Randomized Controlled Trial of a Prenatal and Postnatal Lactation Consultant Intervention on Infant Health Care Use

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Objective: To determine whether infants of women randomized to a prenatal and postpartum lactation support intervention incur fewer otitis media-, respiratory tract-, or gastrointestinal-related visits than controls.

Design: Randomized, unmasked controlled trial recruiting women from prenatal care settings. Breastfeeding sensitive (BFS) illness visits for otitis media or respiratory tract or gastrointestinal complaints were obtained up to 12 months.

Setting: Two urban community health centers.

Participants: Analytic sample of 338 low-income, primarily Hispanic and/or black mother-infant dyads (n=163 for the intervention group and n=175 for the control group).

Intervention: Study lactation consultants attempted 2 prenatal meetings, 1 postpartum hospital and/or home visit, and telephone calls as needed. Controls received the standard of care.

Main Outcome Measures: Combined outpatient and emergency department visits with illness and BFS illness diagnoses.

Results: There was a significant interaction between treatment and Medicaid; among those not receiving Medicaid, the number of otitis media visits was higher among controls (P=.03). Visits for any illness and BFS, gastrointestinal, or respiratory tract illnesses did not differ by treatment group. Intervention group infants received more breast milk than controls, but exclusive breastfeeding rates remained low and did not differ between groups at any point.

Conclusions: Only the number of otitis media visits was reduced, in a subset of the intervention group. The intervention did not reduce visits for respiratory tract or gastrointestinal illness. Limited intervention contact and low exclusive breastfeeding rates may have attenuated intervention effects. Future interventions designed to yield markedly increased breastfeeding rates may show greater effects in low-income multiethnic samples. Health coverage for visits may moderate intervention effects.


VERWHELMING EPIDEMIOLOGICAL evidence exists that "even in developed countries, breastfeeding protects against gastrointestinal and (to a lesser extent) respiratory tract infection, and that the protective effect is enhanced with greater duration and exclusivity of breastfeeding." In the first year of life, protective effects are reported for otitis media, respiratory tract infections, and gastrointestinal illnesses. Still, US breastfeeding rates at 6 months (35%) and 12 months (16%) do not meet the Healthy People 2010 goals of 50% and 29%, respectively. Exclusive breastfeeding rates remain low and stagnant.

It is infeasible and unethical to perform random assignment of breastfeeding. There are only 4 randomized controlled trials (RCTs) of breastfeeding intervention effects on child morbidity. In a multisite RCT in Belarus, the intervention group had less gastrointestinal infection and atopic eczema but no differences in respiratory tract infection up to 12 months. An intensive peer counselor intervention (up to 13 contacts) yielded a reduced incidence of diarrhea, 38% vs 12% in controls. A small US-based RCT reported that the $301 cost of a postpartum community nurse or peer counselor intervention was partially offset by formula and health care cost savings. In Mexico, infants of mothers who received home peer support for breastfeeding had a lower incidence of diarrhea than controls, 26% vs 12%.

We conducted an unmasked RCT of a best-practices prenatal and postnatal lac-
tation consultant (LC) intervention on infant emergency department (ED) and outpatient site care for up to 12 months. Maternal self-report of health care use for symptoms of otitis media, respiratory tract illness, and gastrointestinal illness and computerized medical center (MC) data for these breastfeeding sensitive (BFS) illnesses were obtained. Weekly breastfeeding outcomes up to 12 months were assessed via a standardized tool that measured 7 levels of breastfeeding.

**METHODS**

**RECRUITMENT**

The Moms into Learning About Kids (MILK) study assessed breastfeeding and infant health care use outcomes up to 12 months. This article reports on infant health care use outcomes. Breastfeeding outcomes and detailed methods are reported elsewhere.25 Briefly, prenatal care patients at 2 Bronx, NY, sites were recruited from August 1, 2000, through November 30, 2002. Eligibility criteria included English or Spanish speaking, twin or singleton pregnancy, and gestation before 24 weeks. Exclusion criteria included medical or obstetric complications for which breastfeeding is contraindicated and long-term use of medications incompatible with breastfeeding.

Eligible, consenting women were randomized by a research assistant. Randomization used an undisclosed blocking factor, stratified by center, with sealed, coded envelopes. All study materials were professionally translated into Spanish. The MC’s institutional review board approved the study.

**TRIAL ENROLLMENT**

As shown in the Figure, 382 women were randomized into the study (188 into the intervention group and 194 into the control group). Of these, 21 were excluded at postnatal follow-up (15 in the intervention group and 6 in the control group). Of the remaining 364 mother-infant dyads, 26 were lost to all follow-up (both self-reported and computerized MC infant health visit data) and are excluded from analysis. Of the remaining 338 infants who comprise the analytic sample, 304 mothers had 1 or more follow-up interviews (145 in the intervention group and 159 in the control group) at which time they reported infant ED or outpatient visits to sites outside the MC (OMC) for up to 12 months. We obtained computerized data of ED and outpatient visits to MC-affiliated sites for 289 of the 338 infants (142 in the intervention group and 147 in the control group). Well-child visits for MC and OMC visits were excluded. Thus, outcome data are available for 93% of eligible mother-infant dyads ([364−26]/364=93%). Data were not collected for women who were approached but did not enroll.

**DATA COLLECTION**

A prenatal baseline interview obtained data on demographics and breastfeeding experience and intentions. Postpartum telephone interviews at 1, 2, 3, 4, 6, 8, 10, and 12 months assessed infant feeding and health care use. The 1-month interview collected details about the immediate postpartum experience, whereas subsequent interviews focused on weekly feeding and infant health care use. Participants were compensated.

**MASKING**

The research assistants were not masked to treatment group. To minimize bias, research assistants were trained in standard procedures for classifying outcomes and completed follow-up with women in both groups. The MC data were extracted from the MC database by an analyst masked to treatment group. The LCs who provided the intervention were not masked to treatment group.

**POWER ANALYSIS**

The power analysis assumed that infants who are primarily breastfed up to 6 months would incur $901 in health care costs in the first year of life vs $1105 for exclusively bottle-fed children. These data come from 2 samples in which 34% and 14% of infants were primarily breastfed at 3 months. Under these
assumptions, 138 women per group are needed to detect a difference (α = .05; β = .20; 2-tailed test).

ASSESSMENT OF INFANT HEALTH CARE OUTCOMES

OMC Data

Postnatal follow-up interviews asked women to recall any OMC ED or outpatient visits for symptoms of illness in general and for symptoms of gastrointestinal, respiratory tract, or otitis media conditions in particular. Maternal report of gastrointestinal, respiratory tract, and otitis media symptoms (classified separately from respiratory tract illness by design) was based on definitions used by others. The recall period was the time since the last interview or postdischarge from birth if at the first follow-up interview.

MC Data

The MC computerized data identified the date, site, and diagnoses (International Classification of Diseases, Ninth Revision [ICD-9]) of all infant visits to the 2 EDs or 21 health clinics affiliated with the MC, including the 2 recruitment sites.

DESCRIPTION OF THE INTERVENTION

After the baseline interview, the MILK research assistant referred intervention participants to a study LC, who arranged to meet at an upcoming clinic visit or the participant’s home. Per protocol, the LC was to meet individually with each intervention participant twice prenatally and attempt 1 postpartum hospital and/or 1 home visit. Prenatal and home visits averaged 60 minutes; hospital visits averaged 90 minutes. The LCs also provided postpartum telephone support as needed for up to 12 months.

One LC, of Dominican descent, was en route to obtaining International Board of Certified Lactation Consultants certification. The other LC, born in Trinidad, was certified at the study’s inception. Those LCs who are certified by the International Board of Certified Lactation Consultants28 are trained in lactation physiology and support and management of breastfeeding. Neither LC had other allied health training.

The initial prenatal meeting provided basic breastfeeding education. The second meeting addressed what to expect in the postpartum period and specifics about initiating breastfeeding. Neither LC had other allied health training.

控治 (ie, outcomes) sample and the randomized sample. Differences between women randomized into the intervention and control groups, as well as within-treatment group differences between those excluded and the analytic sample, were tested for statistical significance. Descriptive statistics are shown as mean (SD) or number (percentage). Only foreign birth differed between the sites (K. A. B., unpublished data, November 2004) and was thus controlled for in multivariate analyses, which pooled data for the 2 sites. No significant differences were found between the analytic (ie, outcomes) sample and the randomized sample.

Treatment group differences in the proportion of women reporting any breastfeeding (combined levels 1-6), 50% or more breastfeeding (combined levels 1-4), and exclusive breastfeeding (level 1) for postpartum weeks 1 to 52 were tested by the Mantel-Haenszel \( \chi^2 \) test.

We computed the rate of all sick care visits and those with BFS illness diagnoses for 52 person-weeks of observation. For the MC data, we assumed a 52-week observation period (ie, no participant missing any computerized MC data). For OMC data, the date of the last interview denoted the end of each infant’s observation period. For women missing all OMC data, we imputed OMC data by treatment group. The MC and OMC

artificial milk, and vitamin drops was not assessed. Thus, our definition of exclusive breastfeeding does not conform to the stricter World Health Organization definition. The 7 levels in the schema are as follows:

1. 100% Breast milk
2. More than 80% breast milk combined with less than 20% artificial milk or solids
3. More than 50% to 80% breast milk and the rest artificial milk or solids
4. 50% Breast milk and 50% artificial milk or solids
5. More than 20% to 50% breast milk and the rest artificial milk or solids
6. Less than 20% breast milk combined with more than 80% artificial milk or solids
7. 100% Artificial milk or solids (includes weaned).

SELECTION OF BFS DIAGNOSES

A physician panel reviewed the list of ICD-9 codes found in the MC data (masked to treatment group) and classified those for which breastfeeding might reduce the incidence or severity as otitis media (all BFS illnesses), respiratory tract and BFS illnesses, and gastrointestinal and BFS illnesses. Respiratory BFS diagnoses included viral enteritis not otherwise specified (008.80), unspecified viral infection (079.99), acute pharyngitis (462.00), group (464.40), acute upper respiratory infections (465.90), acute bronchitis (466.00), nasal and sinus disease not elsewhere classified (478.10), pneumonia organism, unspecified (486.00), bronchitis (490.00), asthma (493.90), cough (786.20), and respiratory syncytial virus (466.11).30 Gastrointestinal BFS diagnoses included esophageal reflux (530.81), gastritis/gastrroduodenitis (535.50), noninfectious gastroenteritis not elsewhere classified (538.90), unspecified constipation (564.00), vomiting alone (787.03.91), and reflux esophagitis (303.10).6 Otitis media BFS diagnoses included suppurative otitis media not otherwise specified (382.40) and unspecified otitis media (382.90).32

We did not assess breastfeeding-associated hypernatremia of the infant because proper diagnosis and treatment require hospitalization, which was not an outcome measure.35 Although jaundice rates are higher in breastfed children,34 there was no jaundice reported in the OMC data and just 2 cases (ICD-9 code 774.60), 1 per group, in the MC data.

STATISTICAL ANALYSES

Differences between women randomized into the intervention and control groups, as well as within-treatment group differences between those excluded and the analytic sample, were tested for statistical significance. Descriptive statistics are shown as mean (SD) or number (percentage). Only foreign birth differed between the sites (K. A. B., unpublished data, November 2004) and was thus controlled for in multivariate analyses, which pooled data for the 2 sites. No significant differences were found between the analytic (ie, outcomes) sample and the randomized sample.

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Variables with bivariate associations yielding \( P \leq .20 \) were used in initial multiple linear regression models, which also tested for interactions with treatment group. Given the nonnormal distributions of the health care outcomes data, each variable was transformed logarithmically (\( \log(\text{total number of visits} + 1) \)). Independent variables were assessed for significance using a monitored backward stepwise procedure. Using data from all participants regardless of treatment group, covariates and treatment group interactions with associations of \( P < .05 \) were retained in the final multivariate models to assess the significance of the intervention. All tests of significance were 2-tailed, with \( \alpha = .05 \). Analyses were based on an intent-to-treat model.

### Baseline Characteristics

Baseline characteristics for the analytic sample of 338 women are given in Table 1. No significant treatment group differences were found. The sample was primarily Hispanic (56%) and African American (36%) according to participant-reported, investigator-defined options, and 40% were foreign born. Nearly two thirds were multiparous (62%). Combined breast milk and formula was the most common prenatal breastfeeding intention (48%). Detailed data about the birth and immediate postpartum experience, reported elsewhere, did not differ by treatment group, including low birth weight (<2500 g, 8% for sample) and neonatal intensive care unit admissions (13% for sample).

### Retention in and Use of Infant Health Care by Data Source

Table 2 indicates the retention in and use of OMC and MC data by treatment group. The OMC data in Table 2 were based on an intent-to-treat model.

#### Table 1. Demographics of Sample*

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Control (n = 163)</th>
<th>Outcome (n = 157)</th>
<th>Total (n = 320)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>25.1 (6.4)</td>
<td>25.0 (5.9)</td>
<td>25.0 (6.0)</td>
</tr>
<tr>
<td>High school graduate</td>
<td>110 (55.8)</td>
<td>110 (55.7)</td>
<td>110 (55.7)</td>
</tr>
<tr>
<td>Married or has partner</td>
<td>67 (40.3)</td>
<td>67 (40.2)</td>
<td>67 (40.2)</td>
</tr>
<tr>
<td>Foreign born</td>
<td>57 (35.1)</td>
<td>57 (35.6)</td>
<td>57 (35.6)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>101 (61.7)</td>
<td>101 (61.2)</td>
<td>101 (61.2)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>67 (40.9)</td>
<td>66 (40.5)</td>
<td>66 (40.5)</td>
</tr>
<tr>
<td>Other</td>
<td>18 (10.9)</td>
<td>18 (11.0)</td>
<td>18 (11.0)</td>
</tr>
<tr>
<td>Medicaid recipient</td>
<td>89 (54.4)</td>
<td>89 (54.4)</td>
<td>89 (54.4)</td>
</tr>
<tr>
<td>Other children</td>
<td>114 (69.4)</td>
<td>114 (69.3)</td>
<td>114 (69.3)</td>
</tr>
<tr>
<td>Previously breastfed</td>
<td>60 (36.2)</td>
<td>60 (36.2)</td>
<td>60 (36.2)</td>
</tr>
<tr>
<td>Intentions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only breast milk</td>
<td>62 (37.8)</td>
<td>62 (37.8)</td>
<td>62 (37.8)</td>
</tr>
<tr>
<td>Both</td>
<td>87 (53.4)</td>
<td>87 (53.4)</td>
<td>87 (53.4)</td>
</tr>
<tr>
<td>Only formula</td>
<td>110 (65.7)</td>
<td>110 (65.7)</td>
<td>110 (65.7)</td>
</tr>
<tr>
<td>Do not know</td>
<td>21 (12.6)</td>
<td>21 (12.6)</td>
<td>21 (12.6)</td>
</tr>
</tbody>
</table>

*Data are presented as number (percentage) unless otherwise indicated. Outcomes include mother-infant dyads with medical center and/or outside medical center self-reported data. Outcome samples exclude the 21 mother-infant dyads who were ineligible for follow-up and the 26 infants for whom neither any medical center nor outside medical center infant health care use data were obtained.

#### Table 2. Retention and Use of Infant Health Care by Data Source and Treatment Group*

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Intervention</th>
<th>Control</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>OMC data at follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤3 mo</td>
<td>131 (80.4)</td>
<td>147 (84.0)</td>
<td>278 (82.2)</td>
</tr>
<tr>
<td>≤6 mo</td>
<td>114 (69.5)</td>
<td>138 (78.9)</td>
<td>252 (74.6)</td>
</tr>
<tr>
<td>≤9 mo</td>
<td>102 (62.6)</td>
<td>125 (71.4)</td>
<td>227 (67.2)</td>
</tr>
<tr>
<td>≤12 mo</td>
<td>92 (56.4)</td>
<td>107 (61.1)</td>
<td>199 (58.9)</td>
</tr>
<tr>
<td>MC data with any visits</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–3 mo</td>
<td>139 (85.3)</td>
<td>144 (82.3)</td>
<td>283 (83.7)</td>
</tr>
<tr>
<td>3–6 mo</td>
<td>120 (73.6)</td>
<td>117 (66.9)</td>
<td>237 (70.1)</td>
</tr>
<tr>
<td>6–9 mo</td>
<td>106 (65.0)</td>
<td>108 (61.7)</td>
<td>214 (63.3)</td>
</tr>
<tr>
<td>9–12 mo</td>
<td>100 (61.3)</td>
<td>98 (56.0)</td>
<td>198 (56.6)</td>
</tr>
</tbody>
</table>

Abbreviations: MC, medical care; OMC, outside medical care.

*Data are presented as number (percentage) in initial multiple linear regression models, which also tested for interactions with treatment group. Given the nonnormal distributions of the health care outcomes data, each variable was transformed logarithmically (\( \log(\text{total number of visits} + 1) \)). Independent variables were assessed for significance using a monitored backward stepwise procedure. Using data from all participants regardless of treatment group, covariates and treatment group interactions with associations of \( P < .05 \) were retained in the final multivariate models to assess the significance of the intervention. All tests of significance were 2-tailed, with \( \alpha = .05 \). Analyses were based on an intent-to-treat model.
data appear roughly comparable through the 12 months. Regarding treatment group, rates for both OMC and MC declined to just more than 70% at 6 months, approximately 65% at 9 months, and 59% by 12 months. With computerized MC data results in 100% retention for the study period for the outcomes sample. Both OMC (retention) and MC (use) data were available for more than 80% of the sample through 3 months, declining to just more than 70% at 6 months, approximately 65% at 9 months, and 59% by 12 months. With regard to treatment group, rates for both OMC and MC data appear roughly comparable through the 12 months.

**DETECTION OF BIAS IN INFANT HEALTH OUTCOMES DATA**

To detect potential surveillance and/or selection biases in the MC and OMC data, we performed a series of treatment group comparisons (data not shown).

### Follow-up for OMC Data

We compared baseline characteristics of participants with OMC data at 13, 26, 39, 48, and 52 weeks (ie, retained in follow-up interview) with those without OMC data (ie, lost to follow-up interview) at those weeks, both within and across treatment groups. These baseline characteristics included age, educational level, foreign birth, race/ethnicity, marriage or partner status, Medicaid use, parity, prior breastfeeding experience, and infant feeding intention at baseline. Both attrition rates and characteristics of those retained at quarterly periods were similar for the 2 groups.

### Any OMC Data vs Any MC Data

We compared baseline characteristics of participants with any OMC data (n = 304) with those with any MC data (n = 289) by treatment group. No significant differences were detected.

### Use of MC as Primary Source of Care

To examine treatment group differences in reliance on the MC as a routine source of infant care, we examined rates of well-child visits (ICD-9 code V-20) up to 12 months. Similar proportions had any MC well-child visits (81% in the intervention group vs 76% of controls), 1 to 2 visits (7% in the intervention group vs 6% of controls), and 3 or more visits (67% in the intervention group vs 70% of controls).

### WEEKLY BREASTFEEDING OUTCOMES

Table 3 presents data for any breastfeeding, breastfeeding 50% or more of the time, and exclusive breastfeeding by treatment group for selected weeks for the 304 women with self-reported data (MC data). At 2 weeks, significantly more intervention group women were breastfeeding (87% in the intervention group vs 65% of controls; P ≤ .001) and giving their infants 50% or more breast milk (66% in the intervention group vs 46% of controls; P ≤ .001). The intervention group was significantly more likely to breastfeed at each week, up to and including week 20 (53.0% vs 39.3% for controls; P ≤ .03), except for week 18 (data not shown). Group differences for 50% or more breast milk remained statistically significant for each week, up to and including week 9 (45.8% vs 33.1% for controls; P ≤ .03; data not shown). There were no differences in exclusive breastfeeding rates at any time, which peaked for both groups at 2 weeks.

### INTERVENTION COMPONENT RECEIVED BY SOURCE OF INFANT HEALTH OUTCOMES DATA

We compared intervention participants with MC data, OMC data, or either data with regard to their receipt of the intervention’s various prenatal and postnatal components. As indicated in Table 4, 124 (76%) of the intervention group outcomes sample received any intervention. Ninety-nine (61%) had prenatal intervention, 97 (60%) had postnatal intervention, and 72 (44%) had both prenatal and postnatal intervention. Participants with MC and those with OMC data had similar patterns of receiving the prenatal and postnatal interventions.

### VISITS WITH BFS ILLNESS DIAGNOSES BY DATA SOURCE: DESCRIPTIVE DATA

Table 5 presents descriptive data by treatment site (ED or outpatient), data source (OMC vs MC), and type of

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**Table 3. Any, 50%, and Exclusive Breastfeeding by Selected Weekly Intervals up to 52 Weeks by Treatment Group**

<table>
<thead>
<tr>
<th>Interval</th>
<th>Any</th>
<th>50% or More</th>
<th>Exclusive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>P Value</td>
</tr>
<tr>
<td>2 wk (n = 300)</td>
<td>124 (86.7)</td>
<td>102 (65.0)</td>
<td>.001</td>
</tr>
<tr>
<td>6 wk (n = 292)</td>
<td>99 (72.3)</td>
<td>85 (54.8)</td>
<td>.002</td>
</tr>
<tr>
<td>13 wk (n = 273)</td>
<td>79 (60.8)</td>
<td>66 (46.2)</td>
<td>.02</td>
</tr>
<tr>
<td>20 wk (n = 257)</td>
<td>62 (53.0)</td>
<td>55 (39.3)</td>
<td>.03</td>
</tr>
<tr>
<td>26 wk (n = 251)</td>
<td>51 (44.3)</td>
<td>45 (33.1)</td>
<td>.07</td>
</tr>
<tr>
<td>52 wk (n = 181)</td>
<td>15 (18.3)</td>
<td>15 (15.2)</td>
<td>.57</td>
</tr>
</tbody>
</table>

*Data are presented as number (percentage).
BFS illness (gastrointestinal [>1], respiratory tract including asthma [>2], respiratory tract excluding asthma [>2], and otitis media [>1]). Both treatment groups had similar patterns of OMC and MC visits, suggesting limited surveillance bias.

VISITS WITH ILLNESS AND BFS ILLNESS DIAGNOSES: MULTIVARIATE LINEAR REGRESSION

Table 4 presents the multivariate linear regression analysis of factors associated with any illness and BFS illness diagnosis–related visits. Results are shown for analyses after adjustment for any covariates that were associated with the outcomes at P<=.20 in bivariate analysis. Apart from treatment group, adjusted and unadjusted β coefficients and 95% confidence intervals are given only for variables with adjusted β coefficients (P<.05).

Only otitis media visits were reduced, in a subset of the intervention group. Infants of controls without Medicaid had significantly more (P=.03) otitis media–related visits (mean [SD]=0.88 [1.73]; data not shown) than infants of intervention group participants without Medicaid (mean [SD]=0.36 [0.98]; data not shown) (ie, a Medicaid-by–treatment group interaction). Treatment group was not associated with reduced visits for respiratory tract or gastrointestinal illness. Gastrointestinal illness visits were reduced in infants of multiparous women (multiparous mean [SD]=0.85 [1.57]; primiparous mean [SD]=0.71 [3.06]; data not shown). The number of respiratory tract illness visits was greater for boys.

Boys had more visits with illness diagnoses (boys: mean [SD]=7.77 [8.84]; girls: mean [SD]=5.27 [3.93]; data not shown) and more visits with any BFS illness diagnoses (boys: mean [SD]=6.14 [9.68]; girls: mean [SD]=3.77 [4.83]; data not shown). Medicaid was associated with more BFS illness diagnosis–related visits in the intervention group (mean [SD]=5.56 [9.13] vs mean [SD]=3.91 [6.91] for those without Medicaid; data not shown), but there was no such difference among controls (ie, a Medicaid-by–treatment group interaction).

This RCT assessed the effect of a prenatal and postnatal LC intervention on infant respiratory tract–, gastrointestinal–, and otitis media–related outpatient and ED visits up to 12 months. In multivariate analysis, treatment effects for respiratory tract, gastrointestinal, any BFS, and any illness visits were not statistically significant. For otitis media, there was a significant treatment group–by–Medicaid interaction, with reduced visits for the intervention group’s non-Medicaid participants relative to its Medicaid participants. Possibly, lack of coverage for health visits in this low-income sample combined with the intervention to reduce the number of otitis media–related visits. Infant visits for otitis media (39% in the intervention group vs 47% of controls) are comparable to national data; 44% of infants 12 months or younger have an episode of otitis media.33 As reported elsewhere, the intervention group had significantly greater breastfeeding intensity in multivariate analysis.23

Boys, who have greater susceptibility to infections,36 had more sick care, combined BFS illness, and respiratory tract illness visits than the sample’s girls. Infants of multiparous vs primiparous mothers in our sample had more gastrointestinal illness visits, consistent with other data.12,17 The BFS illness visits were reduced in the intervention group’s non-Medicaid participants relative to its Medicaid participants. It is not clear why no such difference was found among controls.

Our finding of only modest effects is undoubtedly related to relatively low LC contact in the intervention group. Analyses were based on intent to treat. The MILK LCs were part-time consultants. Just 44% of the intervention group had both prenatal and postnatal LC contact; 24% had no LC contact at all. Some declined LC assistance when contacted; others were difficult to locate in a timely manner. Immediate postpartum assistance is critical for establishing breastfeeding. This lack of a routine physical presence, and integration with clinic staff in particular, impeded the LCs’ ability to contact women. Greater intervention contact would likely have led to greater breastfeeding intensity and reduced infant illness.

In addition, the low rate and lack of group difference in exclusive breastfeeding rates may have blunted the intervention’s effect. Power analyses were based on data comparing infants exclusively breastfed for 3 months (34% and 14% in 2 middle-class, primarily non-Hispanic white samples) to never-breastfed infants.27 In sharp contrast, exclusive breastfeeding in the MILK study declined from a high at 2 weeks (20% in the intervention group and 19% in the control group; P=.80) to half that at 3 months (9% in the intervention group and 11% in the control group; P=.43).

Findings from our sample (low-income, multiethnic women; 60% multiparous) may have limited generaliz-
ability to other groups. Certainly, Medicaid’s interaction with treatment group suggests that findings might differ in samples with equal coverage for health visits. Our intervention had a stronger effect on breastfeeding among multiparous women.25 Simultaneously, infants of multiparous women had more gastrointestinal illness visits. Thus, there are likely to be differences by parity in terms of both infant illness and patterns of health care use.

A study strength is the combination of both MC computerized data and self-reported OMC visits. Nationally, the average number of office visits for children at less than 200% of the federal poverty level is 5.08 for children younger than 1 year. Rates for children above the federal poverty level are similar (Suk-fong Tang, PhD, American Academy of Pediatrics, written communication, December 19, 2003). Our sample’s mean (SD) number of sick care visits alone (MC and OMC) was 7.04 (7.38), suggesting relatively high ascertainment of infant health outcomes.

In comparison with previous data on breastfeeding interventions and child health, our findings differ with regard to exclusive breastfeeding and health care outcomes. In the large Belarus trial of a hospital-based intervention, intervention site infants vs controls were more likely to be exclusively breastfed at 3 months (43.3% vs 6.4%; \( P < 0.001 \)) and 6 months (7.9% vs 0.6%; \( P < 0.001 \)). The incidence of gastrointestinal illness was reduced, but that of respiratory tract infections and otitis media were not.21 In a Mexican home-based peer counselor trial, rates of exclusive breastfeeding were increased and diarrhea incidence decreased by more than half.14

### Table 5. Visits for Breastfeeding Sensitive Diagnoses by Data Source: Descriptive Data*

<table>
<thead>
<tr>
<th>Visit</th>
<th>Intervention (n = 163)</th>
<th>Control (n = 175)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OMC</td>
<td>MC</td>
</tr>
<tr>
<td>ED visits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1 GI illness</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>&gt;2 Respiratory tract illnesses</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>&gt;1 Case of otitis media</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Outpatient visits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1 GI illness</td>
<td>0</td>
<td>33</td>
</tr>
<tr>
<td>&gt;2 Respiratory tract illnesses</td>
<td>38</td>
<td>77</td>
</tr>
<tr>
<td>&gt;1 Case of otitis media</td>
<td>32</td>
<td>37</td>
</tr>
</tbody>
</table>

### Table 6. Visits With Illness and BFS Illness Diagnoses: Multiple Linear Regression Analysis*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Illness</th>
<th>BFS Illness</th>
<th>GI Illness</th>
<th>Respiratory Tract Illness</th>
<th>Otitis Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjusted</td>
<td>−0.06 (-0.29 to 0.17)</td>
<td>0.25 (-0.10 to 0.59)</td>
<td>0.03 (-0.09 to 0.16)</td>
<td>0.22 (-0.09 to 0.53)</td>
<td>0.20 (0.00 to 0.39)†‡</td>
</tr>
<tr>
<td>Unadjusted</td>
<td>−0.07 (-0.28 to 0.14)</td>
<td>0.01 (-0.20 to 0.23)</td>
<td>0.03 (-0.10 to 0.16)</td>
<td>−0.02 (-0.21 to 0.18)</td>
<td>0.02 (-0.11 to 0.15)</td>
</tr>
<tr>
<td>Maternal Medicaid use by treatment group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjusted</td>
<td>−0.49 (-0.95 to 0.03)†</td>
<td>−0.48 (-0.89 to -0.06)†</td>
<td>−0.32 (-0.58 to -0.05)†</td>
<td>−0.32 (-0.58 to -0.05)†</td>
<td>−0.32 (-0.58 to -0.05)†</td>
</tr>
<tr>
<td>Unadjusted</td>
<td>−0.41 (-0.84 to 0.03)</td>
<td>−0.39 (-0.78 to 0.00)</td>
<td>−0.32 (-0.58 to 0.05)</td>
<td>−0.32 (-0.58 to 0.05)</td>
<td>−0.32 (-0.58 to 0.05)</td>
</tr>
<tr>
<td>Maternal parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjusted</td>
<td>−0.13 (-0.26 to 0.00)†</td>
<td>0.24 (0.02 to 0.47)†</td>
<td>0.22 (0.01 to 0.43)†</td>
<td>0.23 (0.00 to 0.44)</td>
<td>0.23 (0.00 to 0.44)</td>
</tr>
<tr>
<td>Unadjusted</td>
<td>−0.13 (-0.26 to 0.00)</td>
<td>0.26 (0.03 to 0.49)</td>
<td>0.22 (0.01 to 0.43)</td>
<td>0.23 (0.00 to 0.44)</td>
<td>0.23 (0.00 to 0.44)</td>
</tr>
</tbody>
</table>

Abbreviations: BFS, breastfeeding sensitive; CI, confidence interval; GI, gastrointestinal.

The \( \beta \) coefficients refer to regression models for which the outcome is the log of the number of visits + 1. None of the following were associated with the outcomes and are therefore excluded from the Table: maternal variables: age, educational level, marital status, US born, race/ethnicity, previously breastfed, and baseline breastfeeding intention; infant variables: low birth weight, neonatal intensive care unit admission, maternal perception of newborn health problem, day care use, and age at last interview.

† \( P < 0.05 \).
‡ There was a significant interaction between treatment and Medicaid. In this model, treatment group was significant for non-Medicaid participants (\( P < 0.03 \)) but not for Medicaid participants (\( P = 0.20 \)).
ences in exclusive breastfeeding, which remained low throughout the study. On the basis of these trials, we posit that had there been differences in exclusive breastfeeding rates, gastrointestinal illness–related visits might also have been reduced.

In conclusion, future interventions with low-income, multiethnic women must increase breastfeeding intensity significantly if they are to demonstrably affect infant health. At the same time, intervention levels need to be feasible in practice. Clearly, achieving the proposed Healthy People 2010 goal of 60% of women exclusively breastfeeding at 3 months will be challenging.

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