


Newborn physical condition and breastfeeding behaviours: Secondary outcomes of a cluster-randomized trial of prenatal lipid-based nutrient supplements in Bangladesh

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Abstract

Prenatal nutritional supplements may improve birth outcomes. This study aims to examine the effect of prenatal lipid-based nutrient supplements (LNS), compared with iron and folic acid (IFA), on general newborn physical condition and feeding behaviours. We conducted a cluster-randomized effectiveness trial that enrolled 4,011 pregnant women at ≤ 20 gestational weeks. LNS and IFA were provided to women in 48 and 16 clusters, respectively, for daily consumption until delivery. We collected data on household socio-economic, food insecurity, and maternal characteristics during early pregnancy and on newborn condition and feeding within 72 hr of delivery. We analysed intervention effects on these secondary outcomes using mixed models with analysis of covariance for continuous outcomes and logistic regression for dichotomous outcomes. Among 3,664 live births, intervention groups did not differ in newborn response, mother's rating of the general condition of her newborn, early initiation of breastfeeding (EIBF), suckling ability, or frequency and exclusivity of breastfeeding in the first 24 hr. If the mother perceived her infant to be healthy, EIBF was more likely (OR [95% CI]: 2.08 [1.46, 2.97]) and frequency of breastfeeding in the first 24 hr was greater (mean difference [95% CI]: 3.0 [1.91, 4.01]), but there was no difference in exclusive breastfeeding in the first 24 hr. Newborn condition and early breastfeeding practices were not affected by giving mothers prenatal LNS versus IFA. However, early breastfeeding practices were related to maternal perception of her newborn's condition. Thus, interventions to improve breastfeeding practices for newborns with poorer perceived health status may be useful.

KEYWORDS

breastfeeding, maternal nutrition, newborn health, newborn response

1 | INTRODUCTION

Many studies have been conducted to examine the effect of prenatal nutritional supplements on birth outcomes such as infant mortality,

preterm delivery, low birth weight, and small or large for gestational age (Fraser & Abu-Saad, 2010; Haider & Bhutta, 2017; Imdad & Bhutta, 2012; Scholl, Hediger, Schall, Fischer, & Khoo, 1993; Smith et al., 2017). But to our knowledge, no studies have examined the

effect of such interventions on the general physical condition of the newborn at birth, based on characteristics including time to start crying and the quality of crying and movement, or early breastfeeding practices such as early initiation of breastfeeding (EIBF), suckling ability, and frequency and exclusivity of breastfeeding in the first 24 hr after birth. In health facilities, physical condition at birth is most commonly assessed using the Apgar score, a 10-point scale that scores heart rate, respiratory effort, muscle tone, reflex irritability, and colour. Each of the factors is rated at 60 s after birth and again 5 min later by qualified medical persons (Apgar, 1952). A lower Apgar score is associated with a higher risk of neonatal and infant mortality (Casey, McIntire, & Leveno, 2001; Ilidromiti, Mackay, Smith, Pell, & Nelson, 2014) and with poorer short-term as well as long-term motor and cognitive development (Odd, Rasmussen, Gunnell, Lewis, & Whitelaw, 2008; Tweed, Mackay, Nelson, Cooper, & Pell, 2015). In countries where most deliveries occur in the home, or where no medically qualified person is available to assess the newborn using Apgar, other methods for assessing the physiological condition of the newborn at birth are necessary, such as interviewing the mother or birth attendant using a few simple questions regarding the timing and quality of crying and movement, and breastfeeding behaviour after birth.

Initiation of breastfeeding is recommended within the first hour after birth (World Health Organization [WHO]), defined as EIBF. EIBF has been associated with reduced neonatal mortality (Debes, Kohli, Walker, Edmond, & Mullany, 2013; Edmond et al., 2006; Khan, Vesel, Bahl, & Martinez, 2015), but there is little information on whether prenatal nutritional supplementation might affect EIBF by improving maternal nutrition and increasing the confidence of the mother in putting the baby to the breast soon after birth.

We conducted the Rang Din Nutrition Study (RDNS), a cluster-randomized controlled effectiveness trial in rural north-west Bangladesh, to evaluate the effectiveness of home-fortification approaches in the first 1,000 days for preventing maternal and child undernutrition. In the RDNS, women were provided with lipid-based nutrient supplements (LNS) for pregnant and lactating women (LNS-PL) or iron and folic acid (IFA) during pregnancy and early post-partum, and their children were provided with LNS for children (LNS-C), micronutrient powder (MNP), or no supplement from 6 to 24 months. We previously demonstrated that LNS-PL increased birth weight and reduced newborn stunting (Mridha et al., 2016) and that the group receiving both LNS-PL and LNS-C had improved child growth status at 18 to 24 months of age compared with the group in which the mothers received IFA and the children received MNP from 6 to 24 months (Dewey et al., 2017). We also found that daily provision of LNS during pregnancy and to children from 6 to 24 months improved household food security (Adams et al., 2017) and LNS during pregnancy increased mid-upper arm circumference among women aged 25 years or older and those with short stature (Matias et al., 2016). Considering the effects of LNS-PL on birth size, food insecurity, and maternal anthropometric status, it is possible that LNS-PL may also have a beneficial impact on general newborn condition and breastfeeding behaviours by directly improving newborn health or increasing maternal confidence in her ability to breastfeed. This paper examines whether

Key messages

- Although prenatal lipid-based nutrient supplements may improve certain birth outcomes such as birth weight, they did not affect general physical condition or feeding behaviours of the newborn in rural Bangladesh.
- Early initiation of breastfeeding was more likely if the mother considered her infant to be “healthy” at birth.
- Further research is warranted to evaluate interventions to improve early breastfeeding practices for high-risk newborns, perceived to have “poor” health status by their mothers.

LNS-PL had any effect on newborn response (timing and quality of crying, breathing, and movement soon after birth), mother's rating of the general health condition of her newborn, EIBF, suckling ability, and frequency and exclusivity of breastfeeding in the first 24 hr after birth. A secondary objective was to examine how these outcomes are related to each other.

2 | METHODS

2.1 | Study setting and design

The study was conducted in 11 rural unions (the lowest administrative unit of the local government of Bangladesh) of the Badarganj and Chirirbandar subdistricts in north-west Bangladesh, as described previously (Mridha et al., 2016). The study was carried out by three partners: LAMB; icddr,b; and the University of California, Davis (UCD), with technical support provided by FANTA. It was implemented within the Community Health and Development Programme (CHDP) operated by a local non-government organization (LAMB), which delivered the study interventions. UCD and icddr,b jointly evaluated the interventions. Health services normally provided by the CHDP include maternity services at a safe delivery unit (SDU) in each union, regular home visits for antenatal, postnatal, and child care by village health volunteers and community health workers (CHWs), and monthly educational sessions to promote maternal and child health.

The trial was a single-blind (researcher), longitudinal, cluster-randomized controlled effectiveness trial with four equal-sized arms: (a) comprehensive LNS: women received LNS-PL during pregnancy and the first 6 months post-partum, and their children received LNS-C from 6 to 24 months of age (LNS-LNS group); (b) child-only LNS: women received IFA (one tablet of 60 mg of iron and 400 µg of folic acid) daily during pregnancy and every alternate day during the first 3 months post-partum, and their children received LNS-C from 6 to 24 months of age (IFA-LNS group); (c) child-only MNP: women received IFA (as described above), and their children received MNP containing 15 micronutrients from 6 to 24 months of age (IFA-MNP

group); and (d) control group: women received IFA (as described above), and their children received no supplements (IFA-control group). For the analyses herein, the last three groups are combined because all women received IFA during pregnancy, and analyses are based on two groups (LNS and IFA) according to the intervention during pregnancy.

We defined a cluster as the supervision area of a CHW. For the randomization, the study statistician at UCD first stratified all 64 clusters in the 11 unions by subdistrict and union and then randomly assigned each cluster to one of the four arms (each containing 16 clusters; Mridha et al., 2016).

The study protocol was approved by the institutional review boards of UCD; icddr,b; and LAMB. The study was registered at ClinicalTrials.gov (NCT01715038). We obtained verbal consent from union representatives before beginning the study and completed randomization of clusters before seeking individual participant consent (Mridha et al., 2016).

2.2 | Study interventions

Table S1 shows the supplement composition. LNS-PL (one 20-g sachet per day) was modelled on the UNICEF/WHO/United Nations University international multiple micronutrient preparation for pregnant and lactating women and similar products used in Ghana and Malawi (Arimond et al., 2015). LNS-PL was produced by Nutriset SA in Malaunay, France. The dose of IFA was based on WHO (2012) recommendations. IFA tablets were produced by Hudson Pharmaceuticals Ltd. in Bangladesh.

Supplements were delivered to participants by CHDP staff. The distribution scheme and key educational messages are described elsewhere (Dewey et al., 2016; Mridha et al., 2016).

2.3 | Enrolment and data collection

The CHWs and village health volunteers identified pregnant women via LAMB's pregnancy surveillance system (Mridha et al., 2016). Women potentially eligible for the RDNS evaluation were contacted at home by evaluation staff to obtain consent for screening. Eligibility criteria included gestational age ≤ 20 weeks (gestational age was calculated based on the first day of the last menstrual period, elicited from the mother by the CHW) and no plans to move away during pregnancy or the following 3 years. All eligible women were invited to participate in the study. Women who consented were interviewed to collect baseline data at enrolment and scheduled for anthropometric and clinical data collection at the SDU. Supplement delivery began after each woman's baseline SDU visit.

Data collection was performed by two separate teams: the "SDU visit team," which collected clinical and anthropometric data at the SDU, and the "home visit team," which enrolled mothers and collected baseline and follow-up data at participants' homes.

Baseline data were collected at enrolment on household socioeconomic status, food insecurity, number of under five children in

the household, as well as maternal age, education, body mass index, and knowledge, attitudes, and practices relevant to nutrition. We collected data on household food insecurity using the household food insecurity access scale (Swindale & Bilinsky, 2007). Follow-up procedures during pregnancy and just after childbirth are described elsewhere (Mridha et al., 2016). Birth visits were conducted by trained interviewers who visited the women in their homes or place of delivery within 72 hr of delivery to collect data on delivery and newborn status. The numbers of birth visits are shown in Figure 1. During this visit, the mother or primary caregiver of the baby was asked how long after birth the baby started crying or breathing for the first time (options were within 1 min, between 1 and 5 min, after 5 min, did not cry or breathe, not applicable, and do not know), how did the baby cry immediately after birth (options were slowly, normally or loudly, did not cry, not applicable, and do not know), how did the baby move immediately after birth (options were slowly, normally or forcefully, did not move, not applicable, and do not know), what was the overall condition of the newborn baby (healthy, sick, not applicable, and do not know), how long after birth the baby was put to the breast or fed breastmilk for the first time, whether the baby suckled when put to the breast for the first time, how many times in the first 24 hr of birth the baby was breastfed, and what was fed within 24 hr other than breastmilk.

To the extent possible, data collectors were kept blind to group assignment, although those conducting home visits might have seen supplements in the home. Quality control procedures (Mridha et al., 2016) included having supervisors reinterview at least 10% of randomly selected participants.

2.4 | Sample size calculation and statistical analyses

When designing the main study, we calculated a minimum required sample size of 788 pregnant women per group (total of 3,152), based on detecting an effect size of >0.2 (difference between groups, divided by pooled SD) for the primary outcome (length-for-age z score) with one-sided hypotheses, power = 0.8 and $\alpha = .05$, assuming an intracluster correlation = .01, and allowing for 20% attrition by the time all children reached 24 months (Dewey et al., 2017). Because we exceeded the target sample size during enrolment (Mridha et al., 2016), we subsequently decided to conduct our analyses by using a more conservative two-sided hypothesis approach to be consistent with other recent trials. With our observed sample size of 3,664 live births, two-sided testing, group allocation of 3:1, an outcome prevalence of 80%, and the same assumptions as above, we are powered to detect a prevalence difference of at least 5% corresponding to an odds ratio of 1.4 or greater.

The newborn response variable was created from the answers to the three questions on crying, breathing, and movement soon after birth. We defined newborn response as "good" when the newborn cried or breathed within 1 min after birth, cried normally or loudly, and moved normally or forcefully immediately after birth. We defined newborn response as "not good" when any of the conditions for good

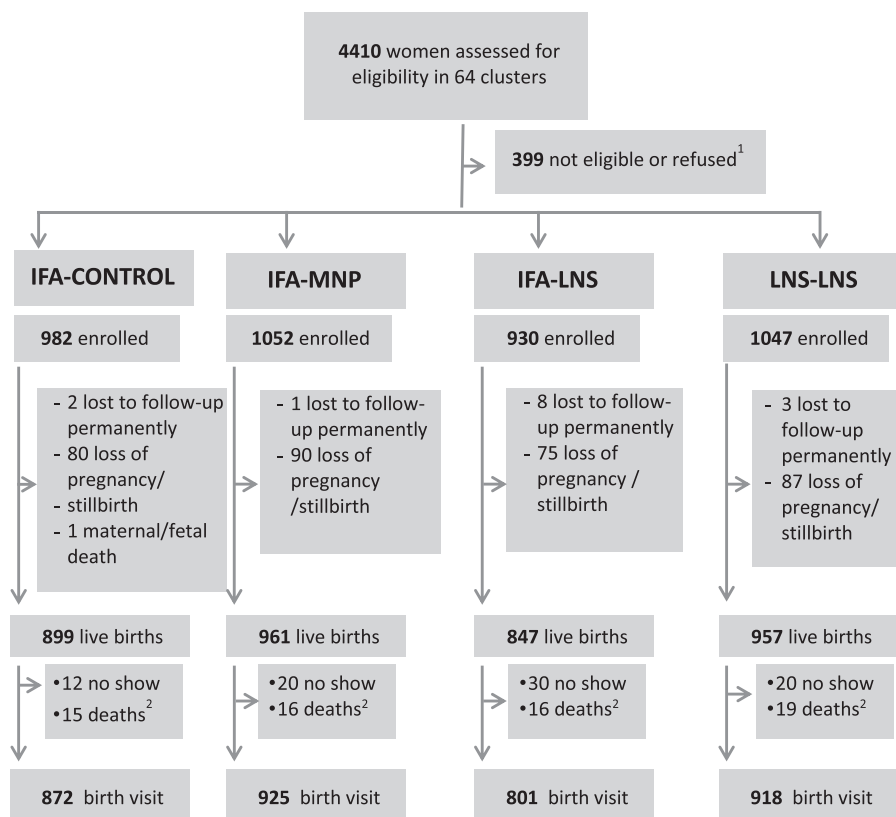


FIGURE 1 Study flow chart. ¹A total of 366 gestational age > 140 days, 22 planned to leave the study site, 8 refused to consent, and 3 husbands refused to consent. ²Most of these deaths occurred at <14 days post-partum: 14 IFA-control, 15 IFA-MNP, 15 IFA-LNS, and 17 LNS-LNS. IFA-control, women received iron and folic acid supplement during pregnancy and the first 3 months post-partum, and children did not receive supplements; IFA-LNS, women received iron and folic acid during pregnancy and the first 3 months post-partum, and children received lipid-based nutrient supplements from 6 to 24 months of age; IFA-MNP, women received iron and folic acid during pregnancy and the first 3 months post-partum, and children received micronutrient powder from 6 to 24 months of age; LNS-LNS, women and children received lipid-based nutrient supplements

newborn response were not present. Rating of the general condition of the newborn by the mother or birth attendant was categorized as healthy or not healthy ("sick"). Time to put the baby to the breast was recorded in minutes, hours, and days and subsequently categorized as early (within 1 hr) or late (more than 1 hr) to define EIBF. Suckling ability was defined by whether the newborn baby suckled when put to the breast for the first time. Frequency of breastfeeding in the first 24 hr after birth was defined as the reported number of times the baby was put to the breast or breastfed in the first 24 hr. Exclusive breastfeeding in the first 24 hr was defined as giving only breastmilk (oral saline or medicines prescribed by a doctor were allowed) to the newborn baby in the first 24 hr.

From several socio-economic status variables, we used principal components analysis to calculate a household socio-economic status index from a set of 19 yes/no questions about whether or not a household owned a particular item (radio, television, cell phone, irrigation pump, refrigerator, watch or clock, fan, sewing machine, shelving, table, chair, bed, bicycle, motorcycle, animal-drawn cart, car/truck, engine boat, rickshaw, and tube-well) in which higher values represented higher socio-economic status. Participants were categorized into four levels of household food insecurity (severe, moderate, mild,

and none) using the household food insecurity access scale manual (Swindale & Bilinsky, 2007). Season at birth was categorized into seven intervals, as previously described (Mridha et al., 2016).

We developed a detailed data analysis plan before starting the analysis and revealing group assignment. Analysis was by intention-to-treat. We analysed effects of the intervention using mixed models with analysis of covariance for continuous outcomes and logistic regression for dichotomous outcomes to test the null hypothesis of no difference between the intervention groups. All models included a random effect of cluster nested within treatment group and a random effect of union nested within subdistrict to account for the cluster level randomization. We evaluated the unadjusted effect of intervention group and repeated the analysis with adjustments for prespecified enrolment covariates (maternal body mass index, age, education, and parity; number of <5 children in the household, household socio-economic status, and food insecurity; time period in study; and child sex) if they were associated with the outcome ($P < .10$) in bivariate analysis. For dichotomous outcomes, we calculated cluster-adjusted group percentages and 95% CI and based the statistical comparisons on unadjusted and covariate-adjusted log odds of the outcome occurring.

A conceptual framework (Figure 2) was developed to guide the analysis of how the newborn health and feeding outcomes are related to each other. We expected that (a) the infants whose newborn response (timing and quality of crying, breathing, and movement soon after birth) was good would be more likely to be rated as healthy, be put to the breast early, and be able to suckle when first put to the breast; (b) the infants who initiated breastfeeding early would be more likely to be exclusively breastfed in the first 24 hr; (c) the newborns who were rated as healthy would be more likely to be put to the breast early, be exclusively breastfed in the first 24 hr after birth, and be more frequently breastfed in the first 24 hr; and (d) the infants who were able to suckle when first put to the breast would be more likely to be exclusively breastfed in the first 24 hr after birth and would be more frequently breastfed in the first 24 hr.

Per protocol analyses were conducted by limiting the analysis to those who reported consuming their assigned supplement at least four times per week, on average, during the pregnancy.

For analysing how newborn health and feeding outcomes were related to each other, treatment group was controlled for as a covariate in all models, using procedures similar to those described above. Maternal characteristics were not controlled as covariates in these models because they are not part of the conceptual model. Associations were assessed with mixed models using logistic regression or analysis of covariance, and descriptive statistics were used to understand the direction of the relationships.

3 | RESULTS

A total of 4,410 women were screened for eligibility between October 15, 2011, and August 31, 2012; of these, 4,011 were enrolled. After enrolment, 332 (8.3%) women had loss of pregnancy/stillbirth, and there was one maternal/fetal death (in the IFA-control arm); another 14 (0.35%) women were lost to follow up during pregnancy. A total of 3,664 live births occurred between January 15, 2012, and May 5, 2013. There were 30 twin deliveries (including stillbirth), and one twin from each pair was randomly selected for analysis.

At baseline, sociodemographic, anthropometric, and food security characteristics of the mothers of the children were similar across the study arms (Table 1), except for a small difference in maternal

education. Mean age of the women was ~22 years. Average family size was ~4.6 people. Average gestational age at enrolment was ~37 weeks. About 40% of the women were nulliparous. At baseline, 9.1%, 29.0%, 14.5%, and 47.4% of households were categorized as having severe, moderate, mild, and no food insecurity, respectively. Nearly half (47.0%) of deliveries occurred at home, and 56% of the deliveries were attended by a medically trained service provider. The average (\pm SD) timing of the birth visit interview was 2.05 (\pm 2.85) days after delivery. About 39% of the infants were low birth weight, and 14% were born preterm. About 81% of the newborns were put to the breast or fed breastmilk within 1 hr after birth. During pregnancy, 64% of the women in the LNS group and 92% of the women in the IFA group reported regular consumption of their study supplement (every day or almost every day).

There were no significant differences between intervention groups in newborn response, mother's rating of the general condition of the newborn, EIBF, suckling ability, or frequency and exclusivity of breastfeeding in the first 24 hr after birth (Table 2). The results did not differ when adjusted for covariates (data not shown).

Results from per protocol analyses were similar to intention-to-treat analysis. The only difference was a marginal intervention group difference in suckling ability after birth; 84.1% of the LNS group versus 80.0% of the IFA group were able to suckle when they were put to the breast for the first time (OR [95% CI]: 1.29 [0.99, 1.63]).

The newborn was more likely to be rated as healthy if the newborn response was good (98.7 vs. 73.0%; OR [95% CI]: 28.77 [19.89, 41.60]). EIBF was more likely if the newborn response was good (83.5 vs. 76.7%; OR [95% CI]: 1.52 [1.28, 1.82]) or the infant was rated as healthy (82.5 vs. 68.7%; OR [95% CI]: 2.21 [1.71, 2.86]). Exclusive breastfeeding in the first 24 hr did not differ significantly by maternal rating of the overall condition of the newborn (Table 3). However, exclusive breastfeeding in the first 24 hr was more likely if the infant initiated breastfeeding within 1 hr of birth or the newborn was able to suckle when first put to the breast. The reported ability of the newborn to suckle when first put to the breast was significantly more likely if newborn response was good (83.9 vs. 72.9%; OR [95% CI]: 2.00 [1.69, 2.38]). Average frequency of breastfeeding in the first 24 hr was significantly higher if the newborn was rated as healthy or the newborn was able to suckle when first put to the breast (Table 3).

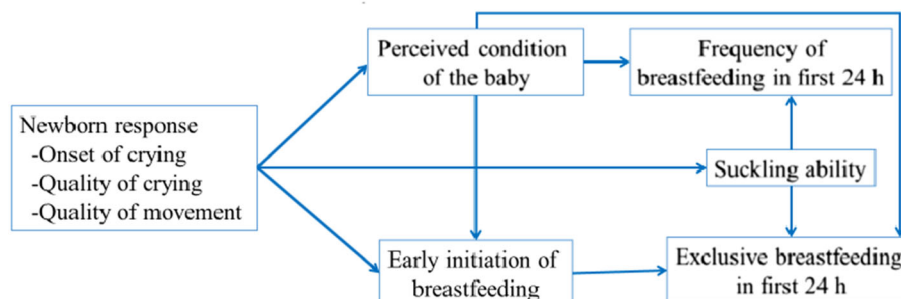


FIGURE 2 Conceptual framework for how the newborn health indicators are related to each other

TABLE 1 Baseline characteristics and pregnancy outcomes

Variable	LNS (mean \pm SD)	IFA (mean \pm SD)
Number of women	1,047	2,964
Age (years)	21.8 \pm 4.9	22.0 \pm 4.9
Gestational age at enrolment (days)	91.9 \pm 26.3	92.0 \pm 26.7
Nulliparous, <i>n</i> (%)	1,042 (42.0)	2,958 (39.2)
Height (cm)	150.6 \pm 5.5	150.5 \pm 5.5
BMI (kg/m ²)	19.9 \pm 2.7	20.0 \pm 2.7
Years of education	6.4 \pm 3.2	6.1 \pm 3.3
Household asset index	0.02 \pm 2.18	0.03 \pm 2.21
Household food insecurity, <i>n</i> (%)		
Food secure	369 (48.2) (17.1)	1,024 (47.3)
Mildly food insecure	205 (26.8)	302 (13.9)
Moderately food insecure	61 (8.0)	639 (29.5)
Severely food insecure	200 (9.2)	
Number of loss of pregnancy/stillbirth, <i>n</i> (%)	87 (8.3)	246 (8.3) ^a
Number of live births, <i>n</i> (%)	957 (91.4)	2,707 (91.3)
Sex of the child, male, <i>n</i> (%)	494 (50.3)	1,386 (50.2)
Twin delivery, <i>n</i>	6	24
Gestational age (weeks)	39.5 \pm 2.2	39.3 \pm 2.3
Birth weight (g)	2,630 \pm 410	2,590 \pm 410
Birth attended by medically trained provider (%)	55.9	55.8
Time to interview after birth (days)	2.11 \pm 2.86	2.01 \pm 2.70

Abbreviations: BMI, body mass index; IFA, iron and folic acid; LNS, lipid-based nutrient supplements.

^aIncluding one maternal/fetal death.

TABLE 2 Newborn health indicators by maternal supplement during pregnancy

Variable	LNS (%) <i>n</i> = 918	IFA (%) <i>n</i> = 2,598	OR or mean diff. [95% CI]	<i>P</i> value
Newborn response is good	66.3	67.7	0.95 [0.81, 1.12] ^a	.562
Perceived overall condition of the baby is healthy	89.4	90.6	0.90 [0.70, 1.16] ^a	.414
EIBF (put on breast within 1 hr after birth)	80.8	81.4	1.04 [0.82, 1.32] ^a	.757
Suckling ability after birth	82.0	79.8	1.13 [0.93, 1.37] ^a	.234
Frequency of breastfeeding in the first 24 hr after birth (mean \pm SD)	19.0 \pm 9.2	19.4 \pm 9.1	-0.25 [-1.11, 0.61] ^b	1.000
Exclusivity of breastfeeding in the first 24 hr after birth	84.6	87.7	0.96 [0.77, 1.20] ^a	.727

Note. All models were run separately and included a random effect of cluster nested within treatment group and a random effect of union nested within subdistrict to account for the cluster level randomization.

Abbreviations: EIBF, early initiation of breastfeeding; IFA, iron and folic acid; LNS, lipid-based nutrient supplements.

^aOdds ratio (OR).

^bMean difference.

4 | DISCUSSION

We did not find any effect of a prenatal nutritional supplement on newborn response or mother's rating of the general condition of the newborn, EIBF, suckling ability, or frequency and exclusivity of breastfeeding in the first 24 hr. However, these newborn health and feeding outcomes were strongly related to each other.

These results suggest that these newborn health and feeding outcomes are not strongly influenced by the nutrition of the mother during pregnancy. More important factors are likely the position of the fetus within the uterus (e.g., breech delivery), birth trauma, second born twins, primiparity, maternal age, short or excessive duration of gestation, birth weight above 5 kg, and low birth weight (Catlin et al., 1986; Patel et al., 2015; Thorngren-Jerneck & Herbst, 2001). We

TABLE 3 Associations of breastfeeding practices in the first 24 hr with perceived newborn health condition and feeding variables

Variable	Percent or mean \pm SD	OR or mean diff. [95% CI]	P value
Exclusivity of breastfeeding in the first 24 hr (%)		OR [95% CI]	
Perceived overall condition of the newborn baby			
Healthy (n = 3,288)	86.6	1.25 [0.93, 1.69]	
Not healthy (n = 350)	82.6	Reference	.139
EIBF			
Yes (n = 2,925)	89.1	2.94 [2.38, 3.64]	
No (n = 675)	73.8	Reference	<.001
Suckling ability after birth			
Yes (n = 2,890)	87.1	1.44 [1.15, 1.81]	
No (n = 705)	83.0	Reference	.002
Frequency of breastfeeding in the first 24 hr (mean \pm SD)		Mean diff. [95% CI]	
Perceived overall condition of the newborn baby			
Healthy (n = 3,241)	19.5 \pm 9.0	2.90 [1.86, 3.95]	<.001
Not healthy (n = 310)	16.6 \pm 9.9		
Suckling ability after birth			
Yes (n = 2,854)	19.6 \pm 9.1	1.69 [0.95, 2.43]	<.001
No (n = 695)	18.1 \pm 9.1		

Note. All models were run separately (one predictor at a time) and included a random effect of cluster nested within treatment group and a random effect of union nested within subdistrict to account for the cluster level randomization. Intervention group is additionally controlled for as fixed effect.

Abbreviation: EIBF, early initiation of breastfeeding.

previously demonstrated that birth weight of infants whose mothers received LNS-PL was higher than that of infants whose mothers received IFA (2,629 \pm 408 vs. 2,588 \pm 413 g; P = 0.007; Mridha et al., 2015), but this did not seem to influence the general condition of the newborn or breastfeeding practices.

The strong association between the mother's perception of the general condition of her newborn and the composite newborn response variable reflecting the timing and quality of crying and movement right after birth (also reported by the mother) was expected and indicates consistency of maternal reporting about the newborn. However, we do not know how these variables based on maternal report are related to independent assessments of newborn condition, such as Apgar score. Further research to validate indicators of newborn condition based on maternal report is needed.

In our study, 81.2% of the infants were put to the breast within the first hour after birth, which is much higher than the percentage (51%) reported in a recent national survey in Bangladesh (Bangladesh Demographic Health Survey 2014) and the percentage (40%) reported from a global analysis (Victora et al., 2016). There are many factors that influence EIBF. In our study, infants reported as having good newborn response or rated as healthy were put to the breast sooner than infants with poor newborn response or rated as not healthy, respectively. Other studies indicate that EIBF can be influenced by mother's knowledge about breastfeeding, delivery by C-section, use of intramuscular narcotic analgesia during labour and delivery, routine procedures in the delivery unit (e.g., neonatal screening and measuring weight) right after birth, pregnancy complications, absence of

postnatal guidelines in the hospital, and community level interventions (e.g., mass media campaign and social media; Forster & McLachlan, 2007; Rollins et al., 2016; Takahashi et al., 2017).

About 86% of the infants in our study were reported to be exclusively breastfed in the first 24 hr. Mother's rating of the general condition of her newborn was not related to the likelihood of exclusive breastfeeding. However, exclusivity of breastfeeding in the first 24 hr was strongly associated with EIBF and suckling ability. The latter relationship is understandable, as a mother is likely to supplement her baby with fluids or foods other than breastmilk if she perceives that the baby is not able to suckle. However, in such situations, the mother can be taught techniques for objectively assessing suckling ability and if necessary motivated to feed her baby with alternative techniques such as using a cup, spoon, or syringe to feed expressed breastmilk until the baby's suckling ability improves (Marinelli, Burke, & Dodd, 2001; Thomas, Marinelli, & Hennessy, 2007). Infants who were put to the breast after the first hour postbirth were also less likely to be exclusively breastfed in the first 24 hr, possibly because the first hour after birth could be a critical period for establishment of optimal suckling behaviour (WHO, 2018). These results suggest that interventions tackling both the timing and the exclusivity of breastfeeding of newborns are needed, especially for infants with suboptimal health status at birth.

Strengths of this study include the following: (a) large sample size, (b) randomized design, (c) data collection by a well-trained and standardized team, (d) high adherence to prenatal supplements, (e) supplement distributed by trained health workers from a different

organization than the research interviewers, (f) newborn data were collected within 72 hr of birth, and (g) a low rate of attrition in all intervention groups. The key limitation was the inability to blind participants to the type of supplement provided because of differences in supplement appearance and taste. In addition, we do not have data to demonstrate that maternal perceptions of newborn characteristics can be used as proxies for clinician-based ratings of the newborn such as Apgar scores, and maternal report of breastfeeding practices may not be accurate because of social desirability bias (Grimm, 2010).

5 | CONCLUSION

In conclusion, we did not find any association between prenatal nutritional supplementation and maternal perception of the general condition of the newborn or early breastfeeding practices. However, EIBF and breastfeeding frequency in the first 24 hr were related to maternal perception of the general condition of the newborn. Thus, interventions to improve these breastfeeding practices for newborns with poorer perceived health status may be useful. Further research to examine the relationship between maternal perception of the newborn's health condition and subsequent child morbidity would also be useful.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

CONTRIBUTIONS

All authors contributed to the design or implementation of the study and approved the final manuscript as submitted. KGD was the principal investigator for the overall project. MBU supervised data collection, quality control, and data management and wrote the first draft

of this manuscript. MKM was the local principal investigator at icddr, b and supervised all study activities in Bangladesh. SLM was involved in many aspects of study design and implementation. CAA carried out data analysis. MSAK, ZS, MH, and RRP contributed to study protocols and supervised data collection and quality control at the study site. As corresponding author, MBU states that he had full access to all data and has the final responsibility to submit for publication.

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