum experiences, which were nearly identical for the 2 groups. Essentially the same large proportions of women in the 2 groups had their infants at the centers’ affiliated hospital, thus reducing the risk of bias associated with hospital practice. In addition, this facilitated LC access to participants, because we were notified about births at that hospital. Immediate postpartum experiences were similar, in terms of women being asked if they wanted to breastfeed in the delivery room and breastfeeding in the first 4 hours after birth.

A particular strength of our study is the collection of detailed weekly feeding data up to 52 weeks. Surveys, particularly those based on large, population-based samples, tend to assess only partial or exclusive breastfeeding. Without a full assessment of breastfeeding practices, it is difficult to tailor interventions. In addition, limited outcomes assessments (eg, at 6, 12, and 16 weeks) can obscure and/or distort true differences. For instance, our finding that the intervention group reached the Healthy People 2000 goal of continued breastfeeding to 5 or 6 months would have been obscured had we collected data only at week 26 and not week 20 and week 21 (~5 months). Conversely, reporting a significant difference in ≥50\% breast milk at week 26 (~4 months) would have been a distortion, given the lack of significance in intervening weeks 10 to 14 and from week 17 up to week 52.

Our intervention was innovative, in that it combined multiple skills-based and supportive components, with early prenatal education and support and immediate hospital and home availability. The US

**TABLE 4.** Unadjusted Breastfeeding Intensity Scores at 13 and 52 Weeks, According to Treatment Group and Country of Origin

<table>
<thead>
<tr>
<th>Intensity Score, Median (No.)</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>US Born*</td>
<td>Foreign Born*</td>
<td></td>
</tr>
<tr>
<td>13 wk (range: 13–91)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>61 (81)</td>
<td>51 (64)</td>
</tr>
<tr>
<td>Baseline parity of ≥1</td>
<td>49 (48)</td>
<td>43 (37)</td>
</tr>
<tr>
<td>52 wk (range: 52–364)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>309 (81)</td>
<td>301 (64)</td>
</tr>
<tr>
<td>Baseline parity of ≥1</td>
<td>299 (48)</td>
<td>267 (37)</td>
</tr>
</tbody>
</table>

Median weekly intensity scores ranged from 1 (all breast milk) to 7 (all formula feeding). Higher scores indicate greater formula feeding, whereas lower scores indicate greater breastfeeding. US born denotes the US mainland and Hawaii. Given linguistic and cultural differences, participants born in Puerto Rico were considered foreign born, although Puerto Rico is a US territory.

* The US-born control group differed significantly from all other groups at 13 and 52 weeks, both for the entire sample and for the subsample with baseline parity of ≥1 (P < .05, analysis of variance, Duncan’s multiple-comparisons test). No other groups differed significantly from one another.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Values</th>
<th>13 wk All (n = 304)</th>
<th>OR (95% CI)</th>
<th>52 wk All (n = 304)</th>
<th>Baseline Parity of ≥1 (n = 184)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intent at baseline</td>
<td>Undecided</td>
<td>3.04* (1.22–7.58)</td>
<td>2.52 (0.66–9.64)</td>
<td>3.02* (1.21–7.56)</td>
<td>3.30 (0.81–13.48)</td>
</tr>
<tr>
<td></td>
<td>Formula</td>
<td>10.51* (2.97–37.15)</td>
<td>14.20* (2.50–80.73)</td>
<td>10.05* (3.04–33.20)</td>
<td>11.08* (2.19–56.14)</td>
</tr>
<tr>
<td></td>
<td>Combined</td>
<td>1.57 (0.85–2.87)</td>
<td>1.21 (0.55–2.70)</td>
<td>2.22* (1.19–4.15)</td>
<td>2.36 (1.00–5.56)</td>
</tr>
<tr>
<td></td>
<td>Breast milk</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Logarithm of age†</td>
<td>Years</td>
<td>0.92* (0.88–0.96)</td>
<td>0.95 (0.90–1.01)</td>
<td>3.15* (1.83–5.42)</td>
<td>0.91* (0.86–0.98)</td>
</tr>
<tr>
<td></td>
<td>Age &lt;24 y</td>
<td>1.00</td>
<td></td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age ≥24 y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td>Black</td>
<td>0.44* (0.24–0.79)</td>
<td>0.37 (0.20–0.67)</td>
<td>1.40 (0.48–4.10)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>1.75 (0.60–5.13)</td>
<td>1.00</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hispanic</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group/country of origin‡</td>
<td>Control/US born</td>
<td>5.22* (2.43–11.22)</td>
<td>7.66* (2.75–21.36)</td>
<td>5.25* (2.44–11.29)</td>
<td>8.05* (2.84–22.78)</td>
</tr>
<tr>
<td></td>
<td>Control/foreign born</td>
<td>0.90 (0.40–2.04)</td>
<td>1.37 (0.42–4.48)</td>
<td>1.06 (0.47–2.40)</td>
<td>1.40 (0.43–4.56)</td>
</tr>
<tr>
<td></td>
<td>Intervention/US born</td>
<td>1.67 (0.78–3.53)</td>
<td>1.22 (0.41–3.67)</td>
<td>1.15 (0.54–2.45)</td>
<td>0.91 (0.30–2.74)</td>
</tr>
<tr>
<td></td>
<td>Intervention/foreign born</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>No</td>
<td>1.05 (0.61–1.82)</td>
<td>0.71 (0.41–1.23)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breastfed before</td>
<td>No</td>
<td></td>
<td>1.79 (0.79–4.04)</td>
<td></td>
<td>2.91* (1.24–6.83)</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>NA</td>
<td>1.00</td>
<td>NA</td>
<td>1.00</td>
</tr>
<tr>
<td>Model r²</td>
<td></td>
<td>0.24</td>
<td>0.28</td>
<td>0.25</td>
<td>0.32</td>
</tr>
<tr>
<td>Treatment group§</td>
<td>Control</td>
<td>1.90* (1.13–3.20)</td>
<td>3.71* (1.81–7.59)</td>
<td>2.50* (1.48–4.21)</td>
<td>4.47* (2.13–9.36)</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Breastfeeding intensity scores were dichotomized at the median. ORs indicate the risk of low breastfeeding, compared with the reference category.

* P < .05.

† For ease of interpretation, we present the effect for age, although the model was analyzed with the logarithm of age.

‡ US born denotes the US mainland and Hawaii. Although Puerto Rico is a US territory, women born in Puerto Rico were classified as foreign born, given cultural and linguistic differences.

§ These treatment group ORs and 95% CIs were derived from an alternative logistic regression model that used the same set of significant covariates except that treatment group was used in place of the treatment group-country of origin interaction terms. ORs and 95% CIs for covariates in the alternative logistic regression model were essentially unchanged from those shown.
Preventive Services Task Force meta-analysis found that educational programs had the greatest effect of any single intervention on both initiation (mean difference: 0.23%; 95% CI: 0.12–0.34) and short-term duration (mean difference: 0.39%; 95% CI: 0.27–0.50). In-person and/or telephone support increased short-term duration (mean difference: 0.11%; 95% CI: 0.03–0.19) and long-term duration (mean difference: 0.08%; 95% CI: 0.02–0.16). Notably, the number of subjects included in the meta-analysis of combined effects of education and support for initiation (n = 170), short-term duration of up to 3 months (n = 163), and long-term duration of 4 to 6 months (n = 168) was smaller than our outcomes sample of 304.28

Another strength of our intervention was the personalized continuity of care that our LCs provided across the prenatal and postnatal periods. Our LCs reported that taking the time to develop a rapport with each woman contributed to their effectiveness. Prenatal LC sessions lasted 1 to 2 hours, exceeding the 15 to 30 minutes estimated at the study’s inception. This time investment during the prenatal period is credited with the women trusting and accepting LC support and advice in the postpartum period.25 Postnatally, women who received a home visit from the LC had lower TOTAL13 scores (ie, greater breastfeeding intensity) than did those who did not, which suggests that home visits made an important contribution to the intervention’s success. However, as noted earlier, these unadjusted data must be interpreted with caution. Although results are suggestive, additional analyses beyond the scope of this report are needed to understand more completely the effects of various components of the intervention, controlling for covariates such as prenatal feeding intensity and parity.

A caveat to our work, and a question for future research, is what impact, if any, pumped milk and breast pumps have on breastfeeding. As noted earlier, although study LCs generally discouraged breast pump use unless the mother was separated from her infant, breast pumps were provided free of charge to intervention group women under certain circumstances. We did not collect data on the source of the infant’s breast milk. However, anecdotal data from women in both groups suggested strong interest in the use of breast pumps as a means of avoiding inconvenience or the embarrassment of nursing in public. Particularly for younger mothers (eg, <18 years of age), breast pump use might have contributed to increased breastfeeding duration and intensity.

This trial was based on an intention-to-treat model. This model preserves the balance of randomization, is statistically conservative (biases toward the null hypothesis), and simulates nonresearch situations. Reflecting the vulnerable population served by the health centers, nearly 20% of the intervention outcomes sample did not receive the intervention, 36% did not have a prenatal contact, and 37% did not have a postnatal contact. Less than one half (47%) had both prenatal and postnatal contacts. However, we still found significant differences in breastfeeding duration and intensity in this hard-to-reach, socio-economically disadvantaged population.

In a prospective study, some loss to follow-up is inevitable. Given the nature of our population and the length of planned follow-up monitoring (52 weeks), we view our retention rates as a relative success. Among the 304 women in our outcomes sample, infant feeding data were obtained for 91% at 3 months, 83% at 6 months, 75% at 9 months, 65% at 11 months, and 56% at 12 months. Missing data implications were minimized by several factors. First, feeding patterns are most labile in the first 6 months, and feeding data were available for 83% of participants through that time. Second, given the trend toward increased formula feeding over time, our imputation of the treatment group’s median weekly value for missing weeks is statistically conservative. Third, the potential for bias was reduced by the fact that participants lost to follow-up monitoring at 2, 3, 4, 6, 8, 10, and 12 months did not differ from those retained at those months, with respect to major covariates.

This was a labor-intensive intervention. Accordingly, we sought to develop a general estimate of the average cost per woman for this level of intervention, assuming that the LC was a health center employee and not a consultant. This estimate, which was based on an intention-to-treat model and included costs for travel, supplies, and labor (wage, indirect, and fringe costs), in 2003 was $266 per woman throughout the prenatal and postnatal periods. Additional information on the calculation of this estimate was reported elsewhere.35

Potential recall bias in maternal self-reports of breastfeeding might have resulted in nondifferential misclassification or over-reporting of breastfeeding. Nondifferential misclassification would bias results toward the null hypothesis. Over-reporting of breastfeeding, particularly in the intervention group, might occur if women provided socially desirable answers, particularly if they developed a strong relationship with the LC. Interestingly, in exit interviews conducted for this study, some control group women stated that the postpartum interviews made them more conscious of how they fed their infant. One woman in the control group stated specifically that she kept breastfeeding to 3 or 4 months because she knew the interviewer would ask.25 Under-reporting of breastfeeding is unlikely, given similar feeding intentions at baseline. Mothers can reliably recall breastfeeding duration over many years,50,51 particularly for infants, with no difference in accuracy of recall according to educational level, parity, or number of children.52 No published work validates maternal self-reports of varying levels of breastfeeding intensity. Population-based studies report either duration according to limited intensity (exclusive versus nonexclusive) or duration (without any intensity) and do not validate maternal self-reports.

Related to this, some women found the Index of Breastfeeding Status, which asks for estimates of breast milk given to their infant, to be confusing. Research staff members first asked whether the in-
...fant received more breast milk than formula and then tried to quantify the amount by asking how many feedings of 10 this would correspond to for a given week. One alternative would be to ask how times per day or week, in the past 7 days, the infant was fed each item from a list (eg, breast milk, formula, 100% juice, sweet drinks, or infant cereal). This approach, used in the Food and Drug Administration 1993–1994 Infant Feeding Practices Study and its successor, which is currently underway in the field, may provide a better estimate of the proportion of all intake from breast milk. The disadvantage is that this level of detail is likely to be unreliable over longer recall periods, such as those used in our study.

A limitation of our intervention was that study LCs functioned as outside research consultants. Therefore, it was incumbent on them to schedule the prenatal intervention sessions at the clinic when women were there for prenatal visits. With this vulnerable sample, for which there is an estimated missed appointment rate of 40% for prenatal care visits, scheduling these sessions was difficult. Furthermore, the LCs did not have a routine presence or dedicated office space and were not part of the women’s health care team. This impeded our ability to make prenatal contacts and might have diminished the potency of the intervention.

Another limitation of the intervention was the low postpartum hospital contact rate (25%). Some women, when telephoned at the hospital, declined a LC visit at that time but were later seen at home (home contact rate: 49%). This is consistent with our observation that some women preferred to initiate breastfeeding in the privacy of their homes, rather than in the busy hospital setting. Other women declined a visit altogether, either because they were formula feeding exclusively or because they stated that they did not need LC assistance. Delays in timely notification of the birth and LC scheduling problems also contributed to this low hospital contact rate.

A trial similar to ours, a randomized, nonblinded, clinical, controlled trial of prenatal and postnatal LC support (including the hospital) among low-income women, found significant differences in breastfeeding duration until 2 months of age (37% for the intervention group, compared with 9% for the control group). In contrast, treatment group differences persisted up to 20 weeks in our study (53% for the intervention group, compared with 39% for the control group). Furthermore, the potential for bias was significant in that trial, because the study LC assessed breastfeeding outcomes.

Recently published findings from randomized trials of combined prenatal and postnatal interventions show differences in outcomes according to the intensity of the intervention. A randomized, controlled trial of prenatal provider counseling, combined with (primarily) phone availability of an LC postpartum, had no effect on any breastfeeding or exclusive breastfeeding (Netherlands). In a low-income US Latina population, prenatal (n = 1), daily perinatal, and postpartum home visits (n = 3) from a peer counselor resulted in lower but not statistically significant differences in duration. In a similar population, a more intensive intervention of prenatal home visits (n = 3), daily hospital visits, and postpartum home visits (n = 9) resulted in significantly higher exclusive breastfeeding at 3 months (20.6% vs 1.4% of controls). Thus considerable effort will be required to reach the proposed Healthy People 2010 goal of 60% exclusive breastfeeding at 3 months.

In the future, interventions must target exclusivity, beginning in the prenatal period. Breastfeeding intensity ratios (breast milk/all liquid nutrition) over the first 6 months are associated strongly with breastfeeding duration. In other work, prenatal intent to combine breast milk and formula resulted in shorter planned and actual duration, whereas in our study a prenatal intention other than exclusive breastfeeding was associated significantly with low breastfeeding intensity at 3 and 12 months. Furthermore, protective effects are dose-responsive. A meta-analysis of hospitalizations for treatment of lower respiratory tract disease found a summary relative risk of 0.28 (95% CI: 0.14–0.54) conferred by exclusive breastfeeding for >4 months. There may be a threshold effect for certain outcomes, because 3 vs 6 months of exclusive breastfeeding were equivalent in several measures (not hospitalization) in a large cohort. However, the most recent statements from the American Academy of Pediatrics and the World Health Organization define the optimal duration of exclusive breastfeeding as 6 months.

Goals and interventions targeted toward sustained exclusive breastfeeding are more relevant than those focused solely on any breastfeeding. The primary message of the National Breastfeeding Awareness Campaign, a multimedia effort launched in 2004, is that exclusive breastfeeding for 6 months reduces an infant’s risk of ear infections, gastrointestinal illnesses, and respiratory illnesses and may prevent obesity. Our findings support the focus of and need for such a nationwide effort. In addition, individualized continuity of care provided by interventions such as ours are indicated to achieve the pending Healthy People 2010 goals of 25% exclusive breastfeeding at 3 and 6 months, as proposed at the last interim review (Rosie Li, MD, PhD, written communication, March 4, 2005).

Our study LCs had the proper skills and professional orientation to deliver the intervention. However, they were hampered by their consultant status. A routine clinic and hospital presence (ie, “rounding”) would most likely increase prenatal and postnatal contact rates, particularly for hard-to-reach populations. The intervention’s effectiveness would likely increase with prenatal care provider encouragement; mothers receiving such encouragement are less likely to discontinue feeding. Exclusive breastfeeding at 3 months. We think that routinely offered, individualized, breastfeeding education and support, with clinician encouragement, in the prenatal period and continued support throughout the postpartum period up to 12 months will result in a higher inten-
sity of breastfeeding in the short and long term. In socioeconomically disadvantaged populations, native-born women are at particular risk for low intensity of breastfeeding.

ACKNOWLEDGMENTS

This study was supported by grants from the United States Department of Agriculture, the Maternal and Child Health Bureau, and the Agency for Healthcare Quality and Research.

REFERENCES

34. Moore E. Randomized Controlled Trial of Early Mother-Infant Skin-to-Skin Contact on Breastfeeding Success. Nashville, TN: Vanderbilt University School of Nursing; 2003. Dissertation
44. Scarlett D, Cargill M, Lyn-Sue J, Richardson S, McCaw-Binns A. Breastfeeding prevalence among six-week-old infants at University Hospital of the West Indies. West Ind Med J. 1996;45:14–17

ARTICLES 1425

Downloaded from http://pediatrics.aappublications.org/ by guest on March 12, 2018

Keeping the United States in the Race

“What if we were really having a national discussion about what is most important to the country today and on the minds of most parents? I have no doubt that it would be a loud, noisy dinner-table conversation about why so many U.S. manufacturers are moving abroad—not just to find lower wages, but to find smarter workers, better infrastructure and cheaper health care. It would be about why in Germany, 36 percent of undergrads receive degrees in science and engineering; in China, 59 percent; in Japan, 66 percent; and in America, only 32 percent. It would be about why Japanese on bullet trains can get access to the Internet with cellphones, and Americans get their cell phone service interrupted five minutes from home. It would be about why U.S. 12th graders recently performed below the international average for 21 countries in math and science, and it would be about why, in recent years, U.S. industry appears to have spent more on lawsuits than on R&D. Yes, we’d be talking about why the world is racing us to the top, not the bottom, and why we are quietly falling behind.”

Friedman TL. New York Times. October 14, 2005

Noted by JFL, MD
Randomized, Controlled Trial of a Prenatal and Postnatal Lactation Consultant Intervention on Duration and Intensity of Breastfeeding up to 12 Months
Karen A. Bonuck, Michelle Trombley, Katherine Freeman and Diane McKee
_Pediatrics_ 2005;116;1413
DOI: 10.1542/peds.2005-0435

Updated Information & Services
including high resolution figures, can be found at:
http://pediatrics.aappublications.org/content/116/6/1413

References
This article cites 42 articles, 15 of which you can access for free at:
http://pediatrics.aappublications.org/content/116/6/1413.full#ref-list-1

Subspecialty Collections
This article, along with others on similar topics, appears in the following collection(s):
Metabolic Disorders
http://classic.pediatrics.aappublications.org/cgi/collection/metabolic_disorders_sub
Nutrition
http://classic.pediatrics.aappublications.org/cgi/collection/nutrition_sub
Breastfeeding
http://classic.pediatrics.aappublications.org/cgi/collection/breastfeeding_sub

Permissions & Licensing
Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at:
https://shop.aap.org/licensing-permissions/

Reprints
Information about ordering reprints can be found online:
http://classic.pediatrics.aappublications.org/content/reprints
Randomized, Controlled Trial of a Prenatal and Postnatal Lactation Consultant Intervention on Duration and Intensity of Breastfeeding up to 12 Months
Karen A. Bonuck, Michelle Trombley, Katherine Freeman and Diane McKee
*Pediatrics* 2005;116;1413
DOI: 10.1542/peds.2005-0435

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://pediatrics.aappublications.org/content/116/6/1413