Effect of Primary Care Intervention on Breastfeeding Duration and Intensity

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Objectives. We determined the effectiveness of primary care–based, and pre- and postnatal interventions to increase breastfeeding.

Methods. We conducted 2 trials at obstetrics and gynecology practices in the Bronx, New York, from 2008 to 2011. The Provider Approaches to Improved Rates of Infant Nutrition & Growth Study (PAIRINGS) had 2 arms: usual care versus pre- and postnatal visits with a lactation consultant (LC) and electronically prompted guidance from prenatal care providers (EP). The Best Infant Nutrition for Good Outcomes (BINGO) study had 4 arms: usual care, LC alone, EP alone, or LC+EP.

Results. In BINGO at 3 months, high intensity was greater for the LC+EP (odds ratio [OR] = 2.72; 95% confidence interval [CI] = 1.08, 6.84) and LC (OR = 3.22; 95% CI = 1.14, 9.09) groups versus usual care, but not for the EP group alone. In PAIRINGS at 3 months, intervention rates exceeded usual care (OR = 2.86; 95% CI = 1.21, 6.76); the number needed to treat to prevent 1 dyad from nonexclusive breastfeeding at 3 months was 10.3 (95% CI = 5.6, 50.7).

Conclusions. LCs integrated into routine care alone and combined with EP guidance from prenatal care providers increased breastfeeding intensity at 3 months postpartum. (*Am J Public Health.* 2014;104:S119–S127. doi:10.2105/AJPH.2013.301360)

Breastfeeding is associated with improved health outcomes for both mother and child.[1,2] All major medical organizations recommend exclusive breastfeeding for the first 6 months after birth, with continued breastfeeding for at least 1 year.[3,4] Nationally, 36% of infants born in 2009 were exclusively breastfed at 3 months and 16% at 6 months,[5] falling short of Healthy People 2020 targets of 46%, and 26%, respectively.[6] A recent study found that suboptimal breastfeeding rates incur $2.2 billion in direct pediatric medical costs each year.[7] There are also substantial disparities, with the lowest breastfeeding rates seen among non-Hispanic Black, younger, and less-educated mothers.[8]

Interventions are therefore needed to increase breastfeeding exclusivity and intensity, defined as the proportion of feedings that are breast milk. The United States Preventive Services Task Force (USPSTF) conducted a meta-analysis of randomized controlled trials of primary care–based breastfeeding promotion interventions. Interventions consistently increased rates of any and exclusive breastfeeding, although most findings were not statistically significant, and many studies were of poor quality.[9] Overall, systematic reviews supported the effectiveness of combined pre- and postnatal interventions,[8] scheduled, face-to-face visits,[10] and, for low-income women, on-going personal contact with a health professional.[11] In our previous trial, a pre- and postnatal intervention delivered by lactation specialists certified by the International Board of Certified Lactation Consultants (IBCLCs) had positive effects. However, IBCLCs were not a routine presence at prenatal care, intervention contact rates were suboptimal, and there was no provider involvement.[12] IBCLCs increase breastfeeding rates when integrated in primary care[13,14] and hospitals.[15] Ensuring access to IBCLCs is an action step in the surgeon general's call to action to support breastfeeding.[16]

We conducted 2 randomized controlled trials at urban, prenatal care sites in the Bronx, New York City. The present trials improve upon our previous work by integrating lactation consultants (LCs) into routine practice,[17] in combination with electronically prompted (EP) anticipatory guidance from prenatal care providers. We hypothesized that these interventions would increase breastfeeding intensity and exclusivity at 1, 3, and 6 months postpartum, compared with usual care.

METHODS

We conducted 2 separately funded single-blind randomized controlled trials at urban, medical center–affiliated prenatal care clinics in the Bronx: the Best Infant Nutrition for Good Outcomes (BINGO) trial and the Provider Approaches to Improved Rates of Infant Nutrition and Growth Study (PAIRINGS). At the BINGO site, resident and attending obstetrician or gynecologists and certified nurse-midwives cared for primarily low-income women. At the PAIRINGS site, obstetrician or gynecologist faculty served an economically diverse population. Research assistants recruited women during routine prenatal care from February 2008 to June 2010, with follow-up through September 2011. Enrollment was limited to English- or Spanish-speaking women aged 18 years or older, in the first or second trimester of a singleton pregnancy, without risk factors for premature birth, or maternal or infant conditions that would preclude or complicate breastfeeding (e.g., maternal HIV positive, infant congenital anomaly). The trials were described to prospective participants as studies to test the effect of patient education programs on infant feeding and health.

Eligible patients who signed informed consents were randomized using sequentially numbered opaque sealed envelopes, generated by the study's biostatistician. Randomization incorporated an undisclosed blocking factor and nativity status (US-born vs foreign-born). In PAIRINGS, 275 women were randomized in a 1:1 ratio to usual care or to both EP counseling from the prenatal care provider and LC support. In BINGO, 666 women were

randomized in a 1:3:3:1 ratio to usual care, EP alone, LC+EP, or LC alone. Both trials employed identical eligibility criteria and EP and LC protocols despite different practice settings and designs (4 arms vs 2 arms).

Following consent, participants completed a baseline interview that assessed demographic characteristics information, infant feeding plans, as well as breastfeeding knowledge and previous experience. Research assistants conducted follow-up telephone interviews in English or Spanish at 1, 3, and 6 months postpartum. All study materials were printed in both languages. Details of participant recruitment, study protocols, and follow-up are available elsewhere.[17]

Study Interventions

Electronic prompt. For women randomized to an EP group, study staff programmed prompts to appear in the electronic medical record during 5 prenatal visits. Each included 2 to 3 brief open-ended questions for providers to ask that portrayed breastfeeding as the norm ("What are your plans for breastfeeding?"), sought to clarify knowledge about how long or how much to breastfeed, and elicited information on social network support (data for EP items are available as a supplement to the online version of this article at http://www.ajph.org).

Lactation consultant. Three study-supported LCs were a routine presence at the prenatal sites and hospitals; 2 were primarily designated for BINGO and 1 for PAIRINGS. The LC protocol included 2 prenatal sessions, a hospital visit, and regular phone calls postpartum through 3 months or until breastfeeding ceased. The prenatal sessions occurred in the examination room, during the 30-plus minutes of "downtime" while waiting for the prenatal care provider. Attempts were made to complete interrupted sessions after the examination. The first session focused on rapport building and education, and the second was on the practical aspects of breastfeeding. The study provided nursing bras and breast pumps to LC group participants as needed. Because the BINGO study was co-located with a pediatric practice, LCs met mothers and their infants at the 1-week routine pediatric visit, modeling practice on a recent review.[18] Postpartum home visits were optional, based upon participant and LC preference and comfort (data for the LC protocol are available as a supplement to the online version of this article at http://www.ajph.org).

Usual care. Neither prenatal care site had explicit breastfeeding promotion or support. Both study hospitals had 1 IBCLC, available weekdays, whose primary focus was women intending to exclusively breastfeeding or at risk for breastfeeding difficulties. Midway through our study, hospital postpartum and labor and delivery nursing staff began attending a 20-hour Certified Lactation Consultant training course (S. Hartman, personal communication, 2013).

Outcome Assessment

Study staff assessed infant feeding at 1, 3, and 6 months postpartum during phone interviews using items adapted from the Infant Feeding Practices Survey II.[19] Exclusive breastfeeding was defined as feeding only breast milk or vitamin supplements, with no water, juice, formula, or solid foods[20] during the past week. Breastfeeding intensity was defined as the percentage of all feedings in the past 7 days that were breast milk. Breastfeeding initiation was defined as ever having been breastfed or fed breast milk. Total duration was defined as the time in days until the mother stopped breastfeeding or feeding breast milk altogether.

It was infeasible to blind participants and clinical staff to treatment group. However, we sought to minimize bias by restricting access to allocation assignment, stripping group assignment from study databases to which research staff had access, and omitting group identifiers from participant interview forms. We monitored implementation of the EP intervention by asking all participants at the 1-month postpartum interview about their recall of the first 5 of 10 total EP items being discussed during prenatal care. We monitored implementation of the LC intervention by (1) documenting all prenatal, hospital, home, and postpartum contacts, and (2) conducting exit interviews, which included queries about experience with study LCs, with a random subsample.

Sample Size

The prespecified primary outcomes for the 2 studies differed. For BINGO, the prespecified primary outcome measure was 3-month breastfeeding intensity. Sample size estimates assumed intervention group increases in median breastfeeding intensities of 25% (LC+EP), 20% (LC), and 12% (EP) compared with the intervention group in our previous trial, and 12% greater median breastfeeding intensity in the BINGO control group compared with the previous trial's control group. These calculations indicated adequately powered analyses (80%) would require samples sizes of EP = 192, LC = 63, LC+EP = 192, and control = 63, assuming a normal distribution of breastfeeding intensity for all 6 possible pairwise comparisons, employing a Bonferroni correction to control a family wise error rate ($\alpha = 0.05$). However, we found that breastfeeding intensity was not normally distributed, and most women stopped breastfeeding altogether during follow-up. The resulting zero-inflated distribution was not amenable to transformation. We therefore categorized breastfeeding intensity as less than 20% (low), 20% to 80% (medium), and greater than 80% (high) of all feeds from breast milk consistent with previous studies[21] and Infant Feeding Practices Survey II analyses. For PAIRINGS, the prespecified primary outcome was exclusive breastfeeding at 3 months. Based on assumed 3-month exclusive breastfeeding rates of 20% in the intervention group and 6% in the control group, we required 104 women per group to detect such a difference with an α of 0.05 and 80% power. Assuming a 20% loss to follow-up in both trials, we enrolled 666 women in BINGO and 275 in PAIRINGS. The prespecified primary outcomes for sample size estimates (intensity in BINGO, exclusivity in PAIRINGS) assumed relatively lower rates of exclusive breastfeeding in BINGO, based on our previous work.

Statistical Analysis

All randomized participants completing 1 or more follow-up interview constituted the analytic sample. Data for the 2 trials were analyzed separately, using the same procedures, described in the following. All statistical tests were 2-tailed, using an α of 0.05. Interview questionnaires were scanned into a digitized database and prepared for analysis using SPSS (PASW Statistics Version 20.0.0 2011; IBM Corporation, Latham, NY) and SAS version 9.2 (SAS Institute, Cary, NC) software. All outliers and missing data were verified to reflect hard copy responses.

We measured baseline associations between treatment group and breastfeeding outcomes using either the χ^2 or Fisher exact test for categorical variables and analysis of variance for continuous variables. We reported the prevalence of initiating, any, and exclusive breastfeeding, and of breastfeeding intensity levels at 1, 3, and 6 months across treatment groups. We used binary logistic regression to calculate the unadjusted odds of ever initiating breastfeeding and of any (vs none) and exclusive (vs nonexclusive) breastfeeding for intervention groups compared with usual care. We used multinomial logistic regression to calculate the unadjusted odds and 95% confidence intervals (CIs) of medium (20%–80%) or high (>80%) versus low (<20%) breastfeeding intensity at 1, 3, and 6 months. Our primary model was an unadjusted intent-to-treat analysis. Separate models were constructed for BINGO and PAIRINGS. Exact logistic regression was used for analyses with predicted cell sizes less than 5.

In secondary analyses, we measured the adjusted odds of high or medium versus low breastfeeding intensity in multivariate-adjusted multinomial models. Following our prespecified analysis plan, model 1 adjusted for baseline characteristics that differed ($P<.2$) among treatment groups. Model 2 further adjusted for baseline covariates associated ($P<.2$) with high intensity breastfeeding at 3 months. The latter model was constructed by sequentially entering covariates by P value ranking into the multinomial model, retaining those with a partial F P value of <.1. This approach produced a parsimonious model that incorporated baseline factors independently associated with each study's primary outcome.

Based on the intent-to-treat analysis, for BINGO's primary outcome of breastfeeding intensity, we calculated the number needed to treat (NNT) to prevent 1 dyad from 80% or less breastfeeding intensity, using the Wilson score method to calculate CIs.[22] For the PAIRINGS primary outcome of exclusive breastfeeding at 3 months, we calculated the NNT to prevent 1 dyad from not exclusively breastfeeding.

In our previous trial, the IBCLC intervention had a greater effect among US-born versus foreign-born mothers.[12] We therefore performed a planned test for an interaction between US- versus foreign-born nativity and treatment group using a cross-product term. In a secondary analysis, we used Cox proportional hazards models to measure the effect of receipt of "any" LC and of "any" EP intervention on time to stopping breastfeeding altogether.

RESULTS

The BINGO analytic sample included 94% of those randomized (628 of 666 participants) and the PAIRINGS analytic sample included 95% of those randomized (262 of 275 participants; Figure A, available as a supplement to the online article at http://www.ajph.org). In both trials, 89% of the analytic sample completed all follow-up interviews. Compared with participants who were randomized, but not analyzed, BINGO's analytic sample was less likely to participate in Special Supplemental Nutrition Program for Women, Infants, and Children (WIC; 43% vs 60%; $P=.04$), whereas the PAIRINGS analytic sample was more likely to plan to return to work in the first 3 months (39% vs 8%; $P=.04$). Qualitative analyses were based on exit interviews with 67 participants.

Description of Samples and Outcome Rates

There were no significant treatment group differences ($P<.05$) in baseline characteristics in either trial (Table 1). Body mass index was high, with 67% and 60% of BINGO and PAIRINGS participants, respectively, reporting overweight or obese prenatal weights. Both samples were largely Hispanic or non-Hispanic Black (approximately 85%). Compared with PAIRINGS, fewer BINGO participants were high school graduates (77% vs 88%) or married (26% vs 41%), and far fewer planned to exclusively breastfeed (37% vs 62%). More BINGO participants received WIC (60% vs 39%) and were born in the United States (70% vs 60%) compared with PAIRINGS participants.

Rates of breastfeeding outcomes (initiating, any, exclusive, and by intensity) are shown in Table 2. Breastfeeding initiation rates (94% in BINGO and 96% in PAIRINGS) exceeded the Healthy People 2020 goal of 82%. In BINGO, any and exclusive breastfeeding rates differed by treatment group at 3 months, and were highest for the LC+EP and LC groups. Breastfeeding intensity (low, medium, or high) did not differ significantly among the 4 groups in BINGO at 1, 3, or 6 months. In PAIRINGS, the intervention group had significantly higher rates of any breastfeeding at 1, 3, and 6 months, and of exclusive breastfeeding at 1 and 3 months. Furthermore, in the PAIRINGS trial, breastfeeding intensity rates differed by treatment group at 1 and 3 months. At 6 months, just 16 of 850 (1.9%) participants in both trials combined were exclusively breastfeeding.

Unadjusted Odds of Breastfeeding Outcomes

The unadjusted odds of initiating (vs not), any (vs none), exclusive (vs nonexclusive), and medium and high (vs low) intensity breastfeeding, compared with usual care, are shown in Table 3. For BINGO's primary outcome, 3-month intensity, both the LC (odds ratio [OR] = 3.22; 95% CI = 1.14, 9.09) and LC +EP (OR = 2.72; 95% CI = 1.08. 6.84) groups were more likely to report high- versus low-intensity breastfeeding compared with usual care. Medium (vs low) breastfeeding intensity at 3 months did not differ from usual care for any treatment group. There were no significant effects on breastfeeding intensity at 1 or 6 months. In related secondary outcomes, BINGO's LC+EP group had greater odds of initiating (OR = 3.29; 95% CI = 1.03, 10.48), 1 month any (OR = 2.10; 95% CI = 1.20, 3.67), 3 months any (OR = 2.10; 95% CI = 1.23, 3.61), and 3 months exclusive (OR = 4.24; 95% CI = 1.01, 37.94) breastfeeding. The EP group did not differ from usual care on any outcome.

For PAIRINGS primary outcome, the odds of exclusive breastfeeding (vs not) at 3 months, compared with usual care, were nearly 3-fold higher in the intervention group (OR = 2.86; 95% CI = 1.21, 6.76). The intervention group also had greater odds of exclusive breastfeeding at 1 month (OR = 4.29; 95% CI = 1.94, 9.47) and at 3 months (OR = 2.86; 95% CI = 1.21, 6.76). The PAIRINGS intervention group was also more likely to report high (vs low) breastfeeding intensity at 1 month (OR = 3.65; 95% CI = 1.90, 7.00) and at 3 months (OR = 2.79; 95% CI = 1.42, 5.48) and to report medium (vs low) breastfeeding intensity at 6 months (OR = 2.21; 95% CI = 1.13, 4.32). Effect sizes for both BINGO and PAIRINGS

TABLE 1—Baseline Participant Characteristics: BINGO Study and PAIRINGS; Bronx, NY; 2008–2011

Characteristics	BINGO No. (%) or Mean ±SD					PAIRINGS No. (%) or Mean ±SD		
	Usual Care (n = 77)	LC (n = 77)	EP (n = 236)	LC+EP (n = 238)	*P*	Usual Care (n = 133)	LC+EP (n = 129)	*P*
Maternal age, y	28.1 ±6.5	26.8 ±5.5	28.1 ±5.8	27.6 ±6.0	.38	28.1 ±5.6	28.2 ±5.9	.94
Gestation, wks	38.8 ±2.1	38.7 ±2.1	38.9 ±2.1	38.8 ±2.4	.97	39.3 ±1.7	39.1 ±1.6	.29
Delivery mode								
Vaginal	45 (58.4)	57 (74.0)	148 (62.7)	137 (57.6)	.07	75 (56.4)	99 (76.7)	< .001
Cesarean	32 (41.6)	20 (26.0)	88 (37.3)	101 (42.4)		58 (43.6)	30 (23.3)	
BMI,[a] kg/m^2								
Normal/low (< 25)	28 (37.3)	24 (32.0)	75 (33.8)	72 (31.0)		59 (44.4)	45 (34.9)	
Overweight (25-29.9)	16 (21.3)	23 (30.7)	59 (26.6)	66 (28.4)	.88	36 (27.1)	41 (31.8)	.29
Obese (≥ 30)	31 (41.3)	28 (37.3)	88 (39.6)	94 (40.5)		38 (28.6)	43 (33.3)	
Race/ethnicity								
Non-Hispanic White	7 (9.1)	2 (2.6)	7 (3.0)	12 (5.0)		7 (5.3)	6 (4.7)	
Hispanic	43 (55.8)	47 (61.0)	133 (56.4)	134 (56.3)		77 (57.9)	69 (53.5)	
Non-Hispanic Black	19 (24.7)	23 (29.9)	74 (31.4)	63 (26.5)	.46[b]	33 (24.8)	42 (32.6)	.59[c]
Non-Hispanic Asian	1 (1.3)	1 (1.3)	2 (0.8)	8 (3.4)		5 (3.8)	2 (1.6)	
Biracial/multiracial/other	7 (9.1)	4 (5.2)	20 (8.5)	21 (8.8)		11 (8.3)	10 (7.8)	
US-born[d]	55 (71.4)	55 (71.4)	162 (68.6)	168 (70.6)	.94	77 (57.9)	79 (61.2)	.58
Enrolled in WIC[a]	43 (56.6)	47 (61.0)	141 (60.0)	145 (60.9)	.92	59 (44.4)	44 (34.1)	.09
High school graduate[a]	56 (72.7)	54 (70.1)	189 (80.1)	184 (77.3)	.25	115 (87.1)	115 (89.1)	.61
Return to work/school < 3 mo	19 (24.7)	32 (41.6)	69 (29.2)	74 (31.1)	.12	49 (36.8)	52 (40.3)	.56
Nulliparous	31 (40.3)	31 (40.3)	85 (36.0)	99 (41.6)	.64	64 (48.1)	50 (38.8)	.13
Never breastfed,[e]	17 (37.0)	10 (21.7)	37 (24.8)	34 (24.5)	.31	7 (10.1)	12 (15.2)	.36
Feeding intention[a]								
Exclusive breastfeeding	29 (37.7)	25 (32.5)	89 (37.7)	92 (38.7)		79 (59.4)	83 (64.3)	
Exclusive formula feeding	11 (14.3)	6 (7.8)	16 (6.8)	21 (8.8)	.44	12 (9.0)	3 (2.3)	.07
Both breast and formula	33 (42.9)	41 (53.2)	125 (53.0)	116 (48.7)		42 (31.6)	43 (33.3)	
Knowledge of breastfeeding[f]	3.5 ±0.99	3.6 ±0.78	3.6 ±0.90	3.5 ±0.91	.78	3.6 ±0.86	3.6 ±0.91	.46
Comfort with breastfeeding[g]	2.3 ±1.6	2.4 ±1.6	2.6 ±1.5	2.6 ±1.5	.46	2.7 ±1.5	3.0 ±1.4	.06

Note. BINGO = Best Infant Nutrition for Good Outcomes; BMI = body mass index; EP = electronically prompted; LC = lactation consultant; PAIRINGS = Provider Approaches to Improved Rates of Infant Nutrition & Growth Study; WIC = Special Supplemental Nutrition Program for Women, Infants, and Children. *P* values are based on the Pearson χ^2 test (2-tailed) for categorical variables; analysis of variance was used for continuous variables.

[a]Columns may not add to 100% because of missing or "don't know" responses.

[b]Monte Carlo estimation of the Fisher test (2-tailed).

[c]Fisher exact test (2-tailed).

[d]In one of the 50 states.

[e]Among parous.

[f]Ranges from 1 to 5; higher numbers indicate increased knowledge about breastfeeding benefit.

[g]Reflects comfort responses of those who reported intent to feed any breast milk in the first few weeks. Ranges from 1 to 5; higher numbers indicate increased comfort with breastfeeding.

were modestly strengthened in adjusted models (Table 4).

The 2 × 2 factorial design of BINGO allowed us to test the independent and synergistic effects of the LC and EP intervention using a cross-product term. We found no evidence of an interaction between the EP and LC interventions for the primary outcome of breastfeeding intensity at 3 months (*P* for interaction = .56). Randomization to any LC intervention was associated with a 2-fold odds of high- versus low-intensity breastfeeding (OR = 2.02; 95% CI = 1.25, 3.27) compared with no LC intervention. Randomization to any EP intervention was not associated with breastfeeding intensity (OR high vs low intensity = 1.06; 95% CI = 0.61, 1.84). We similarly found no interaction between the LC and EP interventions for breastfeeding intensity or any breastfeeding at 1, 3, or 6 months, suggesting that the EP intervention had no independent effect on breastfeeding outcomes in the BINGO population.

Ancillary Outcomes

Number needed to treat. To prevent 1 BINGO dyad from the primary outcome of 80% or less breastfeeding intensity at 3 months, we estimated the NNT to be 8.0 (95% CI = 4.2, 99.7) for the LC intervention and 10.9 (95% CI = 6.2, ∞; NNT 259.7) for the LC+EP intervention.

TABLE 2—Prevalence of Any, Exclusive, and Intensity Levels of Breastfeeding at 1-, 3-, and 6-Months Postpartum: BINGO Study and PAIRINGS; Bronx, NY; 2008–2011

	BINGO, No. (%)					PARINGS, No. (%)		
Breastfeeding	Usual Care	LC	EP	LC+EP	*P*	Usual Care	LC+EP	*P*
Initiation	65 (89.0)	70 (95.9)	207 (92.8)	218 (96.5)	.09[a]	123 (94.6)	122 (98.4)	.17[a]
Any								
1 mo	44 (60.3)	54 (74.0)	158 (70.9)	172 (76.1)	.07	92 (70.8)	108 (87.1)	.001
3 mo	28 (37.8)	37 (50.7)	102 (44.5)	127 (56.2)	.02	57 (44.5)	76 (60.8)	.01
6 mo	20 (27.0)	30 (40.5)	75 (33.0)	80 (34.6)	.37	31 (25.4)	46 (37.7)	.04
Exclusive								
1 mo	7 (9.6)	10 (13.7)	17 (7.6)	31 (13.7)	.17	9 (6.9)	30 (24.2)	< .001
3 mo	2 (2.7)	8 (11.0)	10 (4.4)	24 (10.6)	.02	8 (6.2)	20 (16.0)	.01
6 mo	1 (1.4)	1 (1.4)	4 (1.8)	6 (2.6)	.97[a]	2 (1.6)	2 (1.6)	> .999[a]
			Intensity[b]					
1 mo								
Low	33 (45.2)	28 (38.4)	83 (37.2)	72 (31.9)		51 (39.2)	34 (27.4)	
Medium	23 (31.5)	28 (38.4)	98 (43.9)	87 (38.5)	.09	56 (43.1)	34 (27.4)	< .001
High	17 (23.3)	17 (23.3)	42 (18.8)	67 (29.6)		23 (17.7)	56 (45.2)	
3 mo								
Low	49 (66.2)	38 (52.1)	142 (62.0)	117 (51.8)		78 (60.9)	63 (50.4)	
Medium	19 (25.7)	20 (27.4)	60 (26.2)	70 (31.0)	.09	34 (26.6)	26 (20.8)	.006
High	6 (8.1)	15 (20.5)	27 (11.8)	39 (17.3)		16 (12.5)	36 (28.8)	
6 mo								
Low	59 (79.7)	49 (66.2)	170 (74.9)	162 (70.1)		100 (82.0)	85 (69.7)	
Medium	12 (16.2)	19 (25.7)	47 (20.7)	52 (22.5)	.45[c]	16 (13.1)	30 (24.6)	.06
High	3 (4.1)	6 (8.1)	10 (4.4)	17 (7.4)		6 (4.9)	7 (5.7)	

Note. BINGO = Best Infant Nutrition for Good Outcomes; EP = electronically prompted; LC = lactation consultant; PAIRINGS = Provider Approaches to Improved Rates of Infant Nutrition & Growth Study. Percentages are based on total number of participants for each treatment group. For example, 65 of 73 (89%) participants in usual care reported initiated breastfeeding. *P* values are based on the Pearson χ^2 test (2-tailed), unless otherwise specified.

[a]Fisher exact test (2-tailed).

[b]Intensity is defined as percentage of breast milk feedings over all feedings. Low is < 20%, medium 20%–80%, and high > 80%.

[c]Monte Carlo estimation of the Fisher test (2-tailed).

The analogous NNT for PAIRINGS was 6.1 (95% = CI 3.9, 15.7). For the PAIRINGS primary outcome, we estimated the NNT to prevent 1 dyad from not exclusively breastfeeding to be 10.3 (95% CI = 5.6, 50.7).

Breastfeeding cessation. In a secondary Cox proportional hazards analysis, we measured the effect of our interventions on time to stopping breastfeeding altogether. We found no evidence of an interaction between the LC and EP interventions in BINGO (*P* for interaction = .82). Women randomized to the LC intervention were less likely to wean in the first 6 months than women randomized to no LC intervention (hazard ratio [HR] = 0.80; 95% CI = 0.65, 0.97). Randomization to the EP intervention was not associated with breastfeeding duration (HR = 0.92; 95% CI = 0.73, 1.15). In PAIRINGS, the LC+EP intervention reduced risk of weaning in the first 6 months (HR = 0.71; 95% CI = 0.53, 0.96; *P* = .03).

Lactation consultant contact time. The mean ±SD total time spent by study LCs with participants randomized to an LC group was 174 ±104 minutes in BINGO and 178 ±88.4 minutes in PAIRINGS. Prenatal contacts averaged about 1 hour, hospital visits 40 to 50 minutes, and postpartum contacts more than 1 hour. Among BINGO participants in the LC or LC+EP groups, 8% received a postpartum home visit compared with 30% in the PAIRINGS intervention group (*P* < .001). In our qualitative analysis, we found that PAIRINGS participants were more comfortable and desirous of home visits than BINGO participants.

Intervention fidelity. Among BINGO participants in the LC or LC+EP group, most had 1 or more prenatal (93%), 1 or more hospital (84%), or 1 or more postpartum (85%) LC contact. Similarly, the PAIRINGS LC+EP group had 1 or more prenatal (98%), 1 or more hospital (70%), or 1 or more postpartum (91%) LC contact. Recall of prenatal care providers discussing 5 of 5 EP items was greater in BINGO's intervention groups (EP = 38%, LC = 33%, LC+EP = 50%, control = 22%; *P* < .001) and in the PAIRINGS LC+EP group versus the control group (40% vs 12%; *P* < .001). These data suggested that prenatal care providers might have incorporated counseling about breastfeeding into routine practice. Alternatively, data from the qualitative exit interviews suggested that participants might not have distinguished study LCs from site-based prenatal care providers. In qualitative exit interviews, participants in the EP and LC+EP groups recalled more details about the prenatal care provider's discussions about breastfeeding compared with the control group.[23]

DISCUSSION

We tested the effectiveness of routine, primary care–based, pre- and postnatal breastfeeding promotion interventions in a diverse population of low- and moderate-income women in 2 randomized controlled trials. A professional LC intervention alone and combined with EPs increased exclusive and high intensity (> 80%) breastfeeding at 3 months. For BINGO's primary outcome, both the LC and LC+EP groups had approximately 3-fold higher odds of high (vs low) breastfeeding intensity at 3 months compared with usual care. For the PAIRINGS primary outcome, the LC+EP intervention was associated with approximately 3-fold higher odds of exclusive breastfeeding. These effect sizes exceeded those identified in the USPSTF 2008 meta-synthesis,[9] and a 2012 Cochrane review.[10] We noted that two thirds of participants were overweight or obese, which were risk factors for not breastfeeding or reduced breastfeeding.[24] A previous intervention in overweight or obese women did not improve breastfeeding exclusivity or duration.[25] Interventions were more effective in PAIRINGS, affirming other data that showed

TABLE 3—Unadjusted Odds of Breastfeeding Outcomes, Treatment Groups vs Usual Care: BINGO Study and PAIRINGS; Bronx, NY; 2008–2011

	BINGO LC		BINGO EP		BINGO LC+EP		PAIRINGS LC+EP	
Breastfeeding	OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*	OR (95% CI)	*P*
Initiation, ever vs never[a]	2.8 (0.64, 17.4)[b]	.22	1.57 (0.55, 4.09)[b]	.44	3.29 (1.03, 10.48)[b]	.04	3.46 (0.64, 34.75)[b]	.2
Any (vs none)[a]								
1 mo	1.87 (0.93, 3.78)	.08	1.60 (0.92, 2.78)	.09	2.10 (1.20, 3.67)	.009	2.79 (1.46, 5.32)	.002
3 mo	1.69 (0.88, 3.26)	.19	1.31 (0.77, 2.26)	.31	2.10 (1.23, 3.61)	.007	1.93 (1.17, 3.19)	.01
6 mo	1.84 (0.92, 3.68)	.08	1.33 (0.74, 2.39)	.33	1.43 (0.80, 2.55)	.28	1.77 (1.03, 3.07)	.04
Exclusive (vs not exclusive)[a]								
1 mo	1.50 (0.54, 4.14)	.44	0.78 (0.31, 1.96)	.59	1.50 (0.63, 3.56)	.36	4.29 (1.94, 9.47)	< .001
3 mo	4.40 (0.83, 43.92)[b]	.09	1.64 (0.34, 15.75)[b]	.81	4.24 (1.01, 37.94)[b]	.05	2.86 (1.21, 6.76)	.02
6 mo	1.00 (0.01, 49.56)[b]	> .999	1.31 (0.13, 65.36)[b]	> .999	1.94 (0.23, 90.75)[b]	.92	1.00 (0.07, 14.00)[b]	> .999
			Intensity[c,d]					
1 mo								
Low (Ref)	1.00		1.00		1.00		1.00	
Medium	1.43 (0.68, 3.03)	.34	1.69 (0.92, 3.11)	.09	1.73 (0.94, 3.21)	.08	0.91 (0.50, 1.67)	.76
High	1.18 (0.51, 2.73)	.7	0.98 (0.49, 1.96)	.96	1.81 (0.92, 3.54)	.09	3.65 (1.90, 7.00)	< .001
3 mo								
Low (Ref)	1.00		1.00		1.00		1.00	
Medium	1.36 (0.64, 2.90)	.43	1.09 (0.59, 2.00)	.78	1.54 (0.84, 2.83)	.16	0.95 (0.51, 1.74)	.86
High	3.22 (1.14, 9.09)	.03	1.55 (0.61, 3.98)	.36	2.72 (1.08, 6.84)	.03	2.79 (1.42, 5.48)	.003
6 mo								
Low (Ref)	1.00		1.00		1.00		1.00	
Medium	1.91 (0.84, 4.31)	.12	1.36 (0.68, 2.74)	.39	1.58 (0.79, 3.16)	.2	2.21 (1.13, 4.32)	.02
High	2.41 (0.57, 10.13)	.23	1.16 (0.31, 4.35)	.83	2.06 (0.58, 7.30)	.26	1.37 (0.44, 4.24)	.58

Note. BINGO = Best Infant Nutrition for Good Outcomes; CI = confidence interval; EP = electronically prompted; LC = lactation consultant; OR = odds ratio; PAIRINGS = Provider Approaches to Improved Rates of Infant Nutrition & Growth Study. Usual care was used as the comparison group.

[a]Unadjusted binary logistic regression.

[b]Exact logistic regression.

[c]Unadjusted multinomial logistic regression, odds of medium or high breastfeeding intensity vs low breastfeeding intensity.

[d]Intensity is defined as percentage of breast milk feedings over all feedings. Low intensity is < 20%, medium 20%–80%, and high > 80%.

stronger effects among women with higher background rates of breastfeeding.[10] More PAIRINGS participants had breastfed before and intended to exclusively breastfeed compared with BINGO participants.

The strengths of our trials included random assignment, allocation concealment, blinding of outcomes assessors, prespecification of primary outcomes, high retention rates, and monitoring of implementation. Notably, our approximately 95% retention rates exceeded those from comparable US trials of 71% to 88% at 3 months[26-28] and 71% to 75% at 6 months.[26,27] Moreover, our primary outcome was based on 7-day recall versus recall of 1 to 2 years in national data.[29] In addition, BINGO's factorial design allowed analysis of the separate and combined effects of interventions. Furthermore, testing the LC+EP intervention in 2 study populations enabled us to compare effects between settings with different background rates of breastfeeding. Finally, we collected qualitative data about women's views of the interventions, reported elsewhere,[23] addressing a gap identified in the latest Cochrane review.

Nevertheless, our findings must be interpreted in the context of the study design. We measured our primary outcome via maternal self-report, and social desirability bias might have affected our results. However, in the absence of a biomarker to validate breastfeeding intensity, all breastfeeding interventions relied on maternal self-report. In addition, fidelity to the EP intervention could not be verified with the electronic medical record database.[17,30] Also, low rates of exclusive and high-intensity breastfeeding yielded relatively large CIs, as seen in other trials.[10] Finally, the study samples were not necessarily representative of the US population of childbearing age women, thus potentially limiting generalizability.

Our findings confirmed and extended earlier studies of pre- and postnatal interventions to increase breastfeeding duration and intensity. Consistent with concluding recommendations in a recent Cochrane review, our intervention offered scheduled, ongoing visits integrated into routine care, rather than providing support only when women actively sought help.[10] Our findings also affirmed those of both the USPSTF and Cochrane reviews regarding the need for interventions that span the pre- and postnatal periods.[9,10]

Compared with the USPSTF meta-analysis,[9] our intervention led to higher rates of any, exclusive, and high-intensity breastfeeding

TABLE 4—Adjusted Odds of Breastfeeding Intensity at 1, 3, and 6 Months, Treatment Groups vs Usual Care: BINGO Study and PAIRINGS; Bronx, NY; 2008–2011

	BINGO				PAIRINGS			
Breastfeeding Intensity[a]	Model 1,[b] OR (95% CI)	*P*	Model 2,[c] OR (95% CI)	*P*	Model 1,[b] OR (95% CI)	*P*	Model 2,[c] OR (95% CI)	*P*
1 Month								
LC								
Low	1.00		1.00					
Medium	1.39 (0.65, 2.95)	.39	1.39 (0.62, 3.12)	.43				
High	1.19 (0.51, 2.80)	.68	1.07 (0.41, 2.76)	.89				
EP								
Low	1.00		1.00					
Medium	1.64 (0.89, 3.03)	.11	1.45 (0.75, 2.82)	.27				
High	0.95 (0.47, 1.91)	.88	0.79 (0.36, 1.74)	.56				
LC+EP								
Low	1.00		1.00		1.00		1.00	
Medium	1.70 (0.92, 3.17)	.09	1.73 (0.89, 3.37)	.11	0.86 (0.46, 1.64)	.66	0.83 (0.43, 1.62)	.58
High	1.83 (0.93, 3.62)	.08	1.68 (0.79, 3.61)	.18	3.38 (1.68, 6.79)	< .001	4.61 (2.15, 9.88)	< .001
3 Months								
LC								
Low	1.00		1.00					
Medium	1.37 (0.64, 2.94)	.42	1.44 (0.63, 3.30)	.39				
High	3.66 (1.29, 10.43)	.02	4.53 (1.41, 14.58)	.01				
EP								
Low	1.00		1.00					
Medium	1.10 (0.60, 2.02)	.77	0.93 (0.47, 1.83)	.84				
High	1.63 (0.63, 4.20)	.31	1.54 (0.55, 4.35)	.41				
LC+EP								
Low	1.00		1.00		1.00		1.00	
Medium	1.56 (0.85, 2.86)	.15	1.52 (0.78, 2.96)	.22	0.80 (0.42, 1.52)	.49	0.73 (0.37, 1.44)	.36
High	2.90 (1.15, 7.32)	.02	3.07 (1.11, 8.53)	.03	2.42 (1.16, 5.07)	.02	3.32 (1.45, 7.58)	.005
6 Months								
LC								
Low	1.00		1.00					
Medium	2.10 (0.92, 4.80)	.08	2.31 (0.93, 5.74)	.07				
High	2.82 (0.66, 12.06)	.16	3.25 (0.70, 15.23)	.13				
EP								
Low	1.00		1.00					
Medium	1.41 (0.70, 2.84)	.34	1.25 (0.57, 2.74)	.57				
High	1.24 (0.33, 4.69)	.75	1.16 (0.28, 4.74)	.84				
LC+EP								
Low	1.00		1.00		1.00		1.00	
Medium	1.65 (0.82, 3.33)	.16	1.60 (0.74, 3.46)	.23	2.37 (1.20, 4.70)	.01	2.80 (1.27, 6.17)	.01
High	2.23 (0.63, 7.93)	.21	2.36 (0.62, 9.00)	.21	1.62 (0.50, 5.18)	.43	2.92 (0.70, 12.15)	.14

Note. BINGO = Best Infant Nutrition for Good Outcomes; CI = confidence interval; EP = electronically prompted; LC = lactation consultant; OR = odds ratio; PAIRINGS = Provider Approaches to Improved Rates of Infant Nutrition & Growth Study. Adjusted multinomial logistic regression, odds of medium (20%–80%) or high (> 80%) breast milk feedings over all feedings, treatment groups vs usual care.

[a]Defined as percentage of breast milk feedings over all feedings. Low intensity is < 20%, medium 20%–80%, and high > 80%.

[b]Model 1 adjusted for treatment group variables that differ at baseline (BINGO: planned return to work; PAIRINGS: Special Supplemental Nutrition Program for Women, Infants, and Children recipient, maternal body mass index, parity or past breastfeeding experience, and infant age at interview in both trials).

[c]Model 2 further adjusted for baseline covariates significantly associated with breastfeeding intensity at 3 months (BINGO: nativity status, feeding intention, parity or past breastfeeding experience, high school graduate, maternal body mass index; PAIRINGS: race/ethnicity, nativity status, breastfeeding knowledge and attitudes, feeding intent).

during the first 6 months of life. Regarding any breastfeeding, in the USPSTF meta-analysis, combined pre- and postnatal interventions led to increased breastfeeding rates at 4 to 5 months (risk ratio [RR] = 1.15) and 6 to 8 months (RR = 1.38), but not at 1 to 3 months. We similarly found larger differences at 3 months than 1 month, suggesting that integrated interventions affected sustained breastfeeding more than they affected initiation. Comparatively, the LC+EP intervention in both trials led to approximately 2-fold increased rates of any breastfeeding at 3 months; effects were sustained to 6 months in PAIRINGS. Regarding exclusive breastfeeding, our trials' 3- to 4-fold increased rates at 3 months far exceeded those found in the USPSTF at 1 to 3 months (RR = 1.21).[9] Regarding weaning, the LC+EP intervention was associated with approximately 30% reduced risk through 6 months in both trials, compared with an approximately 10% reduced risk in a 2012 Cochrane review.[10] Among primary care-based randomized controlled trials in low-income women (9 of 10 US-based), there were only modest gains in any breastfeeding at 3 to 6 months (RR = 1.15; 95% CI = 1.01, 1.30).[11] Among US-based randomized controlled trials that targeted minority women, no professional interventions, apart from our previous trial, affected intensity. Anderson et al.[31] reported improved exclusivity with a peer-counseling intervention, but the intervention's 12 home visits might be challenging to translate into clinical practice. Our intervention increased intensity at 3 months with a total of 3 hours of LC contact.

Our findings affirmed the benefit of professional lactation support to increase breastfeeding intensity and duration. Although peer-counseling interventions are often effective,[9,10] we selected IBCLCs as interventionists because their training and certification enable them to practice autonomously within primary care settings.[32] Under the Affordable Care Act,[33] private insurers must cover professional breastfeeding support without cost-sharing. Our results suggested that extending this coverage to Medicaid could reduce disparities in breastfeeding intensity and duration.[34] We found more robust results in PAIRINGS than in BINGO, in part perhaps because of the higher rate of home visits by the PAIRINGS LCs. The PAIRINGS sample was more inclined to breastfeed, and thus, perhaps more likely to request or accept a home visit as well. This suggests that incorporating a routine home visit might increase intervention effectiveness. Further studies are needed to test whether peer counselors could achieve similar results using our LC protocol.

Recent legislation encouraged the use of health information technology to support primary care–based interventions.[34] In the BINGO study, we found that EPs alone did not increase breastfeeding compared with usual care, and we found no additional benefit from the LC+EP intervention versus LC alone. Several factors might have contributed to these results. Exposure to electronic reminders might have led providers to counsel all of their patients on breastfeeding, or with repeated exposure, they might have ignored the prompts altogether. Furthermore, obstetric providers with limited breastfeeding expertise might have been unwilling or unable to engage patients on this topic. Qualitative feedback from providers suggested that they might have lacked the knowledge and counseling skills to respond to participants' questions.[17] Structural interventions, such as resident education, were shown to increase exclusive breastfeeding rates,[35] and thus, would likely boost effects of electronic medical record–based interventions. However, our findings suggested that using electronic reminders alone to prompt busy prenatal care providers to promote breastfeeding was unlikely to have a meaningful effect on breastfeeding rates.

Healthy People 2020 goals for exclusive breastfeeding are a continuing challenge. Although our intervention improved exclusive breastfeeding rates at 3 months compared with usual care, rates in the intervention groups were 20% to 25% below the nationally reported average, and far from the goal of 46%.[5] However, the LC, and LC+EP interventions significantly increased rates of 80% or greater breast milk feeding at 3 months, suggesting the utility of setting goals for what has previously been characterized as "predominant"[21] breastfeeding. Low rates of exclusive breastfeeding at 6 months, even among women randomized to our intervention, underscored the need to address systems issues, including child care, maternity leave,[36] return-to-work requirements, and worksite lactation sites,[37,38] to enable mothers to achieve recommended durations of exclusive breastfeeding.

We found that a combined pre- and postnatal breastfeeding support intervention integrated into routine primary care increased breastfeeding intensity and duration in a diverse, low-income population. These differences were achieved with an average of 3 hours of LC time per participant, suggesting that a full-time LC could deliver our protocol to more than 600 mother–infant dyads per year. Furthermore, successful implementation in both a community health clinic with co-located obstetric and pediatric care and in a prenatal clinic with dispersed pediatric follow-up suggested that our intervention was effective in a variety of settings. Given the substantial maternal and infant morbidity associated with low breastfeeding rates, dissemination of this intervention has the potential to improve health outcomes across 2 generations. ■

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Contributors

K. Bonuck and A. Stuebe had full access to all of the data in the study and both take responsibility for the integrity of the data and the accuracy of the data analysis. K. Bonuck, A. Stuebe, and P. S. Bernstein developed the study concept and design. J. Barnett and J. Fletcher acquired the data. M. H. Labbok was involved in the initial design and revised design for this study, provided part of the training, and helped conceptualize aspects of the analysis. All authors analyzed and interpreted the data. K. Bonuck and A. Stuebe drafted the article. All authors participated in the critical revision of the article for important intellectual content. A. Stuebe, J. Barnett, and J. Fletcher performed the statistical analysis.

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Human Participant Protection

Both trials were approved by the institutional review board of Montefiore Medical Center. A data and safety monitoring board convened yearly during data collection to ensure data integrity and participant safety.

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