



Six-month breastfeeding maintenance after a self-efficacy promoting programme: an exploratory trial

Journal:	<i>Scandinavian Journal of Caring Sciences</i>
Manuscript ID	SCS-2019-0505
Manuscript Type:	Original Article
Keyword-Research Expertise:	Experimental Design, Research in Practice
Keyword-Area of Expertise:	Breast Feeding, Health Promotion, Care

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Manuscripts

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Title:

Six-month breastfeeding maintenance after a self-efficacy promoting programme: an exploratory trial

Short running title:

Breastfeeding self-efficacy promotion

Word count: 2509 (excluding abstract, declaration and references)

Abstract

Background: Breastfeeding care in healthcare settings plays a fundamental role in establishing breastfeeding and longer duration after discharge. Practices though vary among professionals involved and are often inconsistent with good practices recommended, being a threat to women’s breastfeeding self-efficacy. Breastfeeding self-efficacy is considered a predictor for successful breastfeeding and a significant variable amenable to intervention for promoting lactation

Aim: To evaluate the efficacy, feasibility and acceptability of a new breastfeeding self-efficacy promoting programme (SIALAC) on 6-month breastfeeding maintenance.

Methods: In this exploratory multi-centre controlled trial, participants were allocated into control and intervention groups sequentially. Professionals in charge of the treatment groups were trained in between, with an especial focus on reducing variability in practice. Control and intervention group mothers received usual care, and the intervention group received in addition SIALAC, a three stages breastfeeding self-efficacy promoting programme from pregnancy to after birth. Primary outcome was breastfeeding maintenance up to 6 months analysed by Kaplan–Meier and Cox

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3 proportional hazard regression analysis. Data on breastfeeding status and breastfeeding
4 self-efficacy were collected at baseline, and 4, 8 and 24 weeks after birth.
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8 **Results:** From May 2014 through November 2015 participants were enrolled. The
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10 sample consisted of 112 women. No relevant socio-demographic or obstetric difference
11 was found between groups. 6-month breastfeeding maintenance was significantly
12 higher in the intervention group compared to control group (67 v 55%, $p=0.020$). Hazard
13 Ratio effect size showed that breastfeeding dropout in the control group was 3.3 (CI 1.1,
14 10.1) times higher than that of the intervention group at 6 months. Although
15 breastfeeding self-efficacy scores were higher in the intervention group, the difference
16 was not statistically significant. The programme showed good acceptability from
17 participants and health professionals.
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31 **Conclusion:** Breastfeeding self-efficacy promoting programme SIALAC was beneficial in
32 fostering 6-month breastfeeding survival. Full-scale trial should consider feasibility-
33 related issues identified.
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39 **Keywords:** Breast Feeding; Clinical Trial; Health Education; Health Promotion; Self-
40 Efficacy.
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INTRODUCTION

The triple aim proposed by the Institute for Healthcare Improvement focuses on better care, better health and lower costs (1). Breastfeeding (BF) is associated with extensive health benefits for mothers and infants (2, 3). It achieves significant economic healthcare savings³, not to mention other potential non-healthcare cost savings from a societal perspective. BF care in healthcare settings plays a fundamental role in establishing a pattern of exclusive BF and longer duration after discharge (4,5). Mothers identify health professionals' support as the most important intervention that could have been offered to help them breastfeed (6). Despite these efforts, and the recommendation on exclusive BF up to 6 months, there is a marked decrease in the prevalence of its maintenance (7, 8), with the first trimester playing a critical role (6).

While the reasons are multiple and complex (9, 10), action needs to be taken on BF support services. Health professionals, regardless of specialization, find BF support challenging; they feel they lack preparedness, skills and sensibility (11). Training programmes are essential so that they can provide the best of care (12). The Baby-friendly Hospital Initiative propose as a priority that hospital policies and procedures make sure that health professionals have the knowledge, competence and skills to support breastfeeding women (4). This is key as practices around BF are often inconsistent with good practices recommended, which might be a threat to women's breastfeeding self-efficacy (BSE) (13). BSE is considered a predictor for successful BF (14, 15) and a significant variable amenable to intervention for promoting lactation (13-16).

METHODS

The study presented here is part of a larger project that set out with the purpose of promoting BF, addressing maternal, professional and organisational-level factors, and with a special focus on tackling practice variability. The conceptual framework that guided the project encompassed components of the framework on implementation of innovations (17); the conceptual Model for Developing and Sustaining Interprofessional Care (18); and the self-efficacy construct in the Social Cognitive Theory (19). In methodological terms, the project followed the Medical Research Council's (MRC) framework for complex interventions (20).

Within the context of the project, a BSE-promoting programme (SIALAC) was developed. The acronym stands for synergy, self-efficacy and breastfeeding care in their Spanish forms ('Sinergia, Autoeficacia, LAtancia and Cuidados). In order to reduce professional variability in the provision of BF support, training was offered to the professionals that were to be involved in delivering the programme. The training addressed skills, attitudes and motivation to care for BF women in participatory group sessions, building on their experience and knowledge, as most of them (79.1%) had more than 5 years of professional experience in BF support. Training included strategies to foster BSE according to score (21). Support evidence-based materials were provided with specific advice on how to deal with low score items.

A logic model was used to develop the programme (Figure 1), summarising the problem to be addressed, the theoretically built content and the central components of the intervention and the possible short, medium and long term outputs, directly or indirectly related to the programme.

The specific objectives of the study presented here were:

- To estimate the preliminary efficacy of SIALAC programme to promote BF.

- To explore the feasibility and acceptability of SIALAC programme by professionals and organisations.

In terms of efficacy, it was hypothesized that, when compared with the control group (CG), participants in the intervention group (IG) would report significantly higher: BF rates after giving birth and over time (4 and 8 weeks, and 6 months); and BSE level after giving birth and over time (4 and 8 weeks, and 6 months).

This study consisted on an exploratory multi-centre controlled trial (20). It was carried out in two hospitals and two community clinics attending to the organisation of women health services around pregnancy in Spain; covering from prenatal care, through hospitalisation around delivery to follow up.

Eligible participants were healthy childbearing women in their second trimester (after the 23rd week of pregnancy) attending regular pregnancy check-ups, 18 years or older, intending to BF after giving birth and having no contraindication to do so. Mothers were excluded if they had any condition that would interfere with BF, such as unwillingness to breastfeed, preterm birth (at <37 weeks gestation), BF contraindication in babies (for example, galactosemia), and BF-related especial situations (multiple birth; new-born weight <2000g; leporine lip; or in intensive care unit).

Allocation to groups was done sequentially, by three-month time blocks. First, participants were allocated into CG. Then, health professionals' training took place. After that, participants were allocated to the IG. The rationale for this allocation procedure was two-fold: first, to avoid the potential for contamination, given that the same group of professionals would be in charge of both treatment groups; and second, to facilitate masking, avoiding contact between women in the IG and the CG during hospitalization.

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3 The BSE-promoting programme SIALAC was delivered by nurses and midwives in three stages:

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5 a) week 28-39 pregnancy: women were provided with written information and watched a BSE
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7 enhancing video; b) during hospitalization after birth: specific advice on the items with low
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9 score in BSE Scale-Short Form [BSES-SF] (21) during the observation of a whole breastfeed
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11 (22); c) within 48-72 hours after discharge: a follow-up phone call addressing BF behaviours
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13 and difficulties.
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18 SIALAC was provided to mothers in the IG. Both study groups received usual care. Usual care
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20 is provided by midwives and nurses during regular antenatal visits and after giving birth. It
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22 includes information on breastfeeding benefits, encouragement to put the baby to the breast
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24 within the first hour of life, active observation of a breastfeed and position feedback, and
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26 resolution of doubts up to 6 months after birth.
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30 *Sample size determination*

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32 Using OpenEpi version 3, a sample size of 118 was determined to provide statistical power
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34 >80%, assuming an alpha error of 0.05, and a Cohen's d size effect of 0.523 as of BSES-SF (23).
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39 In line with the objectives and hypotheses mentioned above, the efficacy measures were BF
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41 status and BSE. BF status was determined through mothers' self-report. Participants reported
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43 whether they BF or not and whether they included other foods. Maternal BSE was measured
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45 using the BSES-SF questionnaire (21). Data collection was conducted at four time points in
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47 both groups; from baseline measurement to 6 months follow up.
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52 As covariates socio-demographic, obstetric and BF related characteristics were studied. These
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54 included: maternal age, marital status, family income, education level, occupation, and
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56 smoking behaviour; previous pregnancies and number of children, previous experience with
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3 BF and their satisfaction with it, giving birth method, skin to skin practice, and attendance to
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5 prenatal and BF training.
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8 Acceptability and feasibility were explored by analysing: participants' recruitment and
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10 completion of the programme; the involvement of professionals in the provision of the
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12 programme as well as in data collection; and the use that professionals and mothers did of
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14 the support materials. These aspects were registered in a researcher's diary throughout the
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16 study that was later subject to analysis.
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22 Ethical approval was granted from both Research Ethics Committees relevant to the centres
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24 involved (blinded), as well as permissions from the relevant clinical governances. Written
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26 consent was obtained from participating women. In order to ensure confidentiality, a unique
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28 participant number was used and personal data of participants were kept separate from the
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30 study data.
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34 35 *Data analysis* 36

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38 Socio-demographic and birth related data were summarised using descriptive statistics. In
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40 order to calculate BSES-SF score, if participants omitted one or two items, the mean of the
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42 items answered was multiplied by 14 and the product rounded to the nearest whole number.
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44 If more than two items were unanswered, the case was excluded from the analysis (24).
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46 Continuous and categorical variables were analysed using Student's T test and Chi square test,
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48 respectively.
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53 Kaplan-Meier log-rank test was used to examine BF maintenance throughout the six-month
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55 follow-up period. Cessation of BF was used as endpoint for the analysis. Cox proportional
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57 hazard regression analysis with 95% confidence intervals was used, adjusted for age, BF
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3 previous experience, BF previous duration, BF self-evaluation experience, and education.

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5 SPSS v.21 was used for the analysis. All analyses were done on intention to treat basis.

6 7 8 **RESULTS**

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11 The final sample consisted of 112 mothers (IG n=57, CG n=55). The most common reasons for
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13 exclusion were BF contraindication and infants being admitted to intensive care (see Figure
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19 No difference was found between the IG and the CG in terms of relevant socio-demographic
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21 or obstetric characteristics (see Table 1). The sample's mean age was 34 years. Most
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23 participants (86.5%) were employed and had a university degree (55.4%). About half of the
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25 sample had previous BF experience (see Table 1).

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28 Breastfeeding maintenance was statistically significant in the intervention group compared
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30 to the control group at six months postpartum (67% vs. 55%; $X^2=5.384$, $p=0.020$). The dropout
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32 rate in the CG was 3.3 (CI 1.1, 10.1) times higher than that of the IG. Log-rank test showed a
33
34 significant difference in BF survival between groups ($X^2=4.94$, $p=0.026$) (see Figure 3).

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37 In addition to this effect, in the univariate and multivariate analyses showed previous
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39 experience as significant variable (see Table 2). Participants with previous BF experience of
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41 less than 6 months had 8 times higher risk of giving up than those that had a previous BF
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43 experience of 6 months or more (univariate hazard ratio [HR]: 8.21; 95% CI: 1.65, 40.81 and
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45 multivariate [HR]: 7.8; 95% CI: 1.57, 38.7).

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48 In terms of self-efficacy, while women in the IG consistently reported higher scores, these did
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50 not reach statistical significance (see Table 3).

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3 The programme was received well by participants. The fact that the intervention was
4 delivered within routine consultations might have contributed to this acceptability. The
5 professionals involved valued highly the standardisation and the support materials that
6 SIALAC offered, although the need to register all the data represented extra work.
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13 The professionals in charge of delivering SIALAC were those responsible for the regular visits
14 during pregnancy and this was key in terms of study feasibility. The involvement of several
15 practitioners throughout the study and specifically during data collection, though,
16 represented challenges regarding information sharing at every stage of the project and the
17 coordination in between community clinics and hospitals and among health professionals
18 within each of these centres. Follow-up and data collection were also key issues regarding the
19 feasibility due to the need to make several attempts to contact mothers. The collaborative
20 work between health professionals, managers of the units and researchers, combined with
21 the institutional support were fundamental to face these challenges. This work made possible
22 the delivery of the programme and also knowledge transfer.
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38 **DISCUSSION**

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41 This study reported the efficacy, acceptability and feasibility of SIALAC, a BSE-support
42 programme, in the maintenance of BF up to 6 months. According to the results, SIALAC proved
43 beneficial in BF maintenance, as mothers who received usual care had approximately 3 times
44 the risk of not continuing to BF at 6-month follow-up compared to mothers who received the
45 programme. At previous data collection time points, no differences were observed. This
46 contrasts with previous similar studies, which found significant differences at earlier periods
47 of time (25-28). A possible explanation might be that, while mothers initially receive high
48 support as part of usual care and also from relatives, this support declines a few weeks after
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3 giving birth (25), and it is then when the effect of SIALAC programme is noticeable,
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5 contributing to reach 6-month BF maintenance.
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8 A similar pattern to previous studies was identified at 8 weeks (2, 13), when a decrease was
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10 observed. Components to ameliorate this fall should be explored for the full-scale trial.
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13 Mothers' previous experience has shown to have a significant effect in BF maintenance in this
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15 study. The construct of past experience has been identified as one that contributes to the
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17 maintenance of BF, suggesting also that intention, attitude, and BSE are correlated, reflecting
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19 past BF behaviour (29). This might be a possible explanation for the lack of significant
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21 differences found in BSE in this study, although confirmation cannot be provided, as the study
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23 solely focused on BSE and no data were available on the other variables.
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28 Previous research had shown positive results when addressing BSE (14). In this study, the
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30 item-tailored BSE advice seems to have contributed to the positive rates in maintenance,
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32 although this has not been reflected in BSE scores. The lack of significant differences in BSE
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34 scores between mothers in IG and CG is a common finding in BSE research (14). This may
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36 occur because of several reasons. A natural increase in BSE happens when a behaviour is
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38 practiced, and therefore all breastfeeding mothers increase BSE scores over time (30, 31). It
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40 seems plausible to think that exposure of all participating mothers to the BSES-SF scale
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42 provided them, mothers in CG also, with an opportunity to self-assess their BF process and
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44 identify where the problems and the solutions might be. Nonetheless, this exposure could
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46 not have been prevented, as BSE data collection was necessary for between group
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48 comparisons.
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55 The small sample size might also have played a role in the difficulty in identifying a significant
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57 difference in BSE (23). The confidence interval of the effect on the other outcome variable,
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3 BF maintenance, were in the limit of significance too. Together with the need for an increased
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5 power, this exploratory trial helped identify a number of other issues to be taken into
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7 consideration for the full-scale study. The feasibility exploration recommends for using
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9 electronic methods for data collection, as handwriting entailed certain challenges to the
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11 health professionals. An agreement should be reached with participants at the outset on the
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13 best way to contact them in order to avoid the challenges to reach them. The strength of the
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15 joint action of researchers, nursing managers of the units and health practitioners combined
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17 with institutional support shows that this type of collaboration is a relevant structure in
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19 translating knowledge into practice. Other authors have highlighted the need of collaborative
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21 work in BF implementation initiatives (32).
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28 The use of a theoretical framework in the development of the intervention, as recommended
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30 in the literature (33), and its adaptation to the caring context made possible the creation of
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32 SIALAC. The support materials developed for the programme were highly valued by the
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34 professionals involved as it helped them rely on evidence rather than on their own personal
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36 or professional experience, and decrease variability of clinical practice. Both issues have been
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38 identified as important challenges in BF care provision (11, 34).
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43 Lack of randomisation might be considered the main limitation in this study. After giving
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45 thorough consideration, it was decided that benefits outweighed limitations in the design of
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47 the study. Professionals in charge of both treatment groups were to be the same. To minimise
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49 the threat of potential contamination, a strategy was developed with allocation in blocks and
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51 professionals' training carried out in between. These offered a number of advantages
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53 including: that professionals delivering SIALAC were the same who worked in the natural
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55 setting, it minimised inter-provider variability in delivering the programme, and participants
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3 were blind to group assignment. Moreover, considering the profile of participants in both
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5 study groups an even distribution of potential confounding variables could be assumed.
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11 **References**

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13
14 1. Berwick DM, Nolan TW, Whittington J. The Triple Aim: Care, Health, And Cost. *Health Aff*
15 2008; 27(3):759–69. doi: <https://doi.org/10.1377/hlthaff.27.3.759>
16
17
18
- 19 2. World Health Organization. Global nutrition targets 2025: breastfeeding policy brief. World
20 Health Organization, Geneva; 2018.
21
22
- 23 3. Santacruz-Salas E, Aranda-Reneo I, Hidalgo-Vega A, Blanco-Rodriguez JM, Segura-Fragoso
24 A. The Economic Influence of Breastfeeding on the Health Cost of Newborns. *J Hum Lact* 2019;
25 35(2) 340–48. doi: <https://doi.org/10.1177/0890334418812026>
26
27
28
- 29 4. Hernández-Aguilar MT, Bartick M, Schreck P, Harrel C, Young M, Noble L, Sarah Calhoun S,
30 Dodd S, Elliott-Rudder M, Lappin S, Larson I, Lawrence RA, Marinelli KA, Marshall N, Mitchell
31 K, Reece-Stremtan S, Rosen-Carole C, Rothenberg S, Seo T, Wonodi A. ABM Clinical Protocol
32 #7: Model Maternity Policy Supportive of Breastfeeding. *Breastfeed Med* 2018;13(9):559–74.
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doi: <https://doi.org/10.1089/bfm.2018.29110.mha>
5. Pérez-Escamilla R, Martinez JL, Segura-Pérez S. Impact of the Baby-friendly Hospital
Initiative on breastfeeding and child health outcomes: a systematic review. *Matern Child Nutr*
2016; 12(3):402–17. doi: <https://doi.org/10.1111/mcn.12294>
6. Barclay L, Longman J, Schmied V, Sheehan A, Rolfe M, Burns E, Fenwick J. The
professionalising of breast feeding—Where are we a decade on? *Midwifery* 2012;28(3):281–
90. doi: <https://doi.org/10.1016/j.midw.2011.12.011>

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59
60
7. Balogun OO, O'Sullivan EJ, McFadden A, Ota E, Gavine A, Garner CD, Renfrew MJ, MacGillivray S. Interventions for promoting the initiation of breastfeeding. *Cochrane Database Syst Rev* 2016;11 (CD001688). doi: <http://dx.doi.org/10.1002/14651858.CD001688.pub3>.
 8. Theurich MA, Davanzo R, Busck-Rasmussen M, Diaz-Gomez NM Brennan C, Kylberg E, Baerug A, McHugh L, Weikert C, Abraham K, Koletzko B. Breastfeeding Rates and Programs in Europe: A Survey of 11 National Breastfeeding Committees and Representatives. *J Pediatr Gastr & Nutr*. 2019; 68(3):400-07.
 9. Rollins NC, Bhandari N, Hajeebhoy N, Horton S, Lutte CK, Martines JC, Piwoz EG, Richter LM, Victora CG. Why invest, and what it will take to improve breastfeeding practices? *Lancet* 2016; 387(10017): 491–504. doi: [https://doi.org/10.1016/S0140-6736\(15\)01044-2](https://doi.org/10.1016/S0140-6736(15)01044-2)
 10. Llopis-Rabout-Coudray M, Lopez-Osuna C, Durá-Rayó M, Richart-Mártinez M, Oliver-Roig A. Fiabilidad y validez de la versión Española de una escala de autoeficacia en lactancia maternal (Reliability and validity of the Spanish version of a breastfeeding self-efficacy scale). *Matronas Profesión* 2011;12(1):3–8. Retrieved from: <http://www.federacion-matronas.org/wp-content/uploads/2018/01/03-8-art-orig-fiabilidad.pdf>
 11. Moreira de Almeida J, Barros S, Veiga F. Support of breastfeeding by health professionals: integrative review of the literature. *Rev Paul Pediatr* 2015;33(3):355–62. doi: <https://doi.org/http://dx.doi.org/10106/j.rpped.2014.10.002>
 12. Gavine A, MacGillivray S, Renfrew MJ, Siebelt L, Haggi H, McFadden A. Education and training of healthcare staff in the knowledge, attitudes and skills needed to work effectively with breastfeeding women: a systematic review. *Int Breastfeed J* 2016;12(1):6. doi: <https://doi.org/10.1186/s13006-016-0097-2>

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13. Otsuka K, Taguri M, Dennis CL, Wakutani K, Awano M, Yamaguchi T, Jimba M. Effectiveness of a Breastfeeding Self-efficacy Intervention: Do Hospital Practices Make a Difference?. *Matern Child Health J* 2014; 18(1):296–306. doi:<https://doi.org/10.1007/s10995-013-1265-2>
14. Brockway M, Benzies K, Hayden KA. Interventions to Improve Breastfeeding Self-Efficacy and Resultant Breastfeeding Rates: A Systematic Review and Meta-Analysis. *J Hum Lact* 2017;33(3):486–99. doi:<https://doi.org/10.1177/0890334417707957>
15. Dennis CL. Theoretical Underpinnings of Breastfeeding Confidence: A Self-Efficacy Framework. *J Hum Lact* 1999;15(3):195–201. doi:<https://doi.org/10.1177/089033449901500303>
16. Semenic S, Childerhose JE, Lauzière J, Groleau D. Barriers, Facilitators, and Recommendations Related to Implementing the Baby-Friendly Initiative (BFI). *J Hum Lact* 2012; 28(3):317–34. doi: <https://doi.org/10.1177/0890334412445195>
17. Chaudoir SR, Dugan AG, Barr CH. Measuring factors affecting implementation of health innovations: a systematic review of structural, organizational, provider, patient, and innovation level measures. *Implement Sci* 2013;8(1), 22. doi: <https://doi.org/10.1186/1748-5908-8-22>
18. Registered Nurses' Association of Ontario. *Developing and Sustaining Nursing Leadership*. 2nd ed. Toronto: Nurses' Association of Ontario; 2013.
19. Bandura A. Self-efficacy. In: Ramachaudran VS, editor. *Encyclopedia of human behavior*. New York: Academic Press; 1994. p.71–81

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20. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;a1655. doi: <https://doi.org/10.1136/bmj.a1655>
21. Oliver-Roig A, D'Anglade-González ML, García-García B, Silva-Tubio JR, Richart-Martínez M, Dennis CL. The Spanish version of the Breastfeeding Self-Efficacy Scale-Short Form: Reliability and validity assessment. *Int J Nurs Stud* 2012; 49(2): 169–73. doi: <https://doi.org/10.1016/j.ijnurstu.2011.08.005>
22. UNICEF. The Baby-Friendly Hospital Initiative. (<https://www.ncbi.nlm.nih.gov/books/NBK153471/> [accessed 07.12.19]); 2009
23. Noel-Weiss J, Bassett V, Cragg B. Developing a prenatal breastfeeding workshop to support maternal breastfeeding self-efficacy. *J Obstet Gynecol Neonatal Nurs* 2006; 35(3):349–57. doi: <https://doi.org/10.1111/j.1552-6909.2006.00053.x>
24. Marco Alegría TD, Martínez Martínez D, Muñoz Gómez MJ, Sayas Ortiz I, Oliver-Roig A, Richart-Martínez M. Spanish reference values for the Breastfeeding Self-Efficacy Scale-Short Form BSES-SF. *Anales Sis San Navarra* 2014;37(2): 203–11. doi: <http://dx.doi.org/10.4321/S1137-66272014000200003>
25. Wu DS, Hu J, McCoy TP, Efird JT. The effects of a breastfeeding self-efficacy intervention on short-term breastfeeding outcomes among primiparous mothers in Wuhan, China. *J Adv Nurs* 2014;70(8): 1867–879. doi: <https://doi.org/10.1111/jan.12349>
26. McQueen KA, Dennis C, Stremle R, Norman CD. A Pilot Randomized Controlled Trial of a Breastfeeding Self-Efficacy Intervention With Primiparous Mothers. *J Obstet Gynecol Neonatal Nurs* 2011; 40(1):35–46. doi:<https://doi.org/10.1111/j.1552-6909.2010.01210.x>

- 1
2
3 27. Nichols J, Schutte NS, Brown RF, Dennis CL, Price I. The impact of a self-efficacy
4
5 intervention on short-term breast-feeding outcomes. *Health Educ Behav* 2009; 36(2):250–
6
7 58. doi: <https://doi.org/10.1177/1090198107303362>
8
9
- 10
11 28. McFadden A, Gavine A, Renfrew MJ, Wade A, Buchanan P, Taylor JL, Veitch E, Rennie
12
13 AM, Crowther SA, Neiman S, MacGillivray S. Support for healthy breastfeeding mothers with
14
15 healthy term babies. *Cochrane Database Syst Rev* 2017; 2(CD001141). doi:
16
17 <http://dx.doi.org/10.1002/14651858.CD001141.pub5>
18
19
- 20
21 29. Bartle NC, Harvey K. Explaining infant feeding: The role of previous personal and vicarious
22
23 experience on attitudes, subjective norms, self-efficacy, and breastfeeding outcomes. *Br J*
24
25 *Health Psychol* 2017;22(4):763-85. doi: <https://doi.org/10.1111/bjhp.12254>
26
27
- 28
29 30. Liu L, Zhu J, Yang J, Wu M, Ye B. The Effect of a Perinatal Breastfeeding Support Program
30
31 on Breastfeeding Outcomes in Primiparous Mothers. *West J Nurs Res* 2017;39(7):906–23.
32
33 doi:<https://doi.org/10.1177/0193945916670645>
34
35
- 36
37 31. Ip WY, Gao LL, Choi KC, Chau JPC, Xiao Y. The Short Form of the Breastfeeding Self-Efficacy
38
39 Scale as a Prognostic Factor of Exclusive Breastfeeding among Mandarin-Speaking Chinese
40
41 Mothers. *J Hum Lact* 2016;32(4):711–20. doi: <https://doi.org/10.1177/0890334416658014>
42
43
- 44
45 32. Wieczorek CC, Schmied H, Dorner TE, Dür W. The bumpy road to implementing the Baby-
46
47 Friendly Hospital Initiative in Austria: a qualitative study. *Int Breastfeed J* 2015; 10(1): 1–14.
48
49 doi: <https://doi.org/10.1186/s13006-015-0030-0>
50
51
- 52
53 33. Lucchini C, Lopez-Dicastillo O. Intervenciones que promueven el inicio, duración y
54
55 exclusividad de la lactancia materna: una revisión de revisiones (Interventions that promote
56
57 initiation, duration and exclusivity of breastfeeding. An umbrella review). *Horiz Enferm*
58
59 2017;28(3):33–49. doi: http://dx.doi.org/10.7764/Horiz_Enferm.28.3.33-49
60

1
2
3 34. Anstey EH, Coulter M, Jevitt CM, Perrin KM, Dabrow S, Klasko-Foster LB, Daley EM.
4
5 Lactation Consultants' Perceived Barriers to Providing Professional Breastfeeding Support. *J*
6
7
8 *Hum Lact* 2018;34(1):51-67. doi:<https://doi.org/10.1177/0890334417726305>
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Table 1. Baseline participants' socio-demographic and obstetrical characteristics (n= 112)

		IG (n=57)	CG (n=55)	P- value*
Age (years)	Mean(SD)	34.66 (4.74)	34.35 (7.67)	0.799
Number of live births	n(%)	(n=57)	(n=55)	0.977
First		28 (49.1%)	26 (47.3%)	
Second		24 (40.7%)	25 (45.5%)	
Third or subsequent		5 (8.5%)	4 (7.3%)	
BF previous experience	n(%)	(n=57)	(n=55)	0.846
Yes		29 (50.9%)	29 (52.7%)	
BF previous duration	n(%)	(n=29)	(n=29)	0.873
< 1month		1 (3.4%)	0 (0%)	
Up to 2 months		1 (3.4%)	4 (13.8%)	
Up to 3 months		1 (3.4%)	1 (3.4%)	
Up to 4 months		2 (6.9%)	4 (13.8%)	
Up to 5 months		4 (13.8%)	1 (3.4%)	
Up to 6 months		17 (58.6%)	6 (20.7%)	
> 6 months		3 (10.3%)	13 (44.8%)	
BF self-evaluation experience	n(%)	(n=29)	(n=28)	0.964
Very negative		0 (0%)	0 (0%)	

Negative		1 (3.4%)	2 (7.1%)	
Neither positive nor negative		2 (6.9%)	2 (7.1%)	
Positive		14 (48.3%)	10 (35.7%)	
Very positive		12 (41.4%)	14 (50%)	
Educational level	n(%)	(n=57)	(n=54)	0.285
Primary School		1 (1.8%)	0 (0%)	
Secondary school (High)		5 (8.8%)	4 (7.4%)	
Baccalaureate		9 (15.8%)	7 (13%)	
Job training		11 (19.3%)	8 (14.8%)	
College/University degree		31 (54.4%)	35 (64.8%)	
Marital status	n(%)	(n=55)	(n=54)	0.959
Married		40 (72.7%)	38(70.4%)	
Live as a couple		9 (16.4%)	13 (24.1%)	
Single		6 (10.9%)	2 (3.7%)	
Separated/ divorced		0 (0%)	0 (0%)	
Others		0 (0%)	1 (1.9%)	
Occupation	n(%)	(n=52)	(n=53)	0.877
Unemployed		2 (3.8%)	3 (5.7%)	
Student		2 (3.8%)	0 (0%)	
House wife		2 (3.8%)	4 (7.5%)	

Employed		45 (86.5%)	43 (81.1%)	
Others		1 (1.8%)	3 (5.7%)	
Work	n(%)	(n=46)	(n=45)	0.314
Partial time		10 (21.7%)	10 (22.2%)	
Full time		36 (78.3%)	30 (66.7%)	
Others		0 (0%)	5 (11.1%)	
Annual family income †	n(%)	(n=56)	(n=54)	
Lower income		15 (26.8%)	13 (24.1%)	0.612
Similar income		19 (33.9%)	17 (31.5%)	
Higher income		22 (39.3%)	24 (44.4%)	
Smoking	n(%)	(n=55)	(n=52)	0.572
Yes		6 (10.9%)	4 (7.7%)	
Obstetrical and BF related practices				
		IG (n=57)	CG (n=55)	P- value*
Giving birth method	n(%)	(n=57)	(n=55)	0.148
Vaginal birth		36 (63.2%)	40 (72.7%)	
Instrumental (Assisted vaginal birth)		5 (7%)	6 (10.9%)	
Caesarean		11 (9.3%)	9 (16.4%)	
Skin to skin after birth		(n=52)	(n=54)	0.371

Yes		37 (71.2%)	43 (78.2%)	
Maternal training		(n=53)	(n=54)	0.427
Yes		38 (71.7%)	43 (79.6%)	
BF training		(n=52)	(n=51)	0.134
Yes		25 (48.1%)	32 (62.7%)	

IG: Intervention Group; CG: Control Group; BF: Breastfeeding.

* T-Test for independent samples. † With respect to average income in the country (€22899 gross per year, approximately 12 payments of €1673 net, Salary Structure Survey 2011)

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Table 2. Factors associated with giving up breastfeeding (BF)

Univariate analysis*			
Variable	Category	HR(CI 95%)	p-value
Age		1.003 (0.9, 1.08)	0.942
BF previous duration	>=6 months	Ref	
	<6 months	8.21 (1.65, 40.81)	0.010
BF previous experience	No	1.43 (0.55, 3.71)	0.461
	Yes	Ref	
BF self-evaluation experience	Positive/very positive	Ref	
	Negative/ Neither positive nor negative	2.41 (0.49, 11.95)	0.282
Educational level	University degree	Ref	
	Others	0.87 (0.33, 2.28)	0.771
Group	IG	Ref	
	CG	3.30 (1.08, 10.12)	0.037
Multivariate analysis*			
Variable	Category	HR(CI 95%)	p-value
BF previous duration	>=6 months	Ref	0.042
	<6 months	7.8 (1.57, 38.7)	
	No prev. experience	4.28 (0.92, 19.82)	
Group	IG	Ref	
	CG	3.14 (1.02, 9.65)	0.047

* Cox proportional hazard regression analysis

Table 3. Breastfeeding self-efficacy mean scores by treatment group post-delivery, at 4 and 8 weeks and 6 months.

Breastfeeding Self-efficacy scores by treatment group			
	IG	CG	ITT Analysis
Measurement time	BSES-SF scores Mean(SD)	BSES-SF scores Mean(SD)	P-value*
Post-delivery	46.17 (12.00), n=53	45.13 (11.36), n=54	0.646
4 weeks	55.86 (12.84), n=51	55.76 (10.10), n=51	0.966
8 weeks	58.19 (10.50), n=43	57.42 (11.99), n=45	0.751
6 months	60.53 (7.98), n=40	57.88 (13.13), n=32	0.321

IG: Intervention group; CG: control group.

SD: standard deviation. ITT: intention to treat analyses.

* independent t-test

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3 Figure 1. Logic Model
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6 Figure 2. Participant flow chart, trial recruitment and data collection for control and
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11 Figure 3. Kaplan-Meier survival curves for breastfeeding maintenance in intervention
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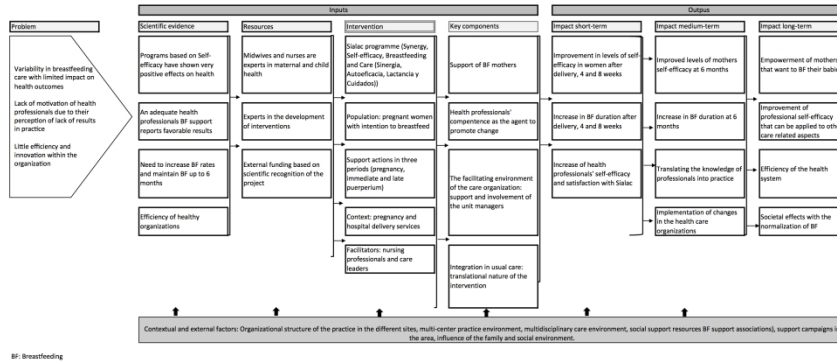
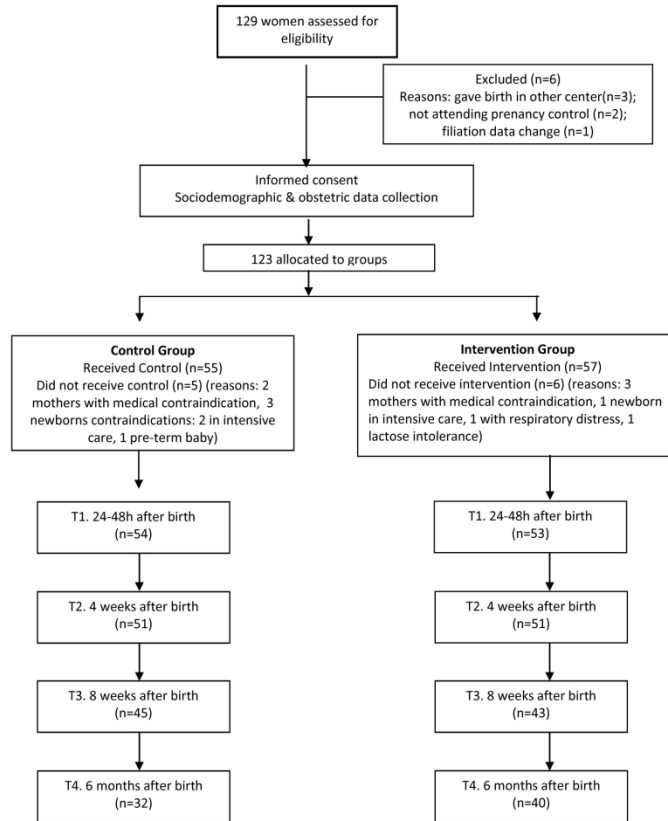


Figure 1. Logic Model

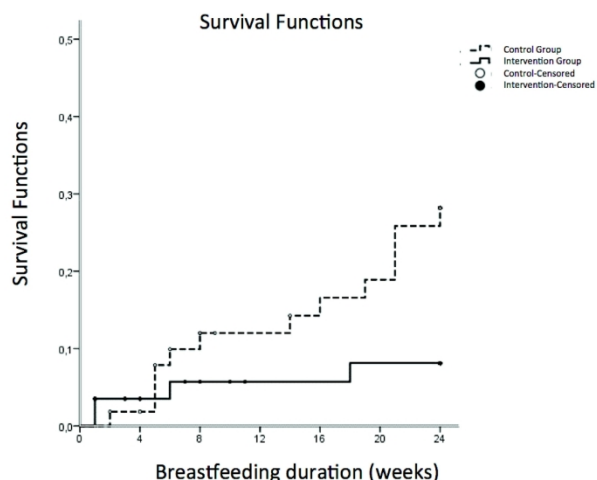
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45 Figure 2. Participant flow chart, trial recruitment and data collection for control and intervention groups

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Overall Comparisons

	Chi-Square	df	Sig.
Log Rank (Mantel-Cox)	4.94	1	0.026

Test of equality of survival distributions for the different levels of intervention

Figure 3. Kaplan-Meier survival curves for breastfeeding maintenance in intervention and control groups
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