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Effectiveness of individualized breastfeeding counseling during the dyad's stay in rooming-in: a randomized, multicenter, open and parallel study

Mariana Torreglosa Ruiz^{1,8*}, Elisa da Conceição Rodrigues², Marialda Moreira Christoffel², Cynthia Viana de Resende¹, Michele Curcino Cavalcanti², Marianne Guterres Ferreira², Jéssica Aparecida da Silva¹, Karine Emanuelle Peixoto Oliveira da Silva³, Monika Wernet⁴, Ana Letícia Monteiro Gomes², Maria Beatriz Guimarães Raponi⁵, Jacqueline Faria de Oliveira⁶, Divanice Contim¹ and Ana Maria Linares⁷

Abstract

Background Breastfeeding counseling is a proven strategy to protect and promote breastfeeding, as evidenced by numerous studies. However, there is limited research on its application during the dyad's stay in rooming-in and its impact on the duration of exclusive breastfeeding. This study aims to evaluate the effectiveness of individualized counseling during the dyad's rooming-in period and its role in maintaining exclusive breastfeeding until the sixth month of life, compared to standard care.

Methods This randomized, multicenter, parallel, and open clinical trial was conducted at two Brazilian university hospitals. A total of 102 primiparous women, who had conditions and intentions favorable to breastfeeding, were enrolled between December 2023 and April 2024. Following hospital discharge, participants were followed up via telephone until the child reached six months of age, with the study concluding in October 2024. Participants were randomly assigned to one of two groups. The intervention group received two to four breastfeeding counseling sessions during their hospital stay, while the control group received standard institutional care. Both groups were provided with educational materials on the benefits of breastfeeding and information on where to seek help if complications arose. During the telephone follow-ups, outcomes were measured without any additional interventions. The primary outcome measured was the exclusive breastfeeding rate since birth to the sixth month.

Results A total of 97 breastfeeding women completed the follow-up, forming the sample for analysis. Compared to the control group, women who received counseling were more likely to maintain exclusive breastfeeding at the fourth month (27/48 (56.2%) vs. 15/50 (30.0%), Prevalence Ratio = 1.88 (Confidence Interval 95% 1.15, 3.07) and the sixth month of the child's life (27/47 (57.4%) vs. 12/50 (24.0%), Prevalence Ratio = 2.40 (Confidence Interval 95% 1.38, 4.16).

*Correspondence:

Mariana Torreglosa Ruiz
mariana.ruiz@uftm.edu.br; marianatorreglosa@hotmail.com

Full list of author information is available at the end of the article



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Conclusion Breastfeeding counseling during the dyad's stay in rooming-in was effective in maintaining exclusive breastfeeding until the child's sixth month of life.

Trial registration UTN: U1111-1284-3559 / RBR-4w9v5rq (2023-03-20).

Keywords Counseling, Breast feeding, Weaning

Background

Breastfeeding is recognized as a promoter and protector of health and child development [1–3], natural, nutritious, and sustainable [4, 5], capable of positively impacting women's and children's health in the short and long term [3–6], with contributions to achieving the Sustainable Development Goals, related to nutrition and food security, reducing inequalities and ensuring gender equality [7].

Given its importance, exclusive breastfeeding is recommended until the child's sixth month of life, and its maintenance is concomitant with the introduction of food for two years or more [8, 9].

Worldwide, 80% of newborns receive breast milk at some point in their lives, 46% begin breastfeeding in the first hour of life, and 48% remain exclusively breastfed at the sixth month, as recommended [5]. In Brazil, 96.2% of children were breastfed at least once in their lives; 62.4% in the first hour of life, but 45.8% remain exclusively breastfed in the sixth month of life [10].

The dyad's stay in the maternity ward and, more specifically, in Rooming-In units consists of a strategic period as it allows timely, early, and individualized intervention in breastfeeding. The facilitating factor is the uninterrupted stay of the child and the mother throughout the entire care period until the hospital discharge [11].

The first mentions of breastfeeding counseling date back to 1990 [12], and the strategy is characterized as a light technology and a low-cost intervention. However, it involves complex and advanced communication skills and requires professional training for its implementation. Breastfeeding counseling is based on Carl Rogers' theory [13–16].

According to Rogers, interpersonal relationships are needed to trigger the individual's change process, considering that each person involved must understand the other's experiential field [17, 18]. According to Rogers' theory, three fundamental attitudes provide a favorable emotional climate for individual changes. The first is congruence or authenticity; the second important attitude is that there are no evaluations and judgments in the relationship; and finally, the use of empathy [19].

Still, according to the theory, the individual is the best judge of himself in his adjustment. It is within himself that he finds all the necessary resources to carry out this adjustment, and therapeutic relationships can be beneficial for changes [17–19].

Breastfeeding counseling is a horizontal approach centered on the person, specifically, on the breastfeeding woman and her family. It permeates clinical management, guidance, and health education. The strategy focuses on communication skills and has two pillars: listening and understanding and developing trust and providing support [13–16].

The approach increases a person's practical knowledge and confidence in breastfeeding [20]. As already mentioned, everyone benefits when breastfeeding women receive the necessary support to breastfeed their babies [5]. However, despite being highly recommended by the World Health Organization (WHO), support from breastfeeding counseling proved to be uncommon, reaching rates of 33% [5].

Considering the low rates of exclusive breastfeeding until the sixth month in Brazilian and global children, Rooming-in, a strategic location and period for actions to protect and promote breastfeeding that counseling is an effective Public Health intervention with an impact on breastfeeding, including the exclusive form and the non-identification of a national, randomized, multicenter clinical trial on the effectiveness of counseling, and more specifically, the effects of this intervention during the period of stay of the dyad in rooming-in, on the duration of exclusive breastfeeding, this study is justified.

The study aimed to evaluate the effectiveness of individualized counseling during the dyad's stay in rooming-in and the maintenance of exclusive breastfeeding until the sixth month of life, compared to usual care.

Method

Study design

This is a multicenter, randomized, parallel, and open clinical trial, entitled "The effect of individualized counseling on the duration of exclusive breastfeeding". The Clinical Trial protocol was registered in the Brazilian Registry of Clinical Trials (UTN: U1111-1284-3559; <https://ensaiosclinicos.gov.br/rg/RBR-4w9v5rq/> 2023-03-20) and published in the journal *Trials* [21]. The recommendations of the Consolidated Standards of Reporting Trials (CONSORT) [22] were strictly adopted in the study.

Inclusion and exclusion criteria

The study included primiparous women over 18 years of age who had a pregnancy with a single fetus, with live birth, gestational age of 37 to 42 weeks, birth weight

greater than 2,500 g, regardless of the method of birth, hemodynamically stable, conscious, oriented, and admitted to the Rooming-in wards of the participating centers at the time of allocation to the study.

Postpartum women and newborns with contraindications to breastfeeding (HTLV 1 and 2 positive or neoplastic treatment with chemotherapy drugs) were omitted; newborns with malformations that prevented or hindered breastfeeding; postpartum women whose newborns were immediately separated after clamping the umbilical cord at birth due to maternal and/or neonatal complications, in which one or both were admitted to Critical Units; postpartum women transferred from other institutions or who had already been discharged (readmission); postpartum women who use illicit drugs; postpartum women diagnosed with intellectual or sensory deficits, with this information highlighted with the medical diagnosis in the medical record. If any of these criteria were detected based on the previous evaluation of the medical records, the postpartum woman was not consulted to participate in the study.

The following were established as exclusion criteria: dyads in which malformations or abnormalities in breastfeeding mechanics or changes in the mother-child bond were detected at the time of allocation. However, it should be noted that there were no exclusions during the allocation.

Postpartum women who were not followed up until the sixth month, after three unsuccessful attempts at telephone contact and contact with a family member, were considered lost to follow-up.

Setting

The study was conducted in the Rooming-in units of a maternity hospital in the interior of Minas Gerais (center A) and a maternity hospital located in Rio de Janeiro (center B), both teaching maternity hospitals linked to Brazilian federal universities.

Center A is a public hospital, a reference for resolving high-risk pregnancies and infectious diseases in the pregnancy-puerperal cycle. The Rooming-in unit has 12 beds and a standard operational protocol for breastfeeding assistance. However, the procedures only include clinical breastfeeding management actions. Furthermore, it is noteworthy that the wards at the institution are individual and have the structure to accommodate the postpartum woman, the newborn, and the companion throughout the hospitalization.

Center B is also a public hospital that offers outpatient, hospital, and multidisciplinary health care for high-risk pregnant women and newborns. The Rooming-in Unit has nine wards with five beds each, totaling 45 beds, and the institution received the title of Baby-Friendly Hospital in December 2020. As the wards are collective in this

center (five dyads per ward), only one dyad was selected to participate in the study to avoid possible response bias, justified by the nature of the intervention.

Trial procedures

Initially, the entire team of researchers was trained in "Breastfeeding Counseling," with a workload of 76 h, 60 h of theoretical and 16 practical hours. The team's training took place in July 2022; all members are nurses.

Concomitantly, the construction of the Breastfeeding Counseling protocol (intervention) was carried out, using as theoretical reference the Breastfeeding Counseling manual [23], WHO guidelines on breastfeeding counseling [13, 15], and the evidence resulting from two review studies carried out by the team [24, 25]. These are two scoping reviews carried out on the following topics: application of breastfeeding counseling in rooming-in [24] and, given the scarcity of studies and details of protocols, the second review of breastfeeding counseling protocols appeared [25].

The protocol was subjected to apparent face and content validation. The following were evaluated: items necessary for execution; intervention script and expected actions; breastfeeding assessment instrument; unexpected actions and possible solutions; initial difficulties in breastfeeding and counseling approach in these situations; and a checklist of counseling skills. For each item of the protocol, a Likert scale was applied, and to verify the agreement between the eight experts that participated, the Content Validity Index (CVI) was calculated [26]. Items with agreement above 80% were considered valid [26]. The protocol validation was carried out in a single round of evaluation, and the final version consisted of 11 sections. From the construction of the intervention protocol, the study protocol was designed and constructed according to the SPIRIT® checklist (Standard Protocol Items: Recommendations for Interventional Trials) [27].

After validating the intervention protocol, data collection instruments for the Control and Intervention groups, and records and standardization of study instruments, a pilot study was carried out with 39 postpartum women, 19 allocated to the Intervention group and 20 for the Control group, with equal distribution in the two study centers. The exclusive breastfeeding rate in the sixth month for the Intervention group was 79%, and for the Control group, 46%, with retention of 80% of the sample during follow-up, which allowed for testing the feasibility of the study and carrying out the sample calculation for the clinical trial.

Description of intervention

Women allocated to the Intervention group received breastfeeding counseling according to the trial protocol. The counseling sessions were held in person in the

dyads' wards, and if the companion was present, he was not the target of the intervention but could observe it taking place. The sessions lasted a maximum of 30 min, and individual difficulties, doubts, and concerns were addressed promptly, following the approach's precepts. Practical help was offered if necessary before starting the intervention, and at the woman's request, the researcher assisted her in the clinical management of breastfeeding.

At least two sessions were held at different periods (morning or afternoon) for each dyad, and two to four sessions were applied depending on hospital discharge and type of birth (on average, 24 h for vaginal births and 48 h for cesarean sections).

The LATCH scale was applied based on the breastfeeding assessment among study participants and aims to signal the need for immediate intervention, referrals, and support after hospital discharge. It assesses the following items: latch (L), audible swallowing (A), type of nipple (T), comfort (C), and hold (H), and the score for each item varies from zero to two. In the sum of the items, scores equal to or below six indicate difficulties in the breastfeeding process and the need for support [28, 29].

The Control group received standard institutional care based on the clinical management of breastfeeding, and data similar to the Intervention group were collected. Notably, at the end of the allocation, both groups received educational material in the form of a video clip, produced for the study and validated by experts, about the advantages of breastfeeding and where to seek help in case of complications in practice after discharge [21].

Both groups were followed through telephone contact from a number provided by the participant at one and two weeks, one, four, and six months of the child's life. In these contacts, no interventions were carried out, just the collection of outcomes. However, if the need for support was detected, the researcher advised the breastfeeding woman to be referred. The data collector was blind to the trial arm.

Trial outcomes

The primary outcome of the study was the rate of exclusive breastfeeding since birth to the sixth month of life. The WHO definition of exclusive breastfeeding defines the outcome as the infant receiving no other foods or liquids except breastmilk, not even water [5], used in this study. Under this definition, the infant may receive prescribed medicines when necessary [5]. The outcome was measured in women's self-reports. During follow-up, the type of breastfeeding and provision of other liquids or foods were asked. Women were asked whether they were exclusively breastfeeding or offered any liquid or food to the child during each follow-up call. In the first week, information about the time of discharge and breastfeeding in the first week was questioned. Afterward, they

were asked about their current situation in the second week, the first, fourth, and sixth months after giving birth. There were no changes in the outcomes or the study protocol.

Sample size calculation

The sample calculation was carried out by the Open Epi® Program and confirmed by the PASS® program; based on the results obtained in the pilot study, considering a significance level of 5% and statistical power of 80%, the inclusion of 88 women was needed and recruited 102 women allowing for 15% loss to follow-up, with equal distribution between the groups, with 51 belonging to the Intervention group and 51 to the Control group.

Randomization

The eligible postpartum women were sufficiently informed about the study's objectives and ensured that they all signed the Free and Informed Consent Form (ICF). During the contact, the researcher emphasized the possibility of participating in the Control or Intervention group depending on its randomization.

The randomization list was created using the Social Package for the Social Sciences (SPSS) version 23.0 program and organized by a center that managed the allocation groups. Once consent was obtained, the researcher contacted members of the randomization center through a Whatsapp® application group to consult the order of inclusion of postpartum women in the research and their allocation group. Center members were not part of the study team, so simple randomization was adopted. From a single list, 48 women (23 in the Intervention group and 25 in the Control group) were recruited in center A and 54 (28 in the Intervention group and 26 in the Control group) in center B, and no differences were found between the centers ($p = 0.834$).

Due to the nature of the study, participants and researchers were not blinded to the intervention at the time of allocation. However, the data collector of the follow-up was blind to the trial arm and the data were analyzed by a researcher who was not directly involved in data collection.

Statistical analysis

The data collected through Google Forms® were imported into a Microsoft Excel® spreadsheet and then into the Statistical Package for the Social Sciences, version 23.0. A descriptive analysis of data relating to sociodemographic, clinical, obstetric, and neonatal variables (absolute numbers and percentages, mean, standard deviation, minimum and maximum values) was carried out. The Chi-Square and Fisher's Exact Tests were applied, considering a significance level of 5%; calculations of prevalence ratios and respective confidence intervals were 95%.

Ethical considerations

The study obtained ethical approval by the Ethics Committees of center A, under opinion no. 5,627,159 on September 6, 2022, and center B, 5,656,072 on September 21, 2022. The study was guided by the Guidelines and Regulatory Norms for Research involving human beings, contained in National Resolution 466/2012/CNS/MS, as well as the ethical principles contained in the Declaration of Helsinki, ensuring that all participants of the study signed the ICF.

Results

One hundred two primiparous women were allocated, and after randomization, they were distributed equally in the Intervention and Control group (51).

There were no exclusions during allocation and at the end of follow-up in the sixth month, data from 97 postpartum women were analyzed, which resulted in 95% sample retention, as represented in Fig. 1. The postpartum women were allocated from 15 December 2023 to 22 April 2024, and the follow-up ended on 22 October 2024.

Table 1 presents the baseline data of postpartum women at the time of allocation, according to study groups. From the base data, it is identified that there are

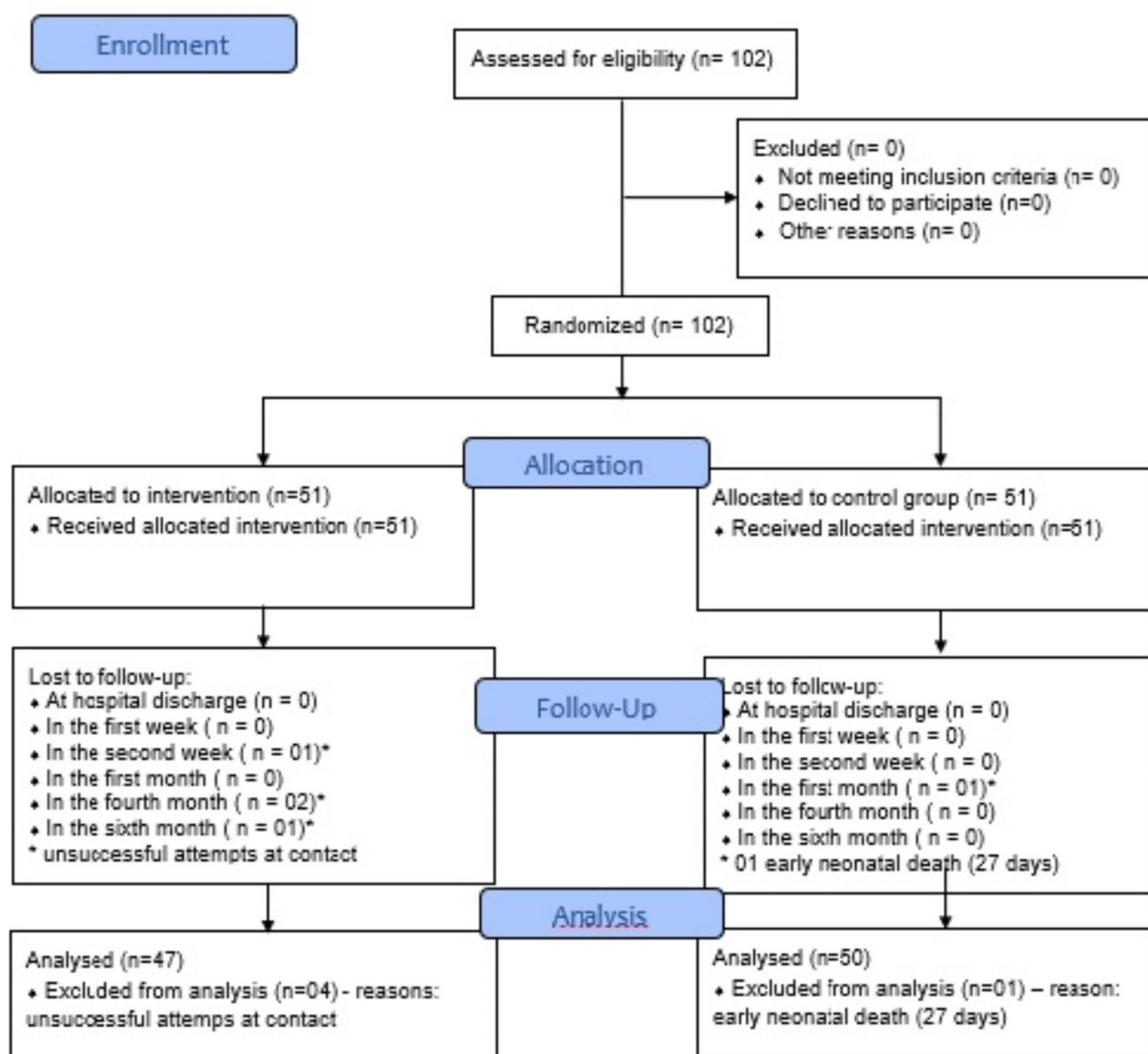


Fig. 1 Flowchart CONSORT 2010

Table 1 Comparison of baseline information of postpartum women in the two groups

Variable	Total (n = 102)	Inter- vention Group (n = 51)	Control Group (n = 51)	p
Maternal age	25.8 ± 6.4	26.2 ± 6.5	25.3 ± 6.2	0.47
Black or brown color	83 (81.4)	43 (84.3)	40 (78.4)	0.61
Lives with partner	77 (75.5)	44 (86.3)	33 (64.7)	0.02
Education higher than complete secondary education	89 (87.2)	43 (84.3)	46 (90.2)	0.55
Income greater than \$500.00	70 (68.6)	38 (74.5)	32 (62.7)	0.29
Paid occupation	60 (58.8)	29 (56.9)	31 (60.8)	0.84
Comorbidities	47 (46.1)	20 (39.2)	27 (52.9)	0.23
Adequate prenatal care	97 (95.1)	47 (92.2)	50 (98.0)	0.36
Prenatal breastfeeding guidelines	62 (60.8)	33 (64.7)	29 (56.9)	0.54
Cesarean section	56 (54.9)	26 (50.9)	30 (58.8)	0.55
Breastfeeding in the first hour	22 (21.6)	11 (21.6)	11 (21.6)	1.00
Score < 6 on the LATCH scale	24 (23.5)	13 (25.5)	11 (21.6)	0.82

no significant differences between the groups, as shown in Table 1.

Table 2 shows the rates of different breastfeeding outcomes during the dyads' follow-up. Exclusive breastfeeding rates have predominated in the Intervention group since the dyad's hospitalization; however, the differences

were not significant until the fourth month. Therefore, it is believed that the intervention may have influenced these indicators from the moment of its application.

Table 3 compares exclusive breastfeeding (EBF) indicators during the follow-up of the dyads, according to the study group. EBF at six months was higher in the Intervention group (28%) compared to the Control group (12%), PR 2.40 (95%CI 1.38, 4.16).

It is noteworthy that during the execution of the trial, interim analyses were carried out every 60 days by a clinical trial safety monitoring committee, with all researchers external to the study team. The committee included an expert on the subject, an expert in randomized clinical trials, an expert in statistics/epidemiological studies, a representative of the Ethics Committee, and a representative of the users (who are in the same condition as the study participants). The committee aimed to evaluate the continuation of data collection, given the findings of adverse events or statistical differences between the groups researched about primary and secondary outcomes, during the execution of the study. As no statistical differences or adverse events were detected, there was unanimity among members to continue the study and finalize the protocol.

Table 2 The outcomes of breastfeeding at the time of hospital discharge, first and second weeks, and first, fourth, and sixth months of the child's life, according to study groups

Variable	Control Group(n)	%	Intervention Group (n)	%	Total	%
Breastfeeding at the time of hospital discharge (n = 102)						
Exclusive	37	72.5	43	84.3	80	78.4
Mixed	11	21.6	07	13.7	18	17.6
Infant formula	03	5.9	01	2.0	04	4.0
Breastfeeding in the first week of life (n = 102)						
Exclusive	34	66.6	38	74.5	72	70.6
Mixed	14	27.5	12	23.5	26	25.5
Infant formula	03	5.9	01	2.0	04	3.9
Breastfeeding in the second week of life (n = 101)						
Exclusive	32	62.7	36	72.0	68	67.3
Mixed	14	27.4	13	26.0	27	26.7
Infant formula	05	9.6	01	2.0	06	6.0
Breastfeeding in the first month of life (n = 100)						
Exclusive	27	54.0	34	68.0	61	61.0
Mixed	17	34.0	16	32.0	33	33.0
Infant formula	06	12.0	-	-	06	6.0
Breastfeeding in the fourth month of life (n = 98)						
Exclusive	15	30.0	27	56.2	42	42.8
Mixed	21	42.0	13	27.0	34	34.7
Infant formula	14	28.0	08	16.8	22	22.5
Breastfeeding in the sixth month of life (n = 97)						
Exclusive	12	24.0	27	57.4	39	40.2
Mixed	17	34.0	07	14.9	24	24.7
Infant formula	21	42.0	13	27.7	34	35.1

Table 3 Comparison of breastfeeding-related indicators between the two groups

Variable	Group		PR	CI	p
	Intervention n(%)	Control n(%)			
EBF at the time of hospital discharge					
Yes	43(42.1)	37(36.3)	1.16	(0.95, 1.43)	0.23
No	08(7.8)	17(16.8)			
EBF in the first week					
Yes	38 (37.2)	34(33.3)	1.12	(0.87, 1.44)	0.52
No	13 (12.7)	17(16.8)			
EBF in the second week					
Yes	36 (35.6)	32(31.7)	1.15	(0.87, 1.51)	0.40
No	14 (13.8)	19(18.9)			
EBF in the first month					
Yes	34 (34.0)	27(27.0)	1.26	(0.92, 1.73)	0.22
No	16 (16.0)	23(23.0)			
EBF in the fourth month					
Yes	27 (27.6)	15(15.3)	1.88	(1.15, 3.07)	0.01
No	21 (21.4)	35(35.7)			
EBF in the sixth month					
Yes	27 (27.8)	12(12.4)	2.40	(1.38, 4.16)	< 0.01
No	20 (20.6)	38(39.2)			

Discussion

Breastfeeding counseling for primiparous women assisted in Rooming-in wards proved to be an effective strategy for maintaining exclusive breastfeeding as recommended.

According to the WHO classification for the indicator, the prevalence of breastfeeding in the first hour of life in the study sample was classified as “very poor” [30]. The WHO classifies the percentages of adherence to breastfeeding in the first hour for mothers and newborns in conditions favorable to breastfeeding between zero and 29% as “very bad,” 30 to 49% as “bad,” 50 to 89% as “good,” and 90 to 100% as “very good” [30].

It is noteworthy that the time at which breastfeeding begins predicts its exclusivity and continuation [3]. In the world, one in every two newborns begins breastfeeding within the first hour [3, 5], and in Brazil, 62.4% of dyads started breastfeeding at this time [10]. Nevertheless, this estimate of over 60% breastfeeding in the first hour in Brazil may have been overestimated. The low prevalence in this study can be attributed to the high rates of cesarean sections in the national territory. However, it highlights the need to improve this practice in the institutions studied.

Studies indicate that scores greater than six on the LATCH scale during the dyad's stay in rooming-in increased by five [31] and nine times [32] the chance of maintaining exclusive breastfeeding in the six weeks after birth. In the study sample, 23.5% of breastfeeding women had scores equal to or below six. However, according to the author who created the scale, correcting the items

promptly and the newborn's lifespan tends to improve breastfeeding and overcome difficulties [28].

In the study sample, exclusivity of breastfeeding reduced over time, with rates of 70% in the first week, 42.8% in the fourth month, and 40.2% in the sixth month of life. The rates found in the study are below the national averages, which indicate 59.7% of exclusive breastfeeding in the fourth month, 45.8% in the sixth month [10], and the world average, which is 48% in the sixth month of life [5]. However, it is noteworthy that in the group that received the intervention, 56.2% were exclusively breastfeeding in the fourth month, similar to national rates, and in the sixth month, 57.4% of the dyads remained breastfeeding, surpassing national and international, which reaffirms the effectiveness of the intervention. Efforts must be maintained, and strategies must be implemented since the goal of exclusive breastfeeding at the sixth month is 80% [10], and this was not achieved in the national and international scenario nor the study sample.

Breastfeeding counseling proved effective in maintaining exclusive breastfeeding in the fourth and sixth months of the child's life. A systematic review with meta-analysis showed the intervention's positive effect in reducing weaning before the sixth month (Relative Risk=0.91) and before six weeks (Relative Risk=0.87) [14].

Evidence indicates that the use of Breastfeeding Counseling in Rooming-In enabled successful breastfeeding, including in unfavorable cases or complex clinical management [33]; increased the chances of maintaining exclusive breastfeeding until six months [34] and reduced the chances of using formulas during hospitalization

in Rooming-in [35]. Furthermore, studies indicate that empowering breastfeeding women through counseling reduced the belief of insufficient production or weak milk, the leading cause of weaning [36, 37].

Half of breastfeeding women have difficulty breastfeeding in the first three days, requiring support [38]. Furthermore, a study showed that primiparous women have more difficulty initiating breastfeeding than multiparous women, delaying its start [39], which can compromise the success of breastfeeding. Together with the results of this study, these findings highlight the relevance and differential application of counseling in rooming-in.

A study carried out in Finland with 80 breastfeeding women showed that primiparous women were 3.41 times more likely to have breastfeeding difficulties, and those who received adequate breastfeeding support in the hospital were less likely to have breastfeeding difficulties, showing the importance of support for overcoming difficulties [40].

A study in Austria with 140 lactating primiparous women showed similar results to the present study, with a 58% rate of exclusive breastfeeding in the sixth month. The main reasons given for early cessation of exclusive breastfeeding were the belief of insufficient milk production and inadequate infant weight gain. Women who received postpartum breastfeeding support breastfed exclusively for significantly longer ($p < 0.05$) [41].

A qualitative study with a phenomenological approach carried out in Norway showed that women intended to wean when they received support through counseling. This was essential for them not to interrupt it, to (re) establish themselves, and to continue breastfeeding. The women emphasized that the approach made them perceived as breastfeeding mothers as well as women with their own needs [42].

The studies presented highlight the importance of support for primiparous women and the effectiveness of the breastfeeding counseling strategy for overcoming difficulties and maintaining exclusivity, as recommended.

It should be noted that this study only included primiparous women, as we wanted a homogenous sample in which previous experience with breastfeeding was not considered. As a limitation, the low rates of breastfeeding in the first hour in this study it indicates low levels of breastfeeding support in these institutions. However, such limitations point to knowledge gaps that can be addressed in subsequent studies and highlight the study's originality.

Given the strategy's long-term benefits, the study makes an important contribution to practice. It is important to rethink professional training and revisit staffing, institutional philosophy, and public policies aimed at protecting and promoting breastfeeding.

Conclusion

Breastfeeding counseling during the dyad's stay in Rooming-in proved to be effective in maintaining exclusive breastfeeding until the child's sixth month of life.

Abbreviations

CI	Confidence interval
CNS/MS	National Health Council/Ministry of Health
CONSORT	Consolidated Standards of Reporting Trials
CVI	Content Validity Index
EBF	Exclusive Breastfeeding
GC	Control Group
GI	Intervention Group
HIV	Human Immunodeficiency Virus
HTLV	Human T-cell Lymphotropic Virus
ICF	Free and Informed Consent Form
LATCH	Scale that assesses the following items: latch (L), audible swallowing (A), type of nipple (T), comfort (C), and hold (H)
PR	prevalence ratio
RR	relative risk
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SPSS	Social Package for the Social Sciences
WHO	World Health Organization

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Author contributions

MTR is the research coordinator. MTR, ECR, MMC, KEPOS, MW, ALMG, MBGR and AML designed the study. CVR, MCC, MGF and JAS collected the data. All authors (MTR, ECR, MMC, CVR, MCC, MGF, JAS, KEPOS, MW, ALMG, MBGR, JFO, DC and AML) contributed to the critical review and the preparation of the manuscript. All authors (MTR, ECR, MMC, CVR, MCC, MGF, JAS, KEPOS, MW, ALMG, MBGR, JFO, DC and AML) read and approved the final version of the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The research project was approved by the Research Ethics Committee of the Clinic Hospital of Federal University of Triângulo Mineiro under Opinion No. 5,627,159, CAAE: 61321122.3.1001.8667 and School Maternity Committee of the Federal University of Rio de Janeiro under Opinion No. 5,656,072, CAAE: 61321122.3.3001.5275. Before the start of data collection, all participants will sign a free and informed consent form (ICF).

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

¹Stricto sensu Graduate Program in Health Care, Federal University of Triangle Mineiro, Av. Getúlio Guaritá, 107, Uberaba, Minas Gerais 38025-440, Brazil

²Posgraduate Program in Nursing, Anna Nery School of Nursing, Rua Afonso Cavalcanti, 275, Cidade Nova, Rio de Janeiro, Rio de Janeiro 20211110, Brazil

³Health Department, Collegiate of the Nursing Course, State University of Feira de Santana, Avenida Transnordestina, SN, Feira de Santana, Bahia 44036-900, Brazil

⁴Pos graduate Program in Nursing Federal, University of São Carlos, Rodovia Washington Luis, km 235, São Carlos, São Paulo 13565905, Brazil

⁵School of Medicine, Nursing Course, Federal University of Uberlândia, Avenida Pará, Bloco 2U, 1720, Umuarama, Uberlândia, Minas Gerais 38400-902, Brazil

⁶Clinic Hospital of Federal University of Triangle Mineiro, Av. Getúlio Guaritá, 130, Uberaba, Minas Gerais CEP: 38025-440, Brazil

⁷University of Kentucky, *27 Rose St, Lexington, KY 40536, USA

⁸Didactic-Scientific Department of Nursing in Hospital Care, Institute of Health Sciences, Federal University of Triangle Mineiro, Av. Getúlio Guaritá, 107, Uberaba, Minas Gerais CEP: 38025- 440, Brazil

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