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Impact of plant-derived galactagogues on breast milk production and blood prolactin levels in early postpartum mothers of preterm infants: A double-blind randomised controlled trial.

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Abstract

Background: Preterm infants require efficient care and provision of adequate nutrition to enhance their survival and minimise complications that may arise during growth and development. Breast milk represents the sole recommended source of nutrition for preterm infants until 6 months after birth.

Objective: This study investigated the effect of plant-derived galactagogues on breast milk production and serum prolactin levels of early postpartum mothers, as well as on the weight of their preterm infants.

Methods: A double-blinded, randomised and controlled study design was used to determine breast milk volume and serum prolactin levels on days 1 and 7 of early postpartum mothers of preterm infants given food products containing plant-derived galactagogues (granola or chocolate drink) or the corresponding placebo food products. The weight of the preterm infants fed on breast milk was also measured on days 1 and 7.

Results: Mean breast milk volume was significantly increased in mothers who received the granola (p < 0.0001), chocolate drink (p < 0.0001), granola placebo (p < 0.0001) and chocolate drink placebo (p = 0.0007) by day 7. Serum prolactin levels of the mothers and the weight of the preterm infants were not significantly different on day 7 compared to the values obtained on day 1. There was no significant correlation between breast milk volume and either serum prolactin levels or infant weight on days 1 and 7 for the intervention and placebo groups.

Conclusion: Plant-based galactagogues did not increase breast milk supply or affect serum prolactin levels in early postpartum mothers with hypogalactia. Further research is needed to elucidate the molecular mechanisms regulating breast milk production and composition in lactating women

$\textbf{Keywords:} \ Preterm \ babies, \ galactagogues, \ breast \ milk, \ serum \ prolactin$

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INTRODUCTION

Breastfeeding is a crucial aspect of maternal and infant health, especially for preterm infants, due to

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their vulnerability to diverse health challenges. Breast milk provides essential nutrients, antibodies, and growth factors that promote optimal growth and development of preterm infants [1]. It is estimated that 13.4 million infants were born preterm in the year 2020 globally, and preterm births occurring from 32 to < 37 weeks of gestation were the most predominant [2]. In the largest tertiary hospital in Ghana, the preterm birth rate doubled from 9.3% to 18.9% over a

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decade [3]. Infants born before the recommended 37 weeks of gestation are at risk of developing complications that could lead to mortality or long-term adverse outcomes in those who survive beyond five years [4]. It is, therefore, essential to provide adequate breastfeeding and medical care to preterm infants to boost their survival, growth and development during the early stages of life.

Lactating mothers of preterm infants may experience challenges with producing adequate breast milk, which can affect compliance with the highly recommended exclusive breastfeeding of infants till six months after birth. A notable cause of ineffective breastfeeding of preterm infants is reduced production of breast milk in lactating mothers, even though other factors such as ill-health in mothers or infants, weak suckling by infants and lack of nipple stimulation can also affect optimal breast milk production and location of infants. Sub-optimal breast milk production in lactating mothers of preterm babies is also influenced by the emotional and psychological status of the mother, especially when they are temporarily separated from their babies receiving treatment at the neonatal intensive care unit of hospitals [5]. Lactating mothers of preterm infants affected by hypogalactia can boost breast milk production via galactagogues, which are available as medications or present in indigenous diets and commercial food products

Pharmacological galactagogues such as metoclopramide, domperidone, chlorpromazine and sulpiride can boost breast milk production and prolactin secretion [9]. These synthetic galactagogues induce an increase in breast milk production by stimulating prolactin synthesis in lactotrophic cells of the anterior pituitary gland [9]. Pharmacological galactagogues can cause significant adverse effects in both lactating mothers and infants, gastrointestinal disorders, extrapyramidal symptoms, amenorrhea, severe depression and seizures. Hence, their prescription to lactating mothers must be guided by the need to improve breast milk production and tolerance of the potential side effects. Notable galactagogues from herbs and other plant sources include fennel (Foeniculum volgare), fenugreek (Trigonella foenumgraecum), moringa (Moringa oleifera), alfalfa (Medicago sativa), milk thistle (Silybum marianum), and ginger, even though their precise mechanism of action for enhancing breast milk production is currently unknown [10-12].

In Ghana, the use of galactagogues is reported as 67.7% in the northern and southern parts, and the most common lactogogues used by mothers include groundnut/peanut soup prepared with Bra leaves (Hibiscus sabdariffa), hot black tea, Werewere/Agushi (Citrulus colocynthis) prepared with Bra leaves, and Abemudro (a polyherbal formulation) [13]. Hormones such as oxytocin, progesterone, cortisol and oestrogen are also vital in stimulating breast milk production in lactating mothers [9]. The severe adverse effects that might be associated with synthetic galactagogues render plant-derived galactagogues the preferred agents for boosting breast milk production, especially in lactating mothers having a history of nontolerance of these adverse effects from the synthetic agents. Moreover, several lactating mothers would avoid synthetic galactagogues when they are enlightened on the potential to cause side effects in neonates. Hence, plant-derived galactagogues represent a suitable agent for boosting breast milk production and efficient lactation of preterm infants in mothers that produced inadequate volumes of breast milk.

In Ghana, commercial food products containing plantderived galactagogues are usually recommended as intervention products for early postpartum mothers of preterm infants producing insufficient breast milk after child delivery. This practice necessitates continual investigations of the effect of these lactation products on breast milk production in early postpartum mothers. The present study investigated the impact of food products containing plant-derived galactagogues on breast milk production and serum prolactin levels of early postpartum mothers and the weight of the preterm infants. The data from this study provide evidence-based insights that healthcare professionals can use to offer informed guidance and support to lactating mothers of preterm infants.

MATERIALS AND METHODS

Study design and participants

This was a double-blinded, randomised and controlled study, which involved early postpartum mothers of preterm infants at the neonatal intensive care unit of the 37 Military Hospital in Accra, Ghana. The participants who met the inclusion criteria were recruited over six months, as they reported to the study site. The study had four arms: two intervention groups and two placebo (control) groups, each comprising 6 participants (Fig. S1). The inclusion criteria were mothers (18 - 45 years old) of preterm infants (born before or on the 37th week of gestation) from 1st to 10th day of postpartum with daily breast milk volume below 300ml and mechanically pumping breastmilk throughout the days before the onset of the study (at least four times per day). Lactating mothers of full-term infants were excluded from the study.

Other exclusion criteria were lactating mothers with breast engorgement, mothers on medications for inducing breast milk production, mothers who were ill, mothers taking diuretics, pseudoephedrine, anticholinergics, warfarin or any anticoagulant or oestrogen-containing birth control pill, mothers who had undergone surgery that could affect their ability to produce breast milk or mothers diagnosed with polycystic ovary syndrome, asthma or atopic diseases. Mothers who are allergic to peanuts, mothers of infants with congenital anomalies or acute conditions and mothers with obstetrical evaluations recommending exclusion were also not recruited for the study.

Lactation products

The lactation products used for the study are indicated below:

- Chocolate drink (FDA/Dk 21-1461): cocoa powder, i) chia seeds, flax seeds, cinnamon, fenugreek, fennel, brewers' yeast.
- Chocolate drink placebo (FDA/Ce 21-1461A): cocoa ii) powder, chia seeds, flax seeds, cinnamon.
- Granola (FDA/Dk 21-1047): rolled oats, raisins, almonds, honey, pumpkin seeds, flax seeds, chia seeds, brewer's yeasts, fennel, and fenugreek.
- Granola placebo (FDA/Ce 21-1047A): rolled oats, raisins, brewers' yeasts, almonds, honey, pumpkin seeds, flax seeds and chia seeds.

Determination of the effect of lactation products on breast milk volume, serum prolactin levels and infant weight

Participants were randomly allocated to the intervention and placebo groups via a secret ballot procedure. The study design was also aligned with the requirements of the per protocol analysis. Participants in the intervention groups received a lactation product (granola or chocolate drink) containing plant-derived galactagogues for 7 days, along with lactation guidance on how to enhance breast milk production. They consented to physically pump breast milk 4-6 times daily at intervals of at least 3 hours. The participants in the control groups received lactation products (granola placebo or chocolate drink placebo) without the plant-derived galactagogues, and lactation advice was provided for both groups. They were also required to physically pump breast milk four to six times daily at intervals of at least three hours. All lactating mothers recruited for the study received training and supervision on best practices for optimal breast milk pumping. The breast milk volume of all early postpartum mothers and the weight of the preterm infants were measured on day 1, before administering the intervention and placebo products (baseline measurements), and at 24hour intervals until day 7.

Two (2) millilitres (ml) of whole blood were collected via venipuncture for the measurement of serum prolactin levels of the mothers, which were measured on day 1 prior to administering the intervention and placebo products (baseline measurements) and on the 7th day of the study. The whole blood samples were centrifuged at 2,000 x g for 10 minutes at 4°C, and the serum obtained was used to measure prolactin levels via the chemiluminometric method using the Advia Centaur XP device (Siemens).

Data Analysis

All data were stored using Microsoft Excel 2013, and the statistical analysis was done using IBM SPSS version 25 software. Demographic and clinical information (age, marital status, educational level, mode of delivery, employment status, gravidity, parity and gestational age of infants) was analysed for all the study participants in each group (intervention or placebo). The Kolmogorov-Smirnov Test of Normality was used for the assessment of conformity with a normal distribution of the data on breast milk volume, serum prolactin levels and infant weight. The mean, standard deviation and range for serum prolactin, breast milk volume and infant weight were also determined. An unpaired T-test was used to determine whether the mean breast milk volume, serum prolactin levels or infant weight measured on day 1 significantly differed from those on day 7 for each of the four groups. The unpaired T-test was also used to evaluate whether the mean breast milk volume, serum prolactin levels or infant weight measured for the placebo group was significantly different from the corresponding intervention group on days 1 and 7. The Pearson and Spearman's rank correlation coefficients were also determined to assess the correlation between breast milk volume and either serum prolactin levels or infant weight. A p-value of less than 0.01 was considered statistically significant.

RESULTS

Thirty-two early postpartum mothers initially consented to participate in the study (Fig. S1). However, eight mothers were later excluded from the study due to the loss of their preterm infants (3 mothers), lack of interest in the study (2 mothers) and mothers citing personal reasons to discontinue the study (3 mothers). Hence, the total sample size used in this study was 24 mothers of preterm infants. The granola intervention group, chocolate drink group, granola placebo group and chocolate drink placebo group had 6 participants for each group (Table 1). Two mothers were between 40 and 49 years old, and eleven mothers were in the age range of 20 to 29 years, which was the highest frequency of participants. This was followed by the 30 to 39 years age range, which had 10 participants. More than half of the mothers (14 participants) were married, and the remaining were single. For educational background, tertiary education had ten mothers, followed by eight mothers with senior high school education and five with junior high school education.

Mothers who delivered their preterm infants through spontaneous vaginal delivery, which is a normal birth through the vagina requiring no surgical procedure, were 11 participants, and the mothers that delivered through a Caesarean Section (CS) were 13 participants. Analysis of the gestational age of the infants indicated that most infants were in the late preterm range (35 - 37 weeks; 14 infants)and was followed by the moderate preterm range (33 - 34)weeks; 6 infants), very preterm (28 - 32 weeks; 3 infants), and extreme preterm (< 28 weeks; 1 infant). The number of pregnancies (gravidity) had four categories: mothers in the first pregnancy had 8 participants, the second pregnancy had the highest number of participants (9), the third pregnancy had the least number of participants (2) and the fourth or more pregnancy had 5 participants. Parity, which is the number of successful deliveries, had the most participants (13) being non-first-time mothers and 11 participants being first-time mothers.

Chocolate drink placebo

(n = 6)





Table 1. Demographic feature	ures of mother and babic	es of the study population	ı
	Granola (n = 6)	Chocolate drink (n = 6)	Granola placebo (n = 6)
Age	, ,	,	
10 – 19 years	-	-	-
20 – 29 years	2	3	4
30 – 39 years	4	2	1
40 – 49 years	-	1	1
Marital status			
Single	2	2	4
Married	4	4	2
Educational level			
No level	-	-	-
Junior High	1	3	-
G ' YY' 1	•		^

2 3 0 2 4 Senior High 3 2 4 Tertiary 1 Mode of Delivery 2 3 2 Vaginal 4 C.S. 3 2 **Employment** Employed 4 3 5 2 Unemployed 3 1 Gravidity 3 1 1 3 1st pregnancy 2nd pregnancy 2 3rd pregnancy 2 4th pregnancy/more Parity Primiparous Multiparous 5 5 2 1 Gestational Age 1 Extreme (< 28 weeks) _ -Very Preterm (28-32 weeks) 2 1 4 1 Moderate (33–34 weeks) 2 Late preterm (35–37 weeks) 6 2

Analysis of the effect of the intervention and placebo products on breast milk volume, serum prolactin and infant weight

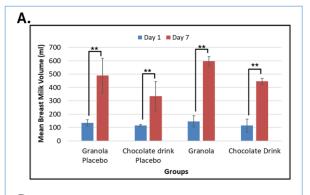
Breast milk volume, serum prolactin levels and infant weight were measured on day 1 (baseline) and on day 7 to ascertain the effect of the intervention and placebo products on these parameters. The values from the 6 participants were used to calculate each group's mean and standard deviation. Prior to administering the lactation products on day 1 (baseline), the breast milk volumes collected from the participants in the intervention (granola and chocolate drink) groups were not significantly different from those in the corresponding placebo groups (Table 2). A four-fold increase in the mean breast milk volume was recorded for the participants on granola treatment on the seventh day compared to the baseline, whereas a 3.63-fold increase was obtained for the participants on granola placebo (Fig. 1A). Moreover, a 3.88-fold increase in mean breast milk volume was obtained on day seven compared to the baseline for the participants on chocolate drink and a 2.87-fold increase was obtained for participants on chocolate drink placebo. The highest difference in mean breast milk volume from day 1 to day 7 was obtained for participants on the granola treatment. It was followed by participants on the granola placebo and the chocolate drink. Participants on the chocolate drink placebo recorded the lowest difference in mean breast milk volume. The mothers given the granola or chocolate drink products containing galactagogues produced significantly higher mean breast milk volume on day seven compared to the mean volume reported on day 1 (p < 0.0001 for granola and p < 0.0001 for chocolate drink).

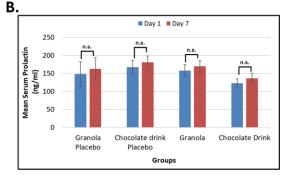
The mean breast milk volumes of the mothers on placebo products were also significantly different on days 1 and 7 (p < 0.0001 for granola placebo and p = 0.0007 forchocolate drink placebo). Collectively, these data demonstrate that the placebo products caused statistically significant improvement in breast milk production in the early postpartum mothers of preterm infants within the 7day study duration. The inclusion of the natural galactagogues in granola and chocolate drink also caused an additional modest increase in breast milk volume on day 7 relative to the corresponding placebo products, even though the difference in breast milk volumes was not statistically significant (Table 2). The mothers on granola placebo and chocolate drink placebo recorded modest increases in mean prolactin levels on day 7 compared to day 1 (14.5 ug/ml and 13.8 ng/ml, respectively, Figure 1B). The inclusion of galactagogues in the granola and chocolate

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drink did not cause statistically significant increase in the mean prolactin levels on the 7th day compared to day 1 (p = 0.2422 for granola and p = 0.0993 for chocolate drink). The data also indicated that the mean prolactin level for the participants in the chocolate drink group was significantly lower relative to the chocolate drink placebo group on both day 1 and day 7 (Table 3). It can be inferred that the relatively low mean prolactin levels in the chocolate drink group is not dependent on the effect of the lactation product and might reflect the physiological states of the participants on day 1. Further analysis demonstrated there was no statistically significant correlation between breast milk volume and serum prolactin levels on days 1 and 7 for each treatment group (Table 4).

The preterm infants of the 24 mothers were weighed on day 1 (baseline) and day 7 to ascertain the effect of the lactation products consumed by their mothers on the weight of the infants. The difference in mean weight of the infants whose mothers consumed the granola product was equivalent to the infants whose mothers consumed the granola placebo product, indicating that consumption of these products by the mothers had no detectable effect on the weight of their infants on day 7 (Figure 1C). Moreover, the difference in the mean weight of the infants whose mothers consumed the chocolate drink was similar to the infants whose mothers consumed the placebo chocolate drink. Statistical analysis also indicated no significant difference in the mean infant weight reported on day 7 compared to the baseline weight for all four groups in the study. Moreover, the low





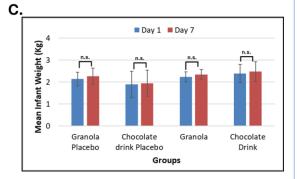


Figure 1. Effect of lactation products on breast milk production, serum prolactin levels and infant weight.

Table 2. S	statistical analy	ysis of brea	st milk vol	umes from	the
control ar	d intervention	groups on	days 1 and	17	

p-value
0.5608
0.9355
0.0780
0.0351

Table 3. Statistical analysis of serum prolactin levels from the control and intervention groups on days 1 and 7

Comparison of control and intervention groups	p-value
Day 1	
Granola Placebo vs. Granola	0.5270
Chocolate drink placebo vs. chocolate drink	0.0008
Day 7	
Granola Placebo vs. Granola	0.6199
Chocolate drink placebo vs. Chocolate drink	0.0007

Table 4: Correlation analysis between breast milk volumes and serum prolactin levels for the control and intervention groups on days 1 and 7

Groups	Pearson correlation coefficient	p-value
Granola placebo		
Day 1	-0.3846	0.451
Day 7	0.8122	0.050
Chocolate drink placebo		
Day 1	-0.2454	0.639
Day 7	0.1504	0.776
Granola		
Day 1	-0.001	0.99
•		
Day 7	-0.094	0.859
Chocolate drink		
Day 1	0.6467	0.165
Day 7	0.4992	0.313

infant weights recorded by the chocolate drink placebo group relative to the chocolate drink group on days 1 and 7 were not statistically significant (Table 5). Furthermore, no statistically significant correlation was obtained between breast milk volume and infant weight on days 1 and 7 for each treatment group (Table 6). Hence, it can be inferred that the consumption of products containing galactagogues by the mothers did not lead to a significant increase in the weight of the infants on the seventh day of the study.

Local diets consumed by the participants were believed to boost breast milk production

Lactating mothers producing inadequate breast milk after childbirth are usually encouraged to consume indigenous diets believed to boost breast milk production. The participants in this study were not restricted from consuming these diets during the duration of the study. On the seventh day of the study, the participants were interviewed to obtain information on diets they consumed during the study, which are believed to boost breast milk production.

Seven of the 12 participants in the placebo groups indicated they consumed hot millet porridge, whereas 4 participants from the intervention (granola & chocolate drink) groups consumed hot diets containing galactagogue (Table S1). Three participants from the intervention and placebo groups consumed groundnut-containing foods, which are believed to boost breast milk production. One participant from the placebo group consumed soup made from jute (ayoyo) leaves, which is also believed to boost breast milk

production in lactating mothers. We infer that consumption of these indigenous foods might have contributed to boosting breast milk production in participants from both the intervention and placebo groups.

DISCUSSION

The present study assessed the effect of two food products containing plant-derived galactagogues on breast milk production and serum prolactin levels in early postpartum mothers of preterm infants. We also evaluated the impact of the mothers' consumption of these galactagoguescontaining food products on the weight of preterm infants. The intervention and placebo products investigated by this study caused a significant increase in mean breast milk volume in the early postpartum mothers by day 7. However, mean serum prolactin levels of the mothers and mean infant weight were not significantly different on days 1 and 7. Moreover, the study identified no correlation between breast milk volume and either serum prolactin or infant weight.

Fennel and fenugreek are derived from the seeds of Foeniculum volgare and Trigonella foenumgraecum, respectively, and are notable for enhancing breast milk production in lactating mothers [5,18]. A previous study has reported that consumption of herbal tea containing fenugreek led to a significant increase in breast milk volumes in the first few days after childbirth [19]. Moringa oleifera also boosts breast milk production in early

Table 5. Statistical analysis of infant weights from the control and intervention groups on days 1 and 7 Comparison of control and intervention groups p-value Day 1 0.5844 Granola Placebo vs. Granola Chocolate drink placebo vs. Chocolate drink 0.1270 Granola Placebo vs. Granola 0.6725 Chocolate drink placebo vs. Chocolate drink 0.1153 p-value < 0.01 was considered statistically significant

Groups	Pearson correlation coefficient	p-value
Granola placebo		
Day 1	0.3312	0.521
Day 7	-0.2705	0.604
Chocolate drink placebo		
Day 1	0.5743	0.233
Day 7	-0.6167	0.192
Granola		
Day 1	-0.6104	0.198
Day 7	0.5399	0.269
Chocolate drink		
Day 1	0.08204	0.877
Day 7	0.5254	0.284

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postpartum mothers of preterm infants [20]. Our data demonstrate that both the intervention and placebo food products used in this study caused a significant improvement in breast milk production in lactating mothers of preterm infants. The data also highlight the crucial role of these lactation products in minimising undernutrition in preterm infants caused by insufficient breast milk production. We also demonstrated that the increase in breast milk production was not due to increased serum prolactin levels after administering the food products containing galactagogues. Even though higher levels of serum prolactin in lactating mothers have been associated with increased breast milk production [21], our data indicate that the basal threshold of prolactin necessary for stimulating the production of breast milk is sufficient to attain breast fullness in mothers of preterm infants consuming food products containing galactagogues [10].

The events leading to childbirth can be stressful and may result in a concomitant delay in breast fullness and a reduction in lactose concentration in breast milk [14,15]. Breastmilk is predominantly carbohydrates, fats, proteins, and water; hence, lactating mothers are usually advised to eat well and consume foods containing agents known to boost breast milk production, especially when the volume of milk produced daily is insufficient for the nutritional needs of the neonate. The fulfilment of the dietary needs of preterm infants is vital for facilitating their survival and proper growth and development during the first weeks after birth. Breastfeeding also enhances the immunity of neonates against infectious diseases, highlighting the vital role of breast milk in ensuring well-being and good health in infants [16,17]. Preterm infants typically have birth weight below 2.5kg, necessitating adequate nutrition using breast milk to facilitate holistic growth and development. Continuous monitoring of the weight of preterm infants after birth also enables pediatric healthcare professionals to evaluate the health status and well-being of the infant [22].

We demonstrated that there was no difference in the weights of preterm infants who received galactagoguescontaining food products during the 7-day study period and those who received the placebo. This observation may be attributed to the study's short duration. A longer duration for monitoring the weight of preterm infants whose mothers are continuously receiving galactagogues-containing food products would provide comprehensive insight into the plant-derived galactagogues' effect on the infant weight. Assessment of the effect of the plant-derived galactagogues on lactose concentration and other nutrients in breast milk would also provide useful data for an in-depth evaluation of the nutritional benefits of galactagogues-stimulated breast milk for preterm infants. Psychological well-being, stress, diet, and the environment of lactating mothers are potential confounding factors that may affect breast milk production in the study participants. Hence, a potential limitation of this study is the absence of the measurement of cortisol levels in the study participants who received either the intervention or placebo lactation products.

Conclusion

Plant-based galactagogues had no effect on serum prolactin levels or the amount of breast milk produced in early postpartum mothers with hypogalactia. The molecular processes that control the bioavailability of prolactin, composition and production of breast milk in nursing mothers require further investigation.

DECLARATIONS

Ethical consideration

Both the Ethical and Protocol Review Committee of the College of Health Sciences at the University of Ghana (Protocol Identification Number: CHS-Et/M:8-p4.12014-2015) and the Institutional Review Board of the 37 Military Hospital (Protocol Identification Number: 37MH-IRB/MP/IPN/684/2023) gave their approval to the study protocol. A consent form was signed by each participant after they had been provided with all of the required information regarding the study.

Consent to publish

All authors agreed on the content of the final paper.

Funding

None

Competing Interest

The authors declare no conflict of interest

Author contribution

WAM conceptualised the study, designed the study, and provided overall supervision. ESA and NG collected data, conducted initial analyses, and drafted the manuscript. VA performed critical revisions and the submission process. EO, MAA, EPA, and IO contributed scientific guidance, data interpretation, and manuscript refinement.

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Availability of data

Data is available upon request to the corresponding author

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Supplementary

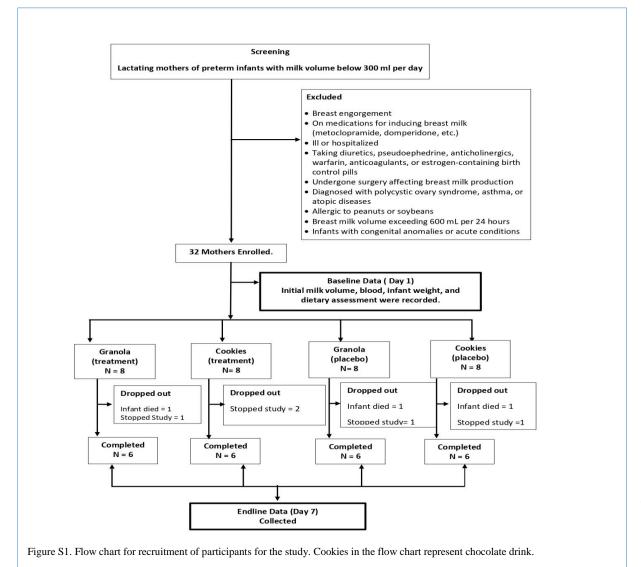


Table S1. Number of participants that consumed local diets believed to boost breast milk production in lactating mothers.

Galactogogues-containing diets	Intervention groups $(n = 12)$	Placebo groups (n = 12)
Herbs-related galactogogues	-	1 participant (soup containing jute leaves)
Hot diets containing galactogogues	4 participants (hot millet porridge, hot corn porridge)	7 participants (hot millet porridge)
groundnuts	3 participants (groundnuts & maize, groundnut soup, mashed kenkey & groundnuts)	3 participants (mashed kenkey & groundnuts)
Non-galactogenic foods	4 participants (apples, watermelon, rice)	2 participants (coconut, tom brown porridge)