

## REVIEW ARTICLE

# Pacifier use and interruption of exclusive breastfeeding: Systematic review and meta-analysis

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## Abstract

Identifying modifiable risk factor for exclusive breastfeeding (EBF) interruption is key for improving child health globally. There is no consensus about the effect of pacifier use on EBF interruption. Thus, the aim of this systematic review was to investigate the association between pacifier use and EBF interruption during the first six month. A search of CINAHL, Scopus, Web of Science, LILACS and Medline; from inception through 30 December 2014 without restriction of language yielded 1,866 publications (PROSPERO protocol CRD42014014527). Predetermined inclusion/exclusion criteria peer reviewed yielded 46 studies: two clinical trials, 20 longitudinal, and 24 cross-sectional studies. Meta-analysis was performed and meta-regression explored heterogeneity across studies. The pooled effect of the association between pacifier use and EBF interruption was 2.48 OR (95% CI = 2.16–2.85). Heterogeneity was explained by the study design (40.2%), followed by differences in the measurement and categorization of pacifier use, the methodological quality of the studies and the socio-economic context. Two RCT's with very limited external validity found a null association, but 44 observational studies, including 20 prospective cohort studies, did find a consistent association between pacifier use and risk of EBF interruption (OR = 2.28; 95% CI = 1.78–2.93). Our findings support the current WHO recommendation on pacifier use as it focuses on the risk of poor breastfeeding outcomes as a result of pacifier use. Future studies that take into account the risks and benefits of pacifier use are needed to clarify this recommendation.

## KEYWORDS

exclusive breastfeeding, meta-analysis, meta-regression, pacifiers, risk factors, systematic review

## 1 | INTRODUCTION

The recommendation of the World Health Organization (WHO) is that exclusive breastfeeding (EBF) should be practiced until the sixth month of life of the infant because it prevents child mortality and promotes quality of life in the short and long-term (Victora, Aluísio, Barros, França, et al., 2016; Grummer-Strawn & Rollins, 2015; Sankar et al., 2015; Horta, Loret de Mola, & Victora, 2015; Lodge et al., 2015; Peres, Cascaes, Nascimento, & Victora, 2015; Horta, Bahl, Martines, & Victora, 2013). Unfortunately, EBF duration remains substantially lower around the world (Labbok, Wardlaw, Blanc, Clark, & Terreri, 2006; Cai, Wardlaw, & Brown, 2012; Victora et al., 2016) making the identification of modifiable risk factors for lack of EBF a high priority.

Pacifier use has been identified as a factor associated with shorter duration of EBF in observational studies (Vogel, Hutchison, & Mitchell,

2001; Hörnell, Aarts, Kylberg, Hofvander, & Gebre-Medhin, 1999; Victora, Behague, Barros, Olinto, & Weiderpass, 1997). A recent cross-sectional analysis conducted with data from two Brazilian surveys showed that pacifier use was inversely associated with EBF rates with this association remaining stable across time (Buccini, Perez-Escamilla, & Venancio, 2016). However, because of potential confounding it is unknown if this relationship is indeed causal (Fein, 2009; Cunha, Leite, & Machado, 2009). While researchers have suggested that pacifier use might interfere with the establishment breastfeeding (Neifert, Lawrence, & Seacat, 1995; Righard, 1998; Kronborg & Vaeth, 2009) others have suggested that pacifier use is simply a marker of breastfeeding problems (Victora et al., 1997; Kramer et al., 2001). Consequently, the recommendations for pacifier use vary worldwide (Eidelman et al., 2012; Sexton & Natale, 2009; World Health Organization [WHO], 2008; Canadian Paediatric Society

Community Paediatrics Committee, 2003). WHO strongly discourages the use of pacifiers in breastfed children (World Health Organization [WHO], 2008), with this recommendation being one of the Ten Steps to Successful Breastfeeding upon which the Baby-Friendly Hospital Initiative is based (Perez-Escamilla, Martinez, & Segura-Perez, 2016; Passanha, Benicio, Venancio, & Reis, 2015; DiGirolamo, Grummer-Strawn, & Fein, 2008). On the other hand, the American Academy of Pediatrics recommends using pacifiers to prevent sudden infant death syndrome (SIDS) and there is a general recommendation that pacifiers can be introduced after breastfeeding is well established, at approximately 3 to 4 weeks of age (Eidelman et al., 2012). Accordingly, it has been a challenge for health professionals and parents to have a clear understanding of what to recommend or do in different contexts (e.g., a newborn at high risk of SIDS vs. a mom who is very concerned about following practices that may interfere with EBF).

Systematic reviews (O'Connor, Tanabe, Siadat, & Hauck, 2009; Santos Neto, Oliveira, Zandonade, & Molina, 2008) and meta-analyses (Jaafar, Jahanfar, Angolkar, & Ho, 2012; Karabulut, Yalçın, Ozdemir-Geyik, & Karağaoğlu, 2009) examining the relationship between pacifier use and breastfeeding outcomes have found conflicting results. While reviews based on observational studies have concluded that pacifier use is a risk factor for a reduction in EBF duration (Santos Neto et al., 2008; Karabulut et al., 2009), those that have focused only on RCTs have reported no differences on the duration of EBF as a result of pacifier's interventions (O'Connor et al. 2009; Jaafar et al., 2012). Furthermore, the search and selection criteria used vary greatly across reviews, that is, very strict inclusion criteria leading to the inclusion of just two studies (Jaffar et al. 2012), date restriction (Santos Neto et al., 2008; O'Connor et al., 2009) or language restriction (O'Connor et al., 2009; Karabulut et al., 2009). These methodological variations across reviews call for a more comprehensive review approach that allows for capturing the whole body of evidence. Specifically, it's important to assess both observational and experimental studies without imposing date or language restriction. New reviews in this area also need to address effect modification related to study design characteristics (e.g., observational vs. experimental design, sample size, study socio-economic setting, outcome and exposure measures, and study quality). Therefore, in order to support clinical practice and provide evidence for policies to promote and protect breastfeeding, this study aimed

to perform a comprehensive systematic literature review and meta-analysis to investigate the association between pacifier use and EBF interruption in infants less than 6 months of life, taking into account study design heterogeneity across studies.

## 2 | METHOD

The protocol of this systematic review was registered on the PROSPERO registry prior to starting the literature search (CRD42014014527).

### 2.1 | Inclusion and exclusion criteria

We included observational and experimental studies that evaluated the association between pacifier use and EBF interruption in infants younger than 6 months.

Our systematic review and meta-analysis followed the guidance of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009). We excluded studies that: (a) were not quantitative including review articles (systematic or not) and letters to the editor; (b) included premature babies or newborns with congenital anomalies; (c) combined pacifiers and bottle nipples in the same category; (d) did not report a statistical parameter documenting the size of the association between pacifier use and EBF interruption and lacked data to estimate the effect size of association. In the case that a study used the same sample for data analysis in different publications, we selected the study that provided the most detail pertinent to this review.

### 2.2 | Exposure/intervention: Pacifier use

The key exposure was pacifier use defined as use versus non-use in infants less than 6 months of age (<6 months).

### 2.3 | Outcomes: Interruption of exclusive breastfeeding

We combined all studies that provided information about EBF interruption during the first 6 months of life, without any further age restrictions. EBF was defined as the infant receiving only breast milk (including expressed breast milk or breast milk from a wet nurse)

## Key Messages

- Pacifier use may be a risk factor for the premature interruption of exclusive breastfeeding (EBF). Mothers should be advised about this hazard.
- Mothers should be taught techniques to soothe their babies that do not involve the use of pacifiers
- Well-designed prospective cohort studies in diverse socio-economic and cultural settings are needed to rule out the possibility that pacifier use is simply a marker of either breastfeeding difficulties or maternal motivation to EBF interruption.
- Qualitative studies are needed to gain an in-depth understanding of the reasons behind the introduction of pacifier use in diverse populations.
- Pacifier use recommendations need to be based on a benefit-risk approach focusing on the trade-off between pacifier-related breastfeeding outcomes and SIDS.

allowing the infant to receive oral rehydration solutions (ORS), drops, syrups (vitamins, minerals, and medicines), but nothing else (WHO 2008).

## 2.4 | Search strategy

We searched published literature with the following databases: CINAHL, SCOPUS, Web of Science, LILACS and MEDLINE without language restrictions and from inception through 30 December 2014.

The search terms used were: pacifier use, EBF, epidemiology, cross-sectional, cohort, case-control, and trials. Descriptors for these terms were identified in English and Portuguese from the Medical Subject Headings (MeSH) terms. Each MeSH term found, as well as its synonyms and variations were applied individually in the search to test the sensitivity of each term. This information was used to finalize the search strategy that was used with each database (Table S1). After excluding the duplicates, additional manual searches of the references' lists of the systematic reviews identified (Jaafar et al., 2012; O'Connor et al., 2009; Karabulut et al., 2009; Santos Neto et al., 2008) were performed to identify papers that might fulfill the inclusion criteria and that were not identified in the electronic databases.

## 2.5 | Study selection

Three review authors (GSB, LMP, and CLA) that were previously standardized against each other (Kappa = agreement of 90%); screened the titles and abstracts independently to identify potentially relevant citations. The full texts of all potentially relevant articles were retrieved and independently assessed for eligibility using the predefined inclusion

and exclusion criteria defined above. Any disagreements were solved through a consensus process and, if necessary, by consulting the fourth reviewer with expertise in the area (SIV).

## 2.6 | Assessment of study characteristics and data extraction

The information extracted from each study using a standardized protocol included: study reference (author/year of publication); country/year of study; study design, study quality score; sample size; study outcome (EBF interruption); classification and measurement of exposure (pacifier use), prevalence of EBF interruption; prevalence of pacifier use; OR effect size measure with respective 95% confidence interval (adjusted or crude).

We also identified the covariates included in adjusted models across studies. We quantified how many times each covariate was adjusted for and how many times it was significantly associated with EBF interruption across applicable studies. Then covariates were grouped into the following categories: (a) Mother and family characteristics; (b) Pregnancy and childbirth factors; (c) infant characteristics; (d) breastfeeding technique and family support; (e) breastfeeding assistance. This information was used to identify which covariates are more likely to mediate the relationship between pacifier use and EBF interruption. Table 1 shows the list of specific covariates by group category.

## 2.7 | Quality assessment of studies

Bias risk was assessed with a modified version of the Effective Public Health Practice Project Quality Assessment Tool (EPHPP) (<http://>

**TABLE 1** Covariates identified in adjusted models across studies of association between pacifier use on the interruption of EBF

Category group (number of covariates)	Covariates
(a) <i>Mother and family characteristics</i> (n = 18)	Maternal education; maternal age; mother's occupation or job status; maternal race; maternal emotional distress; parity, had a child under 5 years; mother's BMI; maternal smoking habits or alcohol use; maternal marital status; father's age; working status or occupation of father; father's education; father smoking habits; area of residence; infant stay at the daycare; family income, social class; cohabitation with maternal/paternal grandmother; maternal oral contraceptive use.
(b) <i>Pregnancy and childbirth factors</i> (n = 6)	Type of delivery, cesarean planned; multiple births; if the pregnancy was planned; number of prenatal visits; quality of prenatal care; gestational age when mother started prenatal care.
(b) <i>Infant characteristics</i> (n = 7)	Infant's age; birth weight; sex of the baby; baby's behavior to feed; baby needed special care/ICU or hospitalization in the first months; weight gain during the follow-up; gestational age at birth or prematurity.
(c) <i>Breastfeeding technique and family support</i> (n = 11)	Limiting the number of feedings at night/Breastfeeding during the night/ child sleeps more than six hours; use of formula (after hospital discharge); presence of nipple cracked; breastfeeding technique (maternal complaint/latch/positioning); maternal prior intention to breastfeed, maternal review of the optimal duration of exclusive breastfeeding, length time of maternal decision on how to feed the child; breastfeeding pre-established schedules; father's support and/or family's support; maternal grandmother did not have breastfed, mother did not breast feed, feeding preference of the grandmother; introduction of solid foods; Mother have plenty of milk supply; bed shared or sleep separately from parents; knowledge or prior experience with breastfeeding; pacifier use after the second week of life
(d) <i>Breastfeeding assistance</i> (n = 13)	Birth in Baby-Friendly Hospital; rooming in; pacifier use in the hospital; use formula, supplemental or other liquid in the hospital; type of health service in follow-up (health center with team or pediatrician trained in breastfeeding); place where gets immunization; hospital discharge of the mother and baby at different times; length of hospital stay; first feed the baby; breastfeeding in the first hour, skin-to-skin contact, early initiation of breastfeeding; to receive a counseling and breastfeeding management in the hospital; to receive medical visit at home, to receive nurse visit at home; conflicting guidelines for health professionals

www.ehphp.ca/tools.html) (Armijo-Olivo, Stiles, Hagen, Biondo, & Cummings, 2012). The following six items were classified as either "strong", "moderate", or "weak": (a) selection bias; (b) study design; (c) confounding factors; (d) blinding; (e) data collection methods, and (f) withdrawals and dropouts. Blinding was assessed only in the RCTs included and follow-up attrition did not apply to cross-sectional studies. Regarding "study design", cross-sectional studies had lower initial scores than cohort studies and RCTs, due to their inherent limitations in relation to the establishment of temporality between exposure variable and the outcome. Study quality could then be upgraded or downgraded based on the internal validity of the studies. The articles were classified according to the final score of EPHPP as strong if none of the quality items were weak; moderate if one of the six items was classified as weak; and weak, for studies with more than one item identified as such.

## 2.8 | Data analysis

### 2.8.1 | Effect size measure

Effect measures were presented as pooled odds ratios. For studies that summarized the effect size with estimators other than ORs whenever possible, we converted the estimators to ORs as recommended by Deeks, Altman, and Bradburn (2001). For those that were not possible to convert because the necessary information was not provided, we were able to contact and receive the needed information for three studies (Warkentin, Viana, Zapana, & Taddei, 2012; Warkentin, Taddei, Viana, & Colugnati, 2013; Merten, Dratva, & Ackermann-Liebrich, 2005). Thus, supplementary information was received that enabled the calculation of the OR. For one study, we had to use the RR as a proxy for the OR (Chaves, Lamounier, & César, 2007). Where adjusted estimators were available, they were included; otherwise, crude estimators were considered.

When studies presented two or more infant age categories for EBF interruption, the findings with the EBF measure closer to 6 months was considered for comparison in the meta-analysis because the objective was to evaluate the outcome closer to the WHO recommendation for EBF (WHO 2008). With regards to pacifier use status, we included the findings from the earlier infant age measure based on biological plausibility considerations (Kronborg & Vaeth, 2009; Righard et al. 1998; Neifert et al., 1995) (i.e., if the study examined the association between EBF interruption with pacifier use at both 2 week and at 1 month, we included only the findings for pacifier use at 2 week).

### 2.8.2 | Meta-analysis

A meta-analysis was performed by type of design of epidemiological studies (randomized clinical trial, prospective cohort, and cross-sectional). We examined the impact of heterogeneity using a measure of the degree of inconsistency in the studies' results ( $I^2$  statistic) and by its significance ( $p < 0.05$ ) using a random-effects model (Deeks et al., 2001). Funnel plots and Egger's test were used to evaluate the presence of publication bias (Sterne, Egger, & Smith, 2001).

Due to high heterogeneity across studies identified in the meta-analysis ( $I^2 > 75\%$ ) meta-regression was conducted (Higgins & Thompson, 2002; Higgins, Thompson, Deeks, & Altman, 2003). Meta-regression was specifically used to evaluate the contribution of study

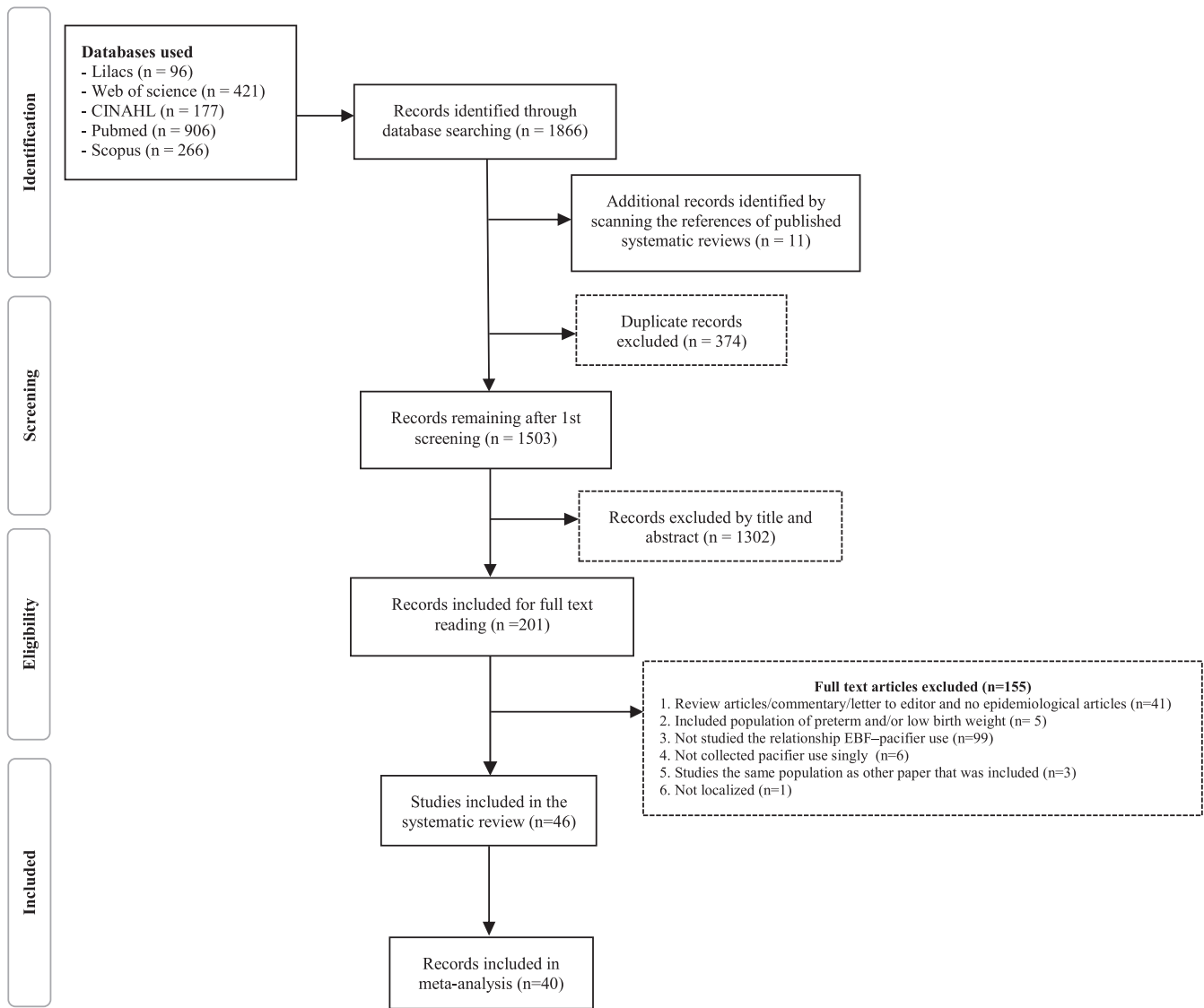
characteristics to the between-study variability (Berkley, Hoaglin, Mosteller, & Colditz, 1995). Study characteristic tested were: Study design (RCT, longitudinal, and cross-sectional); Sample size ( $\leq 300$ , 301–1000,  $>1000$ ); Age of exposure measurement (pacifier) (use among infants: before the second week/hospital discharge, before sixth week, 2–4 month, under 4 or 6 month); Age of outcome measurement (EBF interruption) (among infants: hospital discharge, before the sixth week, between 2 and 4 month under 4 or 6 month); Setting (High income country/multicentric and Middle-/Low-income country), Publication language (English, Portuguese, other), Effect size (adjusted and crude); Study quality score (Strong, Moderate, and Weak); Publication year, dichotomized into before ( $\leq 2009$ ) and after ( $>2009$ ) the publication of the previous reviews and meta-analyses. Each methodological characteristic was included as a covariate in the meta-regression and the percentage of heterogeneity explained by each was calculated (Sterne et al., 2001). All analyzes were conducted using Stata version 14.1 (Stata Corp., College Station, TX, USA).

## 3 | RESULTS

Initially, we identified 1,866 publications in the databases searched electronically, of which 374 were duplicates. The manual screening of the references of the systematic reviews identified yielded 11 additional publications. After screening the title and abstracts of the remaining 1,503 publications, 1,302 publications were excluded. Thus, a total of 201 articles were included for full text reading, and of these 155 articles were excluded resulting in the inclusion of 46 articles in the systematic review (Figure 1).

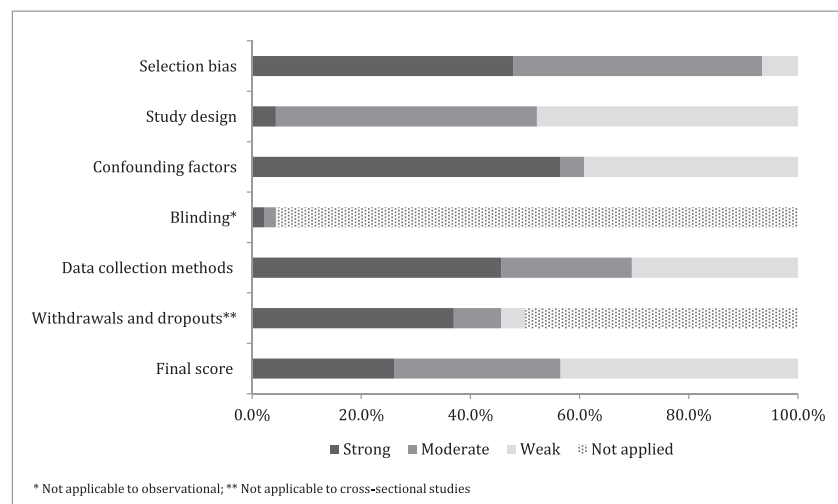
Of the 46 papers that met the inclusion criteria, 40 provided information for the meta-analysis. Twelve studies were classified as having strong quality, 14 moderate quality and 20 weak quality. Figure 2 indicates that only 26.1% of the studies had strong quality. The quality items examine that had the more weaknesses were study design, adjusting for confounding factors, and data collection methods (Figure 2). Almost half of the observational studies used adjusted models to evaluate the association of interest. A total of 55 different covariates were adjusted for across studies (Table 1). Maternal and family characteristics were the covariates used more often in the adjusted models, especially socioeconomic factors and maternal smoking. Followed by covariates reflecting breastfeeding behaviors and intentions, including breastfeeding technique, prior experience breastfeeding and prior intention to breastfeed.

Table 2 shows the characteristics of the studies included in the systematic review. Most of the studies were conducted in Brazil (27 out of 46 studies) followed by Italy (3/46) and New Zealand (2/46). Pacifier use prevalence ranged from 21% (Carrascoza, Possobon Rde, Ambrosano, Costa Júnior, & Moraes, 2011) to 79.7% (Lindau et al., 2014) among children under 6 months. The highest pacifier use prevalence occurred in studies conducted in Brazil and Italy. Different classifications for pacifier use were reported, with the most common being dichotomous (use vs. non use). Other approaches to classify pacifier exposure were based on frequency of use (occasional, frequent, daily, intense, and partial) (Ford et al., 1994; Nelson et al., 2005; Aarts, Hörnell, Kylberg, Hofvander, & Gebre-Medhin, 1999).



**FIGURE 1** PRISMA flow diagram. Pacifier use and interruption of exclusive breastfeeding

**FIGURE 2** Summary of the risk of bias of the studies included in the systematic review based on the checklist Effective Public Health Practice Project Quality Assessment Tool



It is noteworthy that regardless of the design of the study, there was no standard infant age at which pacifier use was measured in prospective studies (hospital, second week, 1 month, sixth week, third month, less than 4 month or 6 month). Most cross-sectional studies

assessed pacifier use status in the last 24 hr. All studies defined EBF according to WHO (WHO, 2008). Of the 46 selected studies, only two were RCTs, 20 were longitudinal and 24 cross-sectional. The RCTs (Jenik et al., 2009; Kramer et al., 2001) found no relationship between

**TABLE 2** Characteristics of studies included in the systematic review

Author/publishing year	Country/year of study	Study design	Quality score	Sample size	Outcome (age group)	Exposure (age group)	Prevalence of EBF interruption <sup>€</sup>	Prevalence of pacifier use <sup>€</sup>	Effect size	Factors at baseline to match intervention and control groups
Jenik, 2009	Argentina 2005–2006	Randomized Clinical Trial	Strong	1021	EBF interruption at 4 months	Pacifier use at 4 months	25.3%	51.4%	OR* 1.04 (0.78–1.40)	Birth weight <sup>(c)</sup> ; type of delivery <sup>(b)</sup> ; maternal age <sup>(a)</sup> ; maternal education <sup>(a)</sup> ; mother smoker <sup>(a)</sup> ; marital status (cohabiting with the father) <sup>(a)</sup> ; birth in BFH <sup>(e)</sup> ; early initiation of breastfeeding <sup>(e)</sup>
Kramer et al., 2001	Canada 1998–1999	Randomized Clinical Trial	Strong	281	EBF interruption at 3 months	Pacifier use at 3 months	65.1%	50.7%	RR 1.0 (0.8–1.1) OR* 1.12 (0.67–1.87)	Mean maternal age <sup>(a)</sup> ; Mean maternal education <sup>(a)</sup> ; Mother smoking during pregnancy <sup>(b)</sup> ; maternal work status <sup>(a)</sup> ; marital status <sup>(a)</sup> ; Parity <sup>(a)</sup> ; prior experience maternal on breastfeeding <sup>(b)</sup> ; mean baby birth weight <sup>(c)</sup>
Lindau et al., 2014	Italy 2000–2001	Longitudinal	Moderate	542	EBF interruption at 4 months	Pacifier use before second week	83.9%	64.4%	OR 2.39 (1.38–4.14)	Maternal emotional distress <sup>(a)</sup> ; type of delivery <sup>(b)</sup> ; attending prenatal classes <sup>(b)</sup>
Vieira, Oliveira, Mendes, & Giugliani, 2014**	Brazil 2004–2005	Longitudinal	Strong	1344	EBF interruption in the first 6 months	Pacifier use in each month	88.7%	44.8%	N/R HR 1.40 (1.14–1.71)	Mother's education <sup>(a)</sup> ; Maternal work status <sup>(a)</sup> ; number of prenatal visits <sup>(b)</sup> ; prenatal care in public service <sup>(b)</sup> ; birth in BFH <sup>(e)</sup> ; breastfeeding counseling at the hospital <sup>(e)</sup> ; mother's partner support breastfeeding <sup>(d)</sup> ; limit the number of feedings at night <sup>(d)</sup> ; cracked nipples <sup>(d)</sup>
Carrascoza et al., 2011	Brazil 2004	Longitudinal	Strong	111	EBF interruption at 6 months	Pacifier use in the follow-up	48.6%	20.7%	N/R OR 11.46 (3.09–42.37)	Social class <sup>(a)</sup> ; maternal work status <sup>(a)</sup>
Vieira, Martins, Vieira, Oliveira, & Silva, 2010	Brazil 2004	Longitudinal	Weak	1309	EBF interruption at the end of the first month	Pacifier use at the end of the first month	40.7%	41.5%	OR 1.58 (1.39–1.80) OR 1.53 (1.34–1.76)	Prior maternal experience with breastfeeding <sup>(a)</sup> ; pre-established schedules for breastfeeding <sup>(d)</sup> ; cracked nipples <sup>(d)</sup>

(Continues)



Barros et al., 2009	Brazil 2006	Longitudinal	Moderate	104	EBF interruption at 6 months	Pacifier use in the follow-up	91.7%	third month: 54%	RR 0.9 (0.6–1.2) OR* 0.59 (0.12–3.07)	N/R	-	-	Maternal education <sup>(a)</sup> , prior maternal experience with breastfeeding <sup>(a)</sup> , use of formula 5 days of life <sup>(d)</sup> , effective breastfeeding technique <sup>(d)</sup>
Kronborg & Vaeth, 2009**	Denmark 2004	Longitudinal	Strong	780	EBF interruption between 1st and 26th week	Pacifier use during the first second week	N/R	64.3%	HR 1.42 (1.19–1.69)	HR 1.42 (1.18–1.72)	Early breastfeeding problems <sup>(d)</sup>	Maternal education <sup>(a)</sup> , prior maternal experience with breastfeeding <sup>(a)</sup> , use of formula 5 days of life <sup>(d)</sup> , effective breastfeeding technique <sup>(d)</sup>	
Espirito-Santo et al., 2007**	Brazil 2003	Longitudinal	Strong	220	EBF interruption in the first 6 months	Pacifier use during the first month	93.4%	63%	HR 1.70 (1.27–2.29)	HR 1.53 (1.12–2.11)	Mother's age <sup>(a)</sup> , number of prenatal visits <sup>(b)</sup> , incorrect breastfeeding technique (latch) in the first month <sup>(d)</sup>	Breastfeeding duration of the previous child <sup>(a)</sup> , parity <sup>(a)</sup> , mother cohabiting with her husband <sup>(a)</sup> , with maternal grandmother <sup>(a)</sup> , with paternal grandmother <sup>(a)</sup> , breastfeeding difficulty (positioning) in the 1st month <sup>(a)</sup> , AM	
Chaves et al., 2007*	Brazil 2003	Longitudinal	Strong	246	EBF interruption at 6 months	Pacifier use in the follow-up	94.7%	N/R	N/R	RR 1.49 (1.11–2.00)	Prior maternal intention to breastfeed <sup>(a)</sup> , birth weight <sup>(c)</sup>	Maternal incorrect answer about breastfeeding technique <sup>(d)</sup> , mother being user of alcohol or tobacco <sup>(a)</sup>	
Xu et al., 2007**	China 2003–2004	Longitudinal	Strong	1219	EBF interruption at 6 months	Pacifier use at second week	97%	60.2%	N/R	HR 1.57 (1.19–2.08)	Maternal work status <sup>(a)</sup> , maternal grandmother have not breastfed their children <sup>(a)</sup> , length decision time of feeding method <sup>(d)</sup>	Mother's age <sup>(a)</sup> , maternal work status <sup>(a)</sup> , maternal education <sup>(a)</sup> , parity <sup>(a)</sup> , type of delivery <sup>(b)</sup> , first feed of the baby <sup>(e)</sup> , baby's behavior to feed <sup>(a)</sup> , initiate breastfeeding within 30 min of birth <sup>(e)</sup> , baby needed special care unit <sup>(a)</sup> , prenatal care <sup>(b)</sup> , grandmother or father do not support breastfeeding in two weeks <sup>(d)</sup> , feeding preference of the grandmother <sup>(a)</sup> , baby's sex <sup>(c)</sup> , family income <sup>(a)</sup>	

(Continues)

TABLE 2 (Continued)

Author/publishing year	Country/year of study	Study design	Quality score	Sample size	Outcome (age group)	Exposure (age group)	Prevalence of EBF interruption €	Prevalence of pacifier use €	Effect size	Factors at baseline to match intervention and control groups
Mascarenhas, Albemaz, Silva, & Silveira, 2006	Brazil 2002–2003	Longitudinal	Strong	973	EBF interruption before 3 months	Pacifier use at 3 months	61%	64%	OR 4.25 (3.19–4.27) OR 4.27 (3.19–5.72)	Maternal work status <sup>(a)</sup> ; family income <sup>(a)</sup> ; father's education <sup>(a)</sup> Maternal education <sup>(a)</sup> ; maternal smoking habits during pregnancy <sup>(a)</sup> ; number of prenatal visits <sup>(b)</sup>
Cotrim, 2005	Brazil 2004	Longitudinal	Moderate	89	EBF interruption at 4 months	Pacifier use at the first week	100%	50.6%	RR 3.75 (1.91–7.34) OR* 2.53 (1.39–4.60)	Breastfeeding during the night <sup>(a)</sup> ; had a child under 5 years <sup>(a)</sup>
Merten et al., 2005	Switzerland 2003	Longitudinal	Moderate	1547	EBF interruption in the first 6 months	Pacifier use in the first week	62.7%	76.8%	HR 1.38 (1.25–1.52) OR* 1.86 (1.46–2.36)	Rooming in <sup>(a)</sup> ; breastfeeding within first hour <sup>(a)</sup> ; breastfeeding on schedule <sup>(a)</sup> ; free use of formula supplements <sup>(a)</sup> Medical problems before, during, and after delivery <sup>(a)</sup> ; type of delivery <sup>(b)</sup> ; maternal smoking <sup>(a)</sup> ; maternal age <sup>(a)</sup> ; ethnic group <sup>(a)</sup> ; region of residence <sup>(a)</sup> ; maternal education <sup>(a)</sup> ; work status <sup>(a)</sup> and income <sup>(a)</sup>
Nelson, 2005	Multicentric (17 countries) 1995–1997	Longitudinal	Moderate	5142	EBF interruption at 10–14th week	Pacifier use most of the time between 10–14th week	57% (20–96%)	49% (12–71%)	OR 1.95 (1.07–3.56) OR 1.85 (1.01–3.38)	Mother intends to breastfeed after birth <sup>(d)</sup> ; multiple pregnancy <sup>(b)</sup> ; maternal age <sup>(a)</sup> ; pacifier use at some moment <sup>(d)</sup>
Butler, Williams, Tukuitonga, & Paterson, 2004	New Zealand 2000	Longitudinal	Moderate	1398	EBF interruption in sixth week	Pacifier use at sixth week	38%	23.8%	OR 2.58 (1.92–3.46) OR 2.48 (1.79–3.44)	Maternal work status <sup>(a)</sup> ; mother was working at 6 weeks <sup>(a)</sup> ; child attend daycare <sup>(a)</sup> ; parity <sup>(a)</sup> ; maternal smoking habits <sup>(a)</sup> ; to receive medical visit at home <sup>(a)</sup> ; to receive visiting nurse <sup>(a)</sup> ; baby sleep separated from their parents <sup>(a)</sup> ; hospital discharge of the mother and baby at different times <sup>(e)</sup>

(Continues)



Giovannini et al., 2004**	Italy 1999–2000	Longitudinal	Strong	2450	EBF interruption at 6 months	Pacifier use at first month	95.3%	N/R	N/R	HR <sub>adj</sub> 1.28 (1.13–1.45)	Mother's body mass index <sup>(a)</sup> ; infant's body weight at age 1 mo <sup>(c)</sup> ; early introduction of solid foods <sup>(d)</sup>	Mother's age <sup>(a)</sup> ; education level <sup>(a)</sup> ; social class <sup>(a)</sup> ; maternal smoking habits <sup>(a)</sup> ; type of delivery <sup>(a)</sup> ; mothers having been breastfed themselves <sup>(a)</sup> ; infant's gender <sup>(c)</sup> ; bodyweight and length at birth <sup>(c)</sup> ; pacifier use at hospital discharge <sup>(e)</sup> ; parity <sup>(a)</sup> ; time at introduction of formula or solid foods <sup>(e)</sup> ; formula promotion at discharge <sup>(e)</sup> ; time at initiation of breastfeeding <sup>(e)</sup>	
Santiago, Bettiol, Barbieri, & Gutierrez, & Del Ciampo, 2003	Brazil 2002	Longitudinal	Moderate	101	EBF interruption at 4 months	Pacifier use at 4 months	39.6%	40.6%	EBF interruption: OR* 4.69 (1.99–1 1.05)	EBF duration: OR 0.23 (0.08– 0.60)	Maternal education <sup>(a)</sup> ; Follow-up with medical or team expert in breastfeeding <sup>(e)</sup>	Parity <sup>(a)</sup> ; use of oral contraceptive <sup>(a)</sup> ; planned pregnancy <sup>(b)</sup> ; birth weight <sup>(c)</sup> ; weight gain in the months of follow-up <sup>(c)</sup> ; child sleeps more than 6 hr <sup>(d)</sup>	
Ingram et al., 2002**	England 1996–1998	Longitudinal	Moderate	1400	EBF interruption at second week EBF interruption at sixth week	Pacifier use at the second week Pacifier use at the sixth week	N/R	N/R	N/R	2 <sup>a</sup> week: OR <sub>adj</sub> 3.07 6 <sup>a</sup> week: OR <sub>adj</sub> 4.52	6th week: Mother have plenty of milk supply <sup>(d)</sup> ; not provide other liquid to the child in the hospital <sup>(a)</sup> ; have sufficient support in the hospital <sup>(e)</sup> ; maternal age <sup>(a)</sup> ; breastfeeding problems <sup>(d)</sup> ; family support <sup>(d)</sup> ; health professionals advice and support <sup>(e)</sup>	6th weekchild's sex <sup>(a)</sup> ; birth weight <sup>(c)</sup> ; gestational age <sup>(c)</sup> ; parity <sup>(a)</sup> ; type of delivery <sup>(b)</sup> ; to receive conflicting advice from health professionals <sup>(e)</sup> ; mother has enough help at home <sup>(a)</sup> ; days in hospital <sup>(e)</sup>	
Aarts et al., 1999	Sweden 1989–1992	Longitudinal	Moderate	506	EBF interruption at 4 months	Pacifier use at the first month	60%	15.4%	OR* 1.82 (1.20–2.76)	N/R	-	-	-
Riva et al., 1999	Italy 1995	Longitudinal	Moderate	1365	EBF interruption at 6 months	Pacifier use at the first month	91.9%	73.0%	RR 1.42 (1.24–1.62)	RR <sub>adj</sub> 1.35 (1.18–1.55) OR <sup>§</sup> 1.35 (1.18–1.55)	Maternal education <sup>(a)</sup> ; supplemental use in the hospital <sup>(e)</sup>	Maternal age <sup>(a)</sup> ; mother's BMI <sup>(a)</sup>	

(Continues)

TABLE 2 (Continued)

Author/publishing year	Country/year of study	Study design	Quality score	Sample size	Outcome (age group)	Exposure (age group)	Prevalence of EBF interruption €	Prevalence of pacifier use €	Effect size	Factors at baseline to match intervention and control groups
Barros et al., 1995	Brazil 1993	Longitudinal	Moderate	605	EBF interruption at 4 months	Pacifier use at the first month	66.7%	54.8%	OR* 4.53 (3.12–6.58)	N/R
Alves, Oliveira, & Moraes, 2013	Brazil 2003–2006	Cross-sectional	Strong	2003: 589 2006: 707	EBF interruption among child under 6 months	Pacifier use in the last 24 hr	2003: 30.2% 2006: 46.7%	2003: 50.9% 2006: 43.6%	EBF interruption: OR* 3.12 (2.48–3.93) EBF duration: RP <sub>adj</sub> 0.59 (0.50–0.70)	Maternal education (a), type of delivery (b), (c), infant's age (c), infant follow-up in a breastfeeding baby-friendly unit care (e)
Demitto, Bercini, & Rossi, 2013	Brazil 2010–2011	Cross-sectional	Weak	362	EBF interruption before 6 months	Pacifier use (yes/no)	N/R	N/R	OR 3.2 (1.94–5.24)	N/R
Siti, 2013	Malaysia 2006	Cross-sectional	Weak	2167	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	N/R	33.6%	OR 9.02 (3.35–25.27)	Area of residence (b)
Warkentin et al., 2013	Brazil 2006	Cross-sectional	Weak	1704	EBF interruption before 6 months	Pacifier use (yes/no)	N/R	39%	HR 1.14 OR* 2.33 (1.76–3.09)	Area of residence (a), (b), Gestation planned (b), maternal education (b), skin-to-skin (e), sex of child (e), breast-feeding within 1 hour (e)
Campagnolo, Louzada, Silveira, & Vitolo, 2012	Brazil 2008	Cross-sectional	Weak	573	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	0–4 month: 52.9% 4–6 month: 78.6%	N/R	OR 3.05 (2.11–4.41)	Maternal work status (b), Parity (a)
Leone, 2012	Brazil 2008	Cross-sectional	Moderate	724	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	60.9%	47.2%	N/R	Baby age (c), weight birth (c), maternal work (a)
Queiluz, Pereira, Santos, Leite, & Ricco, 2012	Brazil 2009	Cross-sectional	Moderate	275	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	70.2%	51.6%	OR 1.50 (0.89–2.52)	Maternal work status (a)
Salustiano, Diniz, Abdullah, & Pinto, 2012	Brazil 2008	Cross-sectional	Weak	667	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	60.3%	34.3%	OR 4.2 (2.8–6.3)	N/R

(Continues)

Souza, Migoto, Rossetto, & Mello, 2012	Brazil 2008	Cross-sectional	Weak	325	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	66.2%	50.5%	OR 1.94 (1.15–3.28)	N/R	-	-
Warkentin et al., 2012	Brazil 2007–2010	Cross-sectional	Weak	636	EBF interruption before 6 months	Pacifier use before 3 months	N/R	79.8%	OR* 1.66(1.09–2.52)	HR 1.87 (1.57–2.24)	Prematurity <sup>(c)</sup> , maternal age <sup>(a)</sup>	-
Bouanene, ElMhamdi, Sriha, Bouslah, & Soltani, 2010	Tunisia 2008	Cross-sectional	Weak	354	EBF interruption at 3 months	Pacifier use before 3 months	84.7%	78.9%	EBF duration: OR 0.17 0.08–0.36 EBF interruption: OR* 4.07 (1.58–10.50)	N/R	-	-
Nascimento et al., 2010	Brazil 2005	Cross-sectional	Weak	839	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	56.3%	49.8%	OR* 2.18 (1.67–2.84)	RP 1.69 (1.37–2.09)	Infant's age <sup>(c)</sup> , Maternal education <sup>(a)</sup>	Maternal work status <sup>(b)</sup>
Parizoto, Parada, Venancio, & Carvalho, 2009	Brazil 1999–2003–2006	Cross-sectional	Strong	1999: 496 2003: 674 2006: 509	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	1999: 91.5%; 2003: 82.4%; 2006: 75.8%	1999: 65.8%; 2003: 57.7%; 2006: 54.0%	OR* 2.44 (1.61–3.71)	RP 2.03 (1.44–2.84)	-	Maternal education <sup>(a)</sup> , parity <sup>(a)</sup> , type of delivery <sup>(b)</sup>
Kacho, Yadollah, & Pooya, 2007	Iran 2003–2004	Cross-sectional	Weak	220	EBF interruption at 6 months	Pacifier use (yes/no)	51.4%	45.5%	OR* 4.18 (2.37–7.37)	N/R	-	-
Franca, Brunken, Silva, Escuder, & Venancio, 2007	Brazil 2004	Cross-sectional	Weak	275	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	65.5%	43.3%	OR 3.27 (1.08–3.24)	OR 3.26 (1.64–6.50)	Mother's age <sup>(a)</sup> , parity <sup>(a)</sup> , Maternal education <sup>(a)</sup>	-
Carvalho et al., 2007	Brazil 2004	Cross-sectional	Moderate	380	EBF interruption among child under 4 months	Pacifier use in the last 24 hr (under 4 months)	62.0%	53.9%	OR 2.69 (1.76–4.11)	OR 2.63 (1.70–4.06)	Maternal difficulty or complaint on breastfeeding <sup>(d)</sup>	Maternal work status <sup>(a)</sup> , parity <sup>(a)</sup> , maternal age <sup>(a)</sup>
Mikiel-Kostyra 2005a	Poland 1995	Cross-sectional	Weak	11422	EBF interruption at hospital discharge	Pacifier use while in hospital	31.1%	2.8%	OR 4.97 (3.83–6.45)	N/R	-	-
Mikiel-Kostyra 2005b	Poland 1997	Cross-sectional	Weak	10156	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	sixth month 91.0%	51.0%	OR 2.49 (2.28–2.71)	OR 2.38 (2.17–2.61)	Maternal education <sup>(a)</sup> , maternal occupation <sup>(a)</sup> , Mother smoking habits <sup>(a)</sup> , maternal age <sup>(a)</sup> , parity <sup>(a)</sup> , maternal opinion about optimal duration of BF and EBF <sup>(a)</sup> , father's education <sup>(a)</sup> , father's occupation <sup>(a)</sup>	Maternal marital status <sup>(a)</sup> , father's age <sup>(a)</sup> , working sector of the mother and father <sup>(a)</sup> , father being a smoker <sup>(a)</sup> , sex of the child <sup>(c)</sup> , birth weight <sup>(c)</sup>
Franco, Nascimento, Reis, Issler, & Grisi, 2008	Brazil 2005	Cross-sectional	Weak	514	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	56.4%	49.3%	OR* 4.04 (2.73–5.97)	N/R	-	-

(Continues)

TABLE 2 (Continued)

Author/publishing year	Country/year of study	Study design	Quality score	Sample size	Outcome (age group)	Exposure (age group)	Prevalence of EBF interruption of EBF	Prevalence of pacifier use <sup>€</sup>	Effect size	Factors at baseline to match intervention and control groups
Vieira, Almeida, Silva, Cabral, & Netto, 2004	Brazil 2001	Cross-sectional	Weak	1216	EBF interruption at 6 months	Pacifier use in the last 24 hr (under 6 months)	61.5%	59.2%	RP 1.60(1.39–1.84)OR* 2.18(1.72–2.76)	N/R
Audi, Correa, & Latorre, 2003	Brazil 1999	Cross-sectional	Weak	346	EBF interruption among child under 6 months	Pacifier use in the last 24 hr (under 6 months)	4–6 months 90.4%	43.4%	OR 4.19(2.38–7.41)	OR 4.41 (2.57–7.59) Type of delivery <sup>(b)</sup>
Cotrim, Venancio, & Escuder, 2002	Brazil 1999	Cross-sectional	Weak	22188	EBF interruption in under 4 months	Pacifier use in the last 24 hr (under 4 months)	80.8%	61.3%	OR 3.26(3.00–3.50)	N/R
Kelmannson, 1999	Russia 1998	Cross-sectional	Weak	192	EBF interruption between 2 and 4 months	Pacifier use between 2 and 4 months	50.5%	60.9%	OR* 1.81(1.00–3.26)	N/R
Ford et al., 1994	New Zealand	Cross-sectional	Weak	1592	EBF interruption at fourth week	Frequent pacifier use in the last two weeks	39.0%	18.3%	OR 2.00(1.39–2.40)	OR 1.96 (1.35–2.84) Multiple pregnancy <sup>(b)</sup> ; infant needed hospitalization in the NICU <sup>(c)</sup> ; Maternal marital status <sup>(b)</sup> ; Occasional use of pacifiers in the last two weeks <sup>(d)</sup> Maternal work status <sup>(b)</sup> ; sex of the child <sup>(e)</sup> ; maternal race <sup>(a)</sup> ; Maternal age <sup>(a)</sup> ; parity <sup>(a)</sup> ; gestational age when mother started prenatal care <sup>(b)</sup> ; Pre-natal care <sup>(b)</sup> ; bed sharing <sup>(d)</sup> ; infant birth weight <sup>(e)</sup> ; Maternal smoke habits <sup>(a)</sup>

<sup>€</sup>Prevalence provided by publication or calculated from data provided in the paper. The prevalence corresponded to the age group as defined in the outcome and intervention.

<sup>§</sup>OR adjusted calculated from data provided by the study.

\*OR unadjusted calculated from data provided by the study.

\*\*Not included in the meta-analysis because it was not possible to calculate the OR with the data available.

\*\*\*Not included in the meta-analysis because it was not possible to calculate the IC with the data available.

#Relative Risk (RR) was considered in the meta-analysis as a proxy of OR

N/R – Not reported

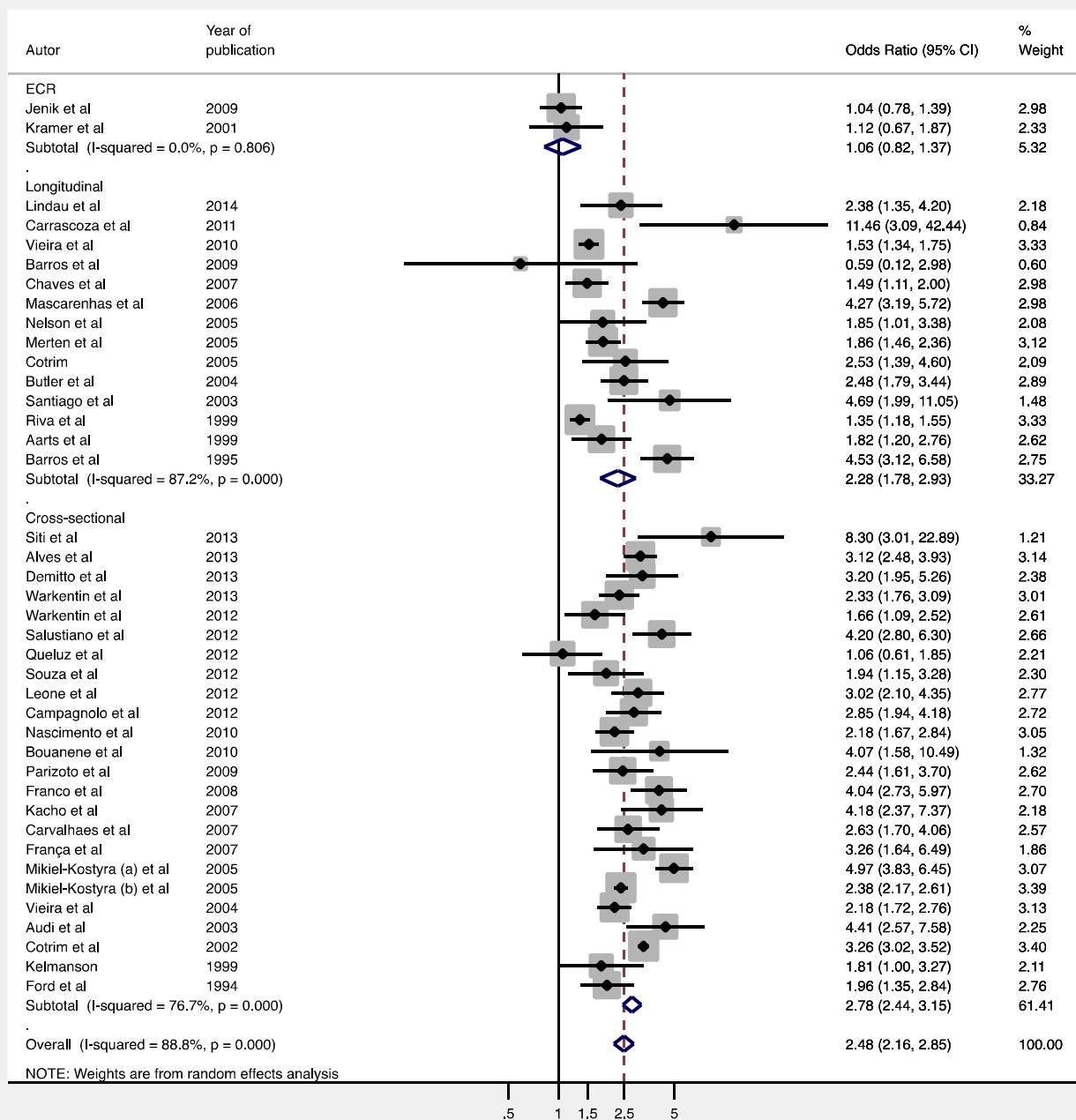
a,b – Mikael-Kostyra et al (2005) published the results from two surveys in the same paper, so the results are presented by survey (a) 1995 and (b) 1997

Category variable group:(a) Mother and family characteristics; (b) Pregnancy and childbirth factors; (c) Infant characteristics; (d) Breastfeeding technique and family support; (e) Breastfeeding assistance

pacifier use and the duration of EBF in the third month of life. Both included only women highly motivated to breastfeed. Both studies used different interventions to test the hypothesis that use of pacifier influences EBF duration. Jenik et al. (2009) randomized participants to the intervention (pacifier use) or control group. Parents of intervention group infants were given a pacifier, a type that was not typically used in the country, and they were advised to start using it only after breastfeeding had been established and the baby was gaining weight at 15 days. By contrast, Kramer et al. (2001) randomly assigned participants to avoiding using pacifiers (intervention group) or to the control group. The intervention group was explained the pros and cons of pacifier use and discussed strategies to soothe the baby without using a

pacifier. Although the intervention led to a reduction in pacifier use or prevented the early introduction of it, the intervention was not associated with EBF duration.

Findings were mixed across study designs (Figure 3). The OR summarizing the pooled random effects for the association between pacifier use and interruption of EBF was 2.48 OR (95% CI, 2.16–2.85), although heterogeneity was high ( $I^2 = 88.8\%$ ). Stratifying results by study design showed that the pooled random effects OR for RCTs was 1.6 (95% CI, 0.82–1.37), for longitudinal studies it was 2.28 (95% CI, 1.78–2.93) and for cross-sectional studies it was 2.78 (95% CI, 2.44–3.15). Heterogeneity was high among observational studies but not among RCTs (Figure 3).



**FIGURE 3** Random effects of meta-analysis of studies evaluating the association between pacifier use and EBF interruption

Egger's test suggests the absence of publication bias ( $p = 0.958$ ). However, the asymmetrical plot observed in the funnel plot (Figure 4) may be due to low methodological quality of small studies and can indicate others sources of heterogeneity of smaller studies (Sterne et al., 2001).

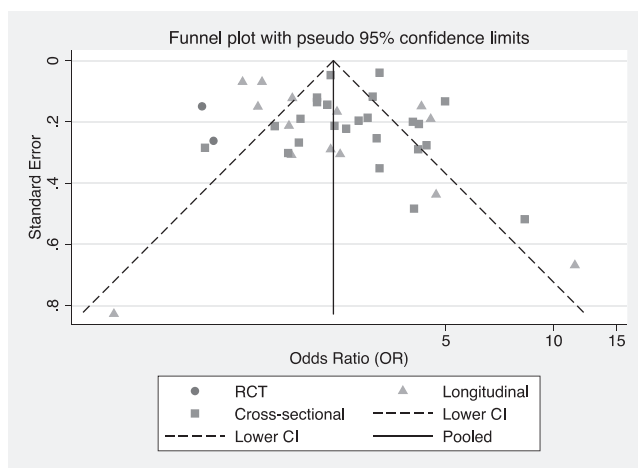
In the subgroup analyses, the higher pooled effects were observed in observational versus RCTs, studies with infants who were younger at assessment of pacifier use, studies with low methodological quality, and studies carried out in middle- and low-income countries (Table 3).

Meta-regressions showed that the study design contributed 40.2% of the global heterogeneity. Others study characteristics such as the age of assessment of pacifier use; the age of assessment of EBF interruption; study quality score and setting explained 31.7%, 8.4%, 5.3%, and 2.8% of the global heterogeneity, respectively.

## 4 | DISCUSSION

We found a positive association between pacifier use and EBF interruption in observational studies (longitudinal and cross-sectional) and no association in the RCTs, which were of strong quality but had very limited external validity. Previous systematic reviews (O'Connor et al., 2009; Santos Neto et al., 2008) and meta-analyses (Jaafar et al., 2012; Karabulut et al., 2009) examining the influence of pacifier use in breastfeeding outcomes were published between 2008 and 2009; despite divergences in the search and selection criteria and possible bias inherent in each of them, collectively both reviews and meta-analyses found results consistent with our review.

Our meta-analysis and meta-regression quantified for the first time the high level of heterogeneity across studies examining the association between pacifier use and EBF. This heterogeneity was explained mainly by the study design, sample size, and socio-economic setting as well as differences in the infants' age of assessment of pacifier use and a lack of a standard definition of "pacifier use" (i.e., age of introduction, frequency, and intensity of use).



**FIGURE 4** Funnel plot estimates from studies evaluating pacifier use and interruption of EBF versus the standard error of measurement by study design

Strengths and weaknesses inherent to designs of the studies, such as, randomization and bias risk should be considered for determining the internal and external validity and thus the likelihood for a causal relationship between pacifier use and early interruption of EBF. The impact on EBF may vary accordingly to the effectiveness of implementation of the pacifier use or avoidance intervention. Both RCTs found that compliance with the pacifier use or avoidance intervention was low, so the impact of the intervention on EBF might have been strongly diluted especially when using intent-to-treat analyses. To address this issue, observational analyses of RCTs have been recommended (Victora, Habicht, & Bryce, 2004). Indeed, when pooling the data from both the intervention and control groups, Kramer et al. (2001) found an association between pacifier use and EBF interruption. Besides, both RCTs included only women who were highly motivated to breastfeed (Kramer et al., 2001; Jenik et al., 2009) and one of them also had as inclusion criteria for breastfeeding to be established and for the infant to be gaining weight at 15 days of life before recommending the introduction of the pacifier (Jenik et al., 2009). This may explain why in our meta-analysis, the RCTs provided an indication of minimal effect, or no effect, while observational studies provided an estimate of the maximal effect (Black, 1996). Indeed, the literature has shown that women's lack of motivation or intention to breastfeed (Victora et al., 1997; Chaves et al., 2007; Nelson et al., 2005; Mikiel-Kostyra, Mazur, & Wojdan-Godek, 2005; Xu et al., 2007; Boccolini, Carvalho, & Oliveira, 2015) as well as the initial difficulties in breastfeeding (Victora et al., 1997; Carvalhaes, Parada, & Costa, 2007; Kronborg & Vaeth, 2009; Espirito-Santo, de Oliveira, & Giugliani, 2007; Boccolini et al., 2015) are strong predictor of EBF interruption. These predictors can also determine both the likelihood of introduction of pacifiers as the patterns of their use (daily, partial, and intense) (Victora et al., 1997; Kramer et al., 2001; Aarts et al., 1999). Thus, despite their relatively stronger internal validity, RCTs can have major external validity limitations (Black, 1996; Victora et al., 2004), preventing the extrapolation of findings from RCT's to the general population, that is, women who are less motivated to breastfeed or to the context when the pacifier is introduced before breastfeeding is established as mentioned by Jenik et al. (2009).

A possible advantage of the prospective studies reviewed (vs. RCT's and cross-sectional) is that the influence of age of introduction of pacifiers (Aarts et al., 1999) as well as pacifier use pattern (e.g., frequent user, often user, and occasional user) (Aarts et al., 1999) on breastfeeding behaviors can be investigated. Although these analyses could be key to better understand the relationship between pacifier use and EBF interruption most prospective studies reviewed did not conduct them. This is relevant for understanding if and how age of introduction of pacifiers and their pattern of use mediate or modify the relationship between pacifier use and EBF interruption (Vogel et al., 2001; Kronborg & Vaeth, 2009; Buccini et al., 2016; Howard et al., 1999). A possible strategy for better standardizing studies in this area is to categorize pacifier use as dichotomous based on its introduction before the second week or not (Kronborg & Vaeth, 2009; Lindau et al., 2014; Xu et al., 2007; Ingram, Johnson, & Greenwood, 2002), or use in the first month (Espirito-Santo et al., 2007; Giovannini et al., 2004; Aarts et al., 1999; Barros et al., 1995; Riva et al., 1999) by the time breastfeeding is more likely to be established. This study design standardization attempt may be highly relevant as our review

**TABLE 3** Univariate meta-regression and pooled odds ratio estimates of association between pacifier use on the interruption of EBF based on 40 studies

	n*	Pooled OR (CI 95%)	Meta-regression	
			p-value <sup>†</sup>	% Explained heterogeneity <sup>‡</sup>
<b>Study design</b>				
RCT	2	1.06 (0.82–1.36)	index	40.2
Longitudinal	14	2.28 (1.78–2.93)	0.025	
Cross-sectional	24	2.78 (2.44–3.15)	0.003	
<b>Sample size</b>				
>1000	15	2.30(1.83–2.88)	index	1.5
301–1000	15	2.96 (2.46–3.55)	0.116	
≤ 300	10	2.18(1.47–3.22)	0.001	
<b>Exposure measurement (pacifier)</b>				
Use among children under 4 or 6 months	24	2.62 (2.30 - 2.99)	index	31.7
Use of 2–4 months	8	2.10 (1.30–3.40)	0.183	
Use before 6 <sup>th</sup> week	5	2.05 (1.47–2.86)	0.221	
Use before the second week / hospital discharge	3	3.27(1.90–5.64)	0.414	
<b>Outcome measurement (EBF interruption)</b>				
Among those younger than 4 or 6 months	25	2.54 (2.17–2.97)	index	8.4
Between 2 and 4 months	11	2.35(1.59–3.46)	0.593	
Before the 6 week	3	1.90 (1.39–2.60)	0.303	
Hospital discharge	1	4.97 (3.83–6.45)	0.134	
<b>Setting</b>				
High income country/multicentric	12	1.93 (1.50–2.48)	index	2.8
Middle-/Low-income country	28	2.79 (2.37–3.29)	0.020	
<b>Publication year</b>				
≤2009	22	2.57 (2.15–3.08)	index	0.04
>2009	18	2.36 (1.89–2.95)	0.567	
<b>Publication language</b>				
English	17	2.25 (1.82–2.77)	index	–2.5
Portuguese	22	2.66 (2.21–3.21)	0.275	
Other	1	4.07(1.58–10.49)	0.383	
<b>Effect size</b>				
Adjusted	17	2.50 (2.06–3.03)	index	–11.0
Crude	23	2.45 (1.99–2.99)	0.812	
<b>Quality score</b>				
Strong	7	2.25 (1.40–3.61)	index	5.3
Moderate	13	2.19 (1.69–2.83)	0.966	
Weak	20	2.77 (2.34–3.28)	0.230	
<b>Total</b>	<b>40</b>	<b>2.48 (2.16–2.85)</b>		

\*number of studies;

†p-value of the meta-regression;

‡R<sup>2</sup> adj (proportion of variance between studies)

found that pacifier use definition and infant age at which it was assessed – was the second characteristic that best explained the heterogeneity across studies included in the meta-analysis. Whereas analyses from prospective studies can be adjusted for wide variation in potential confounders, RCT's are designed to equalize confounders between groups at baseline, once again, limiting their external validity (Victora et al., 2004).

An important question that our review raises is: Which would be the best study design to further test and explain the complexity of the relationship between pacifier use and the EBF interruption? This

question is not simple to answer as it involves not just measuring and understanding biological but also behavioral pathways (Grimes & Schulz, 2002). In this case, the causal pathway can happen at least through three paths: (a) pacifier introduction leading to EBF interruption where the effect of pacifier use and the pattern of use (frequency and intensity) can lead to “nipple confusion” (Neifert et al., 1995; Righard et al. 1998); (b) EBF interruption or breastfeeding problems leading to pacifier introduction (i.e., reverse causality meaning that breastfeeding problems or interruption leads to the introduction of pacifier rather than the reverse); where pacifier use could be a marker



of breastfeeding difficulties or reduced motivation to breastfeed (i.e., both pacifier introduction and interruption of EBF based on maternal preference) (Victora et al., 1997; Kramer et al., 2001); (c) mothers (families) who follow the recommendation of avoiding pacifier may also try to follow other recommendations to breastfeed exclusively for longer such as breastfeeding on demand (Feldens, Ardenghi, Cruz, Scalco, & Vitolo, 2013).

Prospective studies that evaluated the effect of very early pacifier use on later breastfeeding outcomes (DiGirolamo et al., 2008; Soares et al., 2003; Howard et al., 2003; Vogel et al., 2001; Hörnell et al., 1999; Victora et al., 1997) as well as the studies that separated the effects of early breastfeeding problems from the effects of pacifier use (Kronborg & Vaeth, 2009) support conducting further research to find out if the associations between pacifier use and poor breastfeeding outcomes is causal or not. Future studies need to take into account in their designs ways to deal with the possibility of reverse causality (Grimes & Schulz, 2002). For example, Vogel et al. (2001) found in a prospective longitudinal study that in almost all cases, the pacifier was introduced prior to complete weaning from breast milk, and not the other way around. Also, cohort studies need to carefully measure the level of motivation that mothers have to breastfeed and the way they use the pacifier. Ultimately, better-designed prospective cohort studies and RCT's are needed to confirm or refute the hypothesis that pacifier use increases the risk of the premature discontinuation of EBF.

Crude and adjusted ORs were not significantly different, probably because of the wide variety of covariates used across the included studies. However, based on our heterogeneity analyses, we recommend for future observational studies to apply multivariable analyses that adjust for and test for effect modification by maternal age and education, intention to breastfeed during pregnancy, onset and nature of breastfeeding difficulties, and family support (Victora et al., 2016; Boccolini et al. 2015; Buccini, Benício, & Venancio, 2014). Furthermore, future studies in this area should standardize the age at which pacifier use is assessed and also provide a clear definition of "pacifier use" including age of introduction, frequency, and intensity of use. Because the level of economic development of the countries modified the relationship between pacifier use and EBF it's strongly recommended to conduct studies in this area in different world regions using the standard methodologies recommended above.

This meta-analysis should be interpreted considering some possible limitations. First, all systematic reviews and meta-analyses are subject to publication bias. In order to minimize this limitation, this study was based on a comprehensive and sensitive search. Studies were included regardless of methodological quality and the electronic search strategy was supplemented by a manual search of studies. In addition, we tested formally for publication bias and did not find it. Second, to minimize selection bias the protocol for this systematic review was registered a priori (CRD42014014527 PROSPERO). Third, there was strong statistical heterogeneity across studies as it was expected because we included studies with different methodologies as well as different definitions for pacifier use (intervention or exposure). To address the high level of heterogeneity, we used the random effect option for summarizing the effect size of the association. Also, one of the RCT's included (Jenik et al., 2009) is likely to have a conflict of

interest related to the funding source (Di Mario, Cattaneo, Basevi, & Magrini, 2011). Because all these potential limitations were taken into account in the design of this systematic review and meta-analysis, we conclude that our systematic review findings are indeed robust.

In view of the available evidence, given the limitations of the RCT's included, it can be concluded that despite the lack of association found in the RCT's, observational studies strongly suggest that pacifier use may be a risk factor for the premature discontinuation of EBF. A recent robust Brazilian study published after the search was completed supports this conclusion (Buccini et al., 2016). The trade-off between a potentially strong benefits that may result from improved breastfeeding outcomes resulting from reducing pacifier use (Buccini et al., 2016), as well as the protection of EBF against SIDS (Hauck, Thompson, Tanabe, Moon, & Vennemann, 2011) vis-à-vis the possible protection of pacifiers against SIDS (Hauck, Omojokun, & Siadaty, 2005), should be considered when making recommendations about pacifier use and EBF practices on a large-scale. The current WHO recommendation on pacifier use is supported by our findings as it focuses on the risk of poor breastfeeding outcomes as a likely result of pacifier use. Future benefit-risk analyses studies should examine if the trade-off between pacifier-related breastfeeding outcomes and SIDS justifies maintaining the current recommendation or if it needs to be expanded to offer more context-specific options.

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## CONFLICTS OF INTEREST

The authors have no conflicts of interest to disclose.

## CONTRIBUTIONS

GSB has designed the systematic review project. She conducted all steps of bibliography searches and paper selection also conducted the analysis, interpreted the results and drafted the paper. RP-E has interpreted the results and drafted the paper. LMP has participated in the steps of paper selection and reviewed the final version of the paper. CLA has participated in the steps of paper selection and reviewed the final version of the paper. SIV has designed the systematic review project also interpreted the results and drafted the paper.

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## SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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