

A Controlled Study on Baby-Friendly Communities in Italy: Methods and Baseline Data

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Abstract

Aim: This study reports the research methods and baseline data of a project aimed at assessing the effect of an intervention based on the 7 Steps of the Baby Friendly Community Initiative (BFICI) on the rate of exclusive breastfeeding at 6 months in Italy.

Subjects and Methods: In this controlled, nonrandomized study, nine Local Health Authorities were assigned to an early and nine to a late intervention group. Data on breastfeeding in infants followed up from birth to 12 months were gathered at baseline and in two subsequent rounds, after the 7 Steps were implemented in the early and late intervention groups, respectively. Step-down logistic regression analysis, corrected for the cluster effect, was used to compare breastfeeding rates between groups.

Results: At baseline, there were no significant differences in breastfeeding rates at birth ($n=1,781$) and at 3 ($n=1,854$), 6 ($n=1,601$), and 12 ($n=1,510$; loss to follow-up, 15.2%) months between groups. At birth, 96% of mothers initiated breastfeeding, 72% exclusively (recall from birth). At 3 months, 77% of infants were breastfed, 54% exclusively with 24-hour and 46% with 7-day recall. At 6 months, the rate of any breastfeeding was 62%, with 10% and 7% exclusive breastfeeding with 24-hour and 7-day recall, respectively. At 12 months, 31% of the children continued to breastfeed.

Conclusions: The project is ongoing and will allow estimation of the effect of the BFICI.

Introduction

THE BABY FRIENDLY HOSPITAL (BFH) INITIATIVE (BFHI), with its 10 Steps for Successful Breastfeeding, is an evidence-based effective intervention that contributes to increasing the initiation, exclusivity, and duration of breastfeeding.^{1,2} The BFHI alone, however, does not create the conditions necessary to achieve the standards recommended by the World Health Organization, UNICEF, and many national policies and professional associations.³⁻⁶ Worldwide, rates of exclusive breastfeeding at 6 months of age fall short of those recommended⁷⁻⁹; other interventions are clearly needed to improve them.¹⁰ Several community interventions, such as primary-care-based educational programs,^{11,12} competent professional support at home or in health facilities,¹³ home visits by trained professionals,¹⁴ home-based peer counseling,¹⁵ or the involvement of fathers as practical breastfeeding

supporters,^{16,17} have been shown to be effective. These separate interventions have proven so promising that in some countries there has been an attempt to integrate these and other interventions into Baby Friendly Community Initiatives (BFICIs),¹⁸⁻²⁰ generally considered as an effective framework.²¹

The Italian National Committee for UNICEF, which has promoted and coordinates the BFHI in Italy, has also promoted a BFICI, developed by a national working group between 2002 and 2006 and pilot-tested in a small area in the city of Milan. The initiative, publicly launched in 2007 and based on the Seven Point Plan used in the United Kingdom and New Zealand, includes tools for planning, implementation, monitoring, and evaluation described in a companion article.²² In 2009, 18 Local Health Authorities (LHAs) (Bassano del Grappa, Biella, Bologna, Cesena, Forlì, Friuli Occidentale, Mantova, Marche, Massa Carrara, Milano, Milano 1, Milano 2,

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Oristano, Roma B, Sondrio, Trieste, Verbania, and Verona) that had expressed an interest in the BFCI accepted the invitation and the challenge, from the Italian National Committee for UNICEF, of working towards BFCI accreditation. This was an opportunity to set up a research project to examine the effectiveness of the BFCI in terms of rates and duration of exclusive breastfeeding at 6 months of age, a recognized research priority.²³ This article describes the project and reports some baseline data.

Subjects and Methods

The project, approved by the Ethics Committees of all the participating institutions (the 18 LHAs listed above and the Institute for Maternal and Child Health IRCCS Burlo Garofolo, Trieste, Italy), was designed as a controlled, non-randomized trial involving 18 LHAs in nine regions in northern and central Italy (Fig. 1). According to the study protocol, nine of the 18 LHAs were to start implementing the 7 Steps of the BFCI after the baseline data collection, with the remaining nine doing so after a delay of about 12 months, after a second data collection. However, some LHAs had already undertaken a few steps toward the BFCI: the LHA in Milan, because it had a leading role in developing the materials and tools and pilot-testing them in a small area, and others because they had been part of the BFCI working group, had previously worked on developing draft policies, or had conducted some limited staff training, especially where there was a BFH, although there were no interventions carried out in hospitals as part of this project. For this reason, it was impossible to randomize the 18 LHAs to intervention and control groups; they were instead paired based on the reported baseline rate of exclusive breastfeeding at around 5 months of age, on the population of the LHA, and on its density (i.e., whether the LHA was mostly urban or mostly rural). Within each pair, LHAs were then assigned to the early (LHAs 5, 6, 8–10, 14–16, and 18) or late (LHAs 1–4, 7, 11–13, and 17) inter-

vention groups based on whether they had already implemented some actions or not.

To be able to compare the rates of exclusive breastfeeding at 6 months, the primary outcome of the study, between groups and within them over time, it was decided to gather data in three phases: at baseline, 1 year later (i.e., after implementation of the 7 Steps in the early intervention group of LHAs), and 2 years later (i.e., after implementation in the late intervention group of LHAs). Cohorts of infants were followed up from birth to 12 months of age, with interviews at discharge and at 3, 6, and 12 months, in each of the three data collection phases. Mothers were recruited consecutively, until the intended sample size was attained, in the hospitals serving the 18 LHAs. After informed consent, the first interview with the mother was conducted face-to-face just before discharge using a 36-item questionnaire that included three questions on feeding both within the previous 24 hours and from birth (Has the baby had breastmilk? Has the baby had formula? Has the baby had other fluids, and if so what?) and questions on potential confounders, as well as basic information used to identify the subject. If, for any reason, it was not possible to conduct the interview with the mother during her hospital stay, a telephone interview was carried out within 1 week of giving birth using the same questionnaire and the same recall periods; this occurred with 212 (12%) mothers. These interviews at discharge or within a week were performed by the staff in charge of the BFCI in each LHA. The interviews at 3, 6, and 12 months (plus or minus 7 days) included five yes/no questions on foods and fluids taken in the previous 24 hours (breastmilk, formula, animal milks, non-nutritive fluids, and solids or semisolids), plus an additional question for infants fed only breastmilk on other foods and fluids taken in the previous 7 days. These questions, complemented in the interview at 12 months by questions on breastfeeding problems and ways they were solved or not, were administered by researchers of the Management and Health Laboratory at the Scuola Superiore Sant'Anna, Pisa, Italy, specialized in conducting surveys using computer-assisted telephone interviewing methods. These interviewers were unaware of the assignment to the early or late intervention groups. The different categories of feeding were automatically derived from the different combinations of answers.^{24,25} All infants were followed up to 12 months of age irrespective of their feeding status.

The sample size for each cohort was established on the assumption that the BFCI could result in a 10% increase in the rate of exclusive breastfeeding at 6 months, from the baseline 25% estimate, as a weighted and adjusted average of the range from 10% to 60% reported for 2007 or 2008 by the 18 LHAs at around 5 months of age. These reports were based on data gathered most often at immunization sessions or, less often, during small cross-sectional or longitudinal surveys, with questionnaires, definitions of feeding categories, and recall periods that were not standardized and on samples that might have been not representative of the population. The final sample size of 1,740 mother–infant pairs was based on the above assumption, resulting in 348 subjects per study arm with 5% precision and a power of 80%, subsequently doubled to take into account a possible design effect of 2 (due to the cluster design of the study), and finally increased by 20% for possible loss to follow-up. The final sample size for each of the 18 LHAs was determined in proportion to their size in terms of estimated number of annual births. Exclusion criteria for



FIG. 1. The location of the 18 Local Health Authorities included in the project. Members of the early intervention group are indicated in bold type.

the enrollment of mothers were an infant birth weight lower than 2,000 g, any postpartum condition that required admission into a neonatal intensive care unit, the practical impossibility of conducting the interview (mother or relative unable to understand Italian, English, French, or Spanish), and residence of the mother outside the area covered by the LHA. As described in the companion article,²² data collection included a self-assessment completed by the LHA on the progress made in implementing the 7 Steps, with each step being assessed using a set of three to 11 criteria based on the same model used for the self-assessment of the BFHI.²⁶ In addition, each LHA is supposed to develop annual action plans and report on the degree of implementation.

After a phase of planning and pilot testing of the tools,²² baseline data collection was started in September 2009 and was successfully completed; the second phase of data collection is over, and the third one is underway. Data from face-to-face interviews are manually inputted into custom EpiData (EpiData Association, Odense, Denmark) files and later exported to Microsoft® (Redmond, WA) Excel, by the research assistants in each of the 18 sites. Those from the computer-assisted telephone interviewing system are recorded answer by answer in real time and automatically saved into a separate relational database, one for each phase of data collection, and are then extracted to Microsoft Excel

files. Finally, all the data from each phase are integrated into a single Microsoft Excel file in Trieste, using the individual ID codes for record linkage. Data are then checked for completeness, consistency, and accuracy, and research assistants at the 18 sites are notified of possible mistakes for correction after comparison with the original paper records. Data analysis is carried out using Stata® software (Stata-Corp, College Station, TX). Differences in rates of breastfeeding between early and late intervention groups at different time points are assessed with step-down logistic regression models that retain only the variables associated with breastfeeding at the 0.05 level of significance and take into account the effect of the cluster design (cluster command in Stata). The tested variables are as follows: maternal age, nationality, education, paid occupation, living with a partner, smoking before and during pregnancy, maternal prepregnancy body mass index, gestational diabetes, parity, twin pregnancy, attending an antenatal course, birth in a BFH, type of delivery, analgesia or anesthesia in labor, intention to breastfeed, gestational age, birth weight, timing of the first breastfeed, rooming-in, baby-led feeding, and use of bottle and/or pacifier during hospital stay. The results of the logistic regression models are used to obtain adjusted breastfeeding rates at different ages, with 95% confidence intervals adjusted for the effect of the cluster design.

TABLE 1. CHARACTERISTICS OF THE MOTHERS AND INFANTS INCLUDED IN THE ANALYSIS, BY STUDY GROUP

| | <i>Early intervention</i> | <i>Late intervention</i> | <i>p value</i> |
|---|---------------------------|--------------------------|----------------|
| Mean (SD) age (years) | 32 (5) | 32 (5) | 0.234 |
| Mean (SD) education (years) | 14 (4) | 13 (4) | 0.002 |
| Employment (paid occupation) | 74% | 78% | 0.110 |
| Italian | 85% | 86% | 0.626 |
| Living with the partner | 97% | 95% | 0.036 |
| Smoking | | | |
| Before pregnancy | 28% | 23% | 0.998 |
| During pregnancy | 8% | 6% | 0.029 |
| Referred BMI (kg/m ²) | | | 0.680 |
| <25 | 78% | 80% | |
| 25–29.9 | 15% | 14% | |
| ≥30 | 7% | 6% | |
| Gestational diabetes | 7% | 6% | 0.881 |
| Primiparae | 55% | 55% | 0.991 |
| Attendance to antenatal classes | 42% | 42% | 0.738 |
| At least one session on breastfeeding | 87% | 79% | 0.002 |
| Delivery at term (37–41 weeks) | 92% | 88% | 0.021 |
| Cesarean section rate | 29% | 29% | 0.910 |
| Anesthesia or analgesia during labor/delivery (including cesarean deliveries) | 47% | 38% | <0.001 |
| Mean (SD) birth weight (g) | 3,317 (452) | 3,280 (448) | 0.080 |
| Previous breastfeeding experience | 43% | 42% | 0.679 |
| <6 months | 30% | 40% | 0.002 |
| 6–12 months | 47% | 39% | |
| 13–24 months | 18% | 20% | |
| >24 months | 5% | 1% | |
| Intention to breastfeed current baby | 99% | 98% | 0.403 |
| Exclusively for at least 6 months | 79% | 75% | 0.038 |
| Birth in a Baby Friendly Hospital | 30% | 22% | <0.001 |
| Baby latched on within 1 hour after birth | 59% | 65% | 0.004 |
| Rooming-in (24 hours/day, all infants) | 75% | 77% | 0.361 |
| Baby-led breastfeeding (breastfed infants) | 91% | 85% | 0.001 |
| Baby used bottle (all infants) | 23% | 18% | 0.009 |
| Baby used pacifier (all infants) | 22% | 26% | 0.161 |

BMI, body mass index.

TABLE 2. ADJUSTED RATES OF BREASTFEEDING IN THE EARLY AND LATE INTERVENTION GROUPS AT BASELINE

| Age | Type of breastfeeding | Recall | Early intervention group | | | Late intervention group | | |
|-----------|-----------------------|------------|--------------------------|-------------------|------------|-------------------------|-------------------|------------|
| | | | n | Adjusted rate (%) | 95% CI (%) | n | Adjusted rate (%) | 95% CI (%) |
| Birth | Exclusive | From birth | 923 | 65.7 ^a | 57.4–72.6 | 803 | 61.0 ^a | 52.8–69.1 |
| 3 months | Exclusive | 7-day | 866 | 48.3 ^b | 40.0–57.1 | 761 | 48.3 ^b | 37.0–51.8 |
| 6 months | Exclusive | 7-day | 836 | 7.5 ^c | 4.6–12.6 | 741 | 6.9 ^c | 3.7–12.8 |
| 6 months | Any | 24-hour | 836 | 63.9 ^d | 54.6–72.5 | 741 | 60.3 ^d | 50.6–69.5 |
| 12 months | Any | 24-hour | 789 | 31.8 ^e | 24.7–39.8 | 697 | 29.1 ^e | 22.7–36.5 |

Rates were adjusted for the following statistically significant variables in the logistic regression model:

^aBirth weight, bottle use, pacifier use, rooming-in, breastfeeding session during antenatal care, prepregnancy body mass index.

^bAnalgesia in labor, twin delivery, pacifier use, current smoking, time of first breastfeed, breastfeeding session during antenatal care, maternal education, parity.

^cBirth weight, bottle use, pacifier use, smoking during pregnancy, breastfeeding session during antenatal care, maternal education, parity.

^dPrepregnancy body mass index, breastfeeding session during antenatal care, nationality, current smoking, time of first breastfeed, parity, maternal education.

^eType of delivery, bottle use, maternal education, parity, nationality.

CI, confidence interval.

Results

The final database of the first phase of data collection includes 1,781 records of mother–baby dyads, including 42 twins, recruited between September 1, 2009 and March 30, 2010; this is 40 dyads more than the intended sample size. Only one LHA recruited two dyads less than planned. A total of 156 eligible mothers declined to be enrolled for various reasons; there were no differences between participant and nonparticipant mothers except for nationality, with the proportion of foreign women being higher among the latter. For the analysis at 3 months, 1,654 dyads were available, a loss of 7.1%; at 6 months, data were available on 1,601 dyads, a further 3% loss; and at 12 months, 1,510 dyads completed the series of interviews, with a total loss to follow-up of 15.2% (with a range of 5.7% to 27.5% among LHAs), less than the 20% predicted when the sample size was calculated. Table 1 shows the characteristics of the mothers and infants included in the analysis, by study group. The demographic characteristics of the sample were similar to national averages in terms of age and education, whereas the percentage of women with a paid employment was slightly higher. More women in the

sample attended antenatal classes than do on average throughout the country (42% vs. 35%). It is also worth noting that the rate of cesarean delivery in the sample (29%) is well below the national average of 38%, although slightly fewer women had term births (90% vs. 93.1% nationally).

As expected, because of the criteria for pairing, there was no statistically significant difference between the early and late intervention groups at any age and for different feeding categories at baseline, after adjustment for potential confounders (Table 2). The adjusted rates, however, are not the real rates; it is interesting to look at these by LHA. Using 24-hour recall, 96% of mothers were breastfeeding at enrollment, with 77% exclusively, 5% predominantly, and 15% with formula supplements; only 4% were not breastfeeding. Because the 24-hour recall was applied at different days post-birth, because of different discharge policies in different hospitals and because of a small proportion of mothers missed at discharge and interviewed by telephone within the first week, it is interesting to look at the figures with a recall from birth to the day of the interview (Fig. 2). Overall, 72% of infants were exclusively breastfed from birth, whereas the rate of any breastfeeding was 94%. In all the LHAs except two, the rate of

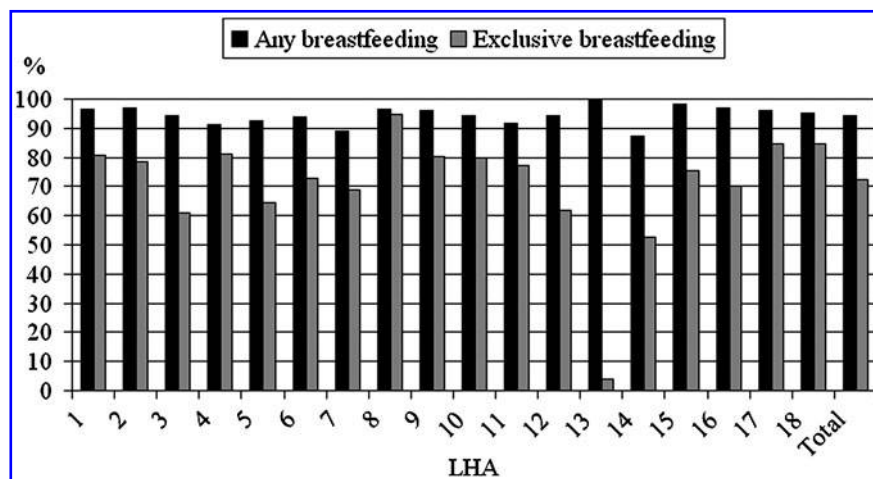


FIG. 2. Rates of any breastfeeding and of exclusive breastfeeding at enrollment (recall from birth), by Local Health Authority (LHA).

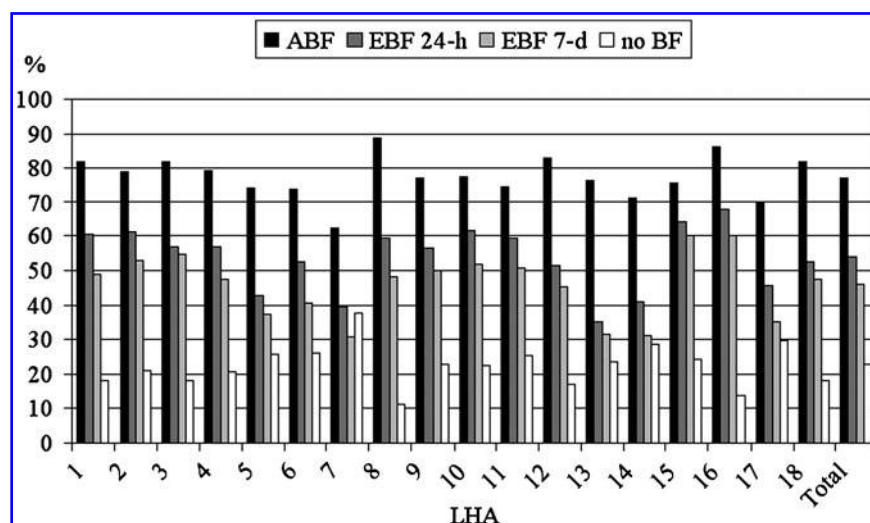


FIG. 3. Rates of any breastfeeding (ABF), exclusive breastfeeding with 24-hour recall (EBF 24-h), exclusive breastfeeding with 7-day recall (EBF 7-d), and no breastfeeding (no BF) at 3 months, by Local Health Authority (LHA).

any breastfeeding was over 90%, with LHA 13 achieving 100%. In the same LHA, however, the rate of exclusive breastfeeding was the lowest (4%) because glucose water was routinely given to almost all newborns. Five other LHAs had rates of exclusive breastfeeding around 60% or lower; all other LHAs, however, were above 70%, with one over 90%.

Figures 3 and 4 show the rates of breastfeeding at 3 and 6 months, respectively. Overall, 77% of infants were breastfed at 3 months, with 54% of them exclusively in the last 24 hours. The correction using the 7-day recall period lowered this figure to 46%, and 23% of infants were no longer breastfed. There were large variations among LHAs, with the lowest rates of 7-day corrected exclusive breastfeeding around 30% and the highest around 60%. At 6 months, the overall rate of any breastfeeding was 62%, ranging from 42% to 76% among LHAs. Rates of exclusive breastfeeding, however, were lower than expected: 10% and 7%, respectively, with the 24-hour

and the 7-day recall. Even for exclusive breastfeeding there was variation among LHAs, with four in the 10–20% range and others below 10%. At 12 months, 31% of the children continued to breastfeed.

Discussion

This article is meant to describe briefly an ongoing study and to report some baseline results. It is too early to report about the degree of implementation of the 7 Steps of the BFCI in the 18 LHAs, let alone speculate on the effectiveness of the initiative. The baseline data on breastfeeding show that the rates at birth and at 3, 6, and 12 months are higher than those reported for Italy for 1999. At that time, exclusive and any breastfeeding at birth were 39% and 91%, respectively; at 3 months they were 47% and 66%, at 6 months they were 5% and 47%, and at 12 months only 12% of infants were

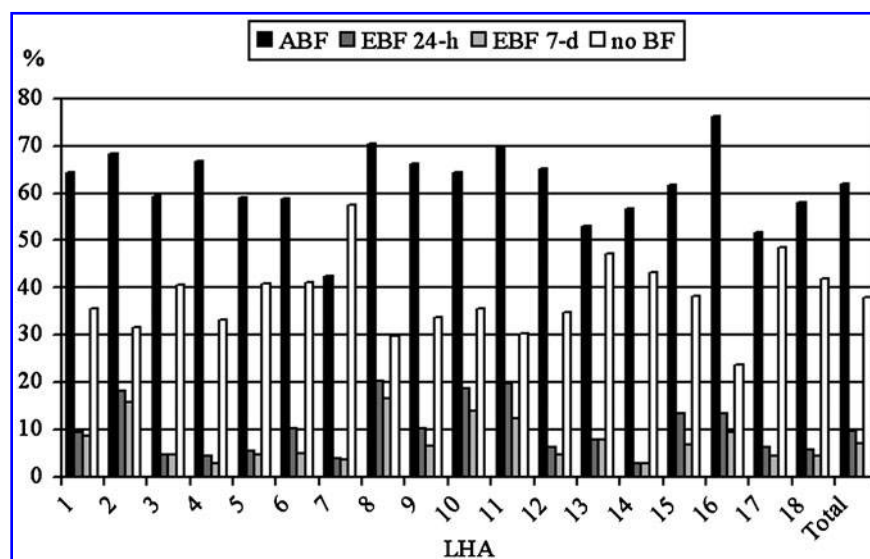


FIG. 4. Rates of any breastfeeding (ABF), exclusive breastfeeding with 24-hour recall (EBF 24-h), exclusive breastfeeding with 7-day recall (EBF 7-d), and no breastfeeding (no BF) at 6 months, by Local Health Authority (LHA).

continuing to breastfeed.^{8,27} In our baseline, the crude average figures are, respectively, 72% and 94% at birth, 54% and 77% at 3 months, and 10% and 62% at 6 months, with 31% for any breastfeeding at 12 months. These large differences may be due to three reasons. First, breastfeeding rates may have gone up in Italy between 1999 and 2009 because of plans, guidelines, educational campaigns, and training activities often carried out after agreements signed by Regional Health Authorities and the Italian National Committee for UNICEF. Second, the 18 LHAs of the study, except for the one in Sardinia, are located in northern and central Italy, where rates of breastfeeding are usually higher than in southern regions.²⁸ Third, the 18 LHAs volunteered to participate in the study, a sign of their commitment to the promotion of breastfeeding, as shown by the presence of accredited BFHs in one-third of the study areas.

The rates of exclusive breastfeeding at 6 months, however, were lower than expected. This is, in fact, the primary outcome of the study, which was estimated as 25% in the protocol and used to determine the sample size. This unexpected finding will not affect the study, as the sample needed to identify a 10% increase from a baseline of 10% is smaller than the one from a baseline of 25%. It does indicate, however, that the different definitions of feeding categories and the different methods (questionnaires, recall periods) routinely used in each LHA to monitor breastfeeding rates may be grossly inaccurate compared with the standard methods used for the study. The major inaccuracies may be related to the infants' ages (much more rigorously determined in the study), the recall periods, and the possible bias of interviewers gathering data for their own LHA, whereas study data were gathered by independent interviewers unaware of the mother's residence or group assignment. Also, contrary to routine data collection, a 7-day recall period was added to the usual 24-hour one in this study. As expected, the 7-day recall period yields rates of exclusive breastfeeding that are lower than those recorded with the 24-hour recall.^{29,30}

The study protocol assumed that nine of the 18 LHAs would start implementing the 7 Steps after the baseline data collection, whereas the remaining nine LHAs would do so after the second data collection phase. The actual implementation does not reflect the protocol, because of various factors potentially present in each of the LHAs, as in other settings.^{31,32} The development and approval of a written infant feeding policy may take different amounts of time in different LHAs, because of factors such as the continuity, importance, and commitment of the decision makers, as well as the complexity of the organization. Some of the 18 LHAs are small and compact, whereas others are large and located in cities like Rome, Milan, and Bologna, where the number of stakeholders to convince is much higher, and interventions will need to be tailored to the local situation.²¹ This obviously has a bearing on the implementation of Step 2 (staff training): it is easier to conduct courses where the number of health professionals is small and stable, whereas it is much more difficult to achieve a high coverage with large numbers of professionals and a high turnover. Similar considerations are relevant for the other steps, and in particular for Step 6 (the provision of a welcoming atmosphere for breastfeeding families) and Step 7 (the promotion of cooperation among healthcare staff, breastfeeding support groups, and the local community), which are closely related. That is to say that,

eventually, the early and late intervention groups may no longer be homogeneous: they may include LHAs with different levels of implementation of the 7 Steps, making the interpretation of their effectiveness somewhat problematic.

To conclude, the BFCI is a complex intervention carried out in socially and geographically different areas.²² Implementing the BFCI 7 Steps requires years of hard work geared toward sustainable changes by policy and decision makers, all categories of health professionals, public and private health organizations, mother-to-mother support groups, volunteer organizations, and local administrators. The challenge is to modify healthcare practices, as in the BFHI, but also to shape and activate mutually supportive networks. It is encouraging to see all this work being done in a coordinated way in the 18 LHAs that have volunteered to participate in this project. Complex interventions are not only difficult to implement, but it is difficult to assess their effects in real life. The design and methods used in this study are far from perfect, but it would be difficult to measure the effect of the BFCI, if any, using the rigorous methods of a randomized controlled trial. The project is already bringing about changes in the way breastfeeding is protected, promoted, and supported in the 18 LHAs. Whether this study will allow us to determine that the BFCI is effective or not, it will have paved the way for better practices in the 18 LHAs and, it is hoped, in other regions of Italy and in other countries.

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Disclosure Statement

No competing financial interests exist.

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