Does the Recommendation to Use a Pacifier Influence the Prevalence of Breastfeeding?

Alejandro G. Jenik, MD, Nestor E. Vain, MD, Adriana N. Gorestein, MD, and Noemí E. Jacobi, MD, for the Pacifier and Breastfeeding Trial Group*

Objective To evaluate whether the recommendation to offer a pacifier once lactation is well established reduces the prevalence or duration of breastfeeding.

Study design A multicenter, randomized, non-inferiority, controlled trial comprising 1021 mothers highly motivated to breastfeed whose newborns regained birth weight by 15 days. They were assigned to offer versus not to offer pacifiers. Primary outcome was prevalence of exclusive breastfeeding at 3 months. Main secondary outcomes were the prevalence of exclusive and any breastfeeding at different ages and duration of any breastfeeding.

Results At 3 months, 85.8% infants in the offer pacifier group and 86.2% in the not offer pacifier group were exclusively breastfeeding (risk difference, 0.4%; 95% CI, –4.9%-4.1%), satisfying the pre-specified non-inferiority requirement of –7%. Furthermore, the recommendation to offer a pacifier did not produce a significant decrease in the frequency of exclusive and any breastfeeding at different ages or in the duration of lactation.

Conclusions The recommendation to offer a pacifier at 15 days does not modify the prevalence and duration of breastfeeding. Because pacifier use is associated with reduced incidence of sudden infant death syndrome, the recommendation to offer a pacifier appears safe and appropriate in similar populations. *(J Pediatr 2009; ■: ■-■).*

A low prevalence and duration of breastfeeding increase the risk of infant morbidity and mortality in both developed and developing countries.[1,2] In 1989, the World Health Organization and United Nations Children's Fund introduced the "10 steps for successful breastfeeding".[3] To assure that breastfed babies are not deterred from learning how to suckle the breast, and thereby from maximizing mothers' milk supply, step 9 states: "Give no artificial teats or pacifiers to breastfeeding infants."[4]

However, research now indicates an association between pacifier use and a reduced risk of sudden infant death syndrome (SIDS),[5-9] leading to the revised American Academy of Pediatrics statement: "Consider offering a pacifier at nap time and bedtime. For breastfed infants, delay the introduction of a pacifier until the infant is 1 month old, to ensure the breast-feeding is firmly established."[10]

Concerns have been raised that pacifiers may result in reduced duration of breastfeeding.[11] Much of the controversy results from the inconsistency in research findings related to breastfeeding and pacifier use. Several observational studies published since the Baby-Friendly Hospital Initiative was developed indicate an approximate doubling of the risk of early weaning with daily pacifier use.[12-16] The question of whether such an association is causal remains: pacifier use could be a marker of breastfeeding difficulties or a mother's reduced motivation to continue breastfeeding. Randomized controlled trials in developed countries have not shown that recommending a pacifier results in shorter breastfeeding duration, except when it is started in the first 5 days after birth.[17-19]

Because of the scarcity of studies with sufficient power and rigorous design to address the impact of recommending pacifiers on breastfeeding, we conducted a multicenter, randomized, single blind, non-inferiority trial to assess the effects of such a recommendation after 2 weeks of age on breastfeeding prevalence and duration.

Methods

Enrollment was conducted with women giving birth at 5 tertiary centers in Argentina: 1) Hospital Italiano de Buenos Aires; 2) Sanatorio Trinidad Palermo; 3) Hospital Materno Infantil de San Isidro; 4) Hospital Paroissien de la Matanza; and 5) Hospital Privado de Bahía Blanca. Institutions 1 and 3 are labeled Baby-Friendly Hospital by the World Health Organization and United Nations Children's Fund, and institutions 3 and 4 are public hospitals.

OfferP	Offering pacifier
Not-OfferP	Not offering pacifier
SIDS	Sudden infant death syndrome

From the School of Medicine, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina (A.J.); Division of Newborn Medicine, Department of Pediatrics, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina (A.J., N.J.); Department of Pediatrics and Neonatology, Sanatorio de la Trinidad Palermo, Buenos Aires, Argentina (N.V., A.G.); Universidad de Buenos Aires, Buenos Aires, Argentina (N.V.); and Fundación para la Salud Materno Infantil (Fundasamin), Buenos Aires, Argentina (N.V., A.G.)

*Additional members and hospitals of the Pacifier and Breastfeeding Trial Group are available at www.jpeds.com (Appendix).

This study funded by International Children Medical Research Association, Switzerland. The sponsors had no role in the study design, data collection, data analysis, data interpretation or writing of this report. The authors declare no conflicts of interest.
This study is registered with ClinicalTrials.gov (NST00306956).

 10.1016/j.jpeds.2009.03.038

All the participating hospitals had established breastfeeding programs, with early initiation of breastfeeding, lactation consultants, and unrestricted rooming-in. Mothers were encouraged to avoid pacifier use until breastfeeding was well established. Patient's obstetricians and pediatricians were informed of the study.

Infants born with at least 37 completed weeks gestational age and 2500 g birth weight, exclusively breastfeeding, whose mothers reported an intention to breastfeed for at least 3 months, were eligible for the study when they were not using pacifiers and lactation was well established at the age of 2 weeks. Lactation was considered well established when the mother experienced let-down, which could be very dramatic or only a feeling of relief of fullness, and the infant regained birth weight. Exclusion criteria were breast problems that could interfere with breastfeeding (persistently sore nipples, mastitis, earlier breast surgery, and severely flat or inverted nipples). Mothers who communicated a preference in the introduction or not of a pacifier were also excluded.

Mothers were invited to participate at 2 weeks after their children's birth. After signing the informed consent, they were randomly assigned to 1 of 2 groups: offering pacifier (OfferP) and not offering pacifier (Not-OfferP).

The OfferP group received a package containing 6 silicone pacifiers (supplied by MAM Babyartikel GesmbH and not sold in Argentina) and a written pacifier guide for parents (**Appendix 2**; available at www.jpeds.com) They were also informed that other pacifiers could be used according to their preference. The Not-OfferP group received a guide with other alternatives for comforting a crying baby.

The randomization scheme was carried out centrally, with consecutively numbered, sealed, opaque envelopes containing randomly generated numbers constructed by an independent statistician. A series of 500 envelopes was given to the research assistant at each participating hospital with instructions to open the envelopes in numerical sequence and to assign the dyads to the corresponding group.

The study was approved by the Human Ethics Committee of the Hospital Italiano de Buenos Aires and the institutional review boards of each participating center. Participants were not compensated except for the free supply of pacifiers aforementioned for the OfferP group.

After the first 300 patients reached the primary outcome, an independent data safety monitoring committee analyzed the results, which required *P* value of .007 to stop the trial.

Outcome Measures

The primary outcome was the prevalence of exclusive breastfeeding at 3 months. The secondary outcomes included the prevalence of exclusive and any breastfeeding at different ages, the duration of any breastfeeding, and compliance with the recommendations assigned to each group (dyads in the OfferP group using a pacifier and dyads in the Not-OfferP group that did not use a pacifier).

Postnatal Follow-up

Participating mothers were interviewed at 1, 2, 3, 4, 5, 6, 8, 10, and 12 months after birth or until breastfeeding ended, by a research assistant who was blinded to group assignment. Interviews were conducted via telephone with a structured questionnaire designed to assess exclusive or any breastfeeding prevalence and duration and whether the baby had used a pacifier. The trial data were entered both in a specially designed online database and on a printed case record form.

Breastfeeding Definitions

Infants exclusively breastfed received breast milk only. No other liquids (other than vitamins or medications) or solid foods were given. Partially breastfed infants received formula or semisolids in addition to breast milk. Any breastfeeding included both of the aforementioned categories.

Statistical Analysis

The study was designed as a non-inferiority trial. In an earlier study in 1 of these hospitals, approximately 60% of mothers were breastfeeding exclusively at 3 months.[20] Because we enrolled only mothers who were already successfully breastfeeding exclusively at 2 weeks and who indicated their intention to continue to do so for at least 3 months, we anticipated that 75% would be breastfeeding exclusively at 3 months.

Sample size calculations determined that with an exclusive breastfeeding rate of 75%, accepting as non-inferiority a reduction in exclusive breastfeeding lactation from 75% to 68% (margin of 7%), 960 mother-infant pairs (480 in each group) would be needed to achieve 75% power. One-sided test with a significance level targeted at 0.025 was used for this calculation. Assuming a dropout rate of 5%, recruitment was increased to 1010 infants to maintain the target number of patients.

Primary analysis was by intention to treat. We compared groups using the Student t test for continuous variables and the χ^2 test or Fisher exact test, when appropriate, for categorical variables. We used the χ^2 test to compare the prevalence of breastfeeding. To minimize the probability of missing true differences, we also analyzed separately those dyads that complied with the assigned recommendation.

Survival curves computed with the actuarial method were used to analyze the association between pacifier use and duration of any breastfeeding. All statistical analyses were performed with Stata software version 8.0 Intercooled (StataCorp LP, College Station, Texas).

Results

From Nov 1, 2005, to May 31, 2006, 1021 mother-infant pairs underwent randomization. Of these, 528 were randomized to the OfferP group and 493 to the Not-OfferP group. Hospitals started recruitment at different dates, but all stopped inclusion of patients on the same day, on completion of the expected sample size.

As shown in **Table I**, the OfferP and Not-OfferP groups were similar in baseline demographic characteristics.

Table I. Baseline characteristics of mother-infant dyads included in the study

	OfferP group (n = 528)	Not-OfferP group (n = 493)
Infant birth weight (g)	3690 (477)	3659 (418)
Cesarean delivery	192 (36%)	174 (35%)
Maternal age	29.30 (5.6)	29.33 (5.8)
Born in Baby-Friendly hospital	143 (29%)	124 (26%)
Earlier breastfeeding	211 (42%)	208 (44%)
Mother smokes	47 (9.4%)	42 (8.9%)
Father lives in household	464 (93%)	438 (93%)
Mother's education		
Elementary	100 (20%)	86 (18%)
High school	155 (31%)	166 (35%)
Tertiary	102 (20%)	83 (18%)
University	142 (28%)	136 (29%)

All values are n (%), except for birth weight and maternal age, which is mean (SD).

Complete data for 499 mother-infant pairs in the OfferP group and 471 in the Not-OfferP group were available for the main outcome analysis at the 3-month assessment (Figure 1).

The prevalences of exclusive breastfeeding at 3 months were 85.8% and 86.2% in the OfferP and Not-OfferP groups, respectively (risk difference, 0.4%; 95% CI, –4.7-4.0).

During the first 4 months, the prevalence of exclusive breastfeeding was >75% in both groups, and risk differences for exclusive breastfeeding remained within the pre-specified non-inferiority margin of –7%. For any breastfeeding, the prevalence was very high, and the risk differences demonstrated non-inferiority at all evaluated times (Figure 2). The risks of continuation with time were also estimated according to the actuarial survival analysis. There were no significant differences in groups for the duration of any breastfeeding (Figure 3).

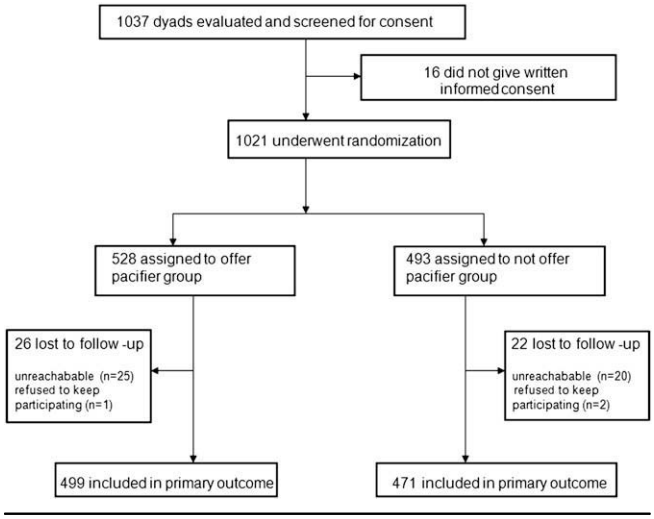

Figure 1. Trial profile.

The results were similar across all centers. No differences were found in groups, when dyads from public and private hospitals were compared separately (Table II; available at www.jpeds.com).

In the OfferP group, 67% of the infants (336/499) used a pacifier, whereas in the Not-OfferP group as much as 40% of the infants (188/471) used it. Pacifier use was significantly different in the groups ($P < .001$). The prevalence of exclusive breastfeeding in the OfferP and the Not-OfferP groups, considering only dyads that complied with the assigned recommendation, were also similar: 85.2% versus 88.34%, respectively. However this study was not powered to analyze these subgroups.

Discussion

In this randomized controlled trial of term-gestation healthy newborn infants who were successfully breastfeeding at 2 weeks and whose mothers reported an intention to breastfeed for at least 3 months, the recommendation for offering a pacifier did not decrease the prevalence of exclusive breastfeeding at 3 months.

A number of observational studies have been published that indicate a negative association between pacifier use and breastfeeding duration.[12-16] Kramer et al stated that breastfeeding and pacifier use are complex behaviors heavily influenced by cultural, motivational, and psychological factors that are extremely difficult to measure, and thus to control for, in observational studies.[18] The use of a pacifier could be the cause of early weaning, but also a marker for breastfeeding difficulties or reduced motivation to breastfeed. The question becomes more relevant in view of the increase in the information about an association between pacifier use and a reduced risk of SIDS, and it can only be adequately answered by randomized studies.

To our knowledge, only 3 smaller randomized controlled trials have investigated the effect of pacifier use and breastfeeding duration. A Swiss trial of healthy, breastfeeding newborns evaluated the effect of the avoidance of pacifier, bottle, and supplemental feeding for the first 5 days versus no restrictions on pacifiers and a more liberally offered fluid supplementation.[17] They found no differences in breastfeeding duration. This study was not designed to evaluate separately the effects of pacifiers and bottle-nipple exposure. The intervention was limited to the peripartum hospitalization.

A more recent trial by Kramer et al, looking at a longer period of pacifier avoidance, randomized mothers of healthy full – term breastfeeding infants during the postpartum stay to groups that were either counseled in pacifier avoidance or given no specific counseling in pacifier use.[18] Although an association between pacifier use and early weaning from the breast was found, no such association was seen when the data were analyzed by group allocation. Because of the wide confidence intervals reported in the trial, a larger sample would have been required to exclude small changes in the risk of early weaning in relationship to counseling.

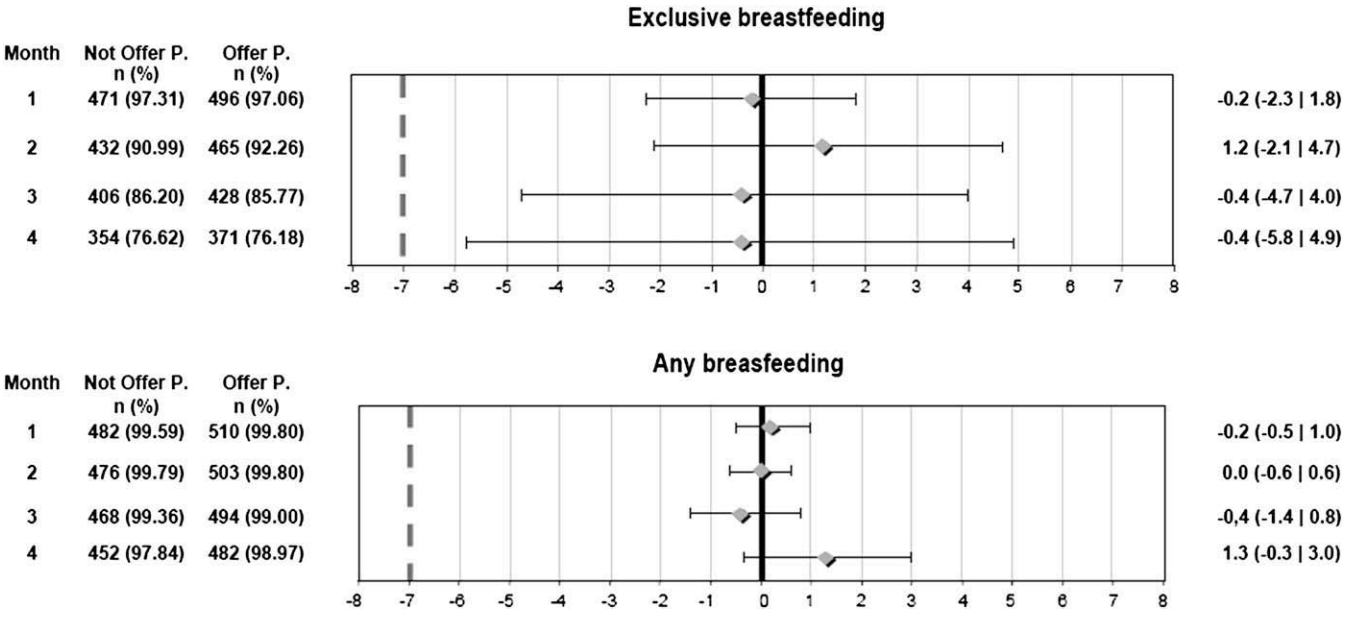

Figure 2. Comparison of prevalence of exclusive breastfeeding (upper part of figure) and any breastfeeding (lower part) between the Not-OfferP and OfferP groups for pre-specified times. The data and 95% CIs for risk differences are shown as point estimates. The vertical dotted line represents the previously determined non-inferiority margin.

Howard et al found that pacifier use in the first 5 days, but not after 4 weeks, postpartum was associated with shorter breastfeeding duration. Unfortunately, the average duration of exclusive breastfeeding in both groups was <1 month, and the average duration of any breastfeeding was <2 months.[19] However, the American Academy of Pediatrics Task Force of SIDS used this information to conclude that pacifier use after the first month does not increase the risk of breastfeeding cessation.[10]

Analyzing 970 mother-infant pairs, our study demonstrates that when breastfeeding is well established, the recommendation to offer a pacifier at 2 weeks does not affect the prevalence and duration of breastfeeding.

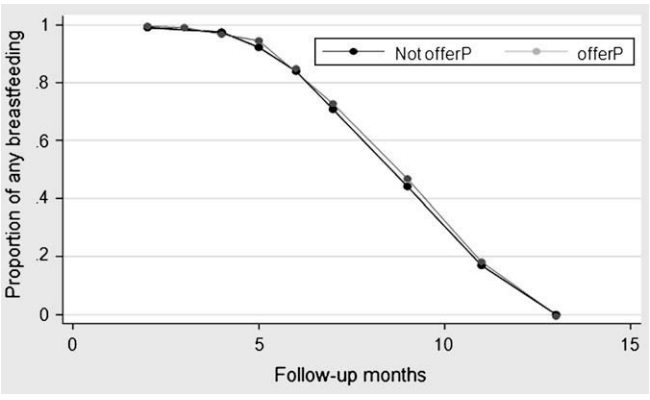

Figure 3. Proportion of infants still breastfeeding according to the assigned group.

In our trial, for the sample size calculation, an incidence of exclusive breastfeeding of 75% at 3 months was estimated. Because both groups had a prevalence >85%, a post hoc analysis demonstrates a power of 86% for the primary outcome.

A clear limitation of our study is that the results may not be applicable when women are less motivated to breastfeed or when pacifiers are introduced before breastfeeding is well established.

Similar to the study by Kramer et al, a large number of mother-infant pairs in this trial did not comply with the recommendation to which they were randomized.[18] At 3 months, only 67% of infants whose mothers received the assignment of offering a pacifier were using it, whereas 40% of infants who were randomized to the not offering pacifier group were using it. This rate of non-compliance is not surprising in a population of healthy mothers and infants, because all parents were informed of the potential advantages and disadvantages of offering a pacifier to their infants. The cultural background of parents, real-life situations such as intense infant crying, and infant preferences, may have influenced the use of pacifiers in our trial. We do not know how effective the recommendation to offer a pacifier would be if information about its effects on decreasing the risk of SIDS was provided or if a pacifier was offered before age 2 weeks.

The incidence of exclusive breastfeeding at 3 months in the dyads that complied with the assigned recommendation was very similar for both groups: 85.2% in the OfferP group versus 88.3% in the not-OfferP group, but the study was not

powered for this analysis. The consistency of these results with those of the intention to treat analysis strongly suggests that recommending to use a pacifier in a population similar to ours does not influence breastfeeding success or duration.

In conclusion, in mothers with a firm intention to breastfeed their infants and who had achieved successful breastfeeding by day 15, the recommendation to introduce a pacifier does not affect the success and duration of exclusive or any breastfeeding. Because pacifier use reduces the risk of SIDS, the recommendation to offer a pacifier after breastfeeding is well established appears safe and appropriate in similar populations. ■

We are indebted to Ariel Fernandez for data management and preparation of tables and figures, to Guillermo Carroli, Carlos Fustiñana, Gustavo Izbizky, Edgardo Szyld, and Peter Weiss (consultant for MAM Babyartikel GmbH) for thoughtful advice, to Richard Schanler, M. Jeffrey Maisels, Waldemar Carlo, and Gonzalo Mariani for reviewing the manuscript, to David Mage and Adele Engelberts for their comments and support, to Daniel Wojdyla for statistical recommendations, to Veronica Marino for secretarial assistance, and most important, to the families and their children who participated in this trial.

Submitted for publication Dec 5, 2008; last revision received Feb 16, 2009; accepted March 19, 2009.

Reprint requests: Alejandro Jenik MD, Department of Pediatrics, Neonatal Unit, Hospital Italiano de Buenos Aires, Gascón 450. Ciudad Autónoma de Buenos Aires, Argentina. E-mail: alejandro.jenik@hospitalitaliano.org.ar

References

1. Ip S, Chung M, Raman G, Chew P, Magula N, DeVine D, et al. Breastfeeding and maternal and infant health outcomes in developed countries. Evid Rep Technol Assess (Full Rep) 2007;1-186.
2. WHO Collaborative Study Team on the Role of Breastfeeding on the Prevention of Infant Mortality. Effect of breastfeeding on infant and child mortality due to infectious diseases in less developed countries: a pooled analysis. Lancet 2000;355:451-5.
3. WHO. Protecting, promoting and supporting breastfeeding: the special role of maternity services (a joint WHO/UNICEFstatement). Geneva: World Health Organization; 1989.
4. Baby Friendly USA. The ten steps to successful breastfeeding: final repot (Internet). East Sandwich, MA: Baby Friendly USA; 2005.
5. Diaz-Rossello J, Conde-Agudelo A, Forteza AC. Pacifiers: protection against sudden infant death syndrome. Lancet 2000;355:1829.
6. Hauck FR, Omojokun OO, Siadaty MS. Do pacifiers reduce the risk of sudden infant death syndrome? A meta-analysis. Pediatrics 2005;116: e716-23.
7. Hauck FR. Pacifiers and sudden infant death syndrome: what should we recommend? Pediatrics 2006;117:1811-2.
8. Mitchell EA, Blair PS, L'Hoir MP. Should pacifiers be recommended to prevent sudden infant death syndrome? Pediatrics 2006;117:1755-8.
9. Moon RY, Horne RS, Hauck FR. Sudden infant death syndrome. Lancet 2007;370:1578-87.
10. The changing concept of sudden infant death syndrome: diagnostic coding shifts, controversies regarding the sleeping environment, and new variables to consider in reducing risk. Pediatrics 2005;116:1245-55.
11. LLLI. LLLI Responds to AAP statement on sudden infant death syndrome. Media releases. Edited Oct 14, 2005.
12. Victora CG, Tomasi E, Olinto MT, Barros FC. Use of pacifiers and breastfeeding duration. Lancet 1993;341:404-6.
13. Ford RP, Mitchell EA, Scragg R, Stewart AW, Taylor BJ, Allen EM. Factors adversely associated with breast feeding in New Zealand. J Paediatr Child Health 1994;30:483-9.
14. Clements MS, Mitchell EA, Wright SP, Esmail A, Jones DR, Ford RP. Influences on breastfeeding in southeast England. Acta Paediatr 1997;86: 51-6.
15. Howard CR, Howard FM, Lanphear B, deBlieck EA, Eberly S, Lawrence RA. The effects of early pacifier use on breastfeeding duration. Pediatrics 1999;103:E33.
16. Vogel AM, Hutchison BL, Mitchell EA. The impact of pacifier use on breastfeeding: a prospective cohort study. J Paediatr Child Health 2001;37:58-63.
17. Schubiger G, Schwarz U, Tonz O. UNICEF/WHO baby-friendly hospital initiative: does the use of bottles and pacifiers in the neonatal nursery prevent successful breastfeeding? Neonatal Study Group. Eur J Pediatr 1997;156:874-7.
18. Kramer MS, Barr RG, Dagenais S, Yang H, Jones P, Ciofani L, et al. Pacifier use, early weaning, and cry/fuss behavior: a randomized controlled trial. JAMA 2001;286:322-6.
19. Howard CR, Howard FM, Lanphear B, Eberly S, deBlieck EA, Oakes D, et al. Randomized clinical trial of pacifier use and bottle-feeding or cupfeeding and their effect on breastfeeding. Pediatrics 2003;111: 511-8.
20. Cernadas JM, Noceda G, Barrera L, Martinez AM, Garsd A. Maternal and perinatal factors influencing the duration of exclusive breastfeeding during the first 6 months of life. J Hum Lact 2003; 19:136-44.

Appendix 1.

In addition to the authors, the following members of the Pacifier and Breastfeeding Trial Group participated in the Pacifier and Breastfeeding Trial: Hospital Italiano de Buenos Aires: A.Pardo; Hospital Paroissien de la Matanza: N.Lopez; Sanatorio Trinidad, Palermo: N. Rossato, G.Corral; Hospital Materno Infantl de San Isidro: S. Russo, M.C. Degregori; Hospital Privado del Sur, Bahía Blanca: M.C.Covas, S.Ventura; Data and Safety Monitoring Board: S. Rodríguez, D. Fariña, E. Bergel; telephone interviews and data entry: P.Abadie.

Appendix 2. Instructions to the mothers who would introduce the pacifiers at 15 days.

- All breastfeeding mother-infant pairs would be followed up at 96 hours postpartum. At this evaluation, mothers should be asked if their milk has come in, and if the answer is "no," they should be provided with immediate assistance by a health care provider trained in lactation management.
- Advise parents and caregivers to clean pacifiers routinely and avoid sharing between siblings.
- Advise parents not to lick pacifiers to clean them. Parents will receive several pacifiers to rotate through cycles of cleaning and use during the day.
- Advise parents and caregivers to exercise judgement and restraint regarding pacifier use. They should be taught to avoid ad lib use throughout the day and limit their use for sleeping instances and soothing breastfed infants.
- Suggest to parents that pacifier use should be curtailed beginning at age 2 years and that pacifier habits be discontinued by or before age 4 years to minimize the development of malocclusion.
- Never attach ribbons or cords to a pacifier; your child may be strangled by them.
- Inspect carefully before each use, especially when the child has teeth. Pull the pacifier in all directions. Throw it away at the first signs of damage or weakness.
- Do not leave a pacifier in direct sunlight or near a source of heat. Do not leave it in disinfectant ("sterilizing solution") for longer than recommended because this may weaken the teat.
- Before first use, place the pacifier in boiling water for 5 minutes, allow to cool, and squeeze out any trapped water from the pacifier. This is to ensure hygiene.
- Clean before each use.
- Never dip teat in sweet substances or medication.

Table II. Comparison of prevalence of exclusive breastfeeding in groups at 3 months in patients at public and at private hospitals

Exclusive breastfeeding	Not-OfferP, n	OfferP, n	RR	95% CI	*P* value
Public hospitals	98 (79.03%)	119 (83.22%)	1.05	0.93-1.18	.38
Private hospitals	308 (88.76%)	309 (86.80%)	0.97	0.92-1.03	.42

RR, Risk ratio.