Effectiveness of a Group Educational Intervention – Prolact - In Primary Care to Promote Exclusive Breastfeeding. A Cluster Randomized Clinical Trial.

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**Abstract**

**Background:** The rates of exclusive breastfeeding at 6 months in Spain are far from the target recommended by the World Health Organization, which is 50% by 2025. Evidence of the effectiveness of group interventions in late postpartum is limited. The objective of this study was to evaluate the effectiveness of the PROLACT group educational intervention for increasing the proportion of mother-child dyads with exclusive breastfeeding at 6 months compared to the usual practice in primary care.

**Method:** Multicentre cluster randomized clinical trial. A total of 434 mother-child dyads (215 in the control group and 219 in the intervention group) who breastfed exclusively in the first 4 weeks of the infant’s life and agreed to participate were included. The main outcome variable was exclusive breastfeeding at 6 months. Secondary variables were the type of breastfeeding, reasons for abandonment, degree of adherence and satisfaction with the intervention. To study the effectiveness, the difference in the proportions of dyads with exclusive breastfeeding at 6 months was calculated, and the relative risk (RR) and number needed to treat (NNT) were calculated with their 95% CIs. To study the factors associated with the maintenance of exclusive breastfeeding at 6 months, a multilevel logistic regression model was fitted. All analyses were performed according to intention to treat.

**Results:** The percentage of dyads with exclusive breastfeeding at 6 months was 22.4% in the intervention group and 8.8% in the control group. The PROLACT intervention obtained an RR of 2.53 (95% CI 1.54-4.15) and an NNT of 7 (95% CI 5-14). The factors associated with exclusive breastfeeding at 6 months were the PROLACT intervention, OR 3.51 (95% CI 1.55-7.93); age > 39 years, OR 2.79 (95% CI 1.02-7.6); previous breastfeeding experience, OR 2.61 (95% CI 1.29-5.29); monthly income/person > 833.33 €, OR 2.15 (95% CI: 0.996-4.65); planning to start work before the infant was 6 months old, OR 0.35 (0.19-0.63); and use of a pacifier, OR 0.58 (95% CI 0.30-1.11).

**Conclusions:** The PROLACT group educational intervention in primary care is more effective than the usual practice for maintaining exclusive breastfeeding at 6 months.

**Trial registration:** The trial was registered with ClinicalTrials.gov under code number NCT01869920 (03/06/2013).

**Introduction**

**Breastfeeding and its benefits**

Breastfeeding (BF) is the natural way of feeding infants and provides the food that is best adapted to the nutritional needs of the baby (1). The World Health Organization (WHO) recommends exclusive breastfeeding (EBF) as a public health strategy during the first 6 months of life, followed by the introduction of complementary feeding with continued BF until the infant is 2 years old (1). It proposes the global goal that by 2025, at least 50% of mothers will exclusively breastfeed their children for the first 6 months (2). Three types of BF are defined: i) EBF, which includes the feeding expressed breast milk or milk from a wet nurse to which oral rehydration solution, drops, syrups, vitamins, minerals or medicines are added; ii) predominant breastfeeding (PBF), which includes BF plus water or water-based drinks and/or fruit juices; and iii) complementary feeding (CF), which includes any solid or liquid food, including milk of non-human origin and infant formula, in addition to breast milk (3).

Breastfeeding is a natural act and a learned behaviour that most mothers can perform; however, it is favoured by the presence of accurate information and support within the family, community and health care system (1).

BF provides numerous maternal and child health benefits. A systematic review that included 28 meta-analyses and systematic reviews showed that BF is associated with a decreased risk of sudden death, necrotizing enterocolitis and other childhood diseases as well as a significant reduction in infant mortality in low-income countries. The study also supports the association of BF with a decreased risk of breast cancer in the mother (4). Several studies in OECD countries also show that BF is associated with significant savings for national health systems via a reduction in the incidence of childhood diseases and a possible decrease in maternal diseases (5, 6, 7), estimating these savings for the Spanish National Health System to be more than 5.6 million euros for each point of increase in the BF rate during 2014 (8).

**Prevalence of breastfeeding and associated factors**

Although the initiation of BF is a mainstream occurrence in almost all countries, there is a progressive decline throughout the first months of life. Data published in 2016 by UNICEF (9) indicate that worldwide, only 43% of children receive EBF at 6 months. The highest rates are found in countries in South Asia and eastern and southern Africa. However, the European region has the lowest rate of all WHO regions at 25% (10). In Spain, the 2006 National Health Survey shows that there was 68.4% EBF at 6 weeks and 24.72% at 6 months. In 2011, there was a slight increase to 28.53%, and in 2017, there was a further increase to 39% (11).

In the Spanish context, there are multiple factors that promote BF, with older age and a university education of the mother, greater weight of the child at birth and delivery at term standing out; in contrast, tobacco consumption by the mother is associated with a lower probability of BF (12). Regarding why mothers do not initiate BF, 34% indicated an immediate return to work, and 32% reported a lack of support from health professionals; for early abandonment of BF, the most frequent reasons were the sensation of low milk production (29%) and returning to work (18%) (13). Another barrier is the commercial promotion of breast milk substitutes in the context of widespread public and professional acceptance of equivalence of breast milk substitutes and BF (14–16). Given these obstacles, it is essential that health professionals develop the skills and attitudes needed to teach and support women to BF and maintain EBF during the first 6 months of their infants’ lives.

**Strategies and interventions to improve breastfeeding rates**
The WHO and UNICEF have introduced the Baby Friendly Initiative (BFI), which aims to encourage health centres and health services to adopt practices that protect, promote and support EBF from birth. The main guidelines for preventive activities and health promotion include recommendations to promote EBF in primary care (PC). Evidence in support of these guidelines comes mostly from individual interventions (17). The Cochrane review and meta-analysis of McFadden et al. 2019 (18) included 63 studies that evaluated educational interventions to promote BF; 3 of these studies evaluated group interventions without associated individual interventions. One of them was conducted in Sydney with Vietnamese women (19) (a population group in Australia with especially low BF rates); the results indicated increases in levels of BF knowledge, attitudes and intention. In the second intervention, which included women in Brazil who were pregnant with twins (20), the intervention did not significantly affect the rates of BF; and in the third, a group intervention in mothers in Croatia (21) that consisted of self-directed training, an increase in BF was observed at the time of the intervention. More studies are needed on the effectiveness of group BF interventions in different contexts.

The Madrid Health Service, operating within the Portfolio of Standardized Services offered by Primary Care, has implemented individual and group interventions to promote BF (22). Educational interventions in this context are carried out at the health centre level; therefore, to study the effect of clustering, cluster designs are needed. The group interventions include an educational intervention designed by a multidisciplinary team of BF experts that uses BF promotion as a means to improve maternal and child health. This intervention is directed towards the 263 health centres of the Community of Madrid, which serve a population of 6,498,560.

The main objective of the study was to evaluate the effectiveness of the PROLACT group educational intervention compared with the usual practice in PC health centres for increasing the proportion of mother-child dyads engaging in EBF at 6 months. The secondary objectives were to evaluate the effectiveness of the intervention for maintaining any type of BF at 6 months and to describe women's adherence and degree of satisfaction with the group educational intervention.

**Materials And Methods**

**Design**

A community-based, multicentre, parallel clinical trial was designed with randomization of 6 months of follow-up clusters. The methodology is described in detail in the study protocol (23). In the preparation of the publication, the CONSORT CLUSTER guidelines were followed (29).

**Setting and study population**

The study was carried out in mother-child pairs at 10 health centres in the Community of Madrid (Spain), which provide health coverage to a population of 2,043,460. Mother-child dyads of women ≥18 years old and their children born at term (≥37 weeks of gestation) with a birth weight ≥2.5 kg who attended the health centres for any reason during the first 4 weeks of the infant's life and who breastfed exclusively between 01/26/2015 and 06/30/2016 were included consecutively. The mothers had to be able to communicate in Spanish to follow the requirements of the study. Participating mothers provided written informed consent. We excluded dyads with mothers who were participating in other clinical trials, could not attend follow-up visits, had clinical contraindications to BF (tuberculosis; chickenpox; herpes lesions in the breast; Chagas disease; HIV; human T-lymphotropic virus (HTLV) I and II; drug dependence; treatment with radioactive isotopes, chemotherapeutic agents or antimetabolites) and/or whose children had clinical conditions that hinder, prevent or contraindicate BF (orofacial malformations, galactose-1-phosphate uridytransferase deficiency).

**Sample size**

The sample size was estimated based on an expected proportion of EBF at 6 months of 24% in our environment (11) and considering a 15% increase in this proportion in the mother-child dyads who received the intervention. For a confidence level of 0.05 and a power of 80%, a sample of 300 dyads was needed. The sample size was adjusted with a design effect of 1.29 (ICC of 0.01 and average cluster size of 30) (24). Losses of 10% were estimated, and the final sample size was 432 dyads (216 per cluster).

**Randomization and blinding**

An independent statistician conducted random assignment to form groups of the same size from the list of participating health centres using Epidat 3.1. Subsequently, mother-child pairs were selected within each unit by consecutive sampling until the number needed for the cluster was reached. Due to the nature of the intervention, neither the mothers nor the health professionals could be blinded. The analysis was performed by researchers who did not know the participants' allocation.

**Variables**

The main outcome variable was EBF at 6 months reported by the mother, based on the WHO guidelines for how the child had been fed in the 24 hours prior to the interview. As secondary outcome variables, the type of feeding at 6 months (EBF, PBF and CF) (3) and the duration of EBF (days) were collected. Variables related to the mother and newborn were also recorded. For the mother, sociodemographic variables (age, education level, income level, nationality, work situation, cohabitation with the partner), obstetric history (pregnancies, abortions, live births, type of delivery, previous BF experience) and lifestyle variables (weight, height, and tobacco consumption) were collected. For the newborn, sex, birth weight, discharge from the hospital with the mother, APGAR score, separation from the mother during the hospital stay and whether the child was breastfed during the first hours after delivery were collected.

The reasons for BF abandonment were collected with an ad hoc questionnaire. Adherence to the intervention was measured as the number of group education sessions attended by the dyad (adequate adherence was considered attendance of at least 85% of the planned sessions). Degree of satisfaction was
measured with the SERVQUAL survey, which has scores ranging from 19 to 190, with 19 indicating minimum satisfaction and 190 indicating maximum satisfaction.

**Data collection**

The nurse or paediatrician collected the baseline variables (1 month postpartum) of the mother and child during consultation after the informed consent form was signed. Five follow-up visits were made at 2, 3, 4, 5 and 6 months after delivery. The visits at 2, 4 and 6 months coincided with the standards of the healthy child protocol and the childhood vaccination schedule of the Community of Madrid, and the 3- and 5-month visits were conducted by telephone within 24 hours after the dyad became eligible for that visit. The information was recorded in an electronic data collection logbook and confidentiality, anonymity, and compliance with current regulations were ensured.

**Intervention**

Intervention group: The complex PROLACT intervention is an educational group intervention based on a BF workshop designed by the expert group of the General Directorate of Primary Healthcare of the Madrid Health Department. Its objectives are the acquisition, reinforcement and/or consolidation of the knowledge and skills needed to initiate and maintain EBF and the development of a positive attitude regarding BF. It consists of theoretical and practical content, active participation of the mothers in discussion groups and the learning of skills through the direct practice of BF.

This intervention was developed in accordance with the recommendations and taxonomy proposed by the Cochrane Effective Practice and Organisation of Care Review Group. The intervention is described in detail in Additional File 1 following the approach proposed by Perera et al (25) and the template for intervention description and replication (TIDieR) (see Additional File 2).

Control group: This group received advice regarding the promotion of BF and the benefits of EBF in individual consultations according to clinical practices described in the portfolio of standardized services of the Community of Madrid (22).

**Statistical analysis**

The database was filtered before the statistical analysis was performed to improve the quality of the data collected. The use of a cluster design was taken into account in all phases of the analysis.

Descriptive analysis (means, medians, frequencies of distribution) of the demographic and baseline characteristics of the dyads in both groups was performed. In addition, we compared the baseline characteristics of the dyads in the 2 groups. Student’s t test or the Mann-Whitney test was used if the normality hypothesis was rejected for the data. If the study variables were qualitative, Pearson's chi-squared test or Fisher's exact test was used when applicable.

The results for the primary outcomes were subjected to an intention to treat (ITT) analysis. Missing values for the main outcome variables were added using the last observation carried forward (LOCF) method. Between-group differences in the proportions of EBF at 6 months in the mother and child dyads were calculated using Fisher's exact test, and confidence intervals were estimated. The relative risk (RR) and the number needed to treat (NNT) with 95% CIs were calculated for EBF.

To study the factors associated with maintaining EBF at 6 months, a multilevel logistical regression model was constructed. The dependent variable was EBF at 6 months, and the independent variable was the treatment group. The model was adjusted for possible confounding factors. Effectiveness was determined using an ITT analysis.

Other secondary analyses included the type of BF at 6 months, described as percentages with 95% CI, and the reasons for abandonment. In the intervention group, adherence and satisfaction with the intervention were described and measured with a Likert-type scale, and the results are reported along with the corresponding 95% CI. All p-values below 0.05 were considered statistically significant for all cases. The STATA 14 software programme was used.

**Results**

Between January 2015 and June 2016, a total of 480 dyads were invited to participate in the study; of these, 4 refused to participate, and 42 did not meet the selection criteria. The final sample included in the study comprised 434 dyads (219 in the intervention group and 215 in the control group). A total of 384 (88.47%) dyads completed the 6-month follow-up. The distribution of losses was not proportional between the groups and was higher in the control group (13.95%) than in the intervention group (5.94%). The flow of participants and the reasons for the losses are presented in Fig. 1.

**Participant characteristics**

The mean age of the women who participated in the study was 32.8 (SD 5) years. A total of 80.2% were of Spanish nationality, 55.1% had a university education, and 72.6% had been actively working prior to delivery. Tables 1 and 2 show the characteristics of the participants.
Table 1: Sociodemographic and clinical baseline characteristics of the mother-child dyads.

|                               | Total (n = 434) | Control (n = 215) | Intervention (n = 219) | P-value |
|-------------------------------|----------------|------------------|------------------------|---------|
| **Sociodemographic characteristics** |                |                  |                        |         |
| Mother's age (years)*         | 32.8 ± 5.0     | 32.5 ± 5.2       | 33.2 ± 4.8             | 0.02    |
| University studies            | 239 (55.1%)    | 103 (47.9%)      | 136 (62.1%)            | 0.003   |
| Paid work                     | 315 (72.6%)    | 150 (69.8%)      | 165 (75.3%)            | 0.19    |
| Planned return to work before 6 months | 246 (78.1%)     | 115 (76.7%)      | 131 (79.4%)            | 0.34    |
| Number of family-unit members* | 2.5 ± 0.76     | 2.7 ± 0.8        | 2.4 ± 0.7              | 0.002   |
| Living with the partner       | 411 (94.7%)    | 200 (93%)        | 211 (96.4%)            | 0.12    |
| Has other children            | 184 (42.4%)    | 106 (49.3%)      | 78 (35.6%)             | 0.004   |
| Dysfunctional family APGAR score | 11 (2.5%)      | 5 (2.3%)         | 6 (2.74%)              | 0.784   |
| **Income/household member**   | 833.33         | 750              | 833.33                 | <0.001  |
| [500–1250]                    | [500–1167]     | [750–1250]       |                        |         |
| Spanish                       | 348 (80.2%)    | 166 (77.2%)      | 182 (83.1%)            | 0.12    |
| **Clinical characteristics**  |                |                  |                        |         |
| Maternal BMI (kg/m²)*         | 24.8 ± 4.1     | 25.3 ± 4.4       | 24.4 ± 3.7             | 0.05    |
| Maternal smoking              | 31 (7.1%)      | 13 (6.0%)        | 18 (8.2%)              | 0.38    |
| Gestational age (weeks)*      | 39 ± 1.17      | 39 ± 1.14        | 39 ± 1.2               | 0.54    |
| Diseases/clinical problems in pregnancy*** | 94 (21.7%)     | 50 (23.2%)       | 44 (20.1%)             | 0.42    |
| Caesarean delivery            | 88 (20.3%)     | 41 (19.1%)       | 47 (21.5%)             | 0.54    |
| Sex of child (male)           | 212 (48.8%)    | 111 (51.6%)      | 101 (46.1%)            | 0.25    |
| Apgar score at 1 minute*      | 8.9 ± 1        | 8.8 ± 1         | 9.0 ± 1                | 0.56    |
| Weight at birth (kg)*         | 3.3 ± 0.4      | 3.3 ± 0.4       | 3.3 ± 0.4              | 0.3     |
| Days of admission of the child* | 3 ± 1.3        | 3 ± 1.5          | 3 ± 1                  | 0.3     |

*mean ± SD **median [IQR]. Family members not including the newborn. ***risk of abortion, risk of premature birth, heart disease, diabetes, hypertension, others. BMI: body mass index.
Table 2
Promotion, perception and experience of breastfeeding.

|                                | Total (n = 434) | Control (n = 215) | Intervention (n = 219) | P-value |
|--------------------------------|-----------------|-------------------|------------------------|---------|
| **Use of pacifier**            | 169 (38.9%)     | 99 (46.0%)        | 70 (32.0%)             | 0.003   |
| **BF in the first 2 hours postpartum** | 346 (79.91%)   | 163 (75.81%)      | 183 (83.94%)           | 0.04    |
| **Use of nipple shields**      | 79 (18.2%)      | 33 (15.3%)        | 46 (21%)               | 0.13    |
| **Support during pregnancy**   | 318 (73.44%)    | 148 (68.8%)       | 170 (78%)              | 0.03    |
| **Family BF support**          | 110 (25.4%)     | 62 (28.8%)        | 48 (22%)               | 0.10    |
| **Mother was breastfed**       | 346 (79.7%)     | 35 (16.3%)        | 53 (24.2%)             | 0.04    |
| **Professional BF support**    | 93 (21.5%)      | 42 (19.5%)        | 51 (23.4%)             | 0.33    |
| **Preparation for delivery by a midwife** | 254 (58.7%)  | 119 (55.3%)       | 135 (61.9%)            | 0.16    |
| **Mother's belief that BF is better than formula feeding** | 424 (97.9%)    | 209 (97.2%)       | 215 (98.6%)            | 0.34    |

**Previous experience**

|                                | Total (n = 434) | Control (n = 215) | Intervention (n = 219) | P-value |
|--------------------------------|-----------------|-------------------|------------------------|---------|
| **Breastfed another child**    | 178 (41%)       | 102 (47.4%)       | 76 (34.7%)             | 0.01    |
| **Breastfed for at least 6 months** | 91 (21%)        | 53 (24.7%)        | 38 (17.4%)             | 0.06    |
| **Made the decision to breastfeed** |               |                   |                        | 0.11    |
| **Before pregnancy**           | 335 (77.4%)     | 171 (79.5%)       | 164 (75.2%)            |         |
| **During pregnancy**           | 83 (19.2%)      | 34 (15.8%)        | 49 (22.5%)             |         |
| **Postpartum**                 | 15 (3.5%)       | 10 (4.7%)         | 5 (2.3%)               |         |

**Person who most influenced the decision**

|                                | Total (n = 434) | Control (n = 215) | Intervention (n = 219) | P-value |
|--------------------------------|-----------------|-------------------|------------------------|---------|
| **No one**                     | 215 (49.7%)     | 123 (57.2%)       | 92 (42.2%)             |         |
| **Partner**                    | 129 (29.8%)     | 49 (22.8%)        | 80 (36.7%)             |         |
| **Another family member**      | 44 (10.2%)      | 26 (12.1%)        | 18 (8.3%)              |         |
| **Health personnel**           | 28 (6.5%)       | 12 (5.6%)         | 16 (7.3%)              |         |
| **Others (including BF support groups)** | 17 (3.9%) | 5 (2.3%)         | 12 (5.5%)             |         |

A total of 94.7% of the mothers lived with a partner, and the median family income was approximately 833 € (IQR 500–1250) per member of the family unit.

A total of 20.3% of the women had a caesarean delivery, and 87.6% underwent delivery and follow-up at health centres in the public network of the National Health System.

A total of 184 women (42.4%) were multiparous; of these, 178 (96.74%) had breastfed a previous child, and 51.12% had breastfed for a minimum of 6 months.

Regarding attitudes toward BF, 424 women (97.9%) stated that BF was better than formula feeding, more than 70% had received some type of promotion or information related to BF during pregnancy, and 79.9% breastfed within the first 2 hours after delivery. There were no multiple births or separation of dyads at the time of birth.

Some baseline differences were found between the 2 groups: the mothers in the intervention group were 0.7 years older than those in the control group; the percentage of primiparous mothers was 64.4% in the intervention group compared to 50.7% in the control group; and only one-third of the children in the intervention group used a pacifier, compared to almost half of the children in the control group. A higher percentage of women in the intervention group breastfed in the first 2 hours after delivery (83.9% versus 75.8%) and had been exposed to BF promotion during pregnancy.

**Primary outcome**

At the 6-month follow-up, 77.2% (95% CI: 71.6–82.7) of the mothers in the intervention group maintained some type of BF, compared to 58.2% (95% CI: 51.5–64.7) of the mothers in the control group. Regarding the main result, 22.4% (95% CI: 16.9–27.9) of the mothers in the intervention group maintained EBF, compared to 8.8% (95% CI: 5.04–12.63) in the control group. The RR was 2.53 (95% CI: 1.54–4.15) at 6 months. The NNT of the PROLACT intervention was 7 (95% CI: 5–15).

Table 3 shows the EBF results at 6 months; without adjusting for any factor, significant differences were observed in favour of the intervention group at all months; the maximum difference occurred in the 4th month, with 24.35% more dyads in the intervention group engaging in EBF.
Table 3
Exclusive breastfeeding at 6 months: differences between the intervention and control groups.

| Visit /month | EBF (%) IG | EBF (%) CG | Difference EBF (%) | RR 95% CI | NNT 95% CI |
|--------------|------------|------------|--------------------|------------|------------|
| First        | 92.69      | 80         | 12.69              | 1.16       | 8          |
|              |            |            | (6.33–19.06)       | (1.07–1.25)| (5–16)     |
| Second       | 82.19      | 63.72      | 18.47              | 1.29       | 5          |
|              |            |            | (10.29–26.65)      | (1.15–1.45)| (4–10)     |
| Third        | 73.97      | 56.28      | 17.69              | 1.31       | 6          |
|              |            |            | (8.88–26.51)       | (1.14–1.51)| (4–11)     |
| Fourth       | 66.21      | 41.86      | 24.35              | 1.58       | 4          |
|              |            |            | (15.25–33.45)      | (1.32–1.90)| (3–7)      |
| Fifth        | 44.75      | 26.98      | 17.77              | 1.66       | 6          |
|              |            |            | (8.9–26.7)         | (1.27–2.16)| (4–11)     |
| Sixth        | 22.37      | 8.84       | 13.54              | 2.53       | 7          |
|              |            |            | (6.84–20.23)       | (1.54–4.15)| (5–15)     |

When the results were adjusted for age, educational level and economic level, the PROLACT intervention was associated with a higher proportion of mothers who engaged in EBF, OR 1.57 (95% CI 1.02–2.41).

In the empty model, the variability explained by the cluster was 0.14; this decreased to 0.049 when the intervention and adjustment variables were introduced in the model.

The median odds ratio (MOR) among centres was 1.48. This can be interpreted as the MOR of EBF of the mother-child dyads at different health centres (comparing the higher-risk centres to the lower-risk centres). The MOR of 1.48 was lower than the intervention OR, suggesting that variation among health centres contributed less to EBF at 6 months than the intervention did. Table 4 shows the factors associated with maintaining EBF at 6 months.

Table 4
Factors associated with EBF at 6 months.

| Factor                        | Odds ratio | p      | 95% CI       |
|-------------------------------|------------|--------|--------------|
| PROLACT intervention          | 3.51       | 0.003  | 1.55–7.93 |
| Mother’s age                  |            |        |              |
| 18–29 years                   | 1.83       | 0.095  | 0.9–3.74   |
| 30–39 years (ref)             | 1          |        |              |
| >39 years                     | 2.79       | 0.045  | 1.02–7.6   |
| Income per family member      |            |        |              |
| <500 euros/person (ref)       | 1          |        |              |
| 500-833.33 euros/person        | 3.52       | 0.005  | 1.47–8.47  |
| >833 euros/person             | 2.15       | 0.051  | 0.996–4.65 |
| Previous BF experience ≥ 6 months | 2.61     | 0.01   | 1.29–5.29  |
| Use of pacifier               | 0.58       | 0.099  | 0.3–1.11   |
| Plan to return to work before 6 months | 0.35 | 0.001  | 0.19–0.63   |

The factors that were associated with maintaining EBF at 6 months were having received the PROLACT intervention, 3.5 (95% CI 1.5–7.93); being older than 39 years, OR = 2.78 (95% CI 1.02–7.6), or younger than 30 years, OR = 1.8 (95% CI 1.47–8.47) compared to mothers between 30–39 years old; and previous BF experience, OR = 2.6 (95% CI 1.29–5.29). The probability of EBF at 6 months was decreased among those who planned to return to work before the child was 6 months old, OR = 0.35 (95% CI 0.19–0.63); those with an income less than 500 euros per member of the family unit (excluding the newborn); and those who used a pacifier, OR = 0.58 (95% CI 0.3–1.11).

Secondary outcomes
At the 6-month follow-up, 4.6% (95% CI 2.5–8.3%) of the mothers in the intervention group maintained PBF, compared to 1.4% (95% CI 0.4–4.3) in the control group, after the initiation of BF; while 50.2% (95% CI 43.6–56.8%) of the mothers in the intervention group maintained PBF, compared to 47.9% (95% CI 41.3–54.6%) in the control group (see Fig. 2). The most frequent reasons for abandonment that the women reported were their own decision to stop BF (56.2%) and returning to work (33.7%).

Among the mothers in the intervention group, 64.5% attended at least 85% of the scheduled sessions, the limit defined as good adherence, and the median satisfaction indicated on the satisfaction scale (min 0 - max 190) was 176 points (IQR: 160–186).

Discussion

Main findings of the studies

The educational group intervention implemented at the health centres increased the percentage of dyads with EBF at 6 months by 3.5 times (95% CI 1.55-7.93) compared to usual practice. Maternal age between 30 and 39 years, lower income per member of the family unit, planning to return to work before 6 months and the use of a pacifier were associated with a lower probability of maintaining EBF.

Comparisons with other studies

The EBF rates obtained in our study are lower than those based on data from national health surveys (11) and those reported in other local and national studies (27), a difference that can be explained by the disparity of measurement methods and definitions used in our context. In this study, the WHO’s recommendations for the measurement of EBF rates were strictly followed. Each month, the mothers were asked either by phone or in person at the PC consultation if, in the previous 24 hours, their babies had been given water or water-based drinks; if they had, the dyads was automatically registered as engaging in PBF, even if it was an isolated situation, and this may explain the low rate of EBF in our study. On the other hand, in Spain, data collection with epidemiological surveys that incorporate BF is not performed periodically and does not always use the indicators and methodology recommended by the WHO (3). Instead, these data are obtained by asking the mothers of children under 5 years of age at the time of the survey what type of BF they had received based on the WHO definitions described above. This method may be a possible recall bias (28). In our region, according to data from the health report of the Community of Madrid in 2012, which uses electronic medical records of PC as a source (29), the rate of EBF and PBF at 6 months is 17.9%. This report did not use the WHO definitions, nor did it identify exclusive BF independently.

Regarding BF in any forms, it should be noted that control group’s rate of 9% is similar to the rates reported in the Community of Madrid Health Report 2012 (29).

The results regarding the efficacy of the intervention for the maintenance of EBF at 6 months are higher than those obtained in the studies included in the systematic review by McFadden et al (18). A group educational BF intervention for mothers of twins increased the probability of BF by 87% during the first 30-40 days but produced a BF rate of only 3.95% at 6 months (20). In a study of Vietnamese women in Australia (19), group intervention resulted in a difference of 24.4% in the percentage of BF at 4 months, but this difference was reduced to 9.5% at 6 months. It is important to note that both studies reported prenatal interventions and did not measure EBF. A postnatal group intervention such as the one used in the present study can more easily address doubts and problems that may arise during BF, which may explain the differences in the effects of the interventions at 6 months. In all cases, additional face-to-face support leads to higher rates of BF at 6 months.

Evaluating the effect of the intervention on any type of BF, we observed an RR of 1.33 (95% CI 1.16-1.52), with 77% BF in the intervention group compared to 58% in the control group at 6 months and 80% BF in the intervention group compared to 54% in the control group, percentages similar to those obtained in other observational studies conducted in different regions of our country.

The results reflect, first, the influence of the mother’s return to work on maintaining EBF. This variable has the lowest effect for women between 30 and 39 years of age, an age range at which the maximum number of women return to the workplace and at which maintaining BF can have negative consequences for job stability and professional advancement. The greater proportions of EBF among women older than 39 years who give birth may correspond to personal maternity options that imply a more favourable context for BF.

In our study, education level and smoking habits, factors that are traditionally associated with BF, were not associated when the results were adjusted for the intervention and economic level. It is likely that while interventions to promote BF, such as the one implemented in the present study, can support changes in habits and facilitate the training of mothers, they cannot modify income level, a factor that also clearly conditions mothers’ return to work.

Previous EBF experience is expected to predispose patients to future success, and the use of a pacifier has been identified in different studies as a factor that decreases the probability of BF.

Strengths and limitations

One strength of this study is its methodological rigor. It followed the methodology and definitions of the types of BF recommended by the WHO and was conducted in the context of a pragmatic cluster RCT that allowed us to study the effectiveness of the intervention in real conditions of practice (35).

Among the limitations and biases of our study, it should be noted that although the centres were randomly assigned, there were baseline differences between groups, with the women in the intervention group having a higher income and education level and less pacifier use. This difference may be due to the differences observed among centres. In the empty model, the centre explained 14% of the variability in EBF; this was reduced to 4.9% after adjustment for the
effect of the intervention and the remaining adjustment variables. It could also be related to the fact that a better socioeconomic situation favoured acceptance of the intervention (e.g., by making it possible to attend group sessions), although the percentages of acceptance were similar.

On the other hand, recruitment was performed prior to randomization, and the dyad was required to start follow-up upon inclusion. This may have led the professionals to offer invitations to participate that were conditioned by the mother’s profile, which could also have contributed to a selection bias. The motivation of the professional who monitored the dyad could not be controlled in any of the groups, a factor that may have interfered with the effect of the intervention. The participation of both centres and professionals was voluntary; thus, those that were more motivated to promote BF may have been more motivated to participate in the study. However, to homogenize and control for this effect, no centre that had a BFI accreditation was incorporated, and if this bias existed, it would have affected both the intervention group and the control group.

As this is a nonpharmacological intervention, there may be differences in the way in which different professionals conduct it. To minimize these differences, the professionals who provided the intervention participated in a 20-hour basic BF training course proposed by the BFI and received training in group education techniques (28).

All these limitations may have conditioned a better result in the intervention group and led to overestimation of the effect; however, given the magnitude of the effect found, it would not have conditioned the relevance of the result.

**Implications of the study findings**

As stated in the Clinical Practice Guideline on Breastfeeding in the Spanish National Guideline Plan (GUIASALUD), “the recommendations of all interventions that obtain an RR > 2 can be adapted as a health policy in most situations” (36). The PROLACT intervention has obtained this effect, and thus, all women in our community could be eligible to receive this group educational intervention at their health centres.

**List Of Abbreviations**

- BF Breastfeeding
- WHO World Health Organization
- EBF Exclusive Breastfeeding
- PBF Predominant Breastfeeding
- CF Complementary Feeding
- OECD Organization for Economic Cooperation and Development
- UNICEF United Nations Children’s Fund
- BFI Baby Friendly Initiative
- PC Primary Care
- HIV Human Immunodeficiency Virus
- HTLV Human T-lymphotropic Virus
- ITT Intention to Treat
- LOCF Last observation carried forward
- RR Relative Risk
- NNT Number Needed to Treat
- CI Confidence Interval
- SD Standard Deviation
- IQR Interquartile Range
- BMI Body Mass Index
- IG Intervention group
- CG Control group
- ICC Intraclass Correlation Coefficient
OR Odds Ratio
MOR Median Odds Ratio
N Number in the Sample

Declarations

Ethics approval and consent to participate

The study was approved by the Hospital Clinico San Carlos Clinical Research Ethics Committee (28 August 2013) and was favourably evaluated by the Central Research Commission for Primary Healthcare Management of Madrid (13 April 2012). Participating mothers provided written informed consent. We confirm that all methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due Regarding data exchange, the Ethics Committee approved this research without considering the option of data sharing. However, they are available from the corresponding author on reasonable request. Each new project based on these data must be previously submitted to Ethics Committee for approval.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

MSM and SMI conceived the study, participated in the design of the study together with RRB and IDC, coordinated the field work and participated in the preparation of the manuscript. JPN and CS participated in cleaning the database and analysing the data, and along with LD, LLF, ICG, MRB, and RRB, they participated in different phases of the study design, analysis and interpretation of the results. MRB, IDC, CS developed the manuscript. The PROLACT group developed the field work at health centres. The entire research team has approved the final version of the manuscript.

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