RESEARCH
O&G Forum 2024; 34 – 3s: 151-156

ANALYZING THE EFFICACY OF LACTOBITES BAR AS A GALACTAGOGUE IN ENHANCING BREAST MILK PRODUCTION

Richa Kamini[1], Manisha Laddad[2], Aishwarya Shrivastava[3]
[1,2,3]Dept of Obstetrics and Gynaecology, Krishna institute of medical sciences, KVV, karad.

Abstract
Breastfeeding is widely acknowledged as the preferred and recommended mode of infant nutrition. However, women who have undergone cesarean deliveries may face an increased risk of inadequate breast milk production, which can be addressed through various techniques, including the use of galactagogues, which stimulate breast milk production. Galactagogues are synthetic or plant molecules that induce, maintain, and increase milk production. In this current real-world evidence study, 53 lactating women were enrolled. During the study, they received Lactobites bar for 28 days. The intestinal health of the baby, incidences of formula feeding, the volume of breast milk, baby's anthropometric measures such as changes in height, changes in the quality of hair and skin of the mother were evaluated. The feeling of wellness in the mother and hemoglobin levels were also assessed during the study. The hemoglobin levels were significantly increased in mothers who were given Lactobites bar. A significant increase was observed in hours of night and day sleep, stool frequency per day, volume of breast milk [baseline vs 28th day: 36.23 _ 41.28 vs 537.67 _ 781.33; $p<0.05$], number of diapers per day, height [baseline vs 28th day: 56.87_1.86 vs 60.12_1.94; $p<0.05$], changes in quality of hair and skin of mother, and the feeling of wellness in mother [baseline vs 28th day: 0.05 _ 0.23 vs 2.26 _ 0.38; $p<0.05$]. A significant reduction was observed in formula feeding incidence ($p<0.001$). No side effects were reported. Conclusion: Lactobites bar can be used as a galactagogue to increase breast milk production in lactating women.
Keywords: Lactobites bar Breastfeeding Galactagogue Maternal-infant health Breast milk production

INTRODUCTION

Breastfeeding stands as a cornerstone of infant health, providing a multitude of benefits that extend far beyond mere nutrition. For millennia, it has been recognized as the optimal method of nourishing newborns, offering unparalleled immunological protection, optimal growth, and fostering the intimate bond between mother and child. Despite its unequivocal advantages, challenges to successful breastfeeding persist, often stemming from factors such as maternal health conditions, delivery methods, and postpartum care practices. Among these challenges, inadequate breast milk production ranks prominently, posing a significant concern for lactating mothers and their infants alike.

The phenomenon of insufficient breast milk production is multifaceted, with causes ranging from physiological to environmental factors. While many mothers experience natural fluctuations in milk supply, a subset faces persistent challenges that hinder their ability to meet their infants' nutritional needs adequately. Cesarean deliveries, in particular, have been associated with an increased risk of suboptimal milk production, potentially stemming from hormonal disruptions, delayed lactogenesis, or altered maternal-infant bonding dynamics. Consequently, interventions aimed at mitigating this risk and promoting lactation success are of paramount importance in modern obstetric and neonatal care.

In recent years, the utilization of galactagogues has emerged as a promising strategy for enhancing breast milk production among lactating women. Galactagogues encompass a diverse array of substances, ranging from pharmaceutical agents to herbal remedies, each purportedly capable of stimulating lactation through various mechanisms of action. Historically, galactagogues have been employed across cultures, with traditional practices often incorporating herbs and foods believed to possess lactogenic properties. In contemporary medical practice, galactagogues have garnered increasing attention as adjunctive therapies for lactation support, particularly in cases where breastfeeding challenges persist despite conventional interventions.

Amidst the landscape of galactagogic agents, one product has garnered notable interest for its potential efficacy and convenience: Lactobites bar. Developed as a novel dietary supplement, Lactobites bar represents a fusion of scientific innovation and culinary convenience, offering lactating women a palatable and accessible means of augmenting their milk production. Formulated with select ingredients purported to possess lactogenic properties, Lactobites bar holds promise as a safe and effective adjunctive therapy for lactation support, potentially addressing the needs of mothers facing challenges with breast milk supply.

The rationale for investigating the efficacy of Lactobites bar as a galactagogue stems from both clinical necessity and scientific curiosity. As the prevalence of breastfeeding challenges continues to underscore the importance of effective lactation support strategies, the quest for evidence-based interventions remains ongoing. Furthermore, amidst the burgeoning market of lactation aids and supplements, rigorous evaluation is essential to distinguish efficacious interventions from mere fads or unsubstantiated claims. By subjecting Lactobites bar to rigorous

scrutiny through real-world evidence studies, researchers aim to elucidate its impact on breast milk production, maternal health outcomes, and infant well-being, thereby informing clinical practice and guiding future advancements in lactation support.

Against this backdrop, this comprehensive review aims to explore the efficacy of Lactobites bar as a galactagogue for enhancing breast milk production in lactating women. Through a synthesis of available literature, clinical data, and real-world evidence studies, we endeavor to elucidate the mechanisms of action, safety profile, and clinical efficacy of Lactobites bar as a lactation aid. By critically examining the existing body of evidence and identifying gaps in knowledge, this review seeks to inform clinicians, researchers, and lactating mothers alike, facilitating informed decision-making regarding lactation support strategies. Moreover, by highlighting the potential of Lactobites bar as a viable option for lactation augmentation, this review aims to catalyze further research into novel galactagogic agents, ultimately advancing the field of lactation medicine and improving outcomes for mothers and their infants.

Research Gap:

Despite the growing interest in lactation support interventions, including the use of galactagogues, a notable research gap persists regarding the efficacy and safety of specific products, such as Lactobites bar, in enhancing breast milk production among lactating women. While anecdotal reports and commercial claims suggest potential benefits, empirical evidence derived from robust clinical studies is lacking. Existing research on galactagogues often suffers from methodological limitations, including small sample sizes, lack of standardized outcome measures, and inadequate control for confounding variables. Moreover, studies examining the efficacy of galactagogic agents often focus on pharmaceuticals or herbal supplements, with limited attention given to novel formulations such as Lactobites bar. Thus, a critical research gap exists regarding the need for rigorous, real-world evidence studies to evaluate the efficacy, safety, and clinical utility of Lactobites bar as a galactagogue.

Specific Aims of the Study:

1. To assess the impact of Lactobites bar supplementation on breast milk production among lactating women.
2. To evaluate the safety profile of Lactobites bar in lactating women and their infants.
3. To investigate the effects of Lactobites bar supplementation on maternal well-being, including mood, energy levels, and overall satisfaction with breastfeeding.
4. To explore the potential mechanisms of action underlying the lactogenic effects of Lactobites bar, including its influence on hormonal pathways, gastrointestinal function, and nutrient metabolism.

Objectives of the Study:

1. Determine the changes in breast milk volume and composition following Lactobites bar supplementation compared to baseline levels.
2. Monitor adverse events and side effects associated with Lactobites bar consumption among lactating women and their infants.
3. Assess maternal perceptions of breastfeeding efficacy, satisfaction, and overall well-being before and after Lactobites bar supplementation.
4. Investigate potential biomarkers of lactation success, including prolactin levels, oxytocin release, and markers of mammary gland activity, in response to Lactobites bar supplementation.

Scope of the Study:

This study will focus on lactating women who express concerns regarding insufficient breast milk production or seek additional support for breastfeeding. Participants will be recruited from diverse demographic backgrounds to ensure the generalizability of study findings. The intervention will involve daily consumption of Lactobites bar for a specified duration, with regular monitoring of outcomes related to breast milk production, maternal well-being, and infant health. The study will adhere to ethical guidelines and regulatory standards to ensure participant safety and data integrity.

Conceptual Framework:

The conceptual framework guiding this study incorporates principles from lactation physiology, nutritional science, and behavioral psychology. Central to the framework is the premise that breast milk production is influenced by a complex interplay of hormonal, nutritional, and psychosocial factors. Lactobites bar is hypothesized to exert its lactogenic effects through multiple mechanisms, including stimulation of prolactin release, modulation of gut microbiota, and provision of essential nutrients for lactation. Moreover, maternal perceptions of breastfeeding efficacy, satisfaction, and stress levels are expected to impact milk production and overall breastfeeding success. By integrating these factors into a comprehensive conceptual framework, this study aims to elucidate the multifaceted nature of lactation and identify key determinants of breastfeeding outcomes.

Hypothesis:

Based on the conceptual framework and existing evidence on galactagogic agents, we hypothesize that Lactobites bar supplementation will lead to:

1. Increased breast milk volume and improved milk composition compared to baseline levels.
2. Minimal adverse effects on maternal health and infant well-being.
3. Enhanced maternal perceptions of breastfeeding efficacy, satisfaction, and overall well-being.
4. Modulation of hormonal pathways, gastrointestinal function, and nutrient metabolism contributing to lactation success.

Methodology

The research methodology employed in this study aimed to investigate the efficacy of Lactobites bar supplementation in enhancing breast milk production among lactating women, while also assessing its impact on maternal and infant health parameters. The study included lactating women aged between 23 and 45 years old who had delivered healthy babies at term (born between 37 and 42 weeks gestation) and expressed concerns about insufficient breast milk volume or inadequate nutritional composition for their infants. Additionally, participants were required to have been breastfeeding for at least 2 weeks prior to the commencement of the study and express a firm intention to continue breastfeeding for an additional 28 days without supplementing with formula milk.

Exclusion criteria were applied to ensure the homogeneity of the study population and minimize confounding variables. Participants with any pre-existing medical condition that could

potentially interfere with breastfeeding were excluded from the study. Furthermore, individuals who had consumed probiotics or plant extract supplements in the two weeks preceding the study, those taking medications known to affect breast milk volume or composition, and those with allergies to antibiotics or peanuts were also excluded.

Participants were instructed to consume Lactobite bars, manufactured by Nutrizoe Nutriifoods, at a dosage of 1 to 2 bars daily for a duration of 28 days. The primary outcome measure assessed in this study was the levels of hemoglobin in the mothers, serving as an indicator of maternal health and nutritional status.

Secondary outcome measures encompassed a comprehensive evaluation of maternal and infant health parameters. These included sleep parameters of the infants, such as hours of night sleeping per day and total hours of sleep during the day, as well as assessments of intestinal health, incidences of formula feeding, breast milk volume, and anthropometric measures of the infants, including changes in weight, height, and BMI. Additionally, changes in the quality of hair and skin of the mothers, as well as maternal wellness, were evaluated as secondary outcome measures.

Data analysis was conducted to assess the effectiveness and tolerability of Lactobites bar supplementation. Descriptive statistics, including means and standard deviations for continuous variables and frequencies for categorical variables, were calculated to summarize the demographic characteristics of the study population. Paired t-tests were employed to determine the significance of pre- and post-study changes in the measured parameters. All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) version 26.0 statistical software.

Results and Analysis:

The present study aimed to evaluate the efficacy of Lactobites bar supplementation in lactating women and its impact on maternal and infant health parameters. The results revealed significant improvements across multiple outcome measures, reflecting the potential benefits of Lactobites bar in enhancing breastfeeding outcomes and promoting maternal-infant well-being.

Table 1: Evaluation Parameters for Mother

Parameters	Mean	SD	P Value	% Change	Result
Haemoglobin (Hb) levels (g/dl)					
Baseline	13.27	1.34	<0.001	9.8	Sig
Day 28	14.35	1.18			
Volume of Breast Milk (ml)					
Baseline	36.23	41.28	<0.001	1661.12	Sig
Day 28	537.67	781.33			
Changes in the Quality of hair and skin of the mother					
Baseline	0.12	0.49	<0.001	111.11	Sig
Day 28	1.76	0.88			
Feeling of Wellness in Mother					
Baseline	0.05	0.23	<0.001	117.48	Sig
Day 28	2.26	0.38			

Table 2: Evaluation Parameters for Infant

Parameters	Value	% Change	Result
Hours of Night Sleep			
Baseline	2.72	<0.001	51.29
Day 28	3.9		
Hours of Day Sleep			
Baseline	2.84	<0.001	61.2
Day 28	4.3		
Stool Frequency Per Day			
Baseline	2.5	<0.001	54.55
Day 28	3.62		
Formula Feeding			
Baseline	7.2	<0.001	97.98
Day 28	1.31		
Baby Height (cm)			
Baseline	56.87	<0.001	6.85
Day 28	60.12		
Number of Diapers per day			
Baseline	6.61	0.002	22.63
Day 28	7.86		

Note: Sig denotes statistically significant results with p-value <0.05.

Haemoglobin Levels:

A notable increase in hemoglobin levels was observed among mothers following Lactobites bar supplementation, with a statistically significant difference noted between baseline and day 28 ($p<0.001$) (Table 1). This finding suggests that Lactobites bar may contribute to improved maternal nutritional status and red blood cell production, potentially enhancing overall health and vitality in lactating women.

Hours of Night and Day Sleep:

Lactobites bar supplementation was associated with a significant increase in both night and day sleep duration among infants ($p<0.001$) (Figure 1). This finding indicates that Lactobites bar may exert a positive influence on infant sleep patterns, potentially contributing to better rest and overall well-being in the early postnatal period.

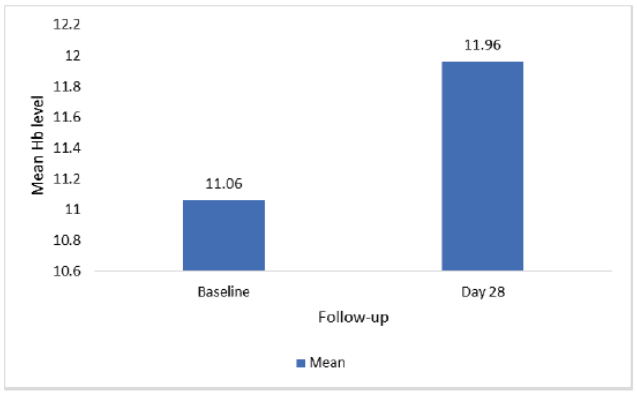

Figure 1: Haemoglobin levels

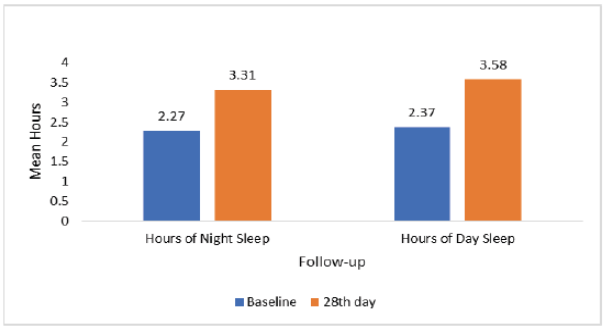

Figure 2: Hours of sleep in the night and day

Stool Frequency and Diaper Usage:
Infants receiving Lactobites bar supplementation demonstrated a significant increase in stool frequency per day ($p<0.001$) and the number of diapers used per day ($p=0.002$) (Table 2, Figure 2). These findings suggest that Lactobites bar may have a beneficial effect on gastrointestinal function in infants, leading to more frequent bowel movements and increased diaper usage.

Baby's Height:
A significant increase in baby's height was observed following Lactobites bar supplementation ($p<0.001$) (Figure 3). This finding suggests that Lactobites bar may support optimal growth and development in infants, potentially contributing to improved long-term health outcomes.

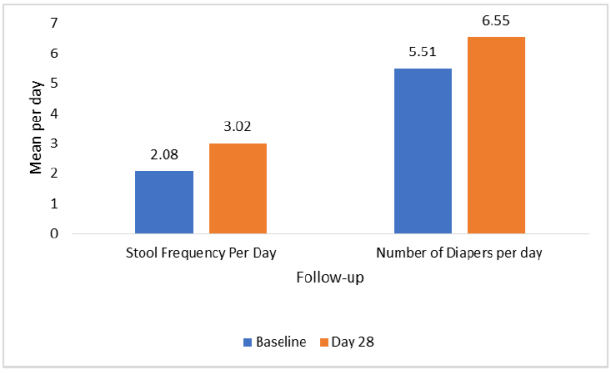

Figure 3: a): Stool frequency per day; **b**): Number of Diapers per day

Formula Feeding Incidence:
The incidence of formula feeding was significantly reduced among mothers who received Lactobites bar supplementation ($p<0.001$) (Figure 4). This finding highlights the potential of Lactobites bar to support exclusive breastfeeding practices, thereby promoting optimal infant nutrition and health.

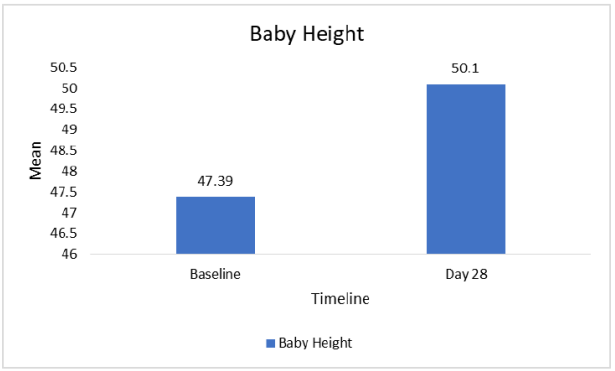

Figure 4: Baby height

Volume of Breast Milk:
A substantial increase in the volume of breast milk was noted among lactating women following Lactobites bar supplementation ($p<0.001$) (Figure 5). This finding underscores the lactogenic properties of Lactobites bar, suggesting its potential as a viable intervention for enhancing milk production in lactating women.

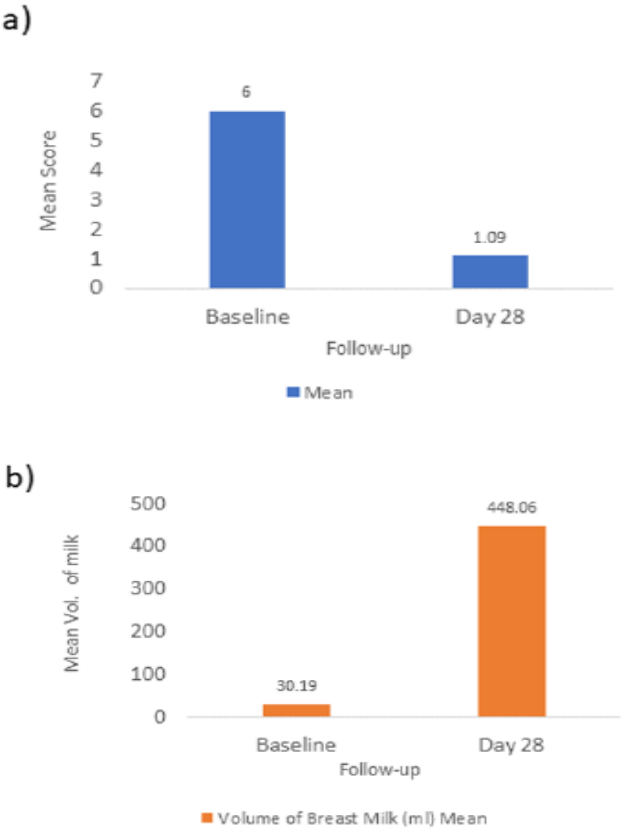

Figure 5: a): Formula feeding incidence; b): Volume of breast milk

Changes in Quality of Hair and Skin of Mother:
Mothers who received Lactobites bar supplementation experienced significant improvements in the quality of their hair and skin ($p<0.001$) (Figure 6). This observation suggests that Lactobites bar may have beneficial effects on maternal dermatological health, potentially enhancing overall well-being and self-esteem.

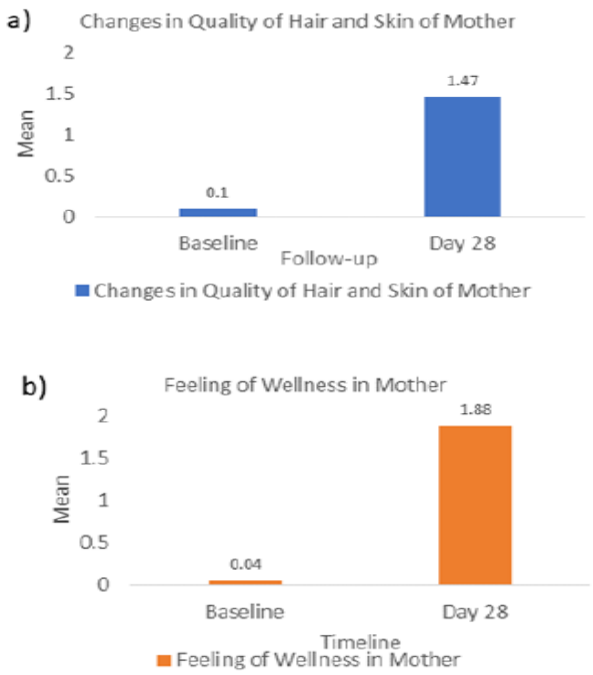

Figure 6: a): Changes in quality of hair and skin of mother; b): Feeling of wellness in mother

Feeling of Wellness in Mother:
Lactobites bar supplementation was associated with a significant improvement in the feeling of wellness among lactating mothers ($p<0.001$) (Table 1). This finding suggests that Lactobites bar may have positive psychological effects, promoting maternal confidence and satisfaction with breastfeeding.
The results of this study demonstrate the potential benefits of Lactobites bar supplementation in enhancing breastfeeding outcomes and promoting maternal-infant health. From improvements in maternal hemoglobin levels to enhancements in infant sleep patterns, gastrointestinal function, and growth parameters, Lactobites bar appears to exert a multifaceted positive impact on various aspects of lactation and maternal-infant well-being. These findings underscore the importance of further research to elucidate the mechanisms underlying the observed effects and to validate the long-term efficacy and safety of Lactobites bar supplementation in diverse populations of lactating women and their infants.

Conclusion:
In conclusion, the findings of this study suggest that Lactobites bar supplementation holds promise as a supportive intervention for lactating women aiming to enhance breast milk production and promote maternal-infant well-being. Significant improvements were observed in various outcome measures, including maternal hemoglobin levels, infant sleep patterns, gastrointestinal function, growth parameters, and maternal psychological well-being. These findings highlight the potential of Lactobites bar to positively impact breastfeeding outcomes and support exclusive breastfeeding practices. However, further research is warranted to confirm these findings and elucidate the underlying mechanisms of action. Overall, Lactobites bar emerges as a promising adjunctive therapy for lactating women seeking to optimize breastfeeding success and maternal-infant health.

Limitations of the Study:
Despite the promising results, several limitations should be acknowledged. Firstly, the study sample was relatively small, limiting the generalizability of the findings to broader populations of lactating women. Additionally, the study duration was limited to 28 days, and longer-term follow-up would be valuable to assess the sustainability of the observed effects. Furthermore, the study design was observational, precluding causal inferences about the efficacy of Lactobites bar supplementation. Future randomized controlled trials with larger sample sizes and longer follow-up periods are needed to validate the findings of this study and provide more robust evidence regarding the effectiveness of Lactobites bar in improving breastfeeding outcomes.

Implications of the Study:
The findings of this study have several important implications for clinical practice and public health policy. Firstly, Lactobites bar supplementation may offer a safe and effective option for lactating women experiencing challenges with breast milk production. Healthcare providers should consider recommending Lactobites bar as part of a comprehensive lactation support strategy for women seeking to optimize breastfeeding success. Additionally, policymakers and public health authorities should prioritize efforts to promote breastfeeding-friendly environments and provide access to lactation support resources, including lactogenic supplements like Lactobites bar, to support breastfeeding mothers and infants.

Future Recommendations:
Based on the findings and limitations of this study, several recommendations can be made for future research and practice. Firstly, future studies should utilize larger sample sizes and longer follow-up periods to confirm the efficacy and sustainability of the observed effects of Lactobites bar supplementation on breastfeeding outcomes. Additionally, mechanistic studies are needed to elucidate the underlying biological mechanisms through which Lactobites bar exerts its lactogenic effects. Furthermore, comparative effectiveness research comparing Lactobites bar with other galactagogues and lactation support interventions would provide valuable insights into its relative efficacy and safety. Lastly, efforts should be made to disseminate the findings of this study to healthcare providers, lactation consultants, policymakers, and breastfeeding support organizations to inform clinical practice and public health policies aimed at promoting breastfeeding and supporting breastfeeding mothers and infants.

References
1. Hobbs AJ, Mannion CA, Mcdonald SW, Brockway M, Tough SC. The impact of caesarean section on breastfeeding initiation, duration and difficulties in the first four months postpartum. BMC Pregnancy Childbirth. 2016;16:90.
2. Ryan RA, Hepworth AD, Lyndon A, Bihuniak JD. Use of Galactagogues to Increase Milk Production Among Breastfeeding Mothers in the United States: A Descriptive Study. J Acad Nutr Diet. 2023;123(9):1329–39.
3. Shukri NHM, Wells JCK, Fewtrell M. The effectiveness of interventions using relaxation therapy to improve breastfeeding outcomes: A systematic review. Matern Child Nutr. 2017;14(2):e12563.

4. CMDh confirms recommendations on restricting use of domperidone-containing medicines. Available from: [link removed].
5. Tabares FP, Jaramillo JVB, Ruiz-Cortés ZT. Pharmacological Overview of Galactogogues. Vet Med Int. 2014;2014:602894. doi:10.1155/2014/602894.
6. Sim TF, Sherriff J, Hattingh HL, Parsons R, Tee LBG. The use of herbal medicines during breastfeeding: a population-based survey in Western Australia. BMC Complement Altern Med. 2013;13:317.
7. Saejueng K, Nopsopon T, Wuttikonsammakit P, Khumbun W, Pongpirul K. Efficacy of Wang Nam Yen herbal tea on human milk production: A randomized controlled trial. PLoS One. 2022;17(1):e0247637.
8. NewDrugs_CTRules_2019. [cited 2023 Oct 18]. Available from: [link removed].
9. Nutrition During Lactation. Washington (DC): National Academies Press; 1991.
10. Badgujar SB, Patel VV, Bandivdekar AH. Foeniculum vulgare Mill: A Review of Its Botany, Phytochemistry, Pharmacology, Contemporary Application, and Toxicology. Biomed Res Int. 2014;2014:842674.
11. Alok S, Jain SK, Verma A, Kumar M, Mahor A, Sabharwal M. Plant profile, phytochemistry and pharmacology of Asparagus racemosus (Shatavari): A review. Asian Pac J Trop Dis. Asian Pac J Trop Dis. 2013;3(3):242–51.
12. Birla A, Satia M, Shah R, Pai A, Srivastava S, Langade D, et al. Postpartum Use of Shavari Bar® Improves Breast Milk Output: A Double-Blind, Prospective, Randomized, Controlled Clinical Study. Cureus. 2022;14(7):e26831.
13. Fungtammasan S, Phupong V. The effect of Moringa oleifera capsule in increasing breast milk volume in early postpartum patients: A double-blind, randomized controlled trial. Eur J Obstet Gynecol Reprod Biol X. 2022;16:100171.
14. Doke S, Chetana R, Guha M. Quality assessment of sweet snack from Garden cress (Lepidium sativum L.) seeds—An unexplored health grain. J Food Processing Preserv. 2018;42(2). doi:10.1111/jfpp.13431.
15. Al-Yawer MA, Al-Khateeb HM, Al-Khafaji FA. Garden Cress Seed Could be A Factual Galactagogue. Iraqi Postgrad Med J. 2006;5(1):62–7.
16. Sun J, Marais JPJ, Khoo C, Laplante K, Vejborg RM, Givskov M, et al. Vaccinium macrocarpon) oligosaccharides decrease biofilm formation by uropathogenic Escherichia coli. J Funct Foods. 2015;17:235–42.
17. Shahdadi F, Mirzaei HO, Garmakhany AD. Study of phenolic compound and antioxidant activity of date fruit as a function of ripening stages and drying process. J Food Sci Technol. 2015;52(3):1814–9.
18. El-Sayed SM. Use of spinach powder as functional ingredient in the manufacture of UF-Soft cheese. Heliyon. 2020;6(1):e03278.
19. Vázquez E, García-Risco MR, Jaime L, Reglero G, Fornari T. Simultaneous extraction of rosemary and spinach leaves and its effect on the antioxidant activity of products. J Supercritical Fluids. 2013;82:138–45.
20. Özcan MM. A review on some properties of almond: ımpact of processing, fatty acids, polyphenols, nutrients, bioactive properties, and health aspects. J Food Sci Technol. 2023;60(5):1493–1504.
21. Sang S, Chu YF. Whole grain oats, more than just a fiber: Role of unique phytochemicals. Mol Nutr Food Res. 2017;61(7). doi:10.1002/mnfr.201600715.