

Monitoring of the implementation of a breastfeeding guideline for six years: a mixed-method study using an interrupted time series approach

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Abstract

Background: Current literature provides poor information about the implementation of health promoting Clinical Practice Guidelines (CPGs) and their longitudinal monitoring. **Purpose:**

The aim of this study was to evaluate the longitudinal impact of a CPG implementation program that promotes breastfeeding, its associated quantitative and qualitative indicators, and direct costs.

Design: A mixed-methods design with a longitudinal approach was utilized, with an interrupted time-series design and the analysis of reports from the implementation program as the qualitative approach.

Methods: Study setting: Maternity and pediatric units of a health area in the Spanish Health System. The implementation of a CPG for the promotion of breastfeeding was evaluated, which included a pre-implementation year (2011), 3 years of implementation (2012-2014), and 2 years of post-implementation (2015-2016). The sample was composed of the mother-infant dyads. A segmented logistic regression analysis was utilized to evaluate the changes in the most important breastfeeding indicators. A deductive thematic content analysis was performed starting with quality indicators and a descriptive economic analysis.

Findings: In the 6 years of monitoring, 7842 mother/infant dyads were recorded. The results of the quantitative indicators showed the presence of 4 stages: baseline, gain, adjustment, and sustainability/saturation. The breast milk at the first feeding had an increasing slope in the gain stage (24% per quarter; OR= 1.24, 95% confidence interval (95%CI) 1.12-1.37). The exclusive breastfeeding at hospital discharge showed significant changes in the period of gain (OR=2.45, 95%CI 1.95-3.08) which was maintained in the adjustment period, with an increase of 18% in the slope of the gain stage (OR= 1.18, 95%CI 1.06-1.32). The longitudinal distribution of the qualitative indicators showed a greater concentration of indicators towards the first half of each phase. The total cost was 209,575€ (\$248,670.17).

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3 **Conclusions:** The implementation of the BF CPG showed early, positive and sustained results
4 in the EBF rates. The implementation implied the application of a complex intervention, with
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6 its qualitative indicators showing a wave-shaped dynamic.
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10 **Clinical Relevance:** Our findings contribute to the understanding and evolution of the main
11 indicators of the implementation of a breastfeeding CPG, providing details on the magnitude of
12 the effect, the process of change, and the associated costs.
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16 **Keywords** Breastfeeding, complex interventions, guidelines, Implementation science,
17 implementation, Implementation strategies, implementation planning, time series.
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20 21 **Introduction**

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23 The World Health Organization (WHO) and the United Nations International Children's
24 Emergency Fund (UNICEF) state that the optimum breastfeeding start period for newborns is
25 within the first hour of life, as a key measure for survival and the maintenance of long-term
26 breastfeeding (BF). These institutions also recommend continuing with exclusive breastfeeding
27 (EBF) until the sixth month of life, and posteriorly with a complementary feeding until the age
28 of two or older, and also propose reaching a rate of 50% of exclusive BF at 6 months by 2025
29 (UNICEF & WHO, 2018; World Health Organization., 2014). Despite these recommendations,
30 only 44% of the infants start BF in the first hour, and only 40% exclusively BF after 6 months
31 of life (United Nations Children's Fund., 2020),
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35 Two systematic reviews on the effectiveness of diverse interventions to improve the EBF results
36 concluded that the implementation of multifaceted intervention strategies with a combination
37 of different activities was necessary, from the prenatal to the postnatal period, and including
38 both the hospital as well as the community (Kim et al., 2018; Sinha et al., 2015). The Baby-
39 Friendly Hospital Initiative (BFHI)(UNICEF & WHO, 2018) has been shown to be the most
40 effective intervention, with improvements observed in the skills and practices of the health
41 professionals in the promotion and support of BF, the center's policies, and the increase in the
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3 rates of BF initiation and duration (Kim et al., 2018; Pérez-Escamilla et al., 2016; World Health
4 Organization., 2017). However, compliance with the BFHI **has** not always **been achieved**, and
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7 the results of **the** BF rates in the short term vary (Hawkins et al., 2014; Howe-Heyman &
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10 Lutenbacher, 2016). Also, the implementation of multifaceted interventions is difficult and
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12 complex, obtaining positive results is **complicated** (Campbell et al., 2007; Cattaneo et al., 2016),
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14 and the cost-effectiveness of these interventions is unknown (Kim et al., 2018).

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17 In the last few years, the implementation of clinical practice guidelines (CPGs) has increased
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19 in **the** health services as a systematic strategy that improves healthcare and patient outcomes
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21 (Hulscher & Wensing, 2020; Shekelle et al., 2012). A review of the literature **on** the
22
23 implementation of CPGs showed **ed** that in the last decade, the studies have preferentially
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25 examined the implementation of CPGs dealing with chronic processes (high blood pressure,
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27 diabetes, pain, stroke, COPD, cancer)(Etxeberria et al., 2018; Friesen-Storms et al., 2018;
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29 McCarter et al., 2018; Pons et al., 2019; Shores et al., 2018; Tomasone et al., 2020). The
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31 strategies **utilized were** many, but the results **were** inconsistent, partly because the studies used
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33 strategies with **very** few components, the implementation **of** theoretical frameworks were not
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35 utilized, or an adequate evaluation of barriers was not performed (Gagliardi & Alhabib, 2015).
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38 Among the strategies, the training interventions for the health care professionals are the most
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40 utilized, with a positive impact on **the** professional's knowledge and behavior, although the
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42 patient outcomes are not always consistent (Gagliardi & Alhabib, 2015). On the other hand, **in**
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44 **order for** the **CPG** recommendations **to be** successfully integrated among health care
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46 professionals and their subsequent clinical practice, a change in the context of the organization
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48 is necessary (Friesen-Storms et al., 2015; Lobach & Hammond, 1997; Stetler et al., 2009). This
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50 requires the **implementation** of complex interventions that are applied to changing
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52 environments, **making difficult** its evaluation and extrapolation to different environments and
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54 contexts (Greenhalgh & Papoutsis, 2018).
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3 However, the current literature provides poor information on the implementation of health
4 promotion CPGs and their longitudinal monitoring. The scarcity of studies on the
5 implementation of the BF CPGs does not provide consistent data on the strategies utilized, the
6 changes produced throughout the implementation, or their impact on the outcomes. Only two
7 studies were found that provided results, with improvements observed on the beliefs,
8 confidence, and training of health care professionals, and a greater relationship between the
9 different levels of health care (Davies et al., 2008; Rempel & McCleary, 2012). The results on
10 the BF rates do not vary after the implementation or can even worsen (Davies et al., 2008;
11 Rempel & McCleary, 2012), and the changes required that could be favorable towards the
12 implementation of this type of CPG, in the context of the organization, providers, and users, are
13 unknown. Thus, our objective, for 6 years, was to evaluate the impact of a CPG implementation
14 program that promotes BF in a health area in Spain, by answering the following questions:

- 15 1) From the start of the implementation of the guide, how long before the first statistically
16 significant changes are detected in the BF quantitative indicators: breast milk at first feeding,
17 EBF after hospital discharge, and skin-to-skin contact?
- 18 2) How do these quantitative indicators vary during the 3 years of CPG implementation and the
19 posterior 2 years of monitoring?
- 20 3) What is the magnitude of the effect of the quantitative indicators?
- 21 4) What changes are produced on the indicators of structures, process, and results throughout
22 the implementation and sustainability of the guideline?
- 23 5) What are the direct costs derived from the 3 years of CPG implementation?

24 **METHOD**

25 **Design**

26 A mixed-methods design was utilized, which implied the combined use of quantitative and
27 qualitative methods to obtain a more complete perspective on the effect of the main quantitative
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3 indicators, as well as the contextual elements involved (Creswell & Plano, 2007). Also, to
4
5 evaluate the intervention and changes produced throughout the 6 years of the study, a
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7 longitudinal study was conducted which included data from Jan 2011 (pre-implementation) to
8
9 Jan 2017 (2 years post-implementation). An interrupted time-series design was utilized as the
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11 quantitative approach, while the qualitative one consisted of the collection and analysis of
12
13 reports and documentation derived from the implementation program. Also, a descriptive
14
15 economic evaluation of the direct costs of the implementation was performed.
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18 19 Setting and sample

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21 The health system of the Autonomous Region of Murcia is divided into different Health Areas,
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23 which are defined according to geographical areas. The study took place in Health Area III,
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25 which is composed of a medium-sized university hospital (286 beds) and 10 community health
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27 centers. The study counted with the participation of the hospital units of maternity, delivery
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29 rooms, pediatrics, and surgery, and the midwife consultation from the primary care centers.
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31 For the quantitative analysis, the sample was composed of mother-infant dyads, both primiparas
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33 and multiparas were included in the sample. The exclusion criteria were: twins or higher order
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35 multiple births, < 37 weeks of pregnancy, those born with severe anomalies, weight < 2500
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37 grams, score < 5 in the APGAR test after 5 minutes, and different hospital discharge dates of
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39 the mother/infant. For the qualitative approach, the units of analysis were the action plans,
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41 reports, and minutes created during the process of CPG implementation. For the studies on the
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43 costs, the economic reports of the Health Area III were analyzed. This health area is responsible
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45 for the unitary management of the health services offered in the geographical area where the
46
47 CPG project was implemented.
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50 51 Intervention

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53 Best Practice Spotlight Organizations®, the Registered Nurses' Association of Ontario
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3 The Best Practice Guidelines of the Registered Nurses Association of Ontario (RNAO) have
4 been implemented in Spain since 2012 following the principles of the Canadian program of
5 Best Practice Spotlight Organizations® (BPSO®), the Nursing and Healthcare Research Unit
6 from the Instituto de Salud Carlos III (Investén-isciii) coordinates this program in Spain as **the**
7 BPSO Host España. The objective of the BPSO® is to apply the RNAO guidelines utilizing
8 strategies of dissemination, implementation, and sustainability (González-María et al., 2020).
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10 The Health Area III of the Region of Murcia participated as a BPSO candidate during the 2012-
11 2015 period, with the implementation of 3 clinical practice guidelines, one of them about BF.
12 The BF CPG includes 16 evidence-based recommendations which seek to optimize the BF
13 results in the community and health organizations. It is directed **at** nurses and the inter-
14 professional team to improve their quality of care in the support for BF (Registered Nurses'
15 Association of Ontario, 2018). The recommendation were organized **into** 3 levels: 1) practice
16 recommendations, which include strategies to **provide** support **for** skin-to-skin contact, the start
17 of breastfeeding during the first hour of life, responsive cue-based breastfeeding, and effective
18 positioning, latch and milk transfer, 2) Education recommendations directed toward **promoting**
19 the continuous education of health professionals to incorporate the theoretical knowledge and
20 the practical skills related to breastfeeding, 3) Organization and system policy
21 recommendations oriented towards the compliance with legal and ethical guidelines related to
22 the relationship with industry and the adaptation of spaces and resources. This Guideline was
23 created based on the model of person- and family-centered care, in recognition of breastfeeding
24 as the optimal feeding practice and physiological norm for newborns, infants, and young
25 children when supplemented with complementary foods after six months. More specifically in
26 our study, the hypothesis was that the implementation of **the** recommendations from the guide
27 would result in the improvement of the BF indicators studied: increase in the rate of EBF after
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3 hospital discharge, increase in the initiation of EBF after birth, increase in skin-to-skin contact,
4 changes at the organizational level, in health care professionals, users, and costs.

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7 In May of 2015, the Health Area III of Autonomous Region of Murcia obtained accreditation
8 as a BPSO® center, in compliance with the conditions of the program. The implementation of
9 the BF guide followed the methodological framework adapted by the RNAO, the Knowledge
10 to Action Framework (KTA), composed of 6 phases (Figure S1): 1) identification of the
11 problem and 2) adaptations to the local context that are developed at the beginning of the year;
12 3) assessment of the facilitators and barriers; 4) adaptation and implementation of these
13 interventions; 5) monitoring and evaluation of the results that simultaneously start in the second
14 half of the first year and continue throughout the following years of implementation, and 6)
15 sustainability, which starts on the third year of implementation onward. Figure S1 describes the
16 actions followed for the implementation of the breastfeeding CPG.

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19 In the first year, an implementation committee was created, which included the Chief of
20 Nursing, the Quality Department supervisor, a Professor from the Nursing Faculty at the
21 University of Murcia (study researcher), the Head of computer systems in the area, and all the
22 leaders from each of the guides that were going to be implemented in the BPSO® program.
23 Afterwards, for the implementation of the breastfeeding guide, an implementation team was
24 created led by a midwife (study researcher), who worked as a supervisor in the
25 maternity/pediatric area, and 3 champions (2 midwives and 1 nurse from the maternity/pediatric
26 area). The members of the implementation committee and the guide leaders were trained by
27 RNAO and Investen-isciii instructors. Through the following years, the training for health care
28 professionals on the implementation of the CPG continued, and these professionals were
29 included as collaborators in the activities of the guide.

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58 This was performed using the three component model for the assessment and quality control of
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3 healthcare proposed by Donabedian (Donabedian, 1997). Indicators of structure, process, and
4 outcome were selected, and the same time, each indicator was sub-divided into four categories:
5 organization, provider, user/family, and costs. The structural indicators are related to those
6 elements of the work environment that facilitate high-quality care and include staffing, models
7 of care, and the like. Process indicators evaluate the extent to which the CPGs' practice
8 recommendations have been implemented. The outcome indicators are the specific client
9 outcomes expected from CPG use (Registered Nurse's Association of Ontario, 2012). The
10 indicators were selected from those suggested in the CPG implementation manual and the BF
11 CPG from the RNAO (Table S1) (Registered Nurse's Association of Ontario, 2012; Registered
12 Nurses' Association of Ontario, 2018). Also included were 2 quantitative outcome indicators
13 proposed by the BPSO® program, which were common to all the BF implementation guides
14 from the RNAO: 1) percent of infants who received breast milk in the first feed, 2) type of
15 feeding received by the infants 24 hours before hospital discharge, and 3) percentage of infants
16 who had skin-to-skin contact immediately or within the first 5 minutes after birth, lasting 1 hour
17 or longer. These indicators have also been recommended by the WHO, as they are related to
18 the initiation and establishment of breastfeeding (UNICEF & WHO, 2018).

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21 Likewise, data were collected related to the sociodemographic and obstetric characteristics of
22 the mother: delivery date, date of discharge, parity, start and end delivery type, use of
23 anesthesia; and the characteristics of the infant: sex, birth weight, weeks of pregnancy, APGAR
24 on the first minute and 5 minutes, and date of discharge. The data were collected from the
25 clinical histories of the maternity unit recorded by nurses and midwives during the hospital stay
26 of the mother-infant, on the computer systems of the hospital. Data were included from the last
27 12 months before the intervention (Jan 1st to Dec 31st, 2011), 3 years of implementation (Jan
28 1st, 2012, to Dec 31st, 2015), and 2 years after (Jan 1st, 2015 to Dec 31st, 2016), for a total of 72
29 months of monitoring (6 years). Also, all the reports on the activities recorded by the CPG
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3 implementation leader during the process of implementation of the CPG were collected, which
4 were kept in the quality service office of the hospital, which included: reports, plans of action,
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7 commission minutes. The economic reports of the Health Area created by the economic
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9 management unit were also included. The implementation team leader was the person in charge
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11 of providing action plans, and minutes. The correct recording of the data was ensured.
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14 Ethics approval and consent to participate

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17 The study was approved by the Ethics Committee of Clinical Research from the Health Area
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19 III from the Region of Murcia (reference number 19/05/2016). Also, it received approval from
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21 the Technical Committee of Analysis and Publications of the Program of implementation of
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23 best practice guides in Centers Committed with Excellence in Care® (BPSO® España).
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26 Data analysis

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28 The following variables were calculated: the percent of infants who received breast milk in the
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30 first feed, EBF 24 hours before hospital discharge, and skin-to-skin contact, grouped by quarter.
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32 These are shown in a time series graph (Figure 1), which shows 4 differentiated stages: 1)
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34 Baseline (Quarters 1 to 4), which include a year of pre-implementation and the first quarter of
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36 the intervention (we do not have first feed BF data), 2) Gain (quarters 5 to 7), second quarter
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38 from the start of the intervention, where a strong increase in the rates of the three indicators is
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40 observed; 3) Adjustment (quarters 8 to 12) coincides with the continuity of the intervention and
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42 the maintenance of the quantitative indicators, although some fluctuations are observed, and 4)
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44 Saturation/Sustainability (quarters 12 to 18) showing the sustainability of the indicators in the
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46 post-implementation period.
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51 To analyze the change produced in the three quantitative indicators throughout the 6 years of
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53 monitoring, a segmented logistic regression analysis was utilized. The following parameters of
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55 the model were calculated: odds ratio (OR) and the confidence interval at 95% (CI 95%) of the
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57 slope at the baseline level, degree of change, and slope change between the previously-
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3 described stages. To understand if there was a confounding variable, a comparative analysis
4 was conducted of the sociodemographic and obstetric variables of the mother and infant
5 according to the 4 stages observed, utilizing Student's t-test, ANOVA and chi-square. The
6 significant results were included in the segmented logistic regression model. The analysis was
7 performed with the SPSS v.26 statistical package for Windows. All the results were considered
8 statistically significant at $p < 0.05$.
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11 All the data provided in the reports were subjected to a deductive analysis of content, in
12 agreement with the previously-selected indicators. Starting with the detailed description of the
13 indicators, a checklist was created that was reviewed and agreed upon by the researchers. Two
14 researchers independently read and examined a total of 7 reports, 5 plans of action created
15 throughout the 3 years of implementation, and 2 years of sustainability, 4 breastfeeding
16 commission minutes, and 5 economic reports. The data obtained were codified following the
17 indicators of structure, process, and outcomes, and distributed into four categories:
18 organization, provider, user/family, and costs. The consistency between the researchers was
19 analyzed, and in the case of disagreement, a third researcher was consulted. The costs obtained
20 according to the indicators specified were added, and the mean year and daily costs were
21 calculated, as well as the cost per average number of births per year.
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41 42 **RESULTS**

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44 Initially, 9486 records (mother/infant dyads) were available, from Jan 2011 to Dec 2016. After
45 the exclusion criteria were applied, 1644 cases were eliminated, with 7842 remaining for
46 analysis (Figure S3). The mean number of deliveries per month was 108, although this value
47 oscillated between 50 in May 2011 (month 5) and 152 in September 2013, (month 33). The
48 comparison between the characteristics of the mothers and the infants in the 4 stages of the
49 study (baseline, gain, adjustment, and sustainability) showed differences in the age of the
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3 mother, parity, end of pregnancy, anesthesia use, and weeks of pregnancy, APGAR at 1 minute
4 and APGAR at 5 minutes after birth (Table S2).

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7 Significant changes were observed in the results of the rates of the quantitative indicators
8 starting in the second 4-month period from the start of the implementation, coinciding with the
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10 qualitative results related to indicators of the organization: signing of agreements, the
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12 establishment of the implementation team and work routines, updating of records; indicators of
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14 the providers: training courses and indicators of the users: access to new BF consultation, 24-
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16 open access to family members and diffusion and promotion of BF (Figure 1 and Figure S3).

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19 The results of the regression, adjusted according to the variables: age-mother, maternal parity,
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21 anesthesia, end of delivery, are shown in Figure 1 and Table S3. BF in the first feed showed a
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23 significant increase in the slope from the gain stage (24% per quarter), and a slight decrease in
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25 the slope from the adjustment phase (17%), the changes in this rate between the adjustment and
26
27 gain stages, and the sustainability and adjustment stages, were not significant. The EBF rate at
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29 discharge showed significant changes in the gain stage (145%), which was maintained in the
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31 adjustment stage and slightly decreased in the sustainability stage, without significant results.
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33 A significant increase is also observed in the slope from the gain stage (18% per quarter).
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35 Concerning skin-to-skin contact, a significant change was only observed in the gain phase,
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37 although its effect disappears in the adjusted analysis.
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47 For 6 years, the qualitative analysis starting with the selected indicators showed a distribution
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49 with a greater concentration of indicators located in the middle of the gain, adjustment, and
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51 sustainability stages, which decreased at the start and end of each stage, and which could be
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53 represented as a wave shape (Figure S2). While the trough coincides with the analysis of the
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55 quantitative indicators, the start of the ascending slope coincides with the application of
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57 measures to improve the implementation; the crest of the wave coincides with the point of
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59 maximum effect of the measures (with a greater concentration of indicators), and the
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3 descending **slope** with the progressive relaxation of these measures, reaching the trough once
4 again, with the next analysis stage signaling the start of a new wave. The changes produced in
5 the organization (Table S4) occurred **at** a specific moment, and these **were** produced especially
6 in the stages of gain and adjustment, coinciding with the greatest increase and posterior
7 stabilization of the quantitative indicators. These are mainly related to the signing of deals,
8 changes in the norms and policies **related to** BF, the development of protocols, and the creation
9 of interdisciplinary commissions in charge of their development and application. Changes were
10 also introduced in the systems of computer records for monitoring the implementation and the
11 new indicators, and human resources and materials increased.

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14 **C**hanges in the physical installations and the creation and modification of spaces occurred in
15 later stages when the adjustment and sustainability of the quantitative indicators **were** produced.
16 At the level of providers (Table S5), the high participation of health care professionals from
17 different levels of responsibility and roles in the maternity-pediatric area is highlighted,
18 including the participation of the most influential managers and clinical leaders, especially
19 midwives. An annual training plan was developed from the first stage that facilitated the
20 continuous training of health care professionals **about** BF, and the implementation of the CPGs.
21 Also, the empowerment of health care professionals was favored, **at the same time** favoring the
22 dissemination of results of the guide in different contexts. These indicators required continuity
23 so that they were repeated **at** all the stages. The results **found** on the users and families (Table
24 S6) **were** related to the **creation** of spaces, schedules, and informational materials directed
25 towards their stay, training, and information and the improvement of their care.

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28 The costs derived from the implementation of the CPG were incurred throughout all the stages,
29 implying a total cost of 209,575€ (\$248,670.17), with a yearly mean of 41,915€ (\$49,734.03)
30 and a daily one of 114.83€ (\$136.25). Assuming a mean of 1307 births per year, this implied
31 an expense of 32€ (\$37.97) per birth. The detailed cost distribution is shown in table S6. The

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3 SC3 and SC4 indicators, related to the cost of spaces, physical resources, and electronic records
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5 have not been included, as these costs were not exclusive to the guide.
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8 **Discussion**

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10 Our findings show a longitudinal view of the implementation of a BF CPG in a health area of
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12 the Spanish National Healthcare System. The intervention had an initial duration of 3 years,
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14 which **is** the estimated time needed by the CPG implementation program of the RNAO to be
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16 accredited as a BPSO®, and it consisted of a multifaceted intervention led by midwives and
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18 nurses, with a multi-professional approach and based on the KTA framework (González-María
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20 et al., 2020). The implementation was shown to be a dynamic process, with a fast start in phases
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22 1 and 2 of the KTA framework in the first months of implementation. Phases 3, 4, and 5 were
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24 addressed almost simultaneously from the middle of the first year, with the evaluation of
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26 barriers and facilitators, implementation of multiple strategies, and monitoring/evaluation. This
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28 was shown to be, as any complex system, an iterative process, with the appearance of new
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30 barriers that created the need to re-adapt the interventions as new changes were applied and the
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32 understanding of the context increased (Reed et al., 2018). Lastly, sustainability was present
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34 starting **on** the third year of implementation and continued during the **following** 2 years of
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36 monitoring, in which barriers for sustainability were assessed and new interventions were
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38 adapted (Graham et al., 2006).
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44 The positive effects of the implementation, in relation to the behavior **observed** of the
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46 quantitative indicators in the timeline studied, are shown as four differentiated stages: baseline,
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48 gain, adjustment, and saturation/sustainability. The baseline was the period previous to the
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50 implementation which served **d** as the reference point for comparing the changes observed after
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52 the implementation. The gain stage was the period in which a pronounced increase was
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54 observed of the outcome indicators in a brief **period of** time, appearing early after the start of
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56 implementation. The adjustment stage started when the indicators reached **a** certain stability,
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3 although some fluctuations were observed. Lastly, a saturation/sustainability phase was
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5 observed where the indicators were stabilized **for** at least two years after the implementation,
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7 and it seemed that the interventions were no longer able to improve, thereby reaching a point
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9 of saturation. The longitudinal distribution of the qualitative indicators showed agreement with
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11 the previous data, as a greater concentration of indicators was observed in the middle of each
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13 phase. Also, it was observed that the indicators related to the structure were unique events,
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15 occurring once, although their effect lasted through time, while the indicators related to the
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17 health care professionals were repeated throughout the years of monitoring. This is a response
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19 to the adaptation of the indicators, and the complexity of this type of context.
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24 The rates of infants who received breast milk in the first feed significantly **increased** in the gain
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26 stage, shifting from a rate of 70%, a result that was higher to those known internationally
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28 (Breastfeeding Committee - Spanish Association of Pediatrics, 2016), to 90-95%, exceeding
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30 the WHO recommendations (UNICEF & WHO, 2018). The intervention had a greater effect
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32 on the rates of EBF at hospital discharge, higher than the mean increase observed in other
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34 studies which **had** also applied the BPSO® program (Davies et al., 2008; Del Rio-Martínez et
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36 al., 2020; Rempel & McCleary, 2012). A significant and important increase **was also observed**
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38 in the gain and adjustment stages, with rates close to 75%, which were very near to those
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40 recommended by the WHO (UNICEF & WHO, 2018). The skin-to-skin rates also increased,
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42 reaching values close to 80%, as recommended by the WHO (UNICEF & WHO, 2018),
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44 although significant differences were not found in the stages **prior**. Data were possibly affected
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46 by the greater number of cesarean sections in the baseline stage.
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51 The qualitative indicators evaluated showed changes mainly at the organizational level, and in
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53 second place at the level of the health care professionals, users, and costs. The Content, Context,
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55 and Process model (Pettigrew et al., 1992) describes if a context is receptive to change through
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57 8 factors. Among the changes produced at the level of **the** organizational context in our study,
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3 6 of these factors were observed. The first factor, The Quality and Coherence of Policy, was
4 observed in the agreement and development of an explanatory policy/view of support to BF by
5 the institution, which is coherent with other measures **applied**, such as the increase in human
6 resources (hiring of a midwife) and materials (improvement of physical installations,
7 acquisition of breast pumps), the application of the international code of marketing breast-milk
8 substitutes, modification of the **system of records**, and the adaptation of access to obstetric units.

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17 The second factor, Availability of Key People Leading Change, has been described as one of
18 the most influential elements (Stetler et al., 2009). Our results showed the participation and
19 leadership of key influential people in diverse environments: managers at different levels of the
20 institution, formal and informal clinical leaders, such as midwives and nurses (frontline
21 clinicians), and experts in **the practice** based on evidence from the university. As postulated by
22 the Theory of Motivating Change, positive peer pressure is a healthy competitiveness whereby
23 the outward display of intrinsic motivation for change in one individual becomes an extrinsic
24 motivator for another (Breckenridge et al., 2019). Also, the selection of the guideline leaders
25 and promoters was conducted **by considering** the personal aptitudes to a greater degree than the
26 professional level, understanding their important roles **as mentors** of other professionals. The
27 Environmental Pressure-Intensity, Scale and Orchestration, the third factor in the model, was
28 shown as the commitment acquired by the management **teams** in the Health Area, with the
29 signing of an agreement with the BPSO Host España for the implementation and performance
30 of monitoring audits, as well as the accreditation after 3 years of implementation and re-
31 accreditation every 2 years (González-María et al., 2020).

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51 The fourth factor, a Supportive Organizational Culture, key in the sustainability of the CPGs
52 (Higuchi et al., 2011), **grew** and **expanded** every year **at** the hospital units involved thanks to
53 the addition of intervention protocols, computer records, materials, and documents for
54 **informing** users and families, and the application of policies that favored BF, and the continuous
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3 training of a large number of health care professionals with different profiles (midwives, nurses,
4 technicians, physicians). These measures favored the use of a systematic and common language
5 between professionals, which reflected the way of thinking and acting that was analogous to
6 their equals (Harillo-Acevedo et al., 2019). Effective Managerial/Clinical Relations was the
7 fifth factor that facilitated change, and our findings showed the creation of multidisciplinary
8 work commissions with scheduled meetings, whose function was to study the barriers and
9 facilitators, and to propose activities in the action plan. This implied the institutionalization of
10 collaborative work, where the making of decisions was conducted in a decentralized manner,
11 favoring the consensus and coordination among health care professionals. The Co-operative
12 Inter-organizational Networks was the sixth factor, and in our results the participation of the
13 members from Investen-isciii, the University and BF support groups was key, as observed in
14 other studies, as it maximizes the potential for successful implementation through collaborative
15 partnerships (Swaites et al., 2020).

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33 The training of health care professionals, a strategy that is commonly utilized in the
34 implementation of a CPG (Gagliardi & Alhabib, 2015), was repeated throughout the present
35 implementation process, obtaining high percentages of health care professionals who became
36 adequately trained, a factor that is positively associated with the increase in BF rates at hospitals
37 (Tomasone et al., 2020). On the other hand, the indicators related to the users showed important
38 changes directed at supporting and empowering the mothers who breastfed their children after
39 delivery. As promoted by the WHO, open-door policies, skin-to-skin protocols, and
40 modifications to the physical surroundings that facilitate the family's access and stay, were
41 developed and implemented (UNICEF & WHO, 2018). The evaluation of direct costs derived
42 from the implementation of the BF CPG showed a mean annual investment per birth of 32€
43 (\$37.97) in the Health Area, which is similar to the costs reported in international studies
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(Holla-Bhar et al., 2015). This is a minimum investment, taking into account the impact to the costs of health care for children and women when BF is inadequate (Bartick et al., 2017).

The results obtained were very positive and placed the midwives and nurses as clinical leaders, promoters of changes at the level of structure, processes, and health outcomes. In spite of this, the health care professionals cannot achieve success alone, and a favorable surrounding is needed that allows the health care professionals to be the managers of change, including multidisciplinary participation and the implication of managers and informal leaders (Ramos-Morcillo et al., 2020).

Limitations of the study

The study was conducted in a single location with specific characteristics (population, infrastructure, resources, etc.), which limits the extrapolation of the results to other contexts. Also, a control group was not available, so caution is required when concluding that the intervention was the cause of improvement in the results obtained. The implementation of a CPG is a complex, multi-component intervention, and the contribution of each strategy to the overall results is difficult to quantify.

It would be interesting to conduct future research studies utilizing more robust designs including a control group. Also, results are still pending on the changes of the main indicators in the long term after the first few years of sustainability, and the evaluation of the cost-effectiveness of the new interventions that allow surpassing the levels reached in the saturation stage.

Conclusions

The implementation of a BF CPG following the BPSO® program from the RNAO has shown early, positive and sustained results in BF rates. The longitudinal impact of these indicators followed a temporal model divided into 4 stages, baseline, gain, adjustment, and saturation/sustainability. The implementation involved the application of a complex

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3 intervention that acted at the macro, meso, and micro levels and required a constant adaptation
4 to barriers, and changing and complex environments. As a result, a wave-shaped dynamic
5 response was observed at the organizational, provider, and user indicators levels. The changes
6 at the level of organization policies, the leadership of the health care professionals, counting
7 with a culture of support, and the environmental pressure, were key elements for the success of
8 the implementation of the CPG and its sustainability through time. The implementation
9 signified the shifting of important resources, collaboration between health care professionals
10 and institutions, and a clear orientation towards the improvement of care for mothers and their
11 families, with a discrete economic expense.

23 Clinical Resources

24 Nursing Best Practice Guidelines. <https://mao.ca/bpg>

25 NICE Postnatal care. <https://www.nice.org.uk/guidance/qs37/chapter/Quality-statement-5->

30 Breastfeeding

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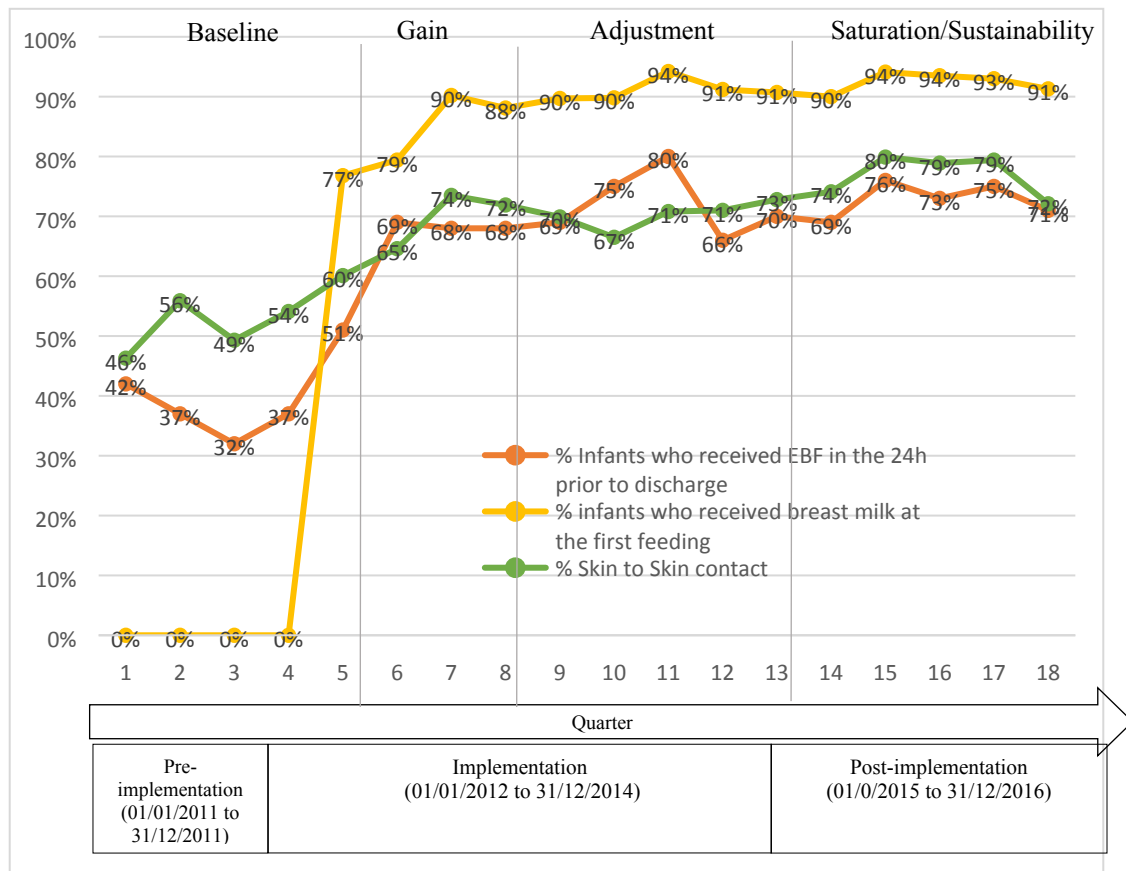


Figure 1. Exclusive breastfeeding rates in the first feed, at hospital discharge and skin-to-skin contact according to quarter monitored

Table S1. Indicators for the evaluation of the Breastfeeding clinical practice guideline

CATEGORY	STRUCTURE (what is needed)	PROCESS (how to do it)	OUTCOME (what happens)
Organization/ Unit	<p>SO1. Policy that clearly identifies the necessary practice</p> <p>SO2. Professional committees. Interprofessional participation.</p> <p>SO3. Synergies with collaborators and external influence.</p> <p>SO4. Forms that facilitated adherence to the guide.</p> <p>SO5. Adaptation of physical installations.</p> <p>SO6. Acquisition of materials and equipment.</p>	<p>PO1. Participation and responsibility of the leading managers and of clinical practice.</p> <p>PO2. Development/modification of policies and procedures.</p> <p>PO3. Meetings with interprofessional teams, affiliation to committees.</p> <p>PO4. Standardized documentation and tools.</p> <p>PO5. Record systems</p> <p>PO6. Responsibility with hiring.</p> <p>PO7. Participation of volunteers.</p>	<p>OO1. Evidence-based philosophy, a strategic aim adapted for everyone.</p> <p>OO2. Promoting common language and consistent terminology.</p> <p>OO3. Increase of awareness of interprofessional communication and interconsultations.</p> <p>OO4. Adequate access to services.</p> <p>OO5. Achieving of objectives related to the improvement of results in patients through the results.</p> <p>OO6. Organization responsibility: monitoring for ensuring quality.</p> <p>OO7. External responsibility through agreements, indicators of accreditation.</p>
Provider	<p>SP1. Number and qualification of staff.</p> <p>SP2. Multidisciplinary collaboration. Roles.</p> <p>SP3. Training-education program.</p>	<p>PP1. and PP2. Awareness/attitude towards the CPG. Knowledge/level of skills.</p> <p>PP3. Leadership of identified promoters/nurses</p>	<p>OP1. Attendance to training program.</p> <p>OP2. Satisfaction of the professionals.</p>
User/Family	<p>SU1. Patient-focused care.</p> <p>SU2. Involvement in the care through the continuity of care.</p>	<p>PU1. Knowledge added from the patients/families during the admission, discharge and transition plan to support groups, care meetings.</p>	<p>OU1. Access</p> <p>OU2. Satisfaction with care received.</p>
Costs	<p>SC1. Cost of additional personnel.</p> <p>SC2. New supplies needed</p> <p>SC3. Cost of documentation, patient forms, electronic records and modification.</p> <p>SC4. Cost of physical spaces and resources.</p>	<p>PC1. Economic support for the training of the staff.</p> <p>PC2. Dissemination of the results of the guide.</p>	<p>OC1. Incremental costs of innovation, included the product costs.</p>

Note:

Interpretation of the acronyms of the indicators: First letter: S=structural, P= process; O=outcome; Second letter: O=organization; P=provider; U=User/Family; C=cost; Lastly, the number corresponds to the order number which corresponds to the indicator in each sub-section.

Table S2. Comparison of the sociodemographic and obstetric variables of the **mothers and infants** grouped according to the **4 stages observed on the follow up**

	BASELINE n= 1795	GAIN n= 1326	ADJUSTMENT n= 2245	SUSTAINABILITY n= 2476	P- value
Age-mother (years)					
mean (SD)	36.2 (5.85)	35.1 (5.76)	34.2 (5.90)	32.6 (6.05)	0.000
Parity					
Primipara %(n)	35.9 (643)	37.6 (496)	35.8 (799)	32.3 (794)	0.005
Multipara %(n)	64.1 (115)	62.4 (824)	64.2 (1430)	67.7 (1663)	
Start delivery					
Non spontaneous %(n)	37.2 (659)	33.6 (409)	33.7 (689)	34.0 (767)	0.079
Spontaneous %(n)	62.8 (1114)	66.4 (808)	66.3 (1357)	66.0 (1486)	
End delivery					
Dystocic %(n)	47.4 (840)	37.1 (451)	37.0 (758)	36.1 (814)	0.000
Eutocic %(n)	52.6 (931)	62.9 (766)	63.0 (1288)	63.9 (1439)	
Anesthesia					
With anesthesia %(n)	49.9 (885)	43.2 (526)	47.5 (971)	46.2 (1041)	0.003
Without anesthesia %(n)	50.1 (888)	56.8 (691)	52.5 (971)	53.8 (1212)	
Sex infant					
Boy %(n)	51.0 (914)	48.2 (638)	50.8 (1141)	52.0 (1287)	0.173
Girl %(n)	49.0 (887)	51.8 (685)	49.2 (1103)	48.0 (118)	
Weeks pregnancy					
mean (SD)	39.4 (1.14)	39.3 (1.17)	39.4 (1.12)	39.4 (1.13)	0.035
Weight infant (gr)					
mean (SD)	3402 (421.5)	3372 (414.6)	3383 (423.2)	3378 (416.8)	0.178
APGAR minute 1					
mean (SD)	8.9 (0.8)	9.0 (0.8)	9.1 (0.7)	9.0 (0.7)	0.000
APGAR minute 5					
mean (SD)	9.8 (0.3)	9.9 (0.3)	9.9 (0.3)	9.9 (0.3)	0.000

SD: standard deviation

Table S3. Segmented logistic regression analysis of the indicators evaluated (n = 7842)

BF First Feeding	ORr	95%CI	P-value	ORa	95%CI	P-value
Baseline Trend	NA	NA	NA	NA	NA	NA
Level change after Gain	NA	NA	NA	NA	NA	NA
Trend change after Gain	1.23	1.13—1.35	0.000	1.24	1.12—1.37	0.000
Level change after Adjust	0.91	0.62—1.34	0.647	0.93	0.61—1.41	0.739
Trend change after Adjust	0.85	0.75—0.97	0.014	0.85	0.74—0.97	0.023
Level change Sustainability	0.58	0.30—1.10	0.536	0.55	0.27—1.11	0.096
EBF Discharge	ORr	95%CI	P-value	ORa	95%CI	P-value
Baseline Trend	0.95	0.87—1.03	0.257	0.95	0.87-1.03	0.254
Level change after Gain	2.50	2.01—3.11	0,000	2.45	1.95—3.08	0.000
Trend change after Gain	1.15	1.04—1.28	0,006	1.18	1.06—1.32	0.002
Level change after Adjust	2.65	1.81—3.89	0,000	2.43	1.62—3.64	0.000
Trend change after Adjust	0.94	0.87—1.02	0,152	0.92	0.86—1.06	0.070
Level change Sustainability	2.06	1.23—3.47	0,006	1.72	0.99—1.06	0.054
Skin-to-skin contact	ORr	95%CI	P-value	ORa	95%CI	P-value
Baseline Trend	1.07	0.99—1.17	0.081	1.12	1.02—1.23	0.018
Level change after Gain	1.45	1.16—1.82	0.001	1.12	0.86—1.45	0.381
Trend change after Gain	0.98	0.88—1.08	0.739	0.96	0.85—1.08	0.534
Level change after Adjust	1.43	0.96—2.13	0.076	1.07	0.67—1.70	0.766
Trend change after Adjust	0.96	0.88—1.04	0.385	0.97	0.88—1.07	0.612
Level change Sustainability	1.62	0.94—2.80	0.080	1.21	0.64—2.30	0.550

ORr: Odds Ratio raw; ORa: Odds Ratio adjusted. NA: Not applicable. BF: breastfeeding, EBF: exclusive breastfeeding; 95%CI: 95% coefficient interval

Variables of adjustment: Age-mother, maternal parity, anesthesia, end of delivery.

Table S4. Results in the Organization according to indicators of structure, process and outcome

STRUCTURE	PROCESS	OUTCOME
<p>SO1. Creation of institutional policy on BF with the unification of criteria related to procedures for clinical practice.</p> <p>SO2. - Creation of team of Project Coordinators. Nurse management, Director of Quality Department, Director of Training Department, Supervisors of units involved, Informatics officer, University professor. - Creation of BF CPG implementation team. Midwife leader and collaborating midwives and nurses. - 3 breastfeeding commissions created.</p> <p>SO3. - Investén-isciii (Health Care Research Unit. Institute of Health Carlos III. Science and Innovation Minister) - Faculty of Health and Social Sciences at the University of Murcia - BF support groups</p> <p>SO4. - Electronic recording of medical histories: • Creation of form for monitoring BF. • Inclusion of milk culture option. • Creation of report on care continuity after discharge.</p> <p>SO5. - Remodeling of neonatal unit: expansion of spaces, room for families, breastfeeding room. - New delivery areas with individual rooms for dilation, delivery and post-delivery. - Creation of new BF consultation room.</p>	<p>PO1. - Manager of the Area of Health and Nursing Director responsible for implementation agreement. - Intermediate managers (area of quality supervisor, supervisors of the maternal-pediatric units) and clinical leaders form part of the committee of implementation of the guide. - External collaborators from the University provide theoretical and methodological support.</p> <p>PO2. - Application of the international code of marketing breast-milk substitutes (removal of baby bottles donated by laboratories, formula feeding advertising material, baby boxes with products). - Creation of new protocols: • Breastfeeding. • Skin-to-skin contact after delivery and cesarean sections. • Low intervention delivery. • Kangaroo method.</p> <p>PO3. - Team of Project Coordinators with monthly meetings. - BF CPG implementation team with monthly meetings. - Nursing commission comprised by multidisciplinary team. (4 midwives, 4 nurses, 5 nursing aids, 3 pediatricians, 1 obstetrician, 1 anesthesiologist, 1 pharmacist, 4 executive positions, 2 BF support groups)</p> <p>PO4. - Implementation and application of milk cultures for the diagnosis of mastitis.</p>	<p>OO1. - Creation of an institutional document about the mission, vision and values, promoting an organization culture with a work philosophy based on evidence.</p> <p>OO2. - Incorporation of the new protocols in the daily clinical practice.</p> <p>OO3. - Biannual meetings are standardized for the organization and planning of the sustainability of the guide in the BF Commission.</p> <p>OO4. - Creation of a neonatal unit with a 24-hour open-door policy.</p> <p>OO5. - Indicators of result linked to the portfolio of services in the area of health. - Increase in BF in the first hour after delivery and hospital discharge (figure 2).</p> <p>OO6. - Preparation of BFHI accreditation at the hospital and 1 Primary Care center. - A 100% monitoring of BF is achieved.</p> <p>OO7. - Signing of an agreement with Investén-isciii for tutoring and support. Delivery of biannual reports including an updated census listing the leaders and promoters involved and the BF indicators. - BPSO® accreditation in 2015. - Commitment of accreditation every 2 years.</p>

<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46</p> <p>- New breastfeeding room in the maternity Ward. SO6. - Equipping the maternity-pediatric units with electric breast pumps. - Equipping with new computer systems for monitoring BF.</p>	<p>- Updating of document for mothers “breastfeeding is the best start”. PO5. - Recording of indicators: start of BF in the first intake and type of BF at hospital discharge. - Recording of milk culture. - Recording of phone call before the first 48 hours after discharge from primary care PO6. - An expert midwife from the staff is freed to train the health professionals in working hours. - Hiring of a midwife for BF consultation. PO7. - Breastfeeding support groups participate voluntarily in the BF commission.</p>	
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Table S5. Results of the Providers according to indicators of structure, process and outcome

STRUCTURE	PROCESS	OUTCOME
<p>SP1. - Staff with participation in the guideline: Nurses:51; midwives:22; nursing aids:52; pediatricians:14; obstetricians:21; anesthesiologists:15; orderlies: 6</p> <p>SP2. - Managers: Quality supervisor, supervisor of the obstetric area, supervisors of pediatrics and maternity. - Clinicians different roles: midwives, nurses, nursing aids, pediatricians, obstetricians, anesthesiologists, pharmacists. - Academicians: expert professor in evidence-based practice, coordination of the implementation of the guide.</p> <p>SP3. Development of an annual training plan:</p> <ul style="list-style-type: none"> ▪ Course on the implementation of CPGs (promoters are recruited and trained on the implementation of the CPG). ▪ Course on the use of the computer program (skills on the monitoring of child nursing) ▪ Training course on BF (courses conducted in small, 2-3 person groups during work hours by expert personnel). 	<p>PP1. and PP2. The professionals in the obstetric area improved their pre-implementation (2011) and post-implementation (2016) beliefs and subjective standards (published data, Harillo-Acevedo et al 2019)</p> <p>PP3. - An implementation guideline committee is established (guideline leader and collaborators) selecting through convenience the professionals with a special implication in this subject.</p> <p>- Dissemination of data obtained from the guide with different events:</p> <ul style="list-style-type: none"> • Regional forum on sexual and reproductive health 2013. • South-Eastern Pediatrics Society meeting 2014. • Scientific symposiums 2014. • Annual scientific symposiums. Faculty of Public Health. University of Murcia • International Meetings in 2016, 2017. • National BF Meeting 2013. 	<p>OP1. - Training of the implementation of the guide for 3 professionals (years 2012-2016). - Training of 19 midwives and 24 nurses from the obstetric area on the use of the computer program for monitoring baby’s records (years 2012). - Training of multidisciplinary team on BF. Year 2012: 27 nurses, 22 nursing aids, 17 midwives, 8 resident nurses. Year 2013: 14 nurses, 9 nursing aids, 10 midwives, 6 physicians, 2 resident nurses and 2 resident physicians. Year 2014: 14 nurses, 12 nursing aids, 1 midwife, 1 resident nurse. Year 2015: 25 nurses, nursing aids, 13 midwives, 1 physician, 3 resident nurses. Year 2016: 66 nurses, 28 nursing aids, 10 midwives, 16 physicians, 5 resident nurses and 12 resident physicians.</p> <p>OP2. The health professionals assess the implementation of the guide as positive. They feel more confident and are able to face complex situation. They are satisfied because they act based on a scientific background (Ramos-Morcillo et al 2020).</p>

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Table S6. Results of the User/Family and Costs of implementation according indicators of structure, process and outcome

STRUCTURE	PROCESS	OUTCOME
User/family		
<p>SU1. - Involvement of the user and family in the care: Delivery unit: individual dilation, delivery and post-delivery rooms are created. Neonatal unit: A 24 open-door unit is created. Maternity unit: Co-habitation is implemented so that the mother and child are not separated during the entire hospital stay, so that the mother is able to provide the child with care after delivery.</p> <p>SU2. - Implementation of a telephone call to the home of the postpartum women 48 after hospital discharge by the primary care midwife.</p>	<p>PU1. Dissemination of the users about the CPG and promotion of BF through:</p> <ul style="list-style-type: none"> - Signage about the BF policy and its promotion in the maternity/pediatric units. - Information about BF: handing out of a leaflet about monitoring of pregnancy in primary care. Showing of a video in hospital TV channel "Breastfeeding does not have a schedule". - Written and verbal information about BF support groups for users and BF support groups near their home. - Review of the prenatal maternal education related with BF. 	<p>OU1. - In the 10 Health Centers, a consultation was included in the monitoring of the pregnancy (week 32 of the pregnancy), to assess the intention to BF, the environment and the knowledge. - Access to new BF consultation for the postnatal advice of the users. - 24 hour open access to family members of the neonatal unit. - Choosing companion during the delivery process.</p> <p>OU2. The users describe the presence of improvements during the process of implementation of the guide, as their experiences have been more and more positive during their different hospital admissions due to the births of their children, before and after the implementation (data in press).</p>
Costs		
<p>SC1: Human resources - Hiring of a midwife: 33,023.00€ (\$38.855,03)/year</p> <p>SC2: Physical resources - Purchasing of breast pumps: 1,824€ (\$2.146,13)/year</p>	<p>PC1: Training of the staff - Hiring of experts for providing training to the multidisciplinary team. Cost: 3.540€ (\$4.165,18) for the period of study (708 euros (\$833,04)/year).</p> <p>PC2: Dissemination of the CPG results. - Paying of enrollment fees for meetings for the dissemination of the implementation results: 960€ (\$1.129,54) during the period of study (320€ (\$376,51)/year).</p>	<p>OC1: Incremental costs of the innovation including the costs of the products. - Acquisition of formula milk by the institution for avoiding the use of milk donated by different commercial brands, with a mean annual cost of 6200€ (\$7.294,95).</p>

Figure S1. Implementation of the Breastfeeding Clinical Practice Guidelines according to the Knowledge-To-Action Framework 6 phases

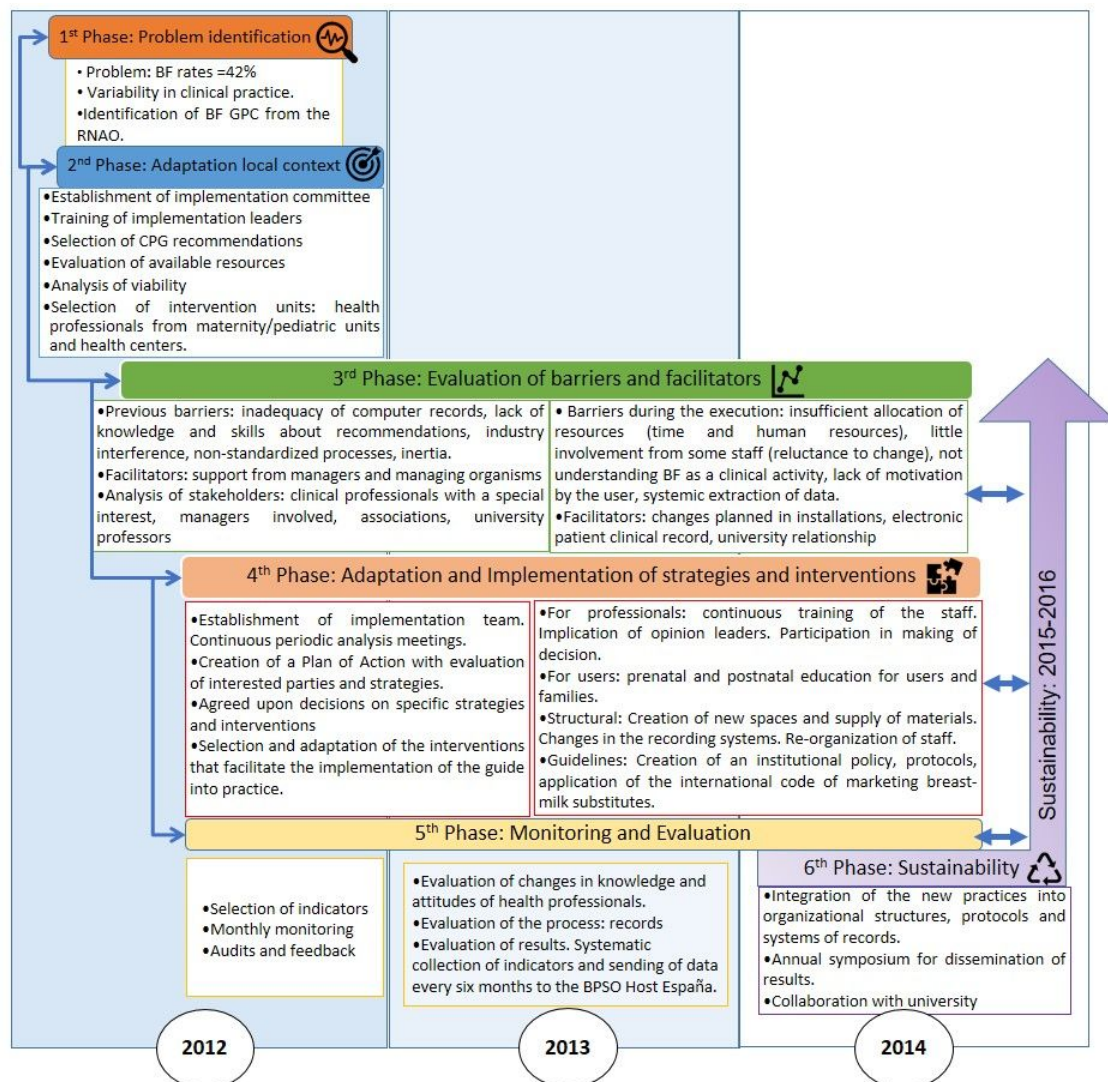


Figure S1. Implementation of the Breastfeeding Clinical Practice Guidelines according to the Knowledge-To-Action Framework 6 phases

Figure S2. Study participants flow chart

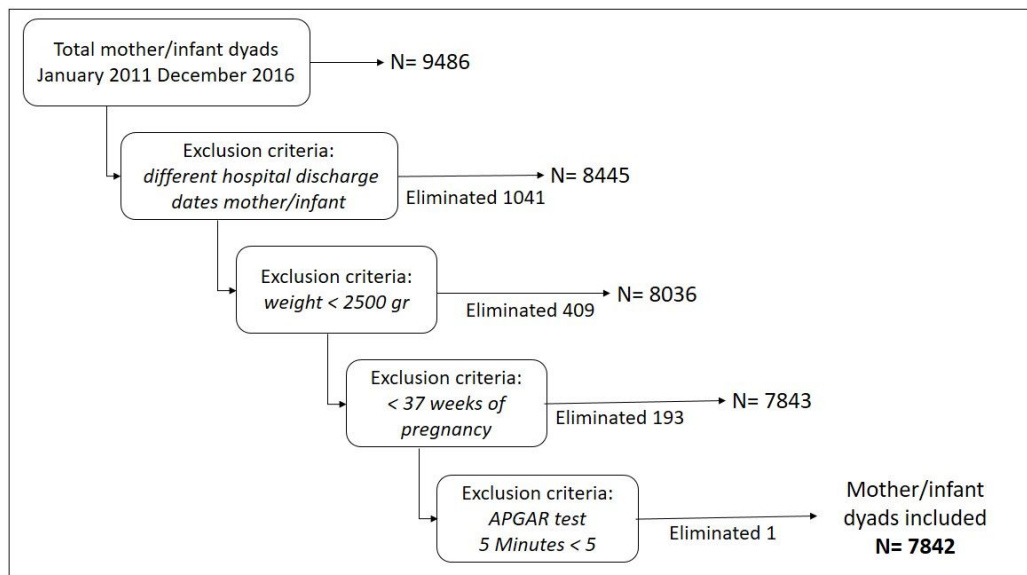


Figure S2. Study participants flow chart

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