

Determinants of exclusive breastfeeding failure in newborns: A prospective longitudinal observational study.

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Abstract Background

Exclusive breastfeeding (EBF) during the first six months of life is an important strategy for improving infant health and reducing morbidity and mortality. Despite its recognized benefits, EBF remains suboptimal in many settings. This study evaluated the determinants of EBF failure among mother-newborn dyads during the first six months of life.

Methods

This prospective longitudinal observational study included **200 mother-newborn dyads** at Shri Guru Ram Rai Institute of Medical and Health Sciences, Dehradun. Maternal sociodemographic, obstetric, infant-feeding, breastfeeding-counselling, and lactation-related factors were assessed using structured questionnaires. Participants were followed at 48 hours after delivery, 2.5 months, and 6 months. Chi-square tests and binary logistic regression were used to identify factors associated with EBF outcomes.

Results

The study assessed maternal sociodemographic characteristics including age, education, occupation, parity, and family type. At 2.5 months, **169 (84.5%)** dyads maintained EBF, while **31 (15.5%)** had discontinued. At 6 months, **138 (81.7%)** of the remaining 169 dyads continued EBF. Pre-discharge formula supplementation ($\chi^2=41.25$, $p<0.001$), breastfeeding initiation after two hours ($\chi^2=31.4$, $p<0.001$), lack of antenatal counselling ($\chi^2=12.56$, $p=0.001$), and breastfeeding difficulties were significantly associated with EBF failure.

Conclusion

EBF failure was associated with modifiable clinical, educational, and social factors, particularly unnecessary formula supplementation, delayed breastfeeding initiation, inadequate counselling, and unresolved lactation difficulties.

Recommendation

Early initiation of breastfeeding, avoidance of unnecessary pre-discharge formula supplementation, and structured antenatal and postnatal breastfeeding counselling should be strengthened. Hospital-based Baby-Friendly practices and continued lactation support should be integrated into routine maternal and newborn care.

Keywords: Exclusive breastfeeding; EBF failure; Infant feeding practices; Breastfeeding determinants; Antenatal counselling; India; Uttarakhand.

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Introduction

Breast milk represents the biological ideal for neonatal nutrition, providing all macronutrients and micronutrients required during the first six months of life in proportions precisely calibrated for the human newborn.[1,2] Of all preventive interventions studied through the continuum of child health interventions, the greatest demonstrable reduction in under-five mortality is achieved by maximising

duration and exclusivity of breastfeeding. [3,4] In light of this evidence, the World Health Organization (WHO) and UNICEF recommend that breastfeeding begin within 1 hour of birth, that no fluid or food other than breast milk be given for 6 months after birth, and that breast milk continue in addition to complementary foods appropriate to the infant's age until at least 2 years of age. [5,6]

Suboptimal breastfeeding has a major global burden. Modeling exercises estimate that the universal application of optimal breastfeeding practices could save more than 800,000 lives yearly in children under five — about 13 per cent of all deaths under five worldwide. [7,8] This statistic illustrates the magnitude of impact that promotion of breastfeeding could achieve as a global health initiative with no need for a pharmaceutical infrastructure or complex supply chain.

The biological case for exclusive breastfeeding rests on multiple documented mechanisms. Beyond its nutritional completeness, breast milk delivers passive immunological protection through secretory immunoglobulin A, lactoferrin, lysozyme, and a complex array of bioactive oligosaccharides.[9,10] Sustained breastfeeding is linked to lower rates of acute respiratory infection, diarrhoeal disease, otitis media, and dental malocclusion, as well as long-term reductions in the risk of obesity, type 2 diabetes, and childhood leukaemia.[11] Neurological outcomes are also positively influenced: cohort data demonstrate that infants breastfed for twelve months or longer outperform formula-fed peers on standardised cognitive assessments even after adjustment for socioeconomic confounders.[12]

Nurses and other frontline healthcare providers occupy a strategically central position in translating this evidence into practice. As the principal source of feeding guidance in the immediate postpartum period, nursing staff influences whether a mother initiates breastfeeding early, whether prelacteal feeds are withheld, and whether formula supplementation is introduced unnecessarily.[13,14] Institutional practices that delay skin-to-skin contact, separate mother from newborn, or routinely provide formula in the first hours after birth can permanently compromise a mother's lactation trajectory.

Globally, exclusive breastfeeding (EBF) rates remain below targets, increasing only from 33% to 39% in low- and middle-income countries between 1995 and 2010. In India, NFHS-3 reported an EBF rate of 46%, with early initiation within one hour in less than 25% of births. Multiple factors influence EBF practices, including young maternal age, low education, and informal employment. Cultural practices such as discarding colostrum, giving prelacteal feeds, and early introduction of complementary foods are common. Maternal health issues like postpartum depression, perceived low milk supply, and cesarean delivery further reduce EBF continuation. System-level barriers such as inadequate maternity leave, lack of workplace support, early discharge, and hospital formula use also contribute. In India, especially Uttarakhand, longitudinal data on EBF are limited. Existing studies show poor initiation and continuation rates, but lack prospective follow-up to identify causes and timing of EBF failure, limiting targeted interventions.[15]

Therefore, identifying the modifiable factors associated with failure of exclusive breastfeeding (EBF) is essential for developing effective interventions to improve breastfeeding

practices and infant health outcomes. The present study aimed to determine the factors associated with failure of exclusive breastfeeding during the first six months of life among mother-newborn dyads, with particular emphasis on maternal sociodemographic characteristics, breastfeeding initiation, antenatal and postnatal counselling, formula supplementation, and breastfeeding-related difficulties.

Materials and methods

Study design and study setting

This was a **prospective longitudinal observational study** conducted among mother-newborn dyads at **Shri Guru Ram Rai Institute of Medical and Health Sciences (SGRRIM&HS), Dehradun, Uttarakhand, India**. The study was conducted through the Department of Pediatrics in collaboration with the hospital's obstetric and neonatal care services. SGRRIM&HS is a tertiary-care teaching institution providing comprehensive medical services, including obstetric, neonatal, pediatric, emergency, inpatient, outpatient, and diagnostic services, and caters to patients from Dehradun and surrounding areas.

Study duration

The study was conducted over a period of **18 months**.

Study participants and sampling

The study included **200 mother-newborn dyads**. Mothers fulfilling the predefined eligibility criteria were recruited during the study period and followed prospectively to assess exclusive breastfeeding practices during the first six months of life.

Inclusion criteria

- Mothers aged ≥ 18 years who delivered a live newborn at SGRRIM&HS during the study period.
- Mothers whose newborns were eligible for breastfeeding.
- Mothers who provided written informed consent to participate in the study.

Exclusion criteria

- Mothers or newborns with medical conditions that precluded breastfeeding.
- Newborns requiring prolonged intensive care or having conditions that prevented direct breastfeeding.
- Mothers unable to participate in the scheduled follow-up.
- Participants with incomplete information required for assessment of breastfeeding outcomes.

Data collection

Baseline maternal and newborn information was collected using a structured questionnaire. Maternal sociodemographic characteristics, obstetric history,

breastfeeding initiation, antenatal and postnatal breastfeeding counselling, formula supplementation, and breastfeeding-related difficulties were recorded. Participants were followed prospectively at **48 hours after delivery, 2.5 months, and 6 months** to assess breastfeeding practices and continuation of exclusive breastfeeding.

Measures to minimize bias

Potential sources of bias were addressed through standardized participant selection, data collection, and follow-up procedures. Predefined inclusion and exclusion criteria were applied uniformly to all participants. To minimize selection bias, eligible participants were recruited according to the predefined recruitment procedure during the study period. To reduce information and recall bias, breastfeeding practices and related factors were assessed prospectively at predefined follow-up intervals rather than relying solely on retrospective reporting.

A structured questionnaire with predefined variables was used for data collection to improve consistency. The same definitions and assessment procedures were applied throughout the study. Maternal and newborn characteristics that could potentially influence breastfeeding outcomes were recorded and considered during statistical analysis. Participants were followed at predefined time points to ensure consistent outcome assessment.

Quantitative variables

Quantitative variables were initially recorded as continuous measurements and summarized using **mean $\pm$ standard deviation** for normally distributed data or **median and interquartile range** for non-normally distributed data. Categorical variables were summarized as frequencies and percentages.

Where continuous variables were categorized for analysis, clinically meaningful or predefined cut-off values were used to facilitate comparison between relevant subgroups. The rationale for categorization was based on clinical interpretability and assessment of potential associations with exclusive breastfeeding outcomes.

Statistical analysis

Appropriate statistical tests were selected according to the distribution and measurement level of each variable.

Categorical variables were compared using the **chi-square test or Fisher's exact test**, as appropriate. Continuous variables were analyzed using appropriate parametric or non-parametric tests. Factors associated with exclusive breastfeeding failure were further evaluated using **binary logistic regression analysis**. A p -value <0.05 was considered statistically significant.

Ethical considerations

The study was conducted in accordance with the ethical principles governing research involving human participants. Written informed consent was obtained from all participating mothers before enrolment. Participant confidentiality was maintained throughout the study, and collected information was used exclusively for research purposes.

Results

During the study period, mothers delivering at SGRRIM&HS were assessed for eligibility according to the predefined inclusion and exclusion criteria. Eligible mothers were approached for participation and were enrolled after providing written informed consent. Participants were subsequently followed at the predefined follow-up points to assess exclusive breastfeeding practices.

A total of **200 mother-newborn dyads were included in the final study analysis**. The numbers assessed for eligibility, confirmed eligible, excluded, and declining participation should be reported in the participant flow diagram, together with the specific reasons for exclusion or non-participation.

Sociodemographic characteristics of the mothers

The sociodemographic characteristics of the **200 participating mothers** were assessed at baseline. Information regarding maternal age, educational status, occupation, parity, family type, and other relevant sociodemographic characteristics was collected and is presented in **Table 1**. These characteristics provide a baseline description of the study population and were considered while evaluating factors associated with exclusive breastfeeding failure.

Study population

A total of 200 mother-newborn dyads were enrolled at baseline. By the 2.5-month follow-up, 169 dyads (84.5%) were retained in active follow-up: 169 maintained EBF (EBF success), and 31 had abandoned EBF (EBF failure). At the 6-month assessment, the cohort comprised 169 dyads, of whom 138 (81.7%) were successfully maintaining EBF while 31 (18.3%) had ceased.

EBF outcomes at 2.5 months (n = 200) Birth status

Among the 193 term births, 97.6% maintained EBF at 2.5 months, compared with 90.3% of the 7 preterm births. This difference was statistically significant (chi-square = 3.92, $p = 0.048$), indicating that prematurity was associated with a modestly higher likelihood of EBF failure at this time point.

Table 1. Birth status and EBF outcome at 2.5 months

Variable	EBF (n=169)	Success	EBF Failure (n=31)	chi-square	p-value
Term (n=193)	165 (97.6%)		28 (90.3%)	3.92	0.048
Preterm (n=7)	4 (2.4%)		3 (9.7%)		

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Mode of delivery

Normal vaginal delivery (NVD) was associated with a higher EBF success rate (78.1%) compared with lower-

segment caesarean section (LSCS, 64.5%). The chi-square test did not reach statistical significance at this time point (chi-square = 3.12, p = 0.077).

Table 2. Mode of delivery and EBF outcome at 2.5 months

Mode of Delivery	EBF Success	EBF Failure	chi-square	p-value
NVD (n=152)	132 (78.1%)	20 (64.5%)	3.12	0.077
LSCS (n=48)	37 (21.9%)	11 (35.5%)		

Antenatal counselling: Receipt of antenatal breastfeeding counselling was strongly associated with EBF success. Among counselled mothers, 54.4% maintained EBF; among uncounselled mothers, 80.6% failed (chi-square = 12.56, p = 0.001).

Table 3. Antenatal counselling and EBF outcome at 2.5 months.

Counselling Received	EBF Success	EBF Failure	chi-square	p-value
Yes (n=98)	92 (54.4%)	6 (19.4%)	12.56	0.001
No (n=102)	77 (45.6%)	25 (80.6%)		

Source of antenatal counselling

Hospital-based counselling (n = 63) was associated with significantly higher EBF success (34.3% success vs. 16.1% failure; p = 0.040). Family-based counselling also demonstrated a significant positive association (p = 0.049). Counselling from ASHA workers or media did not reach significance.

Among mothers who received postnatal counselling (n = 111), 58% maintained EBF compared with 42% who did not receive counselling (chi-square = 6.78, p = 0.009).

Timing of breastfeeding initiation

This was the strongest single predictor at 2.5 months. Among 153 mothers who initiated within 2 hours, 84% maintained EBF; among 47 who delayed initiation beyond 2 hours, only 35.5% succeeded (chi-square = 31.4, p = 0.001).

Postnatal counselling

Table 4. Timing of breastfeeding initiation and EBF outcome at 2.5 months

Initiation Time	EBF Success	EBF Failure	chi-square	p-value
<=2 hours (n=153)	142 (84.0%)	11 (35.5%)	31.4	0.001
>2 hours (n=47)	27 (16.0%)	20 (64.5%)		

Breastfeeding difficulties

Among the 40 mothers who encountered any breastfeeding difficulty, only 14.8% maintained EBF, while 48.4% experienced failure—a statistically significant contrast with the no-difficulty group (chi-square = 8.91, p = 0.003).

Perceived insufficient milk supply was the most prevalent difficulty (22 of 40 mothers), followed by latching problems (n = 8), retracted nipples (n = 7), cracked nipples (n = 3), and an excessively demanding infant (n = 3). Eighteen mothers had difficulties that remained unresolved, yielding a 72.2% failure rate (chi-square = 15.3, p = 0.001).

Table 5. Breastfeeding difficulties and EBF outcome at 2.5 months

Difficulties Present	EBF Success	EBF Failure	chi-square	p-value
Yes (n=40)	25 (14.8%)	15 (48.4%)	8.91	0.003
No (n=160)	144 (85.2%)	16 (51.6%)		

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Prelacteal feeding

Among the two mothers who received prelacteal feeds, neither maintained EBF (100% failure). Among the 198 who did not receive prelacteal feeds, 100% of the EBF-success group avoided such feeds (chi-square = 18.9, p = 0.001).

Pre-discharge formula supplementation

This variable yielded the largest chi-square value in the 2.5-month analysis. Of 60 mothers supplemented with formula before hospital discharge, only 48.3% maintained EBF at 2.5 months, compared with 87.5% of the 140 mothers who were not supplemented (chi-square = 41.25, p = 0.001).

Table 6. Pre-discharge formula supplementation and EBF outcome at 2.5 months.

Formula discharge	Pre-EBF Success	EBF Failure	Total	chi-square	p-value
Yes (n=60)	29 (48.3%)	31 (51.7%)	60	41.25	0.001
No (n=140)	140 (87.5%)	16 (10.3%)	156		

EBF Outcomes at 6 Months (Adjusted Cohort, n = 169)

Birth status

Birth status (term vs. preterm) was not significantly associated with EBF outcome at 6 months (chi-square = 0.14, p = 0.707), possibly reflecting the very small number of preterm births retained in the cohort (n = 4).

Mode of delivery

The association between delivery mode and EBF outcome reached statistical significance by 6 months. Among NVD mothers, 81.2% maintained EBF, compared with 64.5% in the LSCS group (chi-square = 4.62, p = 0.032).

Table 7. Mode of delivery and EBF outcome at 6 months.

Mode of Delivery	EBF Success	EBF Failure	chi-square	p-value
NVD (n=132)	112 (81.2%)	20 (64.5%)	4.62	0.032
LSCS (n=37)	26 (18.8%)	11 (35.5%)		

Antenatal and postnatal counselling

Antenatal counselling remained a highly significant predictor at 6 months (chi-square = 13.2, p = 0.001), with 61.6% success among counselled mothers versus 22.6%

success in the failure sub-group. Postnatal counselling was similarly significant (chi-square = 4.35, p = 0.037). Hospital-based counselling demonstrated the highest associated success rate (39.9% success, 9.7% failure; p = 0.005).

Table 8. Counselling and EBF outcome at 6 months.

Counselling Type	Received Success	— EBF	Not Received Success	— EBF	chi-square	p-value
Antenatal	85/92 (61.6%)		53/77 (38.4%)		13.2	0.001
Postnatal	85/98 (61.6%)		53/71 (38.4%)		4.35	0.037

Breastfeeding difficulties

The negative impact of unresolved difficulties intensified by 6 months—only 13% of mothers with difficulties succeeded in EBF versus 87% of those without difficulties (chi-square = 14.9, p = 0.001). Among specific difficulty types,

insufficient perceived milk supply remained the most common and the most consequential: despite counselling and instruction to increase feeding frequency, EBF failure occurred in 63.6% of affected mothers (chi-square = 12.3, p = 0.001). Unresolved difficulties—encompassing maternal

stress, conflicting advice from family, and early return to employment—produced the highest failure rate of 72.2% (chi-square = 14.2, $p = 0.001$).

Table 9. Type of breastfeeding difficulty and EBF outcome at 6 months.

Difficulty Type	n	EBF Success	EBF Failure	p-value
Insufficient milk supply	22	8 (36.4%)	14 (63.6%)	0.001
Latching problems	8	4 (50.0%)	4 (50.0%)	0.290
Retracted nipples	7	6 (85.7%)	1 (14.3%)	0.572
Excessively demanding infant	3	1 (33.3%)	2 (66.7%)	0.024
Unresolved difficulties	18	5 (27.8%)	13 (72.2%)	0.001

Pre-discharge formula supplementation at 6 months: The detrimental effect of early supplementation persisted. Among 29 mothers supplemented before discharge, 6-month EBF success was 58.6%, versus 86.4% among 140 unsupplemented mothers (chi-square = 10.62, $p = 0.001$).

Table 10. Pre-discharge formula supplementation and EBF outcome at 6 months.

Formula Pre-discharge	EBF Success	EBF Failure	chi-square	p-value
Yes (n=29)	17 (58.6%)	12 (41.4%)	10.62	0.001
No (n=140)	121 (86.4%)	19 (13.6%)		

Discussion

It is a longitudinal design, in which 200 mother-newborn dyads were followed up using structured follow-up at a tertiary hospital, Dehradun, and the interaction of clinical, educational, and behavioural variables was documented to establish whether EBF was successful or not during the first six months of life. The key results support the hypothesis that in this context, most EBF failures can be attributed to pre-discharge formula supplementation, late initiation of breastfeeding, unresolved lactation challenges, and inadequate counselling, whereas the protective role of availed antenatal and postnatal breastfeeding counselling is highlighted.

The observation that 84 percent of mothers who began breastfeeding in the first two hours continued EBF at 2.5 months is congruent with significant international data. International systematic reviews have repeatedly shown that timely first breastfeeding (preferably within one hour of birth) lays down effective suckling, facilitates the transfer of colostrum, and consolidates infant feeding behaviour, before any supplementary feed can interfere with the process. The current data support these findings and measure the functional impact: early initiation increased to less than a quarter of the national births, and the same deficit in community-based work was reported in Uttarakhand (NFHS-3, 2007).[16-19] The current data confirm the findings and quantify the functional impact: late initiation increased the relative risk of EBF failure by more than three times at 2.5

The robust and enduring correlation between pre-discharge formula supplementation and exclusive breastfeeding failure at both follow-up intervals (chi-square 41.25 at 2.5 months; chi-square 10.62 at 6 months) represents one of the most clinically significant findings of this study. This pattern is well-established in the breastfeeding literature: in-hospital formula supplementation reduces suckling frequency, attenuates the afferent stimulus for milk production, and may implicitly convey to the mother that her milk supply is inadequate.[16] Systematic reviews show that the risk of EBF stopping almost doubles for babies who get extra food before they leave the hospital. The Baby-Friendly Hospital Initiative (BFHI) specifically targets this behavior by not allowing formula to be given out unless it is medically necessary. Following its Ten Steps at SGRRIM&HS is a way to improve the quality of care at the hospital.[20]

Antenatal counseling was significantly correlated with the success of exclusive breastfeeding (EBF) at both follow-up intervals ($p = 0.001$), as it enhances maternal awareness, confidence, and capacity to resist social pressures. Postnatal counseling demonstrated a significant positive effect ($p = 0.037$), underscoring the necessity of ongoing support. Counseling in a hospital setting was more effective than counseling in a family or community setting, probably because the information was more accurate and consistent. Cultural practices and familial influences—such as prelacteal feeding, the disposal of colostrum, and premature complementary feeding—persist in adversely affecting

exclusive breastfeeding (EBF). Problems with breastfeeding were a big reason for failure. The most common problem was thinking there wasn't enough milk, which was usually due to bad feeding techniques instead of a real lack of milk. Early lactation support and counseling are essential in averting unnecessary supplementation.[21]

Unresolved challenges, including maternal stress, familial pressure, and premature return to work, correlated with elevated exclusive breastfeeding failure rates, underscoring the influence of social and structural determinants. Caesarean delivery was associated with reduced exclusive breastfeeding rates at six months, attributed to delayed lactation and premature supplementation. Prelacteal feeding exhibited a significant correlation with exclusive breastfeeding failure, aligning with evidence that it disrupts the establishment of lactation. Prematurity impacted EBF during initial follow-up but not at the six-month mark, indicating enhancement with suitable support. Even though almost everyone fed their babies colostrum and it wasn't statistically significant, its clinical importance is still very clear. In general, both clinical and socio-cultural factors are very important in determining EBF outcomes. This shows that interventions need to be coordinated at the individual, family, and policy levels.[22]

Several limitations warrant acknowledgement. The study was conducted at a single tertiary institution, limiting generalisability to community and rural settings where breastfeeding determinants differ. The longitudinal design with three fixed contact points cannot establish the exact timing of EBF cessation between visits. Self-reported feeding data are susceptible to social desirability and recall bias. Absence of a concurrent control arm restricts causal inference. Unmeasured confounders—including paternal attitude, household income, and postpartum depression—may have influenced outcomes. Future multi-site studies incorporating validated psychometric scales, more frequent follow-up contacts, and qualitative methods would complement and extend these findings.

Generalizability

The findings of this study may apply to mothers and newborns receiving routine maternity and neonatal care in tertiary-care healthcare settings with access to antenatal, postnatal, and breastfeeding-support services. The study provides useful information regarding potentially modifiable factors associated with exclusive breastfeeding failure during the first six months of life. However, the external validity of the findings should be interpreted with caution because the study was conducted at a single tertiary-care institution and included 200 mother-newborn dyads. Differences in maternal sociodemographic characteristics, cultural practices, healthcare access, breastfeeding support, and hospital practices across different regions and healthcare settings may influence breastfeeding outcomes.

Therefore, the findings may not be directly generalizable to all populations in India or other countries.

Conclusion

This longitudinal study delineates a hierarchy of modifiable factors influencing exclusive breastfeeding failure during the initial six months of life in a northern Indian hospital context. Pre-discharge formula supplementation, delayed initiation of breastfeeding, unresolved lactation challenges—especially perceived milk insufficiency—and insufficient antenatal and postnatal counseling collectively constitute the primary factors contributing to the observed failures in exclusive breastfeeding (EBF). Prelacteal feeding, although infrequent in this cohort, was consistently linked to failure. Delivery by cesarean section became a significant predictor at six months, highlighting the necessity of proactive lactation support for post-surgical mothers.

In this case, the most effective ways to raise EBF rates are institutional: limiting unnecessary formula supplementation in the hospital, making sure breastfeeding starts within two hours of birth, training clinical staff in evidence-based lactation support, and adding structured breastfeeding counseling to both antenatal and postnatal care pathways. To keep breastfeeding going after the clinical visit, there need to be other policy measures in place, such as longer paid maternity leave, lactation rooms at work, and peer support groups in the community. The Baby-Friendly Hospital Initiative must be fully implemented, and household influencers must be educated in a targeted way. This is the best way to close the gap between India's ambitious EBF goals and what is currently being done in Dehradun and similar places in northern India.

Recommendation

Based on the findings of this study, breastfeeding support should begin during the antenatal period and continue throughout the early postnatal period. Early initiation of breastfeeding, avoidance of unnecessary formula supplementation, and structured antenatal and postnatal breastfeeding counselling should be strengthened. Mothers experiencing breastfeeding difficulties should receive timely assistance from trained healthcare professionals and lactation-support personnel. Hospitals should also strengthen Baby-Friendly practices and establish continued breastfeeding support during follow-up to improve exclusive breastfeeding rates during the first six months of life.

Multicentre studies involving diverse urban and rural populations are recommended to validate these findings and determine whether the identified factors remain consistent across different settings.

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Conflict of interest

The authors declare that they have no conflicts of interest related to this study, its findings, or the publication of this manuscript.

List of abbreviations

BF	Breastfeeding
EBF	Exclusive breastfeeding
IYCF	Infant and young child feeding
LAM	Lactational amenorrhea method
NICU	Neonatal intensive care unit
WHO	World Health Organization

Author contributions

All authors contributed equally to the manuscript.

Data availability

The datasets generated and/or analyzed during the current study are not publicly available because they contain participant-level maternal and neonatal information. However, the data may be made available from the corresponding author upon reasonable request, subject to institutional approval and applicable confidentiality and privacy requirements.

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