Effects of a Mobile Application on Breastfeeding Maintenance in the First 6 Months After Birth: Randomised Controlled Trial (COMLACT Study)

Abstract

Problem: It is necessary to continue promoting breastfeeding rates.

Background: Information and communication technologies have significantly impacted healthcare services and are transforming the sector. There is little evidence of the usefulness of mobile applications to support breastfeeding and increase its duration.

Aim: To assess whether mobile application—LactApp® (Barcelona, Spain)—usage compared with standard care increases the 6-month postpartum breastfeeding rate.

Methods: A multicentre, randomised, controlled clinical trial of parallel groups was conducted. The study was conducted in four public hospitals in Spain from January 2022 to January 2023. 270 Women were randomly assigned to each parallel group.

The women in the intervention group received free access to the mobile application LactApp®, which provides personalised and convenient support to women about BF. Women in the control group received standard care, which included individual counselling about the benefits of maintaining BF for the first 6 months of the baby's life.

Findings: The rate of breastfeeding abandonment at 15 days was 6.4% in the control group vs 0.0% in the intervention group ($p = 0.105$). LactApp® usage did not increase the 6-month postpartum breastfeeding rate compared with standard care (CG = 41.6% vs. IG = 43.6%; p = 0.826).

Discussion: Further studies must explore how technologies can help improve long-term breastfeeding maintenance. The mobile app seems to reduce early weaning in the first 15 days slightly.

Conclusion: Mobile application usage did not increase the breastfeeding rate compared with standard practice but may reduce breastfeeding abandonment in the first 2 weeks postpartum.

Keywords: Exclusive breastfeeding; Breastfeeding; e-Health; Mobile applications; Midwives; Nursing.

Statement of Significance

Problem or Issue
- Breastfeeding has shown multiple benefits for the health of the child and the mother.
- Breastfeeding rates at six months are below the WHO recommendations.

What is already known
- Information and communication technologies have significantly impacted healthcare services and are transforming the sector.
- The usefulness of mobile applications to increase the maintenance of breastfeeding is limited and with mixed results.

What this paper adds
- This study shows how a mobile application could not help to establish or maintain breastfeeding.
- This study emphasises that professional guidance remains more effective in sustaining breastfeeding rates than a mobile application's guidance.
- This study shows the possible limitations of using an application to improve adherence to support breastfeeding.

Introduction

Breastfeeding (BF) confers considerable physical and psychological benefits for both the mother and child (Lau et al., 2018). International organisations such as the World Health Organization (WHO) recommend that exclusive breastfeeding (EBF) should be initiated among infants for the first 6 months postpartum, followed by continued BF until at least 2 years of age (Kim et al., 2018). It is widely recognised that the maintenance of EBF is a central element for child health and survival (Rollins et al., 2016).

The global situation indicates that although almost all countries encourage EBF, there is a gradual decline in its maintenance during the first months of a child's life (Oribe et al., 2015). The global prevalence of EBF at 6 months of age is approximately 40% (Mena-Tudela et al., 2023). In 2012, the World Health Assembly endorsed a global target of increasing the rate of EBF in the first 6 months of life to at least 50% by 2025 (WHO/UNICEF, 2014).

There are numerous and complex factors that negatively affect the BF rate and contribute to early abandonment. These factors can be grouped into three categories: 1) clinical–psychological factors, such as assisted reproduction treatments (Cromi et al., 2015), smoking (Santacruz-Salas et al., 2020), maternal expectations (Rius et al., 2014), pacifier use during the first month of life (Santacruz-Salas et al., 2020), and the sensation of a lack of milk (hypogalactia) (Vila-Candel et al., 2018); 2) environmental factors (family/friends, work, and health system) (Lechosa-Muñiz et al., 2020); and 3) sociocultural and economic factors (Oribe et al., 2015).

Background

Information and communication technologies (ICT) have significantly impacted healthcare services and are transforming the sector. In Spain, 92.8% of women aged 16 to 74 use the Internet at least once a week, according to a report from the National Observatory of Telecommunications and Information Society (Ontsi, 2023). Mobile applications are one of the fastest-growing areas of ICT in the healthcare sector. In 2022, almost 100% of Spaniards owned a smartphone; one-third had a computer, and over half had a tablet. Users spend an average of 4.8 hours daily on applications, up to 1,752 hours yearly (Ditrendia, 2022). The high number of application downloads indicates that this is an emerging tool for seeking medical help and information that could complement traditional forms of BF support (Padró-Arocas, Quifer-Rada, et al., 2021).

Various studies have examined the relationship between the use of applications and the maintenance of BF but found mixed results, as race, economic resources, and social determinants may influence BF maintenance (Doan et al., 2022; Galvão et al., 2021; Griffin et al., 2021; Mieso et al., 2022; Miremberg et al., 2022).

The main objective of our study was to assess the effects of a mobile application on the maintenance of BF at 6 months postpartum, including both exclusive BF and any form of BF (mixed feeding).

Participants, Ethics and Methods

Participants

The study was conducted in four hospitals in Spain, three of which are in the eastern region and one in the western region, from January 2022 to January 2023.

Four hospitals have been selected based on their geographical location, and although the health areas in which each hospital is located will influence the characteristics of the women attended, it allows us to have a broader view of the event to be analysed, allowing

a generalisation of the possible results while limiting biases in the study. Three of the hospitals are located in the eastern region of Spain, while the fourth one is in the country's western part.

In the eastern region, the General Hospital of Castellón was chosen due to the significant population it serves, located in the northeastern part of this region. The other two hospitals, Hospital de la Ribera and Hospital Lluis Alcanyis are situated in the southeast and have a similar number of annual deliveries.

On the other hand, the General Hospital of Cáceres was selected based on the type of care it provides, focusing on women with characteristics different from those in the eastern part of the country. All four hospitals share similarities in the rates of normal vaginal and caesarean births and the rate of treated prematurity; all are part of the IHAN program for assessing healthcare quality during maternity. Breastfeeding rates at discharge are similar in the four centres.

These hospitals provide healthcare services to 500,000 people and witness an average of approximately 5,000 births annually. In this study, pregnant women were recruited from various primary care clinics managed by midwives affiliated with each participating health department during their third trimester of pregnancy.

Once the estimated sample size was known, a list was made with the total number of cases. Simple randomisation for two groups of equal size (intervention group [IG] and control group [CG]) was generated using the Epidat v.4.2 program (*Epidat: Programa Para Análisis Epidemiológico de Datos. Versión 4.2, Julio 2016. Consellería de Sanidade, Xunta de Galicia, España; Organización Panamericana de La Salud (OPS-OMS); Universidad CES, Colombia*). For each group, two types of QR codes were printed on quarter-sized sheets and placed in numbered opaque envelopes, respecting the random sequence. After the process was completed, the envelopes were sealed. The project's principal investigator was responsible for preparing this process, concealing the allocation sequence from the rest of the research team and the midwives who recruited the women, making them blind to the allocation. None of the participating midwives in the sample collection had access to the platform, and they were unaware of the assigned group of each participant. Only the project's data manager had access to the study database.

Based on previously described methods (Qian et al., 2021), assuming that the discontinuation rate of BF at 6 months in the CG is 65% and expecting a discontinuation rate in the IG of 40%, with a significance level of 0.05 and a power of 85%, a total of 164 women were required for a balanced design. With an estimated loss rate of 30%, 214 women were necessary for the study.

The exclusion criteria established during the third trimester were as follows: i) women under 16 years of age; ii) women with cognitive impairments, language barriers, or illiteracy (not able to read Spanish); iii) not having a mobile device with an internet connection; iv) newborns with congenital malformations; and v) twin or multiple pregnancies.

The exclusion criteria established after birth were as follows: i) infant admission to the neonatal intensive care unit (NICU) or postpartum complications requiring maternal admission to the intensive care unit for comparison of the results with other published reports owing to the higher demands of such situations; ii) preterm births (<37 weeks); iii) perinatal death; iv) women who did not respond to the automated messages sent by the platform after three attempts; v) women in the IG who did not complete more than

five consultations in the first 6 months, defined as lack of use; and vi) women in the CG who used the LactApp® application on their initiative.

Methods

A multicenter, randomised, controlled clinical trial (RCT) of parallel groups was conducted. This RCT is reported following the Consolidated Standards of Reporting Trials.

Study Intervention and Fidelity of the Intervention
<u>Both Groups</u>
A plan for email reminders was established to obtain follow-up information on BF while avoiding providing additional information on BF at any time. Per standard clinical practice, the women could attend the maternity and paternity educational program and BF workshops during pregnancy. Each expectant mother was also provided with a printed BF manual (Conselleria de Sanitat, 2010).

The platform was programmed to send a series of emails to all participants based on their probable birth date. Five emails were sent to each participant: one each after birth and at 15 days, 6 weeks, 3 months, and 6 months postpartum.

<u>CG (Usual Care)</u>
The usual clinical practice included individual counselling about the benefits of maintaining BF for the first 6 months of the baby's life and introducing complementary foods. The mother was required to attend at least six scheduled visits, including two with the midwife and four with the primary care paediatrician before the baby reached 6 months of age.

<u>IG (Mobile Application)</u>
LactApp is a free mobile application available on the Apple Store® and Google Play® that provides personalised and convenient support to women about BF. LactApp has been created and designed by Alba Padró Arocas (APA). APA is an International Board-Certified Lactation Consultant (IBCLC) and co-founder of the company LactApp Women's Health (Barcelona, Spain). This company is responsible for managing the data derived from the application in compliance with current legislation and data protection at the European and Spanish levels. The women who participated in the study had access to all available information on LactApp from their initial registration during the third trimester of pregnancy. From the point of registration, users can access up-to-date information supported by expert lactation professionals, allowing them to make informed decisions and resolve doubts before or after birth.

We chose LactApp, a unique tool based on a self-administered questionnaire incorporating over 50 decision trees, evidence-based questions, and official health recommendations. The questionnaire yields 2,300 personalized answers, navigated through 76,100 potential paths, tailored to users' profiles and selected options. LactApp stands among the top 20% of globally downloaded and active apps, utilized by 23% of mothers in Spain. This extensive reach and the tool's nuanced approach, combined with its intuitive interface, strengthen our decision. In our study, LactApp's comprehensive approach, offering thousands of personalized responses, enhanced the precision and effectiveness of breastfeeding support, aligning with our research's evidence-based orientation. LactApp has been development in Spanish and it's available in English

The main functionality of LactApp is its automated BF consultation system. Additionally, the application allows for BF tracking by recording daily feedings, BF-related difficulties, mood, and other relevant aspects. LactApp provides continuously updated information supported by expert lactation professionals and offers a live chat feature for users to

discuss their BF concerns. Moreover, based on the user's due date, the application sends timely reminders, such as appropriate BF positions, feeding frequency, milk extraction techniques, and the significance of EBF. The application covers various topics, including baby care, weight gain, and lactation support for mothers supplementing with formula. It also provides information about creating a milk reserve, handling and storing milk, and administering the stored milk to infants. Usage data for LactApp were reported by the application's administrators, who provided anonymised data for each participant through a unique identification code.

Validity and Reliability of Data Source
The sociodemographic variables were as follows: maternal age (in complete years up to the probable date of birth); country of origin (Spain/Foreign); educational level (primary school or lower/secondary school/university); civil status (single/married/divorced/separated); maternal support (yes/no); employment status (self-employed/professional/managerial/employee/unemployed/student/not seeking work); and hospital of birth.

The obstetric–neonatal variables were as follows: gestational age at the time of birth (in complete weeks); parity (primiparous/multiparous); previous BF experience (yes/no); pregnancy risk (low risk/high risk [endocrinological pathologies/hypertension/assisted reproductive treatment/others]); type of onset of labour (spontaneous/induction/elective cesarean section); type of labour analgesia (epidural/others); type of birth (vaginal birth/instrumental birth/cesarean section); newborn sex (female/male); birth weight (in grams); early skin-to-skin contact with the newborn—initiated before 30 minutes for at least 2 uninterrupted hours—(yes/no/with the companion); and early initiation of BF (within 2 hours/more than 2 hours).

The response variable was the type of BF (exclusive BF/ supplementary feeding [SF]/ mixed BF) at discharge and 15 days, 6 weeks, 3 months, and 6 months postpartum. The indicators for assessing infant and young child feeding practices were as follows: 1) EBF, when the infant received only drops or syrups (vitamins, medicines, or minerals), including expressed or donated milk; 2) SF, when the infant was fed exclusively with artificial milk or supplementary food; and 3) mixed BF, when the infant was fed with a combination of breast milk and artificial milk or supplementary food. The response variable "abandons BF" (yes/no) was constructed; "yes" was answered when the woman fed her baby with formula or supplementary food and "no" when she continued BF at discharge and 15 days, 6 weeks, 3 months, and 6 months postpartum.

After collecting the data, a thorough data verification process was performed, promptly addressing any issues identified. A descriptive analysis was conducted to identify apparent errors and outliers in the data, and cross-checking with the source was conducted when necessary.

The study acknowledges that age, educational level, employment status, and previous BF experience may influence the results. Randomisation is expected to compensate for any poorly distributed characteristics between the groups. However, when such features were detected, they were included as independent variables in multivariate analysis models and exposure variables.

Data Collection
Sample collection was conducted during the third trimester of pregnancy at the primary care midwife consultation in the participating healthcare centres of each health department. After reading the patient information sheet and obtaining informed consent, the midwife handed a numbered envelope to the women. At the end of the visit, the women were required to scan the QR code with their mobile devices and register via

email on the lactation platform after accepting the privacy policy. The registration process was identical for both the IG and CG. Once registered, the IG participants received an additional email with a link to download LactApp.

Collaborating researchers from each health department were given password-protected access to the platform to record birth data and the number of visits made by various healthcare professionals during the study period. The collected information was entered into an electronic form, ensuring compliance with current regulations and guaranteeing confidentiality and anonymity. Losses and dropouts during the study and their causes were recorded. However, the researchers were not authorised to view the planned surveys that the participants completed during the study follow-up.

Finally, the data manager was responsible for matching the participants' survey responses with their birth dates and the follow-ups performed by various healthcare professionals for up to 6 months. In our data collection process, the data manager utilised anonymised user IDs generated by the app to match participants' survey responses with their birth dates. The app does not collect personally identifiable information; instead, it assigns unique, encrypted user IDs to maintain user privacy. This approach ensures confidentiality and complies with data protection regulations. Our methodology prioritises user anonymity and data security, allowing accurate matching while safeguarding participants' privacy rights.

Data Analysis
Descriptive data analyses were performed based on the nature of the variables. Baseline characteristics were analysed between the group with potential losses during follow-up, and the group that completed follow-up using cross-tabulation tables, and mean comparisons were performed using Fisher's exact test or the Mann–Whitney U test, as appropriate.

The association of the baseline and childbirth variables with BF abandonment at discharge and 15 days, 6 weeks, 3 months, and 6 months postpartum was also analysed using cross-tabulation tables and the chi-square or Fisher's exact test, as appropriate, and mean comparisons were conducted using the Mann–Whitney U test.

For the evaluation of the effects of the intervention on the abandonment of BF at discharge and 15 days, 6 weeks, 3 months, and 6 months postpartum, cross-tabulation tables were utilised along with the chi-square test. Further, a multivariate logistic model was used, calculating adjusted odds ratios for each time point and their 95% confidence intervals.

Both per-protocol and intention-to-treat (ITT) analyses were performed. The per-protocol analysis used basic descriptive methods to calculate the mean and standard deviation for continuous variables, the median and interquartile range for non-normally distributed variables, and absolute and relative frequencies for categorical variables. The normality assumption of the variables was checked using the Kolmogorov–Smirnov test. Homogeneity analysis of the groups based on the baseline and childbirth variables was performed using cross-tabulation tables and the chi-square or Fisher's exact test; as appropriate, mean comparisons were performed using the Mann–Whitney U test.

In the ITT analysis, a sensitivity analysis was performed for losses during follow-up. The worst possible outcome (BF abandonment) was assigned to the IG response variable. In contrast, the best possible outcome (no BF abandonment) was assigned to the CG response variable at each time. The differences in the response variable between both groups were evaluated using the chi-square test with all randomised participants.

Data analysis was conducted using SPSS v.26.0 for Windows (IBM Corp. 2018, Armonk, NY, USA) and R (R project 2019, version 4.0.2). The level of statistical significance was set at $p < 0.005$.

Ethical Considerations

The protocol was registered on ClinicalTrials.gov under ID NCT05432700, and the study adhered to the Organic Law 3/2018 of December 5th on the Protection of Personal Data and Guarantee of Digital Rights as well as to the Basic Law 41/2002 of November 14th on the Regulation of Patient Autonomy and the Rights and Obligations Regarding Scientific Information and Documentation. In addition, the ethical principles of the Declaration of Helsinki were respected. The ethical approval from the Research Commission/Ethics Committee on 20/01/2021 preceded the initiation of data collection.

Informed consent was obtained from all participating women. LactApp complies with privacy and cookie policies, ensuring compliance with the measures required by Regulation (EU) 2016/679 of the European Parliament and the Council of April 27th, 2016 on the Protection of Natural Persons Concerning the Processing of Personal Data and on the Free Movement of Such Data, the Organic Law 15/1999 of December 13th on the Protection of Personal Data (LOPD), and Spanish Royal Decree 1720/2007 of December 21st, with due declaration before the Spanish Data Protection Agency. Further, the study complied with Act 34/2002 of July 11th on Electronic Commerce and Information Society Services and the Use of Cookies (LSSICE), expressly requiring consent from registered users of the application.

Results

Characteristics of the Sample

From a sample of 280 women, 10 were excluded from randomisation for the following reasons: two perinatal deaths, six neonatal admissions to the NICU, and two preterm births. Of the 270 randomised pregnant women, 10 (3.7%) were lost to follow-up owing to non-response to the automatic surveys sent to their email: seven at 3 months (70.0%) and three at 6 months (30.0%). Subsequently, 96 women from the IG were excluded owing to non-use of the mobile application. The total analysed sample consisted of 164 participants (Figure 1).
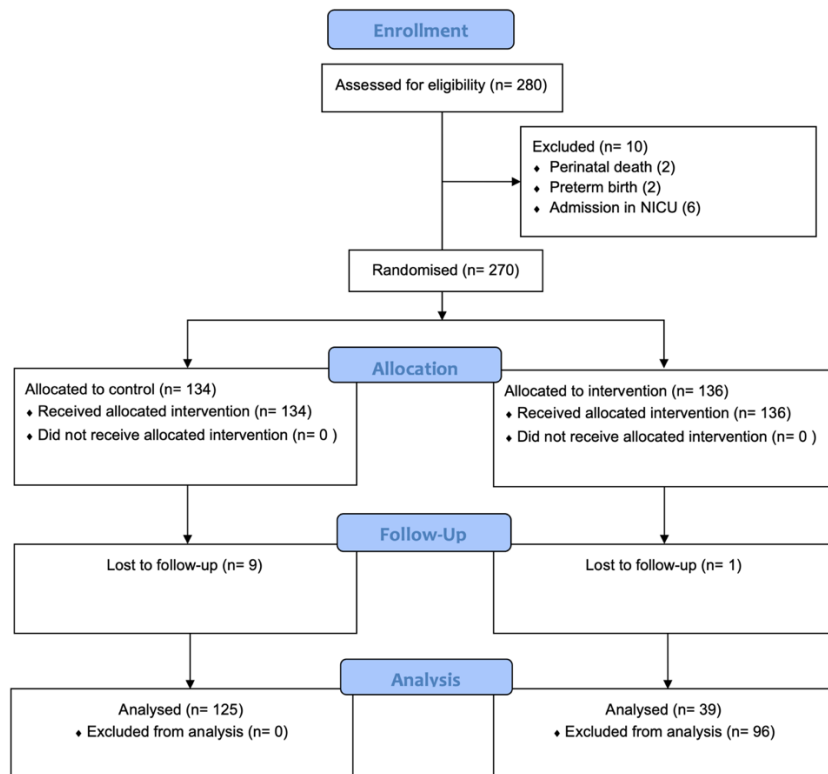
Figure 1. CONSORT Flow diagram of the study.

We compared the baseline characteristics between the following two groups: the group lost to follow-up ($n = 106$ [CG = 9; IG = 97]) and the final analysis group ($n = 164$). We utilised Fisher's exact test and the Mann–Whitney U test, as appropriate, to assess any significant differences between the two groups. There were no significant differences between the groups (except for employment status, $p = 0.042$), indicating that the losses to follow-up were random and did not follow any pattern based on the variables. The homogeneity of the groups was maintained despite the loss of follow-up, which confirmed their random origin.

Sociodemographic and Obstetric–Neonatal Variables

The participants had a mean age of 33.2 ± 4.4 years, with 91.2% (127/164) being born in Spain. The majority had university degrees (55.2%, $n = 82/164$), were married (57.5%, $n = 83/164$), and had paid employment (60.9%, $n = 100/164$). The mean gestational age at birth was 39.2 ± 1.1 weeks; 65.2% were primiparous women (107/164); and the mean birth weight was 3,275.9 ± 440.8 g. Approximately 66.5% (109/164) of the pregnancies were classified as low risk. Among the women, 9.8% (16/169) had gestational diabetes; 4.8% (8/169), hypothyroidism/hyperthyroidism; 2.4% (4/164), preeclampsia; 4.3% (7/164), infertility; and 12.2% (20/164), other conditions (threatened preterm labour [$n = 2$], Crohn's disease [$n = 2$], breech presentation [$n = 3$], placenta previa [$n = 3$], previous caesarean section [$n = 4$], oligohydramnios [$n = 3$], polyhydramnios [$n = 2$], and maternal hip dysplasia [$n = 1$]). The relative rate of previous BF experience was calculated for both groups. In the CG and IG, approximately 17.6% (22/125) and 15.4% (6/39) had prior BF experience, respectively. There were no significant differences in the sociodemographic and obstetric–perinatal variables, except for the country of origin ($p = 0.011$) and educational level ($p = 0.006$), between the CG and IG (Table 1).

Table 1. Sociodemographic and obstetric-neonatal characteristics of the sample (N = 164).

		Group						
		Total (*n* = 164)		Control (*n* = 125)		Intervention (*n* = 39)		
		n	%	*n*	%	*n*	%	*p-*value*
Country of origin	Spain	127	91	71.7	36	28.3		0.011
	Foreign	37	34	91.9	3	8.1		
Educational level	University degree	82	55	67.1	27	32.9		0.006
	Primary and Secondary school	82	70	85.4	12	14.6		
Civil status	Single, divorced	81	60	74.1	21	25.9		0.524
	Married	83	65	78.3	18	21.7		
Maternal support	No	7	6	85.7	1	14.3		0.441
	Yes	127	92	72.4	35	27.6		
Employment status	Unemployed/student/not seeking employment	64	50	78.1	14	21.9		0.647
	Self-employed/professional/managerial/employee	100	75	75.0	25	25.0		
Hospital	Alzira	82	61	74.4	21	25.6		0.904
	Xàtiva	13	11	78.6	3	21.4		
	Castellón	19	14	73.7	5	26.3		
	Cáceres	49	39	79.6	10	20.4		
Parity	Primiparous	107	77	72.0	30	28.0		0.079
	Multiparous	57	48	84.2	9	15.8		
Previous BF experience	Yes	29	22	78.6	6	21.4		0.748
	No	136	103	75.7	33	24.3		
Pregnancy risk	Low risk	109	83	76.1	26	23.9		0.569
	High risk	55	42	76.4	13	23.6		
Labour onset	Spontaneous	159	121	76.1	38	23.9		0.678
	Induction	3	2	66.7	1	33.3		
	Elective C-section	2	2	100.0	0	0.0		
Labour analgesia	Others	50	39	78.0	11	22.0		0.444
	Epidural	114	86	75.4	28	24.6		
Type of birth	Eutocic	75	55	73.3	20	26.7		0.623
	Instrumental	38	30	78.9	8	21.1		

Newborn sex	C-section	32	26	81.3	6	18.8	
	Female	62	45	72.6	17	27.4	0.380
	Male	85	67	78.8	18	21.2	
Early SSC	No	5	4	80.0	1	20.0	
	Yes	129	98	76.0	31	24.0	0.941
	With the companion	10	8	80.0	2	20.0	
Early initiation BF	< 2h	130	99	76.2	31	23.8	0.695
	> 2h	14	10	71.4	4	28.6	

*Chi-squared test; C-section: caesarean section; SSC: skin-to-skin contact.

Per-Protocol Analysis of the Response Variable

During the follow-up period, we observed a progressive decline in the rate of BF from 96.3% ($n = 158/164$) at hospital discharge to 57.3% ($n = 94/164$) at 6 months postpartum. However, no significant differences were found between the CG (58.4%) and IG (56.4%) ($p = 0.826$; Table 2).

Table 2. Analysis of the between-group effect performed by protocol (N = 164)

		Breastfeeding		Abandonment BF		
		n	%	*n*	%	*p*-value*
Group	Control	73	58.4	52	41.6	0.826
	Intervention	22	56.4	17	43.6	

*Chi-squared test

Regarding the effects of the intervention, we did not observe significant differences in the rate of BF abandonment between the IG and CG at any of the five time points: discharge: CG = 6.4% vs. IG = 0.0%, $p = 0.163$; 15 days: CG = 6.4% vs. IG = 0.0%, $p = 0.105$; 6 weeks: CG = 11.2% vs. IG = 7.7%, $p = 0.530$; 3 months: CG = 20.0% vs. IG = 15.4%, $p = 0.520$; and 6 months: CG = 41.6% vs. IG = 43.6%; $p = 0.826$ (Figure 2).
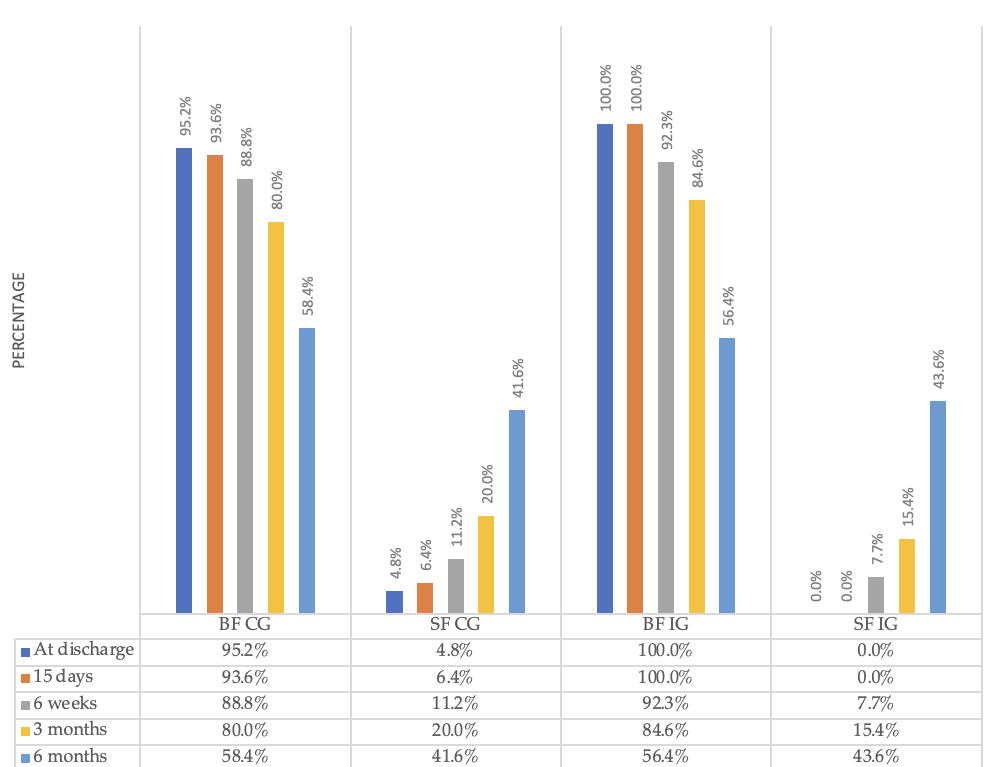
Figure 2. Distribution of early BF abandonment among the intervention and control groups (N = 164).

Table 3 shows a favourable influence on the maintenance of BF at discharge and 15 days postpartum in the IG, although significance was not achieved. At 6 months, there was a negative effect on BF maintenance in the IG, although this effect was not significant. In contrast, none of the variables significantly impacted BF maintenance at 6 weeks and 3 months postpartum. Notably, the country of origin and educational level did not exhibit any significant effects across all periods.

Table 3. Logistic regression of BF abandonment (N = 164).

	Variables in equation	B	Standard Error	Wald	df	p-value*	Exp(B)	95% C.I. lower-upper
At discharge	Group	17.928	6391.762	0.000	1	0.998	61085090 0.5	0.000-
	Country of origin	-1.010	0.925	1.191	1	0.275	0.364	0.059-2.235
	Educational level	-0.085	0.976	0.008	1	0.931	0.919	0.136-6.227
	Constant	-20.251	6391.762	0.000	1	0.997	0.000	
15 days	Group	18.271	6387.606	0.000	1	0.998	86134989. 1	0.000-
	Country of origin	-1.128	0.819	1.895	1	0.169	0.324	0.065-1.613
	Educational level	0.153	0.843	0.033	1	0.856	1.165	0.223-6.077

		B	S.E.	Wald	df	Sig.	Exp(B)	95% CI
	Constant	-20.310	6387.606	0.000	1	0.997	0.000	
6 weeks	Group	0.295	0.685	0.185	1	0.667	1.343	0.350 - 5.147
	Country of origin	-0.236	0.618	0.145	1	0.703	0.790	0.236 - 2.651
	Educational level	-0.271	0.566	0.230	1	0.631	0.762	0.252 - 2.310
	Constant	-2.090	0.815	6.582	1	0.010	0.124	
3 months	Group	0.156	0.516	0.091	1	0.763	1.168	0.425 - 3.211
	Country of origin	-0.508	0.481	1.113	1	0.291	0.602	0.234 - 1.546
	Educational level	-0.207	0.443	0.218	1	0.640	0.813	0.342 - 1.936
	Constant	-1105	0.616	3220	1	0.073	0.331	
6 months	Group	-0.148	0.384	0.149	1	0.699	0.862	0.406 - 1.830
	Country of origin	0.033	0.409	0.007	1	0.936	1.034	0.463 - 2.306
	Educational level	-0.288	0.345	0.698	1	0.404	0.750	0.381 - 1.474
	Constant	-0.090	0.494	0.033	1	0.856	0.914	

*Multiple logistic regression adjusted by group, country of origin and education level.

ITT Analysis of the Response Variable

Of the 270 randomised participants, 134 (49.6%) were classified into the CG and 136 (50.4%) into the IG. Among the 136 women in the IG, 96 did not meet the minimum adherence criterion for the treatment, which was a minimum of five application uses during the intervention, and were therefore excluded from the study, leaving 40 women for analysis in the IG. Loss of follow-up was assumed as an abandonment of BF ($n =$ 10).

Effects of the Intervention on BF Abandonment at 6 Months in the Original Group of 270 Women

The rate of BF abandonment at 6 months was similar in the CG (42.6%) and IG (47.1%), with no significant differences observed (Table 4). The rate of abandonment in the complete IG (47.1%, $n = 136$) was similar to that in the IG with non-adherents excluded (protocol analysis) (43.6%, $n = 39$); these findings indicated that the intervention was not effective in reducing BF abandonment at 6 months and that non-adherence did not interfere with the lack of effect.

Table 4. The effect of the intervention in maintaining BF at 6 months (N = 270)

		Breastfeeding		Abandonment BF		
		n	%	n	%	p-value*
Group	Control (n = 134)	78	57.4	56	42.6	0.384

Intervention (n = 136)		72	52.9	64	47.1	

*Chi-squared test

Baseline Differences Between the Included and Excluded Women in the IG

Non-adherence was more common in the foreign women and those with primary and secondary education than in the other women (Table 5). Although not significant, there was less adherence among the women who had not decided on the type of BF than among their counterparts. There were no significant differences in the rest of the variables.

Table 5. Differences in baseline variables between women included and excluded from the intervention group (N=136)

		Included (n = 40)		Excluded (n = 96)		
		n	%	*n*	%	*p*-value*
Country of origin	Spain	37	92.5	62	64.6	0.001
	Foreign	3	7.5	34	35.4	
Educational level	University degree	28	70.0	34	35.4	<0.001
	Primary and Secondary school	12	30.0	62	64.6	
Civil status	Single, divorced	22	55.0	60	62.5	0.415
	Married	18	45.0	36	37.5	
Maternal support	No	1	2.7	3	4.2	0.691
	Yes	36	97.3	68	95.8	
Employment status	Unemployed/ student/ not seeking employment	14	35.0	49	51.0	0.087
	Self-employed/ professional/ managerial/employee	26	65.0	47	49.0	
Income level per month	<1000 €	11	27.5	17	17.7	0.198
	>=1000 €	29	72.5	79	82.3	
Desired type of BF	Exclusive	34	85.0	63	65.6	0.060
	Mixed	2	5.0	6	6.3	
	Undecided	4	10.0	27	28.1	
Older siblings	No	31	77.5	63	65.6	0.172
	Yes	9	22.5	33	34.4	

		n	Mean	SD	*p*-value**
Maternal age	Included	40	32.8	4.02	0.994
	Excluded	96	32.8	5.18	

*Chi-squared test; **Kruskal Wallis test

Discussion

To our knowledge, this study is the first RCT conducted in our setting to evaluate the maintenance of BF in the first 6 months postpartum, adding evidence to the limited data from RCTs published to date (Doan et al., 2022; Griffin et al., 2021; Seyyedi et al., 2021).

Effects of the Application on the Maintenance of BF

We observed a 39% reduction in the rate of BF from hospital discharge to 6 months postpartum, with no significant differences between the study groups. In Spain, the rate of BF at 6 months, including mixed feeding, is 38.8% (INE, 2017), far below the WHO's target of reaching 50% by 2025 (Lechosa-Muñiz et al., 2020).

We found a disparity in the results regarding the effects of the usage of mobile applications in improving the BF rate. Various studies have concluded that while mobile applications can provide information and support to BF mothers, they cannot offer the same level of individualised and personalised attention as a well-trained healthcare professional (Dinour & Pole, 2022; Doan et al., 2023). In line with this, our study demonstrated no difference in the BF rate between the IG and CG. The application was not considered a valid resource for the women who used it more frequently, as it was ineffective in reducing the abandonment rate compared with the control, in line with other clinical trial data (Griffin et al., 2021; Lewkowitz et al., 2020). Other authors have described the lack of accurate and poor-quality information as another cause for the lack of positive results. Another reason not described in the literature may be related to the application's purpose: LactApp aims to provide up-to-date BF information for women to make BF decisions; however, these women may decide to abandon BF, perhaps owing to social constraints or cultural beliefs. The reasons for BF abandonment in the setting of this study need to be further addressed.

In this study, the lack of accurate and poor-quality information was not a factor since LactApp is a validated application that is about to be evaluated with the Health App label by the Andalusian Health Quality Agency. Therefore, we believe that a possible explanation for this result could be the non-use of the application among the women in the IG. Non-use has not been described relative to LactApp in other research (Padró-Arocas, Mena-Tudela, et al., 2021; Padró-Arocas, Quifer-Rada, et al., 2021). In the present study, the women did not use the application organically, as described in previous publications. As this study is an RCT, the application was given to the women by the researchers, so it may not interest them as expected. Meanwhile, we understand that the use of the application corresponds to the design attractiveness and content that the application presents to maintain the participants' interest.

Notably, the application prevented early abandonment by 6.4% in the first 15 days. Although this difference was not significant, the clinical relevance of a 5% improvement in the BF rate depends on the context in which it is being evaluated, as recognised by other authors (Rollins et al., 2016). In our setting, this improvement could be considered clinically relevant since the long-term BF rate in Spain is limited, and therefore, it could significantly impact the health and well-being of babies and mothers both in the short and long terms (Pérez-Escamilla et al., 2016; Rollins et al., 2016). Although the percentage is small, the intervention could help women make informed decisions about BF and address common problems.

As already suggested by other research (Valero-Chillerón et al., 2022), the reasons for BF abandonment differ in each period. Typically, from birth to 15 days of life, the reasons are related to latch issues, pain mainly produced by nipple cracks, and inadequate weight gain by the neonate. With LactApp, it has also been observed that when women use the application organically, the desired information varies depending on the infant's age (Padró-Arocas, Quifer-Rada, et al., 2021). However, the reasons for abandonment can be multifactorial (psychosocial, family support, labour, or environmental conditions) from that moment until 6 months. We believe that the information that the application provided to the women in the present study may have influenced their decision-making and, together with the professional's evaluation, may have prevented BF abandonment, although this theory should be explored in future research.

Recent clinical trials have shown that mobile applications can increase mothers' confidence and knowledge about BF, supporting the idea that such applications can help improve the BF rate (Seyyedi et al., 2021; Wu et al., 2020). Some applications can also provide reminders and tracking of BF, which can help mothers establish and maintain a regular feeding pattern for their babies. However, more studies are needed to improve

academic understanding of the impact of the usage of mobile applications on BF and their effectiveness in different cultural and geographical contexts. Among the various global strategies implemented to help prevent the abandonment of BF is provision of access to information and resources on BF, including the use of technology (Lechosa-Muñiz et al., 2020; Victora et al., 2016). Accordingly, healthcare professionals must adapt to emerging demands and consider including BF applications in daily practice as an additional tool for community intervention. However, it is essential to recognize that applications should not replace the advice and support of a qualified BF healthcare professional (Qian et al., 2021).

Strengths and Limitations of the Work
We encountered several limitations in our study. First, the level of adherence or decision-making among pregnant women regarding BF may depend on several factors, such as the type of information provided and how healthcare professionals communicate it. We believe that favourable health outcomes largely depend on the complex interaction between healthcare providers and women. Since there is no current standardized and protocolized mechanism for determining women's ability to use the information provided effectively, we believe that it is prudent to assume that the information provided was the same for each woman in the present study (LactApp + professional advice). Therefore, women with low literacy levels may be more prone to making suboptimal decisions owing to their literacy deficits than their counterparts. This reasoning does not ignore the individual efforts that healthcare professionals may have made to address problems such as poor language comprehension, although we believe that the added complexity of attempting to systematize and define such efforts falls outside the scope of our study.

Second, another limitation may be the number of losses during follow-up and excluded women. We analysed the loss group's characteristics and performed an ITT analysis to control this potential selection bias and avoid breaking randomization. We observed no significant differences between the IG and CG, maintaining the effect of sample randomization. During the study, there were cases wherein the participants met the follow-up requirements but did not meet the minimum level of adherence to the intervention and were subsequently excluded from the analysis. In retrospect, we did not fully consider this possibility during the initial sample size calculation, assuming that all participants in the IG would receive the intervention as intended. However, this was not the case. While we did not anticipate this issue, excluding these individuals from the analysis was logical, as they did not receive the intervention. An ITT analysis was conducted to address this question, which included all women in the IG regardless of whether they met the minimum adherence criteria. With a sample size of 164 women, a statistical power of 73% could be achieved in the chi-square test to detect an expected initial difference of 40% versus 60%. Therefore, it is recommended that the results be interpreted cautiously and that further analyses be conducted to confirm and expand on the findings.

Third, regarding the data collection method, the self-administered electronic survey using the Internet has multiple advantages, such as faster data collection, lower cost, and attractive design for respondents (Diaz-Rada, 2012). However, the disadvantage is a lower response rate, meaning that the results must be interpreted cautiously. The research team decided to exclude women registered in the IG who made fewer than five entries in 6 months. Based on the average usage provided by the LactApp company, application users make at least 4.5 consultations during that period. We understand that the lack of intervention does not occur owing to the lack of use.

Fourth, we aimed to maintain linguistic consistency to ensure accurate data collection and interpretation. Although LactApp is available in English, we deliberately focused on the Spanish-speaking population to maintain a homogeneous participant group. This

choice not only facilitated standardized communication and understanding during the study but also minimized potential language-related biases. It is essential to note that most participating primary care midwives did not speak English, reinforcing our decision to focus on Spanish. While this choice limited the diversity of the sample, we considered it crucial to maintain the study's rigor and reliability. In future research, multilingual approaches could be explored to achieve greater inclusivity.

Finally, we acknowledge that the characteristics of the studied population may differ from those in other territories and that different results may be obtained in other populations.

Recommendations for Further Research
It is necessary to explore what factors affect women's application use. Future studies should determine the baseline characteristics of nursing women that could influence their use of mobile applications and explore different application designs that can be truly effective in supporting BF.

Implications for Policy and Practice
It can be tempting for caregivers and managers to recommend the use of BF support applications owing to the increasing number of applications created. However, it is necessary to continue exploring the possible effectiveness of these applications.

Future studies should begin with recognizing that an application should not replace adequate care by health workers or proven effective interventions.

Conclusion
Usage of a mobile application does not increase the BF rate compared with usual clinical practice. Among the reasons described for not finding this relationship may be the purpose of the LactApp, non-organic use of the app, social and cultural factors that will need to be addressed in future studies. Despite not being able to prove it, we believe that the information that the application provided to the women in the present study may have influenced their decision-making and, together with the professional's evaluation, may have prevented BF abandonment, although this theory should be explored.
However, abandonment of BF in the first 2 weeks postpartum may be reduced with the support of the LactApp. Despite this, midwife's initial support after hospital discharge seems essential to prevent early abandonment in the first 6 months postpartum. Further studies are needed to explore the relationship between the use of technologies and long-term maintenance of BF.

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