

# Efficacy of Breastfeeding Support Provided by Trained Clinicians During an Early, Routine, Preventive Visit: A Prospective, Randomized, Open Trial of 226 Mother-Infant Pairs

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**ABSTRACT.** *Background.* Despite growing evidence of the benefits of prolonged breastfeeding for mother and infant health, the rate of breastfeeding at infant age of 6 months remains below the Healthy People 2010 goal. The greatest decrease in the breastfeeding rate occurs during the first 4 postpartum weeks. Mothers who discontinue breastfeeding early are more likely to report lack of confidence in their ability to breastfeed, problems with the infant latching or suckling, and lack of individualized encouragement from their clinicians in the early postdischarge period. Observational studies suggest that primary care physicians can increase breastfeeding rates through specific advice and practices during routine preventive visits. However, robust scientific evidence based on randomized, controlled trials is currently lacking.

*Objective.* The purpose of this study was to determine whether attending an early, routine, preventive, outpatient visit delivered in a primary care physician's office would improve breastfeeding outcomes.

*Design.* The study was a prospective, randomized, parallel-group, open trial.

*Setting.* Participants were recruited at a level 3 maternity facility, with an average of 2000 births per year, in France.

*Participants.* A total of 231 mothers who had delivered a healthy singleton infant (gestational age:  $\geq 37$  completed weeks) and were breastfeeding on the day of discharge were recruited and randomized (116 were assigned to the intervention group and 115 to the control group) between October 1, 2001, and May 31, 2002; 226 mother-infant pairs (112 in the intervention group and 114 in the control group) contributed data on outcomes.

*Intervention.* Support for breastfeeding in the control group included the usual verbal encouragement provided by the maternity ward staff members, a general health assessment and an evaluation for evidence of successful breastfeeding behavior by the pediatrician working in the obstetrics department on the day of discharge,

provision of the telephone number of a peer support group, mandatory routine, preventive, outpatient visits at 1, 2, 3, 4, 5, and 6 months of infant age, and 10 weeks of paid maternity leave (extended to 18 weeks after the birth of the third child). In addition to the usual pre-discharge and postdischarge support, the mothers in the intervention group were invited to attend an individual, routine, preventive, outpatient visit in the office of 1 of the 17 participating primary care physicians (pediatricians or family physicians) within 2 weeks after the birth. The participating physicians received a 5-hour training program on breastfeeding, delivered in 2 parts in 1 month, before the beginning of the study.

*Outcome Measures.* The primary outcome was the prevalence of exclusive breastfeeding reported at 4 weeks (defined as giving maternal milk as the only food source, with no other foods or liquids, other than vitamins or medications, being given). The secondary outcomes included any breastfeeding reported at 4 weeks, breastfeeding duration, breastfeeding difficulties, and satisfaction with breastfeeding experiences. Classification into breastfeeding categories reported at 4 weeks was based on 24-hour dietary recall.

*Results.* Ninety-two mothers (79.3%) assigned to the intervention group and 8 mothers (7.0%) assigned to the control group reported that they had attended the routine, preventive, outpatient visit in the office of 1 of the 17 primary care physicians participating in the study. Mothers in the intervention group were more likely to report exclusive breastfeeding at 4 weeks (83.9% vs 71.9%; hazard ratio: 1.17; 95% confidence interval [CI]: 1.01–1.34) and longer breastfeeding duration (median: 18 weeks vs 13 weeks; hazard ratio: 1.40; 95% CI: 1.03–1.92). They were less likely to report any breastfeeding difficulties (55.3% vs 72.8%; hazard ratio: 0.76; 95% CI: 0.62–0.93). There was no significant difference between the 2 groups with respect to the rate of any breastfeeding at 4 weeks (89.3% vs 81.6%; hazard ratio: 1.09; 95% CI: 0.98–1.22) and the rate of mothers fairly or very satisfied with their breastfeeding experiences (91.1% vs 87.7%; hazard ratio: 1.04; 95% CI: 0.95–1.14).

*Conclusions.* Although we cannot exclude the possibility that findings might differ in other health care systems, this study provides preliminary evidence of the efficacy of breastfeeding support through an early, routine, preventive visit in the offices of trained primary care physicians. Our findings also suggest that a short training program for practicing physicians might contribute to improving breastfeeding outcomes. Multifaceted interventions aiming to support breastfeeding should involve primary care physicians. *Pediatrics* 2005; 115:e139–e146. URL: [www.pediatrics.org/cgi/doi/10.1542/115e139-e146](http://www.pediatrics.org/cgi/doi/10.1542/115e139-e146).

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ABBREVIATION. CI, confidence interval.

The benefits of prolonged breastfeeding for mother and infant health are documented in a vast scientific literature.<sup>1</sup> The American Academy of Pediatrics recommends exclusive breastfeeding for the first 6 months of life, continuing to  $\geq 1$  year with the addition of complementary foods at  $\sim 6$  months of age.<sup>2</sup> In its Healthy People 2010 recommendations, the US Department of Health and Human Services sets goals of 75% of mothers breastfeeding exclusively in the early postpartum period and 50% continuing to breastfeed for at least 6 months.<sup>3</sup>

The hospital has been a particular focus of efforts to promote initiation of breastfeeding in the past decade.<sup>4</sup> As a result, large-scale national surveys indicated that the in-hospital breastfeeding rate reached the highest level recorded to date in the United States (69.5% in 2001) and would meet or exceed the Healthy People 2010 goal of 75% for the early postpartum period if increases in breastfeeding continued at the current rate ( $\sim 2\%$  per year).<sup>5</sup> However, the estimates of any breastfeeding at 6 months of age (from 27.0% to 32.5% in 2001) still fall significantly short of the Healthy People 2010 goal.<sup>5,6</sup> The largest decreases in breastfeeding rates occur during the first 4 postpartum weeks among different subgroups of mother-infant pairs.<sup>7,8</sup> Reasons for early breastfeeding discontinuation are complicated. Mothers who discontinue breastfeeding early are more likely to report a lack of confidence in their ability to breastfeed,<sup>7,8</sup> problems with the infant latching or suckling,<sup>8,9</sup> breast pain or soreness,<sup>8,9</sup> perceptions of insufficient milk supply,<sup>8,9</sup> or a lack of individualized encouragement from their clinicians<sup>8</sup> in the early postdischarge period.

Many interventions directed at early preventable breastfeeding problems and relying on peer counselor or nurse follow-up visits at home or in the clinic have attempted to increase breastfeeding rates. These interventions occur as an adjunct to routine preventive visits, rather than within them, and have had generally limited success.<sup>10-13</sup> In contrast, the results of observational studies suggest that support with breastfeeding problems and promotion of breastfeeding provided by clinicians during routine preventive visits in office settings are associated with higher rates of exclusive breastfeeding.<sup>14</sup> However, randomized trials testing the efficacy of interventions delivered through existing primary health care services are currently lacking.<sup>8</sup> Such trials are challenging to conduct in the United States because mothers, health care providers, managed care organizations, and insurance companies have vested interests in early discharge, home or clinic postpartum follow-up visits, and specific breastfeeding support.

The French health care system differs to some extent from the US health care system.<sup>15</sup> In 2001, the mean length of stay after normal vaginal delivery

was 4.8 days in France. Newborns benefit from routine, preventive, outpatient visits delivered by a pediatrician or a family physician in an office setting during the first 6 months of life (ie, at 8 days, and 1, 2, 3, 4, 5, and 6 months of infant age). The period of paid maternity leave is 10 weeks after the birth, extended to 18 weeks after the birth of the third child. Despite these legal conditions, the prevalence of breastfeeding was 70.8% in our hospital and 58.1% at 1 month of infant age.<sup>16</sup> The decrease in breastfeeding rates during the first 1 month of life is likely to be related to a lack of early adequate breastfeeding support after discharge. Most mothers do not attend the mandatory preventive outpatient visit at 8 days of infant age, because it is usually anticipated in the maternity ward before discharge, for various practical reasons.

The objective of this prospective, randomized, parallel-group, open trial was to determine whether attending a routine, preventive, outpatient visit delivered in a primary care physician's office within 2 weeks after the infant's birth would improve breastfeeding outcomes. Our primary hypothesis was that the exclusive breastfeeding rate at 4 weeks would be increased among mother-infant pairs attending the routine, preventive, outpatient visit (ie, the intervention group), in comparison with those receiving the usual postnatal support (ie, the control group). Our secondary hypotheses were that the rate of any breastfeeding at 4 weeks, breastfeeding duration, the proportion of mothers who experienced no breastfeeding difficulty, and the rate of satisfaction with the breastfeeding experience would be increased among mother-infant pairs in the intervention group, in comparison with those in the control group.

## METHODS

### Setting

Mother-infant pairs were recruited in the maternity section of the department of obstetrics and gynecology of the Chambéry Teaching Hospital (Chambéry, France), a level 3 maternity facility where an average of 2000 deliveries per year have taken place in the past 5 years.

### Participants

The study population consisted of mothers who had delivered a healthy singleton infant (gestational age:  $\geq 37$  completed weeks) and were breastfeeding on the day of discharge. Mother-infant pairs were considered ineligible and were not enrolled in the study if the infant was admitted to a neonatal unit or if the mother was transferred to an intensive care unit, was  $\leq 18$  years of age, was living outside Chambéry and its suburbs, refused or was unable to give consent, was unable to speak French, or was unlikely to complete follow-up monitoring because of psychosocial problems such as homelessness.

### Enrollment and Interventions

Consecutive mother-infant pairs were screened for eligibility by 2 residents 7 days per week. Eligible mother-infant pairs were recruited on the day of discharge. They were randomly assigned either to receive the usual postdischarge support (control group) or to attend a routine, preventive, outpatient visit in a primary care physician's office within 2 weeks after the birth (intervention group).

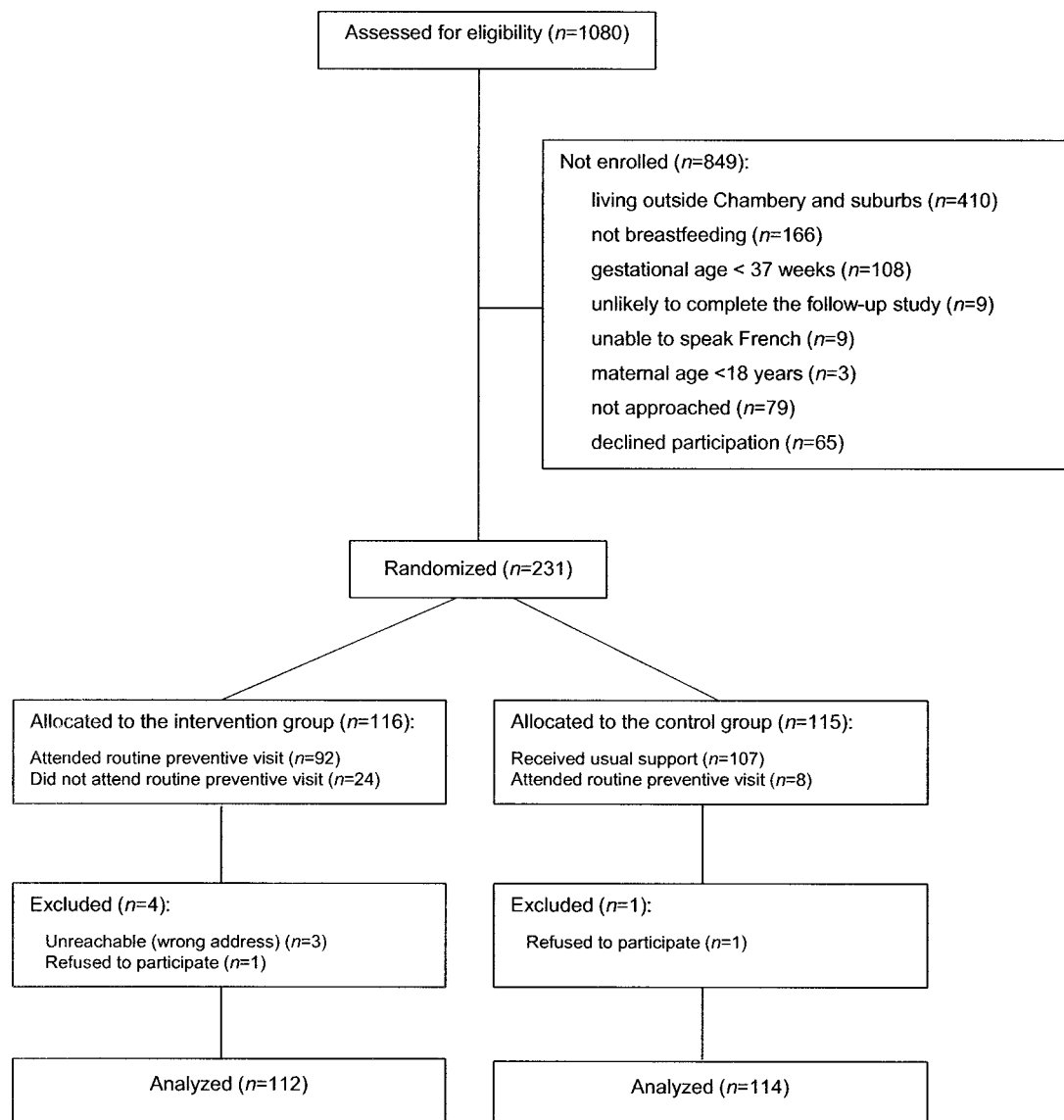


Fig 1. Flow diagram of mother-infant pair progress through the trial.

### Control Group

The mothers in the control group received the usual verbal encouragement to maintain breastfeeding, provided by the maternity ward staff. On the day of discharge, the infant was examined by the pediatrician working in the department, for a general health assessment and an evaluation for evidence of successful breastfeeding behavior. The mothers were also provided with the telephone number of a peer support group that they could call to ask questions and request help. They were not required to attend the mandatory, preventive, outpatient visit at 8 days of infant age, because it was anticipated in the maternity ward before discharge. The postdischarge follow-up monitoring consisted of routine, preventive, outpatient visits in a primary care physician's office at 1, 2, 3, 4, 5, and 6 months of infant age.

### Intervention Group

In addition to the usual pre-discharge and postdischarge support, the mothers in the intervention group were invited to attend an individual, routine, preventive, outpatient visit in the office of 1 of the 17 participating primary care physicians, within 2 weeks after the birth. The participating physicians were pediatricians or family physicians practicing in Chambéry and its suburbs. They had attended a 5-hour training program delivered in 2 parts in 1 month before the beginning of the study. We had developed the training program on the basis of guidelines and review arti-

cles.<sup>17-19</sup> It was intended to improve the physicians' breastfeeding-related knowledge and counseling skills. The topics covered were general health assessment, lactation physiology, feeding position and latch-on assessment, management of common lactation problems (nipple pain, nipple cracks, sore nipples, mastitis, and maternal concern regarding low milk supply), management of infant problems (insufficient weight gain, breastfeeding jaundice, diarrhea, and dehydration), maternal medication use while breastfeeding, and sources of support. The training program was delivered through lectures, panel discussions, role-playing exercises, and printed educational materials. It was delivered as a stand-alone intervention and did not contain any postcourse measures to change health professionals' performance.

### Randomization

The allocation sequence was generated by the statistical adviser of the study with random permuted blocks with a block size of 8. The randomization assignments were unknown to any of the investigators and were concealed in consecutively numbered, sealed, opaque envelopes. The 2 residents opened the envelopes sequentially after the mothers signed the consent forms.

### Data Collection

Baseline data on demographic characteristics, clinical variables, and in-hospital breastfeeding experiences were collected by the 2

residents through chart review and enrollment interviews. The participating physicians were asked to complete and return a questionnaire after each routine, preventive, outpatient visit within 2 weeks after the birth. The data included breastfeeding-related problems and management of those problems (counseling, prescribed medications, or additional visits). Mothers in the control and intervention groups were sent a postal questionnaire when the infants reached 4 and 26 weeks of age, respectively. As described previously,<sup>20,21</sup> we used a postal questionnaire to assess breastfeeding outcomes and satisfaction with breastfeeding experiences, to limit the risk of observer bias. A stamped addressed envelope was enclosed with a cover letter encouraging the mother to complete and return the questionnaire. A second questionnaire was sent to nonrespondents 10 days later. Nonrespondents to the second questionnaire were interviewed by telephone by 1 of the authors.

## Outcome Measures

The primary outcome was the prevalence of exclusive breastfeeding reported at 4 weeks. Exclusive breastfeeding was defined as giving maternal milk as the only food source, with no other liquids (other than vitamins or medications) or foods being given.<sup>22</sup> The secondary study outcomes were prevalence of any breastfeeding reported at 4 weeks, median duration of breastfeeding, breastfeeding difficulties, and maternal satisfaction with the infant feeding experience, rated on a 4-point, single-item scale. Breastfeeding was defined as receipt by the infant of any breast milk. Classification into breastfeeding categories, as reported at 4 weeks, was based on 24-hour dietary recall. Breastfeeding duration was equal to the infant age when the mother completely stopped breastfeeding and was censored at the time of 26 weeks for mothers who reported that they were still breastfeeding at that time.

## Sample Size

On the basis of the results of a previous study,<sup>16</sup> we expected an exclusive breastfeeding rate of 70% at 4 weeks among mother-infant pairs in the control group. We estimated that a sample of 108 mother-infant pairs in each group would have 85% power with a 2-tailed  $\alpha$  error of  $<.05$  to detect a 25% relative increase in the rate of exclusive breastfeeding at 4 weeks (corresponding to a 17.5% absolute increase from 70% to 87.5%). We assumed that ~5% of mothers would be lost to follow-up monitoring; therefore, we planned to include 115 eligible mother-infant pairs in each group.

## Statistical Analyses

Analyses were conducted according to the intention-to-treat principle. Comparisons were performed by using the Student's *t* test for continuous variables and the  $\chi^2$  test or Fisher's exact test,

where appropriate, for categorical variables. In the multivariate analysis, we used a logistic regression model to estimate the odds ratio of exclusive breastfeeding at 4 weeks associated with the intervention, after adjustment for maternal age, white-collar employment status, education status, smoking history, parity, prenatal class attendance, epidural anesthesia, gestational age at delivery, infant birth weight, breastfeeding within 1 hour after birth status, postpartum length of stay, and expected breastfeeding duration. The risks of breastfeeding continuation over time were estimated according to the Kaplan-Meier method and were compared between the 2 groups with the Cox proportional-hazards model. A 2-tailed *P* value of  $<.05$  was considered to indicate statistical significance. Hazard ratios were reported with 95% confidence intervals (CIs). All statistical analyses were performed with Stata 6.0 (Stata Corp, College Station, TX).

The study protocol was approved by the Grenoble University Hospital Institutional Review Board for the Protection of Human Subjects (Comite Consultatif de Protection des Personnes pour la Recherche Biomedicale), the French Data Protection Agency (Commission Nationale de l'Informatique et des Libertes), and the Medical Board of Savoie County (Conseil de l'Ordre des Medecins de Savoie). Written informed consent was obtained from all enrolled mothers.

## RESULTS

### Study Patients

Between October 1, 2001, and May 31, 2002, a total of 1080 mother-infant pairs were assessed for eligibility; 231 were eligible, were approached, provided informed consent, and were randomized (Fig 1). Of these, 116 were assigned to the intervention group and 115 to the control group. The baseline characteristics of the 2 groups were similar (Table 1).

### Attendance at the Routine, Preventive, Outpatient Visit

Ninety-two mothers (79.3%) assigned to the intervention group and 8 mothers (7.0%) assigned to the control group reported that they had attended the routine, preventive, outpatient visit in the office of 1 of the 17 primary care physicians participating in the study (Fig 1). Eighty-seven questionnaires were completed and returned by 13 physicians (range: 1–26 questionnaires per physician). The questionnaires involved 86 mothers in the intervention group and 1 mother in the control group. The mothers attended the physician's office visit at 15.2 days of infant age,

TABLE 1. Baseline Characteristics of the Mother-Infant Pairs

| Characteristics   | No. of Patients (%)             |                            |
|---|---------------------------------|----------------------------|
|   | Intervention Group<br>(n = 116) | Control Group<br>(n = 115) |
| Age, y, mean (SD)   | 29.3 (4.1)                      | 29.7 (4.8)                 |
| Education more than high school graduate                                | 87 (75.0)                       | 84 (73.0)                  |
| White-collar worker   | 92 (79.3)                       | 87 (75.6)                  |
| Living with spouse/partner  | 114 (98.3)                      | 112 (97.4)                 |
| Smoking history   | 27 (23.3)                       | 22 (19.1)                  |
| Prenatal class attendance   | 84 (72.4)                       | 88 (76.5)                  |
| Primiparity   | 58 (50.0)                       | 63 (54.8)                  |
| Epidural anesthesia   | 69 (59.5)                       | 73 (63.5)                  |
| Delivery through cesarean section                                       | 10 (8.6)                        | 10 (8.7)                   |
| Female infant   | 56 (48.3)                       | 53 (46.1)                  |
| Gestational age at delivery, wk, mean (SD)                              | 39.7 (1.3)                      | 39.8 (1.2)                 |
| Infant birth weight, g, mean (SD)                                       | 3314 (441)                      | 3325 (396)                 |
| Apgar score of $<7$ at 1 min  | 1 (0.9)                         | 0                          |
| Breastfed within 1 h after birth  | 48 (41.4)                       | 53 (46.1)                  |
| Expected duration of breastfeeding, mo,<br>median (interquartile range) | 4 (3–6)                         | 4 (3–6)                    |
| Postpartum length of stay of $>4$ d                                     | 57 (49.1)                       | 59 (51.3)                  |
| Return to work or school at 18 wk                                       | 40/112 (35.7)                   | 35/114 (30.7)              |

on average (SD: 4.2 days). The most frequent breastfeeding-related problems reported by the physicians were breast pain or soreness (26 cases, 29.9%), jaundice (15 cases, 17.2%), nipple cracks (14 cases, 16.1%), latching difficulties (6 cases, 6.9%), desire to discontinue (5 cases, 5.7%), oral thrush (3 cases, 3.4%), mastitis (1 case, 1.1%), insufficient weight gain (1 case, 1.1%), and colic (1 case, 1.1%). The most frequent behaviors reported by the physicians were counseling (25 cases, 28.7%), providing information on a peer support group (15 cases, 17.2%), prescribing medications (10 cases, 11.5%), scheduling a subsequent office visit (8 cases, 9.2%), and prescribing a breast pump (5 cases, 5.7%). No mother-infant pair was prescribed laboratory tests.

### Outcomes

Outcomes were unknown for 4 mother-infant pairs in the intervention group and 1 mother-infant pair in the control group (Fig 1). Therefore, data for 112 mother-infant pairs in the intervention group and 114 in the control group were available for analysis.

At 4 weeks of infant age, the rate of exclusive breastfeeding was significantly higher in the intervention group than in the control group (Table 2). In the multivariate analysis, the association between the intervention and exclusive breastfeeding at 4 weeks remained significant after adjustment for potential confounding (adjusted odds ratio: 2.44; 95% CI: 1.18–5.03) (Table 3). No first-order interaction terms for interactions between the intervention group and the predictors entered in the model were statistically significant. With the assumption that missing data were negative outcomes in the intervention group ( $n = 4$ ) and a positive outcome in the control group ( $n = 1$ ) in the sensitivity analysis, the rate of exclusive breastfeeding at 4 weeks remained higher, although not significantly different, in the intervention group, compared with the control group (94 of 116 cases [81.0%] vs 83 of 115 cases [72.2%]; hazard ratio: 1.12; 95% CI: 0.97–1.30). There was no significant difference between the 2 study groups with respect to the rate of any breastfeeding at 4 weeks. The median breastfeeding duration was higher in the intervention group (18 weeks) than in the control group (13 weeks) (Fig 2). The mothers in the intervention group were less likely to report any breastfeeding difficulties (Table 2). The main breastfeeding difficulties reported were breast pain or soreness (28.6% in the intervention group vs 31.6% in the control group), not enough milk (23.4% vs 37.7%), lack of motivation (20.5% vs 30.7%), infant refused

breast (4.5% vs 16.7%), mastitis (2.7% vs 2.6%), and other or unspecified difficulties (24.1% vs 38.6%). The rates of mothers reporting fair or high satisfaction with breastfeeding experiences did not differ significantly between the 2 groups.

### DISCUSSION

This prospective randomized trial demonstrates that, compared with usual care, attending a routine, preventive, outpatient visit in the office of a primary care physician by 2 weeks of infant age is associated with a significant increase in the rate of exclusive breastfeeding at 4 weeks (83.9% vs 71.9%) and longer median breastfeeding duration (18 weeks vs 13 weeks). The benefits of exclusive breastfeeding for infant health are documented in a vast scientific literature,<sup>23</sup> and exclusive breastfeeding is also widely considered to be a strong predictor of longer breastfeeding duration. Our findings were robust, because the increase in the rate of exclusive breastfeeding persisted after controlling for potential confounding factors in the multivariate analysis (adjusted odds ratio: 2.44; 95% CI: 1.18–5.03). The improvements in breastfeeding outcomes were logically paralleled by a decrease in the rate of mothers reporting any breastfeeding difficulties in the intervention group (55.3% vs 72.8%). This was likely related to the high level of attendance at the routine, preventive, outpatient visit in the intervention group (79.3%). This outpatient visit gave the physicians the opportunity to screen and manage early breastfeeding difficulties and to prevent early discontinuation. One surprising finding was that the satisfaction rates were equally high for the 2 groups, despite a significant difference in breastfeeding duration (18 weeks vs 13 weeks). Satisfaction with breastfeeding experiences is probably not entirely determined by the discrepancy between baseline expectations and final outcomes, and unmeasured psychologic factors may affect baseline expectations during breastfeeding experiences, a phenomenon that is called maturation bias.

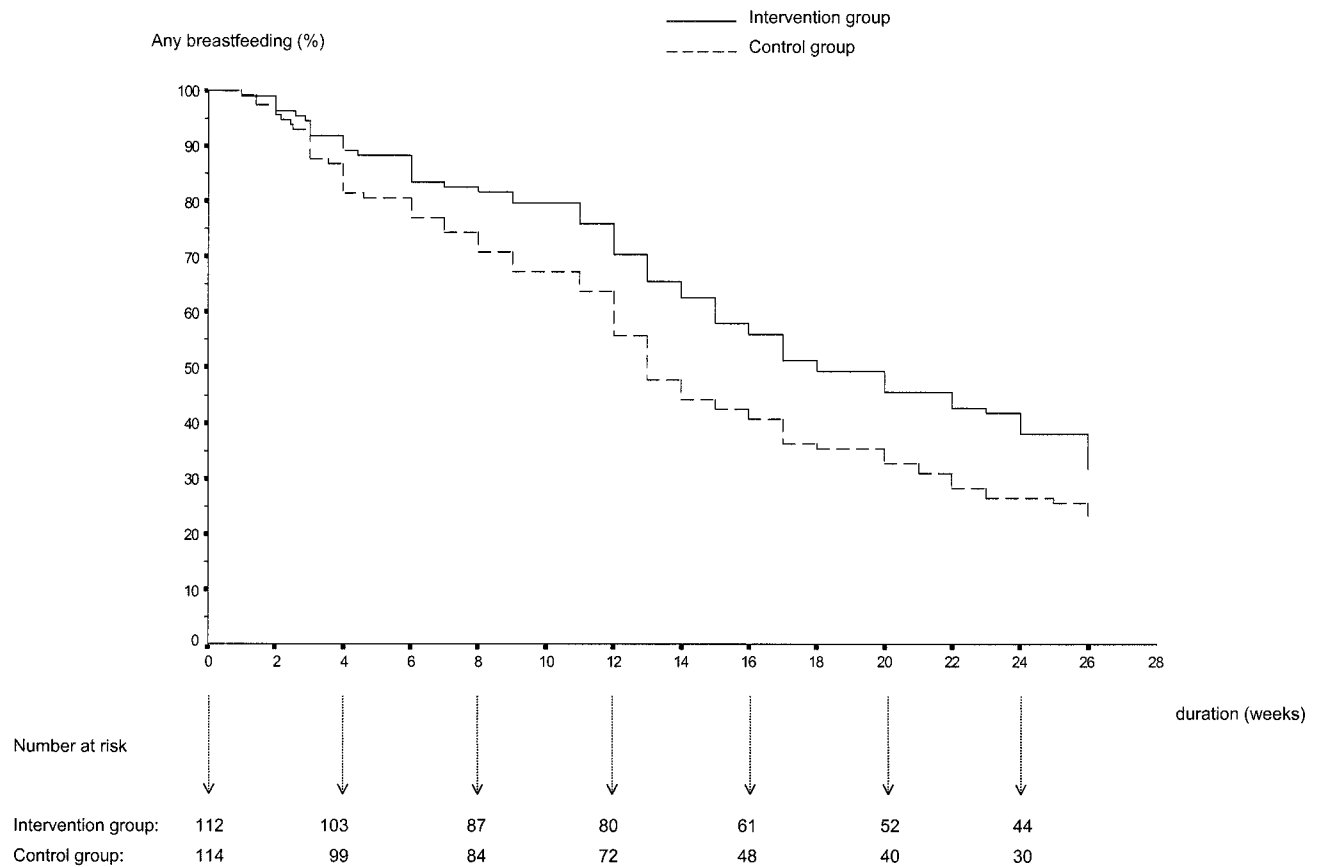
Evidence-based data suggest that exclusive breastfeeding rates are increased by support for mother-infant pairs.<sup>24</sup> Most interventions aiming to support breastfeeding are time-intensive interventions that rely on specifically trained nurses or peer counselors and that occur as adjuncts to routine preventive visits.<sup>8</sup> However, offering support in addition to routine preventive visits has a limited impact on breastfeeding outcomes in developed countries.<sup>12,13,25–27</sup> In contrast, our findings are in accordance with the results of prior observational studies showing that support provided by clinicians through specific ad-

TABLE 2. Univariate Analyses of Outcome Measures

| Outcome   | No. of Patients (%) |                | Hazard Ratio (95% CI) | P Value |
|---|---------------------|----------------|-----------------------|---------|
|   | Intervention Group  | Control Group  |                       |         |
| Exclusive breastfeeding at 4 wk                           | 94/112 (83.9)       | 82/114 (71.9)  | 1.17 (1.01–1.34)      | .03     |
| Any breastfeeding at 4 wk                                 | 100/112 (89.3)      | 93/114 (81.6)  | 1.09 (0.98–1.22)      | .10     |
| Duration of any breastfeeding, wk, median                 | 18                  | 13             | 1.40 (1.03–1.92)      | .03     |
| Reporting any breastfeeding difficulties                  | 62/112 (55.3)       | 83/114 (72.8)  | 0.76 (0.62–0.93)      | <.01    |
| Very or fairly satisfied with experience of breastfeeding | 102/112 (91.1)      | 100/114 (87.7) | 1.04 (0.95–1.14)      | .41     |

**TABLE 3.** Multivariate Analysis of Mother-Infant Pair Characteristics Associated With Exclusive Breastfeeding at 4 Weeks

| Characteristics                          | No. of Patients                           |  | Adjusted Odds Ratio (95% CI) | P Value |
|--|---|--|------------------------------|---------|
|  | Exclusive Breastfeeding at 4 wk (n = 176) | Lack of Exclusive Breastfeeding at 4 wk (n = 50) |                              |         |
| Intervention group                       | 94 (53.4)                                 | 18 (36.0)  | 2.44 (1.18–5.03)             | .02     |
| Age                                      |   |  |                              |         |
| <25 y                                    | 18 (10.2)                                 | 13 (26.0)  | 0.40 (0.14–1.14)             | .09     |
| 25–29 y                                  | 66 (37.5)                                 | 18 (36.0)  | 1.00                         |         |
| 30–34 y                                  | 69 (39.2)                                 | 13 (26.0)  | 1.22 (0.50–2.98)             | .66     |
| ≥35 y                                    | 23 (13.1)                                 | 6 (12.0)   | 0.75 (0.23–2.51)             | .65     |
| Education more than high school graduate | 132 (75.0)                                | 36 (72.0)  | 0.90 (0.37–2.17)             | .80     |
| White-collar worker                      | 139 (79.0)                                | 36 (72.0)  | 1.51 (0.63–3.66)             | .36     |
| Smoking history                          | 34 (19.3)                                 | 13 (26.0)  | 0.98 (0.41–2.33)             | .96     |
| Prenatal class attendance                | 133 (75.6)                                | 37 (74.0)  | 1.92 (0.76–4.84)             | .17     |
| Primiparity                              | 85 (48.3)                                 | 34 (68.0)  | 0.87 (0.32–2.41)             | .80     |
| Epidural anesthesia                      | 100 (56.8)                                | 39 (78.0)  | 0.32 (0.13–0.76)             | .01     |
| Gestational age at delivery              |   |  |                              |         |
| 37–38 wk                                 | 35 (19.9)                                 | 11 (22.0)  | 0.84 (0.32–2.18)             | .72     |
| 39–40 wk                                 | 91 (51.7)                                 | 33 (66.0)  | 1.00                         |         |
| >40 wk                                   | 50 (28.4)                                 | 6 (12.0)   | 3.44 (1.20–9.82)             | .02     |
| Infant birth weight                      |   |  |                              |         |
| <3000 g                                  | 30 (17.0)                                 | 11 (22.0)  | 0.94 (0.36–2.48)             | .90     |
| 3000–3499 g                              | 79 (44.9)                                 | 26 (52.0)  | 1.00                         |         |
| 3500–3999 g                              | 59 (33.5)                                 | 10 (20.0)  | 1.51 (0.62–3.70)             | .37     |
| ≥4000 g                                  | 8 (4.6)                                   | 3 (6.0)  | 0.87 (0.15–4.85)             | .87     |
| Breastfed within 1 h after birth         | 83 (47.2)                                 | 18 (36.0)  | 1.65 (0.75–3.61)             | .21     |
| Postpartum length of stay of >4 d        | 81 (46.0)                                 | 33 (66.0)  | 0.66 (0.26–1.69)             | .39     |
| Expected breastfeeding duration of >4 mo | 83 (47.1)                                 | 17 (34.0)  | 2.49 (1.12–5.53)             | .02     |



**Fig 2.** Kaplan-Meier estimates of any breastfeeding, stratified according to study group.

vice and practices during routine preventive visits is associated with higher exclusive breastfeeding rates and increased breastfeeding duration.<sup>8,14</sup>

This study has broader clinical implications, in

that it demonstrates that common barriers to breastfeeding support by primary care physicians during routine preventive visits can be resolved. Practicing physicians have a considerable knowledge deficit

regarding breastfeeding, a lack of confidence in their counseling skills, difficulties in advising mothers with lactation problems, and limited time to address breastfeeding issues during preventive visits.<sup>14,28</sup> Moreover, substantial gaps in communication between clinicians and mothers regarding breastfeeding may occur during preventive visits.<sup>29</sup> Therefore, we developed a training program on breastfeeding for pediatricians and family physicians who participated in the study. The successful implementation of our training program depended on many factors, including the clinical content, the use of interactive techniques, and the limited amount of time required for its delivery within the constraints of busy practices (5 hours, delivered in 2 parts).

Despite the encouraging findings of our study, it should be noted that the median duration of breastfeeding in the intervention group (18 weeks) was still less than the Healthy People 2010 goal. Breastfeeding support provided by the primary care physician during routine preventive visits is likely to have limited impact, compared with the effects of various barriers that affect breastfeeding duration negatively, such as psychologic factors, cultural factors, and return to work.<sup>30</sup> By 18 weeks, only 33.8% of the mothers in our study had returned to work or school, although maternity leave ranges from 10 to 18 weeks in France. This was in accordance with the results of a prior study conducted in the same area, which suggested that some mothers benefit from extended leave.<sup>20</sup> Specific counseling regarding methods of breastfeeding after the return to work has been recommended,<sup>29</sup> although robust evidence of the effects of such counseling on breastfeeding outcomes is currently lacking.<sup>20</sup> Other approaches, such as part-time work, are also thought to help mothers combine breastfeeding and employment.<sup>30</sup>

The findings of the current study need to be interpreted in the context of its limitations. First, self-selection of motivated clinicians participating in this study was likely an important factor contributing to the improvements in breastfeeding outcomes in the intervention group. Although this trial demonstrates the efficacy of support for breastfeeding delivered by the primary care physician through an early, routine, preventive visit, the effectiveness of this type of support is probably less in daily practice. This issue deserves additional study, although implementation trials of breastfeeding support during routine preventive visits would be challenging to conduct in developed countries.

Second, it was not possible to blind observers in this randomized, open trial, because of interactions with mothers during the outpatient visit and assessment of breastfeeding outcomes. Therefore, we used a postal questionnaire to assess breastfeeding outcomes, to limit the risk of observer bias. Some mothers might have given erroneous information regarding their breastfeeding status at 4 weeks or the duration of breastfeeding. However, it was unlikely that misclassification bias in reporting breastfeeding outcomes differed according to the study group. The 4-week exclusive breastfeeding estimate was based on 24-hour dietary recall, as in most clinical trials.<sup>23</sup>

Some mothers who were exclusively breastfeeding at 4 weeks might not have maintained that status since birth.<sup>31</sup> It is interesting to note that these mothers who did not maintain exclusive breastfeeding since birth returned to exclusive breastfeeding at 4 weeks, which is a positive behavior change. Breastfeeding duration was assessed retrospectively, on the basis of data obtained at 26 weeks. It has been shown that reported breastfeeding duration can be considered accurate, with a long recall period.<sup>32</sup> We did not assess exclusive breastfeeding duration, however, because 6-month exclusive breastfeeding duration recall has been shown to be inaccurate.<sup>33</sup>

Third, our study was conducted in a single setting and focused on a socioeconomically low-risk population living in a medium-sized city. Moreover, the organization of health services has been recognized as a major factor contributing to breastfeeding initiation and continuation.<sup>34</sup> These facts may limit the applicability of our results to other settings or health care systems. In addition, the mean length of stay after normal vaginal delivery is much longer in France than in other Western countries, including the United States. However, the mean postpartum length of stay did not differ between the control group and the intervention group in the current study, and the mothers enrolled in each group were still breastfeeding at discharge, a point that supports the effectiveness of our intervention in improving breastfeeding outcomes.

## CONCLUSIONS

The current study provides preliminary evidence of the efficacy of breastfeeding support through an early, routine, preventive visit in the offices of trained primary care physicians. These findings support the American Academy of Pediatrics policy statement calling for pediatricians to promote and support breastfeeding.<sup>2</sup> Our findings also suggest that a short training program for practicing physicians may contribute to improving breastfeeding outcomes. We recommend that multifaceted interventions aiming to support breastfeeding involve pediatricians and family physicians in developed countries with low or intermediate breastfeeding prevalences.

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