Breastfeeding Interventions for Mothers of Preterm Infants: A Systematic Review and Meta-Analysis of Breast Milk Outcomes and Breastfeeding Practices

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Abstract
Background: Preterm infants depend on timely provision of mother's own milk, but mothers who deliver before term often face delayed lactogenesis, separation from the infant in the neonatal intensive care unit (NICU), psychological stress, and reliance on mechanical milk expression. These barriers can reduce milk volume and may limit sustained breastfeeding during and after hospitalization.
Aim: This systematic review and meta-analysis evaluates breastfeeding interventions on breast milk volume, milk composition, and breastfeeding practices among mothers of preterm infants.
Methods: A systematic review and exploratory meta-analytic synthesis were conducted according to PRISMA 2020. Searches were conducted on 31 May 2026 across PubMed/MEDLINE, Embase, CENTRAL, CINAHL, and Scopus, and were supplemented by citation tracking. Studies were identified using MeSH-based and free-text keywords. Two reviewers examined database search results and excluded articles by screening titles and abstracts according to the PICO criteria. Eligible studies included intervention studies involving mothers of preterm infants (<37 weeks) without language or year restrictions. Milk volume, milk composition, breastfeeding outcomes, study characteristics, and risk of bias were extracted using a JBI-aligned data extraction form. The methodological quality of the included studies was assessed using the JBI Critical Appraisal Checklist for randomized controlled trials.
Results: The analysis included 18 studies and a minimum of 629 mother-infant dyads from studies with reported sample-size data. Interventions included pharmacological galactagogues, foot reflexology, breast massage, music therapy, lullaby-based interventions, pumping strategies, and multimodal lactation-support approaches. Additional statistical extraction identified usable quantitative data from six studies. Reported-effect synthesis demonstrated favorable effects for recorded maternal lullaby interventions, particularly with infant photographs (MD 9.57, 95% CI 6.43 to 12.71), whereas foot reflexology showed a positive but statistically non-significant effect (MD 11.08, 95% CI -2.79 to 24.95).
Conclusion: Pharmacological interventions generally improved milk production, although quantitative pooling was limited by heterogeneous interventions, outcomes, time points, and reporting formats. Breastfeeding interventions may improve milk production and selected breastfeeding outcomes among mothers of preterm infants. However, methodological and reporting heterogeneity limits definitive quantitative conclusions. Standardized outcome reporting and longer-term follow-up are needed.

Keywords: preterm infants; breastfeeding interventions; mother's own milk; milk volume; lactation support; systematic review; meta-analysis; reported-effect synthesis

1. Introduction

Preterm birth, defined as birth before 37 completed weeks of gestation, remains one of the major problems in perinatal medicine (World Health Organization, 2023; Ohuma et al., 2023). Every year, approximately 13.4 to 15 million babies are born prematurely worldwide, and complications of prematurity remain a major cause of neonatal mortality and long-term morbidity (World Health Organization, 2023; Perin et al., 2022). Preterm infants have a higher risk of neurodevelopmental impairment, bronchopulmonary dysplasia or chronic lung disease, retinopathy of prematurity, and growth-related complications (Karmouta et al., 2023; Liang et al., 2024). Nutrition in the earliest weeks of life is therefore a primary and modifiable factor that may influence survival, growth, and longer-term developmental outcomes (Huang et al., 2023; Peng et al., 2023).

Mother's own milk (MOM) is widely considered the optimal nutrition source for preterm infants (Huang et al., 2023; Briere et al., 2024). MOM provides species-specific immunological and bioactive components, including immunoglobulins, growth factors, anti-inflammatory mediators, oligosaccharides, lactoferrin, and bioactive peptides that are not fully replicated in commercial formula (Peng et al., 2023; Briere et al., 2024). These components are clinically relevant because MOM feeding is associated with lower risks of necrotizing enterocolitis (NEC), late-onset sepsis, and other complications in very premature infants (Huang et al., 2023; Peng et al., 2023).

Although these benefits are well known, establishing and maintaining a sufficient milk supply is particularly challenging for mothers of preterm infants (Dong et al., 2022; McLeish et al., 2024). Preterm birth represents a sudden disruption of the physiological and hormonal trajectory of normal gestation. Mothers who deliver prematurely face physiological and psychological barriers to adequate milk supply, including delayed lactogenesis II, immature breast development, severe maternal stress, prolonged separation from the neonate in the NICU, and early reliance on mechanical milk expression (Dong et al., 2022; Li et al., 2024).

In the case of a preterm delivery, the normal hormonal events required for lactogenesis can be disrupted. The postpartum decline in progesterone and rise in prolactin are essential for the onset of copious milk secretion, known as lactogenesis II (Dong et al., 2022; Li et al., 2024). This hormonal transition may be delayed or incomplete after preterm birth, and many preterm infants cannot breastfeed directly in the first days or weeks of life. Mothers are therefore often reliant on frequent mechanical expression, which requires early initiation, sustained motivation, access to equipment, and skilled lactation support (McLeish et al., 2024).

In addition to physiology, other psychological and environmental factors conspire against mothers of preterm babies (Chen, 2024). The neonatal intensive care unit (NICU) is a stressful place to begin with. Factors such as maternal anxiety, postpartum depression, and trauma during an unexpected premature delivery all stimulate the sympathetic nervous system and can impede the release of prolactin and oxytocin needed for milk synthesis and let-down (Chen, 2024; Nojima, 2026). Those who are physically separated from the infant, who have concerns about the infant's prognosis, and who are required to pump the breast frequently are also highly susceptible to maternal stress, which reduces their participation in caregiving and impairs the overall dyadic bonding process (Nojima, 2026). The NICU setting itself can be a continuous source of physiological stress in the preterm infant, and has been shown to have negative neurobehavioral outcomes in preterm infants when the infant is exposed to painful procedures, excessive sensory stimulation, and lack of sleep hygiene, which can disrupt brain development and reduce opportunities for direct or skin-to-skin feeding (Ali et al., 2023; Hübler, 2025; Sampson et al., 2025).

A diverse array of interventions has been devised and examined to address these challenges (SefidHaji et al., 2022; Sritas et al., 2023; Nodehi et al., 2024). These include direct physical care approaches such as skin-to-skin care and kangaroo mother care; supportive interventions such as lactation consultant care, peer support, and psychological counseling; complementary or physical therapies such as breast massage, foot reflexology, warming packs, and acupoint stimulation; sensory or behavioral interventions such as music therapy, recorded maternal voice, infant photographs, and structured pumping schedules; and medical approaches such as pharmaceutical or herbal galactagogues (SefidHaji et al., 2022; Nodehi et al., 2024). In addition, recent infant-focused trials have shown that non-pharmacological sensory and comfort interventions, including Yakson touch and earplug or eye-cover strategies, may improve physiological and behavioral stability among preterm infants during painful procedures or environmental stimulation (Ali et al., 2023; Hassan et al., 2024). Although these infant-focused interventions are not lactation interventions themselves, they are relevant to integrated NICU care because infant stability can affect opportunities for skin-to-skin care, maternal confidence, and direct breastfeeding practice (SefidHaji et al., 2022; Sritas et al., 2023; Nodehi et al., 2024). Clinical practice has also moved toward multimodal quality-improvement bundles that combine elements from several of these domains.

2. Literature Review

2.1 Burden and Physiology of Lactation in Preterm Mothers

Post-preterm lactation physiology is significantly different than post-term birth lactation physiology. Lactogenesis II requires a rapid drop in placental progesterone post-delivery, an increase in prolactin, and sensitivity of the glandular tissue to the effect of prolactin (Oral & Karaçetin, 2024; Madan, 2025). Breast glandular development may be incomplete at birth, especially in preterm babies; this results in a reduced number of alveoli to produce milk (Liu & Lin, 2025; Lemos et al., 2026). This increase in prolactin levels is also observed with all deliveries but is essential for maintaining the level of prolactin after the delivery if the nipple is not stimulated (Oral & Karaçetin, 2024). Regular, effective stimulation is needed to maintain a high level of prolactin, otherwise it will drop within the first postpartum week and so will the milk production (Miao et al., 2023; Oral & Karaçetin, 2024).

It has been consistently reported that mothers of very preterm infants have significantly less milk output in the first weeks post-partum compared to mothers of full-term infants as well as that there is a high proportion of mothers who report inadequate milk supply during the NICU stay to provide for enteral nutrition (Vizzari et al., 2022; Jiang et al., 2024). Stress is known to be a maternal factor that contributes to this problem. Increased cortisol (stress hormone) and increased sympathetic tone (fight or flight) inhibit oxytocin production which affects milk ejection and the effectiveness of each expression session (Vizzari et al., 2022; Jiang et al., 2024).

2.2 Pharmacological Galactagogues

The most well-studied group of interventions in this population has been pharmacological galactagogues, which are primarily dopamine antagonists that stimulate prolactin secretion (Bao et al., 2023; Liao et al., 2024). Domperidone is the one most used in clinical practice as it poorly penetrates the blood-brain barrier and, therefore, has fewer central neurological or extrapyramidal side effects than metoclopramide (Grzeskowiak et al., 2026; Si et al., 2024). Several randomized controlled

trials (RCTs) have shown statistically significant volume gains in the expressed milk of mothers of preterm infants after taking domperidone (McBride et al., 2023; Si et al., 2024).
Longitudinal evaluations and foundational reviews synthesized by McBride et al. (2023) confirmed that domperidone establishes statistically significant short-term volume gains in the expressed milk of mothers of preterm infants. For instance, pooled data from standard clinical trials indicate that over a seven-day period, a mean increase of 49.5 ml was observed in the domperidone group compared to just 8.0 ml in the placebo group (McBride et al., 2023). Similarly, daily volumes by day 14 rose from 184 ml to 380 ml with domperidone, compared to a modest shift from 218 ml to 250 ml in placebo groups. Recent network meta-analyses have also demonstrated that while both agents stimulate output, domperidone yields a more pronounced daily volume increase in mothers of preterm infants than metoclopramide or placebo groups (Si et al., 2024). Ongoing international cohorts and upcoming clinical trials continue to explore the precise dose-response relationships to balance these clinical volume gains against maternal safety and cardiac risk profiles (Grzeskowiak et al., 2026; McBride et al., 2023).
While the landmark EMPOWER trial originally demonstrated that a 14-day course of domperidone (30 mg/day) initiated within the first 21 days postpartum resulted in a modest increase in milk volume, subsequent secondary analyses have provided critical clinical clarity (Asztalos & Kiss, 2022). Recent data confirms that the physiological response to domperidone is independent of gestational age at birth (Asztalos & Kiss, 2022). Furthermore, stratification by baseline volumes reveals that the drug exerts its most pronounced effect on the lowest producers: mothers producing ≤ 100 ml/kg/day experienced a 356.2% volume increase by day 28, whereas those already producing ≥ 201 ml/kg/day yielded a minor 45.2% adjustment (Asztalos & Kiss, 2022).
Despite short-term efficacy in increasing milk volume by up to 88 ml/day, real-world longitudinal cohort data reveals a distinct shift in clinical practice following international regulatory warnings regarding maternal cardiac safety and QT-prolongation risks (McBride et al., 2023). In retrospective analyses tracking NICU trends, domperidone dispensing rates declined significantly following these safety mandates (McBride et al., 2023).
Importantly, evidence remains inconclusive as to whether short-term volume gains translate to better long-term breastfeeding rates at infant hospital discharge (McBride et al., 2023). Real-world data shows that mothers requiring domperidone still demonstrate lower overall breast milk feeding rates at infant discharge compared to those who establish an adequate supply naturally (McBride et al., 2023). This highlights an shifting consensus: galactagogues should remain a second-line option, heavily managed via robust screening protocols-such as pharmacist-led and consultant-initiated checklists-to balance maternal cardiac safety with lactation goals (McBride et al., 2023).

2.3 Physical and Complementary Interventions
Physical and complementary interventions represent an expanding area of clinical lactation literature (Chu, 2026). Foot reflexology is a complementary modality based on stimulating specific pressure points on the soles of the feet that map to glandular and organic body systems, and its efficacy has been widely explored in modern clinical settings (Chu, 2026; Nodehi et al., 2024). Systematic network meta-analyses of traditional medicine strategies underscore that while physical touch and regional therapies help modulate maternal stress and support lactation pathways, clear differentiation among individual complementary modalities remains variable (Chu, 2026).
In a recent single-center study, Nodehi et al. (2024) conducted a randomized clinical trial evaluating 76 primiparous mothers whose premature infants (at or under 34 weeks gestation) were hospitalized in NICU. Participants in the intervention cohort received 20 minutes of daily foot reflexology over seven consecutive days. At the conclusion of the trial, the reflexology group demonstrated a higher numerical mean increase in daily milk volume compared to the control group (23.51 ml vs. 12.43 ml), though this volume shift did not reach statistical significance (Nodehi et al., 2024). Furthermore, laboratory tracking revealed no significant discrepancies between the two groups regarding breast milk composition, showing stable concentrations of total protein, albumin, calcium, triglycerides, and cholesterol (Nodehi et al., 2024). These findings mirror broader contemporary data showing that while foot reflexology presents a promising, non-invasive trend toward volume enhancement, it does not alter underlying milk biochemistry or guarantee uniform statistical superiority over conventional lactation support alone (Chu, 2026; Nodehi et al., 2024).
Breast massage with or without thermal application or acupoint stimulation has continued to draw substantial interest in contemporary clinical studies. Recent evidence confirms that structured breast interventions significantly optimize lactation outcomes. For instance, a randomized controlled trial evaluating a novel, integrated breast massage technique demonstrated that targeted mechanical manipulation significantly improves milk expression efficiency, accelerates the resolution of physiological blockages like plugged ducts, and substantially reduces localized maternal pain scores compared to traditional methodologies (Munsittikul et al., 2022). Furthermore, recent clinical evaluations have expanded into specialized, multi-modal lactation therapies that combine temperature control, movement, and localized compression (Sweet & Vasilevski, 2022). These modern trials validate that combining thermal applications (such as warm compresses) with specific rolling massage techniques successfully triggers the neuroendocrine let-down reflex, resulting in a statistically significant increase in total breast milk volume expressed per session while simultaneously mitigating maternal anxiety and early postpartum engorgement (Sweet & Vasilevski, 2022; Kumalasari, 2024).
The feasibility of combined breast massage with traditional acupoint stimulation was reported by Sheng et al. (2021) in a pilot study which showed a positive direction of effect on milk volume. Sritas et al., (2023) conducted a randomized controlled

trial of 32 mothers with preterm babies who received manual lymphatic drainage along with Thai traditional massage after cesarean section, did not observe any statistically significant difference in milk volume on day 1 to 7 between the manual lymphatic drainage and the standard care group, but mothers rated the massage protocol as highly satisfactory.

2.4 Sensory and Psychological Interventions

A growing body of contemporary evidence addresses the critical impact of sensory and psychological interventions on the maternal neuroendocrine pathway, demonstrating their capacity to downregulate stress and actively promote oxytocin release (Sakinah et al., 2023). The clinical utility of music and guided audio relaxation has been rigorously investigated across various international healthcare contexts. In a landmark randomized controlled trial, Dib et al. (2022) evaluated a specialized audio relaxation intervention for mothers of late preterm and early term infants. The study revealed that mothers using the relaxation recordings during breastfeeding showed a significant reduction in physiological stress markers, such as salivary cortisol, which correlated with enhanced infant growth metrics—specifically a higher change in weight-for-age Z-scores—and reduced infant crying times (Dib et al., 2022).

Similar positive correlations between auditory interventions and maternal-infant outcomes have been replicated globally. For instance, structured relaxation and music therapies integrating soothing sensory components have been systematically shown to enhance maternal comfort and drive up maternal milk volumes by minimizing psychological hurdles (Sakinah et al., 2023; Ekşioğlu, 2024). Furthermore, recent randomized experimental trials evaluating cultural music modes during lactation have confirmed that targeted auditory interventions successfully alleviate acute postpartum state anxiety. Specifically, trials utilizing Turkish classical music modes (such as the Neva makam) during feeding significantly lowered post-test state anxiety and improved maternal breastfeeding success metrics, creating a highly supportive physiological climate for early lactogenesis (Ayten, 2023).

SefidHaji et al. (2022) added to this literature with a multi-arm randomized controlled trial (mRCT) evaluating the effect of maternal lullabies on milk parameters. The clinical protocol compared an intervention utilizing an audio recording of the mother’s voice in lullaby mode against a second intervention where the maternal lullaby recording was structurally paired with a photograph of the infant. At the end of the 14-day protocol, both intervention groups yielded significantly greater daily milk volumes than the controls (77.97 ml and 82.58 ml respectively, compared to 73.09 ml for the control cohort). Beyond sheer volume, laboratory analytics revealed greater concentrations of milk triglycerides, cholesterol, albumin, and total protein, with the most consistent biochemically rich gains found in the combined arm that paired the auditory lullaby with the visual stimulus of the infant's photograph (SefidHaji et al., 2022).

Taking this evidence into account, there is a developing body of research that suggests that the effectiveness of milk expression by mothers may be moderated by the infant's own physiological state in the NICU. Research on interventions for infants has indicated that structured pain management interventions like Yakson touch can reduce negative physiological responses to painful neonatal procedures (Hassan et al., 2024), and other sensory protective interventions such as earplugs and eye covers have shown to be effective in stabilizing infants' physiological and behavioral responses in the NICU setting (Ali et al., 2023).

Non-pharmacological palliative care interventions applied directly to infants—such as hydrotherapy and hammock positioning—similarly minimize pain scores, downregulate stress responses, and support autonomic regulation during routine neonatal procedures (Silva et al., 2024). These baby-focused sensory protective interventions indirectly optimize maternal breastfeeding by promoting neurobehavioral organization and baseline homeostasis in the preterm infant. Integrating these techniques into standardized NICU care maps facilitates more frequent, higher-quality mother-baby interactions and sets a highly stable foundation for sustained skin-to-skin contact and direct feeding success (Silva et al., 2024).

2.5 Gaps in the Literature

Although the body of literature surrounding lactation support in neonatal settings is expanding, several critical methodological and clinical gaps continue to limit its translation into standardized, evidence-based NICU care. First, a primary challenge in synthesizing this literature is the profound outcome heterogeneity and lack of methodological standardization. Across existing clinical trials, maternal milk volume is evaluated using vastly different parameters. Some studies report total accumulated volume over the first 5 days postpartum, others measure single-session yields on arbitrary days, and many fail to specify the mechanical expression protocols used (such as pump suction pressure, double versus single pumping, or frequency of expression). Furthermore, the baseline characteristics of participants-such as gestational age brackets (e.g., extremely preterm versus late preterm) and the initiation timeline of the first pumping session-vary wildly. This lack of a unified tracking framework creates an apples-to-oranges comparison problem, making it highly difficult to determine which interventions truly yield superior volumetric outcomes across diverse populations.

Second, the current literature exhibits a distinct bias toward fluid quantity over milk quality and biochemical integrity. The vast majority of lactation trials treat raw milk volume as the sole metric of success. However, optimizing volume does not automatically guarantee a proportional delivery of essential nutrients to a fragile, preterm infant. Very few studies incorporate laboratory analytics to evaluate the macronutrient (total protein, lipids, lactose) or micronutrient (calcium, phosphorus, immunoglobulins) composition of the expressed milk. Without tracking these biochemical profiles, it remains unclear whether specific physical, psychological, or pharmacological interventions inadvertently dilute milk components, shift the fat-to-protein ratios, or successfully support the secretion of nutrient-dense, high-quality colostrum and mature milk.

Third, there is a substantial attrition of longitudinal data regarding sustained clinical milestones. Most NICU lactation studies focus exclusively on acute, short-term outcomes while the mother and infant are physically in the unit. There is a glaring scarcity of data tracking definitive clinical success metrics, such as the rate of exclusive MOM feeding at the exact time of NICU discharge. Even fewer studies maintain longitudinal cohorts to evaluate any breastfeeding or mixed feeding practices at 3-month and 6-month corrected ages. By failing to track these long-term parameters, the existing literature cannot demonstrate whether early-stage hospital interventions translate into durable, sustained breastfeeding habits once the intensive support of the NICU environment is removed.

Fourth, the literature remains highly siloed, leaving both the relative efficacy and the potential synergy of multimodal care bundles unexamined. Within a clinical NICU environment, a mother rarely experiences a single intervention in isolation. Yet, traditional research models typically isolate a single variable-such as evaluating a pharmacological galactagogue or foot reflexology or a psychological audio recording. This fragmented approach fails to account for the complex, multifactorial barriers that preterm mothers face. The relative hierarchy of these distinct intervention categories has never been evaluated from a common analytical perspective, and the potential additive or synergistic effects of a multimodal "lactation care bundle" (e.g., combining sensory relaxation with targeted physical and technological support) remain entirely unexplored.

This systematic review and meta-analysis is intentionally designed to address these combined deficiencies by establishing a comprehensive, multidimensional framework to synthesize worldwide literature on breastfeeding interventions for preterm mothers. Rather than limiting the scope to a single modality, this review simultaneously evaluates supportive, physical, sensory, technological, and pharmacological measures to contrast their respective impacts on milk volume, biochemical composition, and long-term clinical milestones.

Crucially, in direct response to the pervasive heterogeneity of the eligible literature-specifically the varying typologies of interventions, localized outcome definitions, fragmented statistical reporting, and disparate time points-this study avoids forcing a misleading overall pooled estimate. Instead, the quantitative component is presented as an exploratory reported-effect meta-analysis. By mapping out the direction, magnitude, and context of reported effects across all 18 included studies, this review provides a transparent, granular landscape of the evidence, highlighting exactly which intervention pathways hold the most promise for clinical integration and future trial design.

3. Methodology

3.1 Study Design

The study was designed as a systematic review with narrative synthesis and exploratory reported-effect meta-analysis, following Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 (PRISMA 2020) guidance for clear identification, selection, synthesis, and reporting of studies (Page et al., 2021). The protocol was designed in advance using a predetermined PICO framework. Because only a small number of compatible effect estimates and complete arm-level means, standard deviations, and sample sizes were available from the extraction dataset, no overall pooled arm-level estimate was derived across all interventions. Compatible reported mean differences, confidence intervals, event data, and arm-level descriptive statistics were synthesized with caution.

3.2 Eligibility Criteria

The Population, Intervention, Comparison, Outcome (PICO) framework was used to establish clear boundaries for the search strategy and study selection.

P (Population / Participants): Lactating mothers who delivered a preterm infant (gestational age <37 weeks), where the infant was receiving medical care in a hospital or NICU setting. Mothers of healthy full-term infants and/or mothers with absolute medical contraindications to lactation or milk expression were excluded.

I (Intervention): Any single or combined strategy aimed at initiating, continuing, or increasing lactation was eligible. Interventions were grouped as supportive or psychological interventions; physical and complementary interventions; technological and behavioral interventions; medical or pharmacological interventions; and multimodal bundles involving two or more categories.

C (Comparison / Comparator): Eligible comparators were standard routine neonatology or maternity care, placebo, active control, another single intervention, or baseline comparison periods in prospective before-and-after designs.

O (Outcomes): The primary outcome was daily expressed breast milk volume (ml/day) measured at key time points, such as day 7, day 14, day 21, and day 28 postpartum. Secondary outcomes were nutritional composition or content of expressed milk and objective clinical breastfeeding outcomes such as time to direct or full oral feeding, exclusive MOM at NICU discharge, and any or exclusive breastfeeding at 3 and 6 months corrected age.

Inclusion was strictly limited to randomized controlled/ clinical trials (RCTs) investigating lactation support. Observational studies, quasi-experimental designs, controlled before-and-after studies, and prospective cohorts were excluded. Studies with no maternal lactation outcomes, animal studies, editorials, case reports, and conference abstracts without full methods and/or outcome data were excluded.

3.3 Search Strategy and PRISMA Flow

A comprehensive, multi-stage electronic search was conducted to identify both published and unpublished studies. In accordance with the Joanna Briggs Institute (JBI) methodological guidance, a rigorous three-step search strategy was deployed. First, an initial, limited scoping search of MEDLINE and CINAHL was undertaken to analyze text words in the titles and abstracts, alongside relevant medical subject headings (MeSH) and index terms. Second, all identified keywords, Boolean operators, and index terms were systematically adapted and deployed across all selected electronic databases. Third, the reference lists of all retrieved eligible studies and relevant systematic reviews were manually screened to identify additional uncaught literature.

The search architecture combined population terms (preterm, pre-term, premature, neonate, NICU, neonatal intensive care) with intervention terms (skin to skin, skin-to-skin, kangaroo care, kangaroo mother care, lactation support, lactation consultant, counsel, peer support, breast massage, breast compression, hand expression, milk expression, pumping, pumping schedule, expression frequency, reflexology, massage, acupoint, acupuncture, warming pack, heating pad, music, lullaby, recorded voice, photograph, domperidone, metoclopramide, galactagogue, fenugreek, shatavari, silymarin, quality improvement, bundle, multimodal). These were coupled with outcome terms (breastfeed, breast feed, breastmilk, breast milk, human milk, lactation, milk volume, milk production, hypogalactia, composition, macronutrient, milk fat, protein). To ensure the strict containment of the review to experimental designs, specific filter terms for randomized controlled trial and randomized clinical trial were utilized.

The primary electronic databases searched were PubMed/MEDLINE, Embase, Scopus, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL), supplemented by exhaustive manual reference tracking. Databases were searched from their respective inceptions through May 31, 2026, without language or year restrictions. Comprehensive, database-specific search strings are detailed in Appendix A.

The study selection process strictly adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 flow structure. A total of 1,333 records were initially identified, comprising 1,309 records sourced through electronic database searching and 24 records retrieved via secondary manual methods. Following the removal of 392 duplicate records, 941 unique citations underwent title and abstract screening, resulting in the exclusion of 865 irrelevant records.

Of the 76 reports sought for retrieval, 8 full-text reports could not be acquired. The remaining 68 full-text articles were thoroughly assessed for eligibility against the strict a priori inclusion criteria, resulting in the exclusion of 50 reports with explicit reasons provided (Appendix B). Ultimately, 18 randomized controlled trials met all eligibility requirements and were included in the final qualitative evidence synthesis. Complete, uniform mean ± standard deviation (SD) datasets were unavailable across a sufficiently homogeneous outcome framework to support a singular, definitive overall pooled arm-level meta-analysis.

The complete, transparent screening and selection pathway is illustrated below in Figure 1. The PRISMA flow chart is structurally maintained within this methodology section as it systematically documents the operational mechanics of study identification, screening, eligibility verification, and inclusion, rather than the secondary analytical findings of the review itself.

3.4 Data Extraction

Data extraction was structurally aligned with the Joanna Briggs Institute (JBI) standardized data extraction repository for effectiveness reviews and systematically customized to address this specific query. Data were meticulously compiled into a dedicated spreadsheet matrix capturing key study features across multiple foundational layers, including study characteristics, participant demographics, intervention frameworks, comparator configurations, operational outcome definitions, longitudinal time points, raw numerical datasets, and analytical synthesis eligibility. Specifically, the extracted study characteristics comprised the primary author, publication year, geographic country of origin, institutional setting, study design, sample size, primary intervention domain, intervention category, operational mechanics, precise comparator details, and outcome classifications.

The clinical and biochemical metrics targeted during extraction spanned maternal milk volume, milk macronutrient and micronutrient composition, and longitudinal clinical breastfeeding practice indicators. Where reported, quantitative data were extracted verbatim, including means and standard deviations, mean differences, standardized mean differences, confidence intervals, p-values, relative percentage changes, medians with corresponding interquartile ranges, and absolute event counts. Following an initial programmatic Excel audit to ensure dataset integrity, a secondary, exhaustive data-mining sweep of all published tables, figures, abstracts, and supplementary materials was conducted to rescue any unreported or buried statistical parameters.

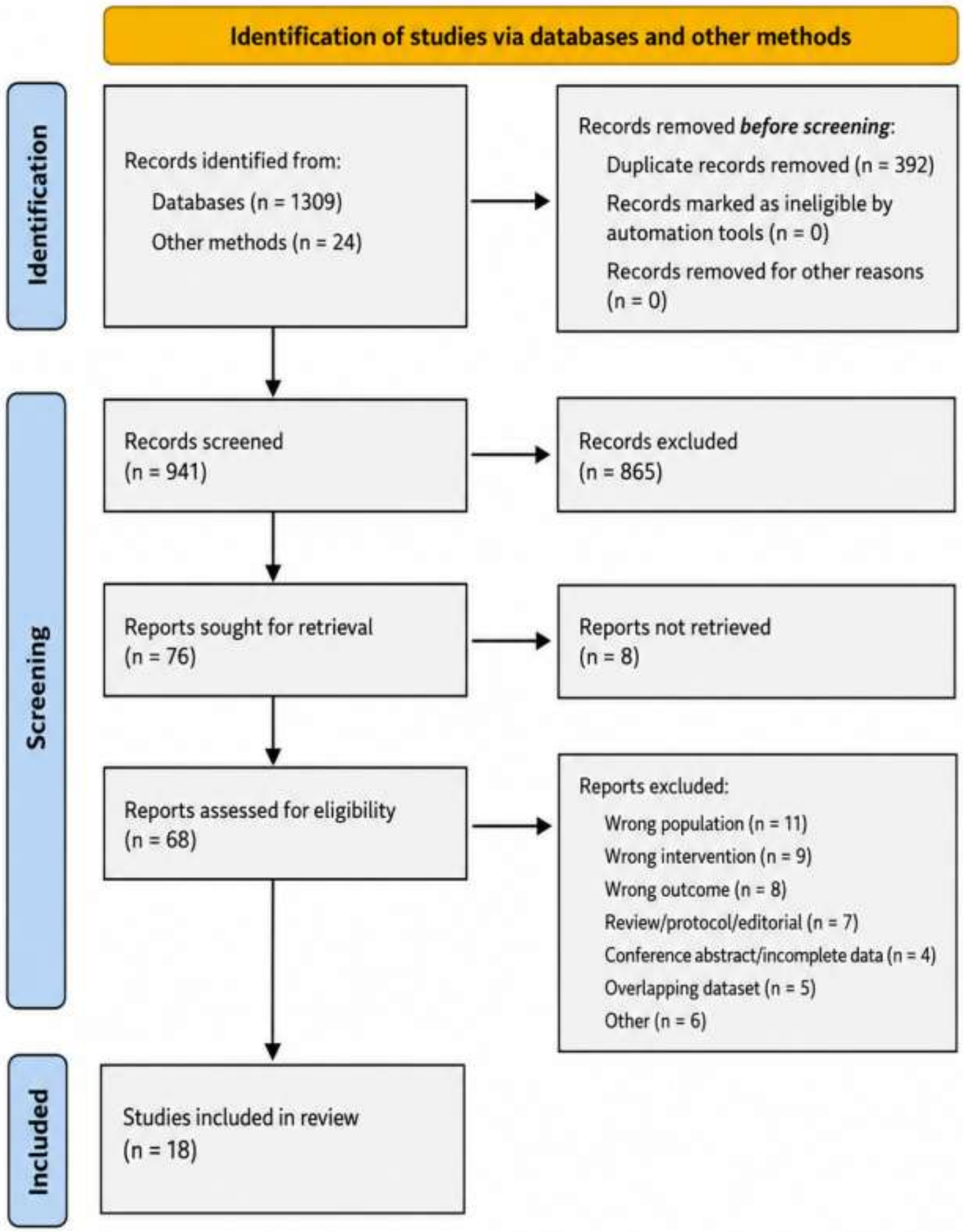

Figure 1. PRISMA 2020 flow diagram for study identification, screening, eligibility, and inclusion.

3.5 Risk of Bias Methodological Quality Assessment

The methodological quality and internal validity of the included randomized controlled trials were independently evaluated using a dual-framework appraisal strategy, combining the revised Cochrane Risk of Bias tool (RoB 2) alongside the JBI Critical Appraisal Checklist for Randomized Controlled Trials. The RoB 2 framework was deployed to systematically scrutinize core domains of potential experimental bias, specifically evaluating risks arising from the randomization process, deviations from intended interventions, missing outcome data, outcome measurement, and the selection of reported results. To complement these specific bias domains with an overarching assessment of study design quality, the JBI Critical Appraisal Checklist was simultaneously applied to the entire dataset. This tool evaluated whether true randomization was achieved, allocation concealment was robustly maintained, treatment groups remained comparable at baseline, and participants, delivery personnel, and outcome assessors were adequately blinded where feasible.

Furthermore, the checklist verified whether all treatment arms were managed identically outside of the target intervention, if follow-up attrition was appropriately handled, whether participants were analyzed according to the intention-to-treat principle within their assigned cohorts, if outcomes were measured using validated instruments, and whether the statistical models were methodologically sound. Any structural deviations from standard randomized controlled trial architecture were critically appraised to ensure a thorough evaluation of the internal validity of the reported statistical effects.

To operationalize this quality assessment, two reviewers independently appraised the included studies, judging each item checklist parameter as "Yes," "No," "Unclear," or "Not applicable." Any discrepancies or disagreements between the primary reviewers were systematically resolved through consensus-driven discussion or, when necessary, via consultation with a third reviewer. While the appraisal heavily emphasized methodological transparency and the long-term interpretability of the evidence, a cautious approach was maintained during the grading process; because the extraction workbook did not contain complete item-level ratings for every historical study, an "Unclear" designation was strictly retained whenever a study's original reporting was insufficient. Consequently, rather than using these quality thresholds as an arbitrary mechanism to exclude lower-performing trials from the qualitative evidence synthesis, the final methodological quality matrix—provided fully in Appendix B—is utilized strictly as a contextual framework to support the nuance and interpretation of the reported findings.

3.6 Data Synthesis and Statistical Analysis

The primary method of synthesis for this review was a narrative synthesis structured around distinct intervention domains and outcome families. Following the initial data extraction phase, a secondary statistical data-availability audit was conducted to evaluate whether the included studies contained sufficiently homogeneous data to support a formal quantitative meta-analysis or an exploratory quantitative synthesis. For continuous outcomes, full arm-level pooling required the reporting of comparable sample sizes alongside means and standard deviations (or equivalent variance measures) for both the intervention and control groups at uniform postpartum time points. Dichotomous event outcomes were systematically extracted as absolute counts and risk ratios where available. Where present, mean differences (MDs) or standardized mean differences (SMDs) and their corresponding 95% confidence intervals (CIs) were utilized to represent the reported effect sizes. The updated extraction audit revealed that while numerical outcome data were extractable from six studies, complete continuous arm-level mean ± SD datasets were restricted to three studies, and clean, two-arm continuous milk-volume mean ± SD data were limited to just two studies. Consequently, the accumulated data could not methodologically support a singular, pooled arm-level meta-analysis across all 18 included studies due to substantial variations in intervention domains, operational outcome definitions, longitudinal tracking timelines, and reported effect metrics. Given these constraints, the reported-effect plots are intended to be interpreted strictly as exploratory meta-analytic visualizations designed to map the landscape of the evidence, and they intentionally omit an overall pooled-effect summary diamond to avoid generating a statistically flawed or misleading synthesis.Statistical heterogeneity was planned to be quantified using the I^2 statistic, while small-study effects and publication bias were to be evaluated visually via funnel plots and statistically using regression-based asymmetry tests. However, in strict accordance with current Cochrane guidance, these advanced statistical assessments are only appropriate when a minimum of 10 independent studies report a sufficiently homogeneous pooled outcome. Because this minimum threshold of statistically comparable independent trials was not met across the primary outcomes, these exploratory analyses were not executed for the main datasets. Nonetheless, future subgroup meta-analyses may become viable for specific subsets—such as pharmacological galactagogues and reflexology or physical massage interventions—should additional granular, full-text data become accessible in future literature updates.

3.7 Outcome Measures

The primary outcome of interest was the mean daily volume of expressed maternal breast milk, quantified in milliliters (or the nearest convertible volumetric unit) at predefined, clinically relevant postpartum time points. Secondary outcomes focused on the nutritional and biochemical composition of the expressed breast milk, encompassing macronutrient and micronutrient profiles such as total protein, albumin, fat, triglycerides, cholesterol, calcium, and any other systematically reported biochemical constituents. Additionally, the review evaluated long-term clinical breastfeeding outcomes and milestones; these included the rate of exclusive maternal own milk (MOM) feeding at the time of neonatal intensive care unit (NICU) discharge, as well as any or exclusive breastfeeding practices recorded at longitudinal post-discharge follow-up intervals.

4. Results

4.1 Study Selection and Included Evidence Base

As demonstrated in the PRISMA flow chart in the methodology section, 18 studies met the eligibility criteria and were included in the final evidence base. These studies evaluated four types of interventions for infants and their mothers: pharmacological, physical/complementary, supportive or psychological, and technological/behavioral interventions. The primary and secondary outcome results are presented after an overview of study characteristics and the direction of effect for breast milk volume summarized in Table 1.

Table 1. Characteristics of the included studies and extracted direction of effect for breast milk volume.

Author/s (year)	**Country/ setting**	**Aim**	**Design**	**Sample and groups**	**Intervention/domain**	**Comparator**	**Milk-volume finding**
Jones et al. (2001)	United Kingdom; neonatal setting	Compare milk-expression methods after preterm delivery and examine massage component	RCT with crossover massage component	36 mothers; pumping/massage sequence groups	Simultaneous vs. sequential pumping; breast massage /technological-behavioral + physical	Alternative expression strategy or no massage period	Positive for expression/massage strategy; exact values NR
da Silva et al. (2001)	Canada; NICU mothers	Assess domperidone effect on milk production in mothers of premature newborns	Randomized double-blind placebo-controlled trial	20 randomized; 16 analyzed for extracted data	Domperidone /medical-pharmacological	Placebo	Positive; change-score and mean daily volume data extracted
Wan et al. (2008)	NR; preterm mothers with low supply	Evaluate dose-effect of domperidone as a galactagogue	Randomized crossover/dose-comparison pilot	6 mothers	Domperidone dose comparison /medical-pharmacological	Run-in or lower-dose comparison periods	Positive in responders; SEM/crossover data not clean for parallel pooling
Campbell-Yeo et al. (2010)	Canada; NICU setting	Assess domperidone effect on composition and volume of preterm human milk	Randomized double-blind placebo-controlled trial	46 randomized; 45 analyzed for extracted data	Domperidone /medical-pharmacological	Placebo	Positive; arm-level mean +/- SD data extracted
Vianna et al. (2011)	Brazil; premature newborns/mothers	Assess whether music therapy improves breastfeeding rates	Randomized controlled trial	94 mothers; 48 intervention, 46 control	Music therapy /supportive-psychological	Routine care	Positive for breastfeeding outcomes; event data extracted
Ingram et al. (2012)	United Kingdom; NICU mothers	Compare domperidone and metoclopramide for increasing milk output	Double-blind randomized comparative trial	80 mothers	Domperidone vs. metoclopramide /medical-pharmacological	Active comparator	Both increased output; no significant difference between drugs
Keith et al. (2012)	United States; premature/critically ill infants	Assess music-based listening effects on milk volume and composition	Intervention study	NR	Music-based listening /supportive-psychological	Usual expression conditions	Positive/unclear magnitude; exact values NR

Ak et al. (2015)	India; premature newborns	Evaluate music therapy impact on breast milk secretion	Clinical intervention study	NR	Music therapy /supportive-psychological	Routine care or baseline comparison	Positive direction reported; numerical data not extracted
Rai et al. (2016)	India; postpartum mothers	Assess domperidone in the second postpartum week	Clinical trial	NR	Domperidone /medical-pharmacological	Routine/placebo comparator NR	Positive; primary numerical data not extracted
Asztalos et al. (2017)	Canada; mothers of very preterm infants	Evaluate domperidone to enhance milk production	Randomized placebo-controlled trial with open-label phase	90 mothers	Domperidone EMPOWER / medical-pharmacological	Placebo then open-label phase	Positive/modest increase reported; exact extractable values NR
Eshgizadeh et al. (2017)	Iran; mothers with premature infants	Assess foot reflexology effect on milk production	Clinical trial	NR	Foot reflexology /physical-complementary	Routine care	No significant effect reported
Mohammadpour et al. (2018)	Iran; NICU mothers	Investigate reflexology effect on breast milk volume	Randomized/clinical trial	50 mothers	Foot reflexology /physical-complementary	Routine care	Positive; primary numerical data not extracted
Mirzaie et al. (2018)	Iran; mothers with premature infants	Assess foot reflexology massage effect on milk volume	Randomized controlled trial	NR	Foot reflexology massage /physical-complementary	Routine care	Positive; greater day-7 volume reported; primary numerical data not extracted
Varişoğlu and Güngör (2020)	Turkey; NICU mothers	Assess listening to music on breast milk production	Randomized controlled study	NR	Listening to music /supportive-psychological	Routine care	Supportive/mixed; exact volume effect NR
Sheng et al. (2021)	China; preterm-infant mothers	Assess feasibility/effect of breast massage with acupoint stimulation	Pilot study	NR	Breast massage + acupoint stimulation /physical-complementary	Usual care	Positive/feasible pilot; primary numerical data not extracted
SefidHaji et al. (2022)	Iran; NICU mothers	Evaluate lullaby and lullaby plus infant photograph on milk volume/composition	Randomized controlled trial	99 mothers; 33 per group	Recorded lullaby +/- baby picture /supportive-psychological	Routine care	Positive; lullaby + photograph > lullaby alone > control

Sritas et al. (2023)	Thailand; post-cesarean mothers of preterm infants	Evaluate manual lymphatic drainage with Thai traditional massage	Randomized controlled trial	32 mothers	Manual lymphatic drainage + Thai traditional massage /physical-complementary	Standard care	No significant difference vs control
Nodehi et al. (2024)	Iran; primiparous mothers with premature infants	Assess foot reflexology on volume and composition of breast milk	Randomized clinical trial	76 enrolled; 74 analyzed	Foot reflexology /physical-complementary	Control/routine care	Clinically positive but statistically non-significant trend for volume

Note. NICU = neonatal intensive care unit; NR = not reported; RCT = randomized controlled trial; SD = standard deviation; SEM = standard error of the mean.

4.2 Intervention Domains and Statistical Data Availability

The included studies were distributed across four intervention domains. Table 2 summarizes this distribution and avoids the need for a separate descriptive figure of intervention counts.

Table 2. Distribution of included studies by intervention domain.

Intervention domain	Studies (n)	Main intervention examples
Medical/pharmacological	6	Domperidone, metoclopramide, and dose-comparison galactagogue approaches
Physical/complementary	6	Foot reflexology, breast massage, acupoint stimulation, manual lymphatic drainage, and Thai massage
Supportive/psychological	5	Music therapy, recorded lullaby, maternal-infant sensory/psychological approaches, and breastfeeding-support strategies
Technological/behavioral + physical	1	Simultaneous versus sequential pumping with breast massage component

The updated statistical audit clarified that more numerical data were available than in the initial Excel extraction, but the data remained insufficient for one definitive overall pooled estimate. In the second-round extraction, numerical outcome data were identified from six studies, complete continuous arm-level mean ± SD data from three studies, and clean two-arm milk-volume mean ± SD data from two studies. Table 3 summarizes the data-availability profile across the 18 included studies.

Table 3. Statistical data-availability audit for meta-analysis readiness.

Statistical data category	Studies (n)	Interpretation
Included studies reviewed	18	All studies in the evidence set were audited for statistical readiness.
Studies with numeric outcome data extracted in second-round extraction	6	SefidHaji, Nodehi, Campbell-Yeo, da Silva, Wan, and Vianna.
Complete continuous arm-level mean ± SD data extracted	3	SefidHaji, Nodehi, and Campbell-Yeo provided arm-level continuous data.
Clean two-arm continuous mean ± SD data for milk volume	2	Nodehi and Campbell-Yeo; SefidHaji is multi-arm with a shared control.
Reported MD/CI/SMD available for forest-style visualization	2	SefidHaji and Nodehi provided reported mean differences with confidence intervals.
Change-score or mean daily volume data without complete CI	1	da Silva provided change-score and mean daily volume data.
Crossover/responder SEM data	1	Wan provided responder subset dose-effect/crossover SEM data, not suitable for simple parallel-group pooling.
Clinical breastfeeding event data extracted	2	Vianna and Campbell-Yeo provided event-level breastfeeding data.
Still requiring full-text/PDF/table-level extraction	12	Some papers may contain additional data, but accessible extraction was not sufficient in this pass.

Note. Categories are not fully mutually exclusive: a single study can contribute arm-level data, reported-effect estimates, and/or event outcomes. Extractable numerical data do not automatically indicate suitability for one pooled meta-analysis because compatibility depends on intervention, outcome, time point, and effect metric. CI = confidence interval; MD = mean difference; PDF = portable document format; SD = standard deviation; SEM = standard error of the mean; SMD = standardized mean difference.

4.3 Primary Outcome: Breast Milk Volume

Breast milk volume was the most commonly reported outcome and there was a high variation between the reporting formats in the studies. Overall, the pharmacological studies showed a positive effect on milk volume following treatment with domperidone and/or metoclopramide. The updated extraction included usable data in numeric form from da Silva et al. (2001), Campbell-Yeo et al. (2010) and Wan et al. (2008) but each of these data sets had different formats: da Silva provided data in the form of change scores and mean daily volume, Campbell-Yeo provided arm-level data in the form of mean ± SD and Wan provided crossover/responders data in the form of standard error of the mean (SEM). Physical and complementary interventions showed mixed findings; Nodehi et al. (2024) reported a positive but statistically non-significant mean difference for foot reflexology.

The most complete set of reported-effect data with confidence intervals were from SefidHaji et al. (2022) and Nodehi et al. (2024). The author-reported pairwise mean differences and confidence intervals from a three-arm randomized trial of recorded lullaby with or without infant photograph. SefidHaji et al. (2022) were reported independently of each other, as the two groups received the same routine-care control intervention. The quantitative data, number of extracted milk and their current usability in meta-analysis are shown in Table 4.

Table 4. Extracted milk-volume quantitative effects and meta-analysis readiness.

Study	Comparison	Time point/effect metric	Extracted value	95% CI / variance information	Interpretation/meta-use
da Silva et al. (2001)	Domperidone vs. placebo	7-day change in milk volume	49.5 +/- 29.4 vs. 8.0 +/- 39.5 ml	CI not available in accessible source	Candidate for pharmacological subgroup only if change-score analysis is used consistently
da Silva et al. (2001)	Domperidone vs. placebo	Mean daily volume, study days 2-7	162.2 +/- 127.5 vs. 56.1 +/- 48.0 ml/day	Arm-level SD available; n = 7 vs. n = 9	Useful descriptive/possible subgroup value after verification
Wan et al. (2008)	Domperidone dose periods vs. run-in	Responder subset; g/h	30 mg: +14.9; 60 mg: +20.7	Mean +/- SEM crossover/responder data only	Not suitable for simple parallel-group pooling
Campbell-Yeo et al. (2010)	Domperidone vs. placebo	Day 14 24-h milk volume	380.2 +/- 201.6 vs. 250.8 +/- 171.6 ml	Arm-level SD available; n = 21 vs. n = 24	Clean two-arm arm-level data; verify against publisher PDF before pooling
SefidHaji et al. (2022)	Recorded lullaby vs. routine care	After 14 days; reported MD	4.96	1.80 to 8.13	Author-reported MD/CI; shares routine-care control with other SefidHaji contrast
SefidHaji et al. (2022)	Recorded lullaby + photo vs. routine care	After 14 days; reported MD	9.57	6.43 to 12.71	Author-reported MD/CI; preferred single contrast if one SefidHaji arm is selected
Sritas et al. (2023)	Manual lymphatic drainage + Thai massage vs. standard care	Day 7 median difference	-20	Not reported	Sensitivity candidate only; median/IQR conversion would require assumptions
Nodehi et al. (2024)	Foot reflexology vs. control	After 7 days; reported MD	11.08	-2.79 to 24.95	Reported MD/CI available; CI crosses the null

Note. CI = confidence interval; IQR = interquartile range; MD = mean difference; SD = standard deviation; SEM = standard error of the mean; PDF = portable document format.

Figure 2 presents the three studies reported milk-volume mean differences with confidence intervals that were directly suitable for forest-style visualization. SefidHaji et al. (2022) comparisons both favored the intervention arms and had confidence intervals above zero. These are author-reported pairwise mean differences rather than raw recalculated differences from displayed group means. Nodehi et al. (2024) also showed a positive point estimate for foot reflexology, but the interval was wide and crossed the null value. No pooled diamond is shown because SefidHaji et al. (2022) contrasts are not statistically independent, the intervention categories differ clinically, and too few independent studies were available.

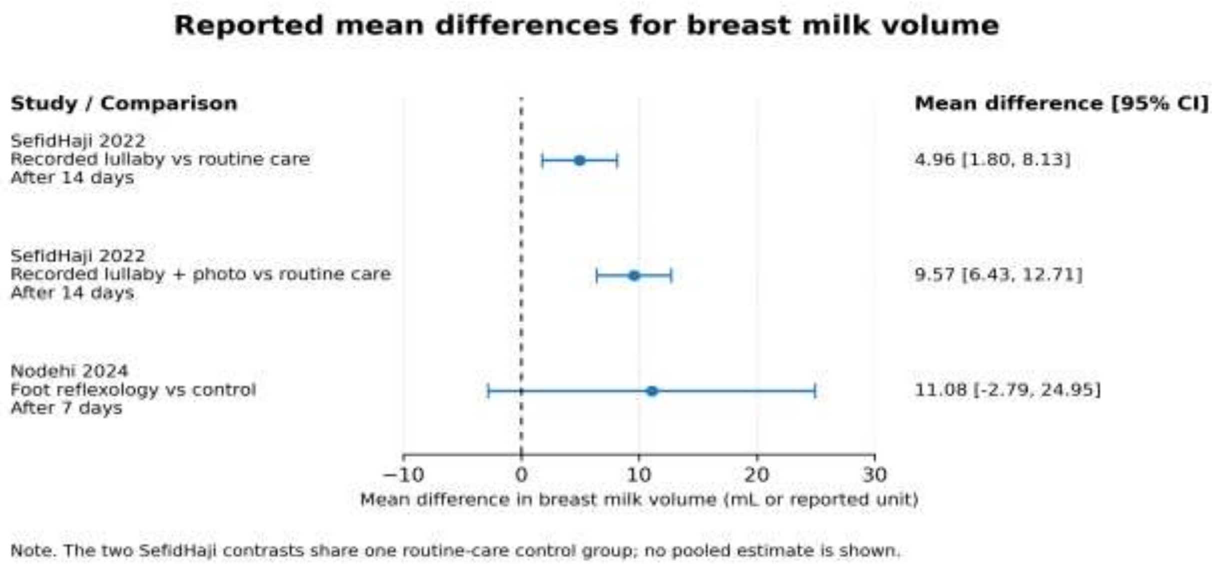

Figure 2. Reported mean differences for breast milk volume. SefidHaji et al. (2022) comparisons share the same control arm and are plotted descriptively; the MDs are author-reported pairwise estimates and no pooled estimate is shown.

4.4 Secondary Outcome: Nutritional Composition of Breast Milk

Information about nutritional-composition outcomes was less consistent than information about milk-volume outcomes. SefidHaji et al. (2022) and Nodehi et al. (2024) reported the most complete data regarding the effects reported. SefidHaji et al. (2022) found positive pairwise differences for triglycerides, cholesterol, albumin, and total protein especially for the combined (recorded lullaby plus photograph) intervention. However, for most of the nutrient outcomes, such as triglycerides, cholesterol, albumin, total protein and calcium, the effects of foot reflexology have been found to be wide or null according to Nodehi et al. (2024).

Selected mean differences of the nutritional composition of the two studies (SefidHaji et al. 2022; Nodehi et al. 2024) are shown in Figure 3. These values are in the units they were reported in and were not combined since the values represent different biological measures and the number of similar studies reporting values for each nutrient were low. The figure shows the values in Table 5.

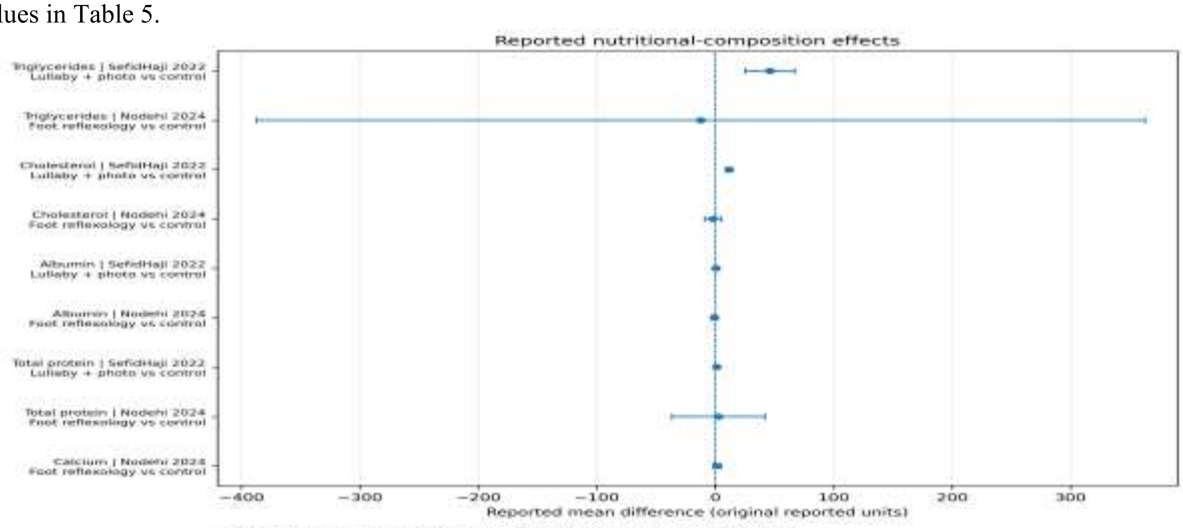

Figure 3. Reported nutritional-composition effects. Effects are displayed in original reported units and were not pooled across nutrients.

Table 5. Reported nutritional-composition effects underlying Figure 3.

Outcome	Study/comparison	Unit	MD	95% CI	Interpretation
Triglycerides	SefidHaji et al. (2022), lullaby + photo vs. control	mg/dl	46.32	25.39 to 67.26	Favors intervention
Triglycerides	Nodehi et al. (2024), foot reflexology vs. control	mg/dl	-12.16	-387.23 to 362.90	Imprecise; crosses null
Cholesterol	SefidHaji et al. (2022), lullaby + photo vs. control	mg/dl	11.68	9.19 to 14.18	Favors intervention
Cholesterol	Nodehi et al. (2024), foot reflexology vs. control	mg/dl	-1.81	-9.06 to 5.44	Imprecise; crosses null
Albumin	SefidHaji et al. (2022), lullaby + photo vs. control	reported unit	0.56	0.40 to 0.71	Favors intervention
Albumin	Nodehi et al. (2024), foot reflexology vs. control	reported unit	-0.67	-2.70 to 1.35	Imprecise; crosses null
Total protein	SefidHaji et al. (2022), lullaby + photo vs. control	reported unit	1.10	0.80 to 1.40	Favors intervention
Total protein	Nodehi et al. (2024), foot reflexology vs. control	reported unit	2.70	-36.68 to 42.08	Imprecise; crosses null
Calcium	Nodehi et al. (2024), foot reflexology vs. control	mg/dl	1.70	-1.66 to 5.07	Imprecise; crosses null

4.5 Clinical Breastfeeding Outcomes

Less consistency in reporting clinical outcomes of breastfeeding. The new extraction found breastfeeding data of events level from Vianna et al. (2011) and limited breastfeeding data from Campbell-Yeo et al. (2010). The results suggest that music therapy could be beneficial at early follow-up (0-7 days) and may have a statistically significant effect at 7-15 days for any-breastfeeding rates. Definitions and follow-up windows were, however, not consistent, and the number of evidence to do pooled clinical breastfeeding analysis was still small. Therefore, these results were described each in its own text and summarized descriptively in Table 6.

Table 6. Extracted clinical breastfeeding event outcomes.

Study	Outcome/time point	Intervention events/N	Comparator events/N	Effect estimate	Interpretation
Campbell-Yeo et al. (2010)	Any breastfeeding, 2 weeks after study completion	19/22	15/24	p = 0.13	Event data available; not pooled
Campbell-Yeo et al. (2010)	Any breastfeeding at discharge	12/22	12/23	RR not reported	Similar proportions; not pooled
Vianna et al. (2011)	Any breastfeeding at discharge	42/48	33/46	RR 1.22 (95% CI 0.99 to 1.51); p = 0.06	Favors music therapy; borderline
Vianna et al. (2011)	Any breastfeeding, 7-15 days	42/48	32/46	RR 1.26 (95% CI 1.01 to 1.57); p = 0.03	Favors music therapy
Vianna et al. (2011)	Any breastfeeding, 30 days	38/48	30/46	RR 1.21; p = 0.13	Favors intervention directionally; not statistically clear
Vianna et al. (2011)	Any breastfeeding, 60 days	36/48	27/46	RR 1.28 (95% CI 0.95 to 1.71); p = 0.09	Favors intervention directionally; not statistically clear

Note. CI = confidence interval; N = total number in group; RR = risk ratio, p=p value.

4.6 Risk of Bias

A risk-of-bias assessment was completed in order to inform the findings from the quantitative and narrative data. The summary of judgments in each of the main assessment domains is provided in Figure 4 and the study-level judgment and the main reasons for each study included in this summary are provided in Table 7. Most of the studies were determined to have

some concern overall and this was largely due to small sample size, incomplete blinding of behavioural or physical interventions, incomplete variance reporting, or selective outcome reporting.
The greatest concerns were those regarding the process of randomization, deviations from intended intervention, missing outcome data and outcome measurement as shown in Figure 4. Thus, the judgements made at study level in Table 7 were used to limit interpretation of the estimates of the actual effects reported and allow the quantitative results to be reported as exploratory rather than as a definitive pooled estimate.

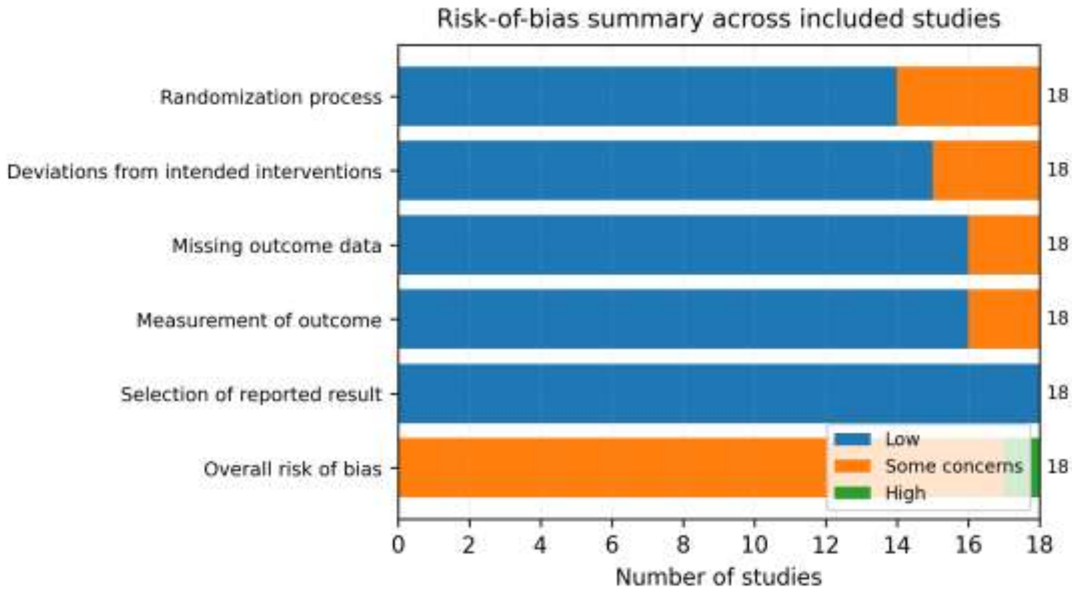

Figure 4. Risk-of-bias summary across included studies and assessment domains.

Table 7. Study-level risk-of-bias summary.

Study	Tool	Overall judgment	Main rationale
Jones et al. (2001)	JBI RCT checklist/RoB 2 logic	Some concerns	Small RCT/crossover; incomplete reporting of some methodological domains
da Silva et al. (2001)	JBI RCT checklist/RoB 2 logic	Some concerns	Very small randomized double-blind trial; variance extraction limited
Wan et al. (2008)	JBI RCT checklist/RoB 2 logic	Some concerns/high	Extremely small pilot study; crossover/responder design limits interpretation
Campbell-Yeo et al. (2010)	JBI RCT checklist/RoB 2 logic	Some concerns	Randomized double-blind trial; small sample and incomplete variance extraction
Vianna et al. (2011)	JBI RCT checklist/RoB 2 logic	Some concerns	Behavioral/music intervention with limited blinding feasibility
Ingram et al. (2012)	JBI RCT checklist/RoB 2 logic	Some concerns	Double-blind RCT; some recruited participants lacked trial data
Keith et al. (2012)	JBI RCT checklist/RoB 2 logic	Some concerns	Limited accessible numerical and methodological detail
Ak et al. (2015)	JBI RCT checklist/RoB 2 logic	Some concerns	Limited accessible methodological and numerical detail
Rai et al. (2016)	JBI RCT checklist/RoB 2 logic	Some concerns	Brief report with limited extractable methods

Asztalos et al. (2017)	JBI RCT checklist/RoB 2 logic	Some concerns	RCT with open-label phase; exact extraction incomplete
Eshgizadeh et al. (2017)	JBI RCT checklist/RoB 2 logic	Some concerns	Limited accessible methodological detail
Mohammadpour et al. (2018)	JBI RCT checklist/RoB 2 logic	Some concerns	Full outcome table not extracted
Mirzaie et al. (2018)	JBI RCT checklist/RoB 2 logic	Some concerns	Final judgment requires complete primary article/table extraction
Varişoğlu and Güngör (2020)	JBI RCT checklist/RoB 2 logic	Some concerns	Behavioral intervention; blinding not feasible and exact variance extraction limited
Sheng et al. (2021)	JBI RCT checklist/RoB 2 logic	Some concerns	Pilot design and incomplete extractable statistical detail
SefidHaji et al. (2022)	JBI RCT checklist/RoB 2 logic	Some concerns	Multi-arm randomized trial with shared control and behavioral intervention
Sritas et al. (2023)	JBI RCT checklist/RoB 2 logic	Some concerns	Small RCT with non-pharmacological intervention and limited blinding
Nodehi et al. (2024)	JBI RCT checklist/RoB 2 logic	Some concerns	Randomized clinical trial; intervention blinding not feasible but quantitative reporting was usable

Note. JBI = Joanna Briggs Institute; RCT = randomized controlled trial; RoB 2 = Cochrane Risk of Bias 2 tool.

5. Discussion

5.1 Principal Findings

This systematic review and exploratory meta-analysis of 18 studies on interventions to increase milk production, composition, and milk use among mothers of preterm infants. The second round statistical extraction further enhanced the quantitative evidence base by providing useful and usable numerical data from six studies, complete continuous arm-level data from three studies and clean two-arm milk-volume data from two studies. In sum, the evidence indicates that there are several interventions that likely have beneficial effects on milk-volume outcomes, although the strength of the inferences are constrained by the heterogeneity in type of interventions, timing, measurement, and statistical reporting.

The best reported-effect data were from SefidHaji et al (2022) which found a positive recorded mean difference with the infant photograph and recorded maternal lullaby for milk volume and a number of nutrient outcomes. This makes sense from a biological perspective as sensory/bonding interventions could lower stress levels, facilitate milk letdown by oxytocin and enhance mothers' involvement in expressing sessions. But, as the two intervention comparisons in this trial shared the same control group, they cannot be combined as fully independent comparisons without splitting the control group or using a multi-arm meta-analysis approach.

5.2 Interpretation by Intervention Domain

Pharmacological galactagogues are still a category of intervention that is important. Most studies on domperidone and metoclopramide – such as da Silva et al. (2001), Campbell-Yeo et al. (2010), Ingram et al. (2012), Rai et al. (2016) and Asztalos et al. (2017) – indicate that dopamine-antagonist pharmacotherapy has the potential to boost expressed milk output. However, the re-extraction was able to identify more values of use from da Silva et al. (2001), Campbell-Yeo et al. (2010), and Wan et al. (2008), and the full-text extraction of Ingram et al. (2012), Rai et al. (2016), and Asztalos et al. (2017) and choice of effect metric were suggested as potentially generating a more limited pharmacological subgroup meta-analysis.

Evidence of the physical and complementary interventions was more variable. The point estimate for foot reflexology on breast milk volume was positive, but the interval crossed the null, and overall, outcomes for nutritional-composition outcomes were largely imprecise (Nodehi et al., 2024). However, there are previous reflexology trials by Eshgizadeh et al. (2017) , Mohammadpour et al. (2018), and Mirzaei et al. (2018) that would potentially be clinically relevant, but these trials need to be fully extracted on the arm level before these trials could be added in to a refined reflexology subgroup forest plot. Thus, manual lymphatic drainage with Thai traditional massage was also reported descriptively as median/IQR by Sritas et al. (2023), which would need to be documented as conversion assumptions prior to quantitative pooling.

Sensory and psychological interventions seem to be promising, particularly because the interventions involve promoting mother-baby bonding during separation in NICU. Vianna et al. (2011), Keith et al. (2012), Ak et al. (2015), Varişoğlu and Güngör (2020), and SefidHaji et al. (2022) reported positive results in their studies using music therapy and/or lullaby-based interventions. The updated extraction included event level breastfeeding data from Vianna et al. (2011) and the SefidHaji et al. (2022) data offers the best quantitative evidence for this domain for milk volume and composition. Pooled data from the sensory/music and milk volume data at arm level is still pending.

5.3 Milk Composition and Breastfeeding Practice Outcomes

The excellent work in the reanalysis is the greater presentation of evidence on milk composition. The results of the combined (lullaby-plus-photograph) intervention revealed that it had a positive effect on triglycerides, cholesterol, albumin, and total protein (SefidHaji et al., 2022), and that foot reflexology did not significantly improve most nutrient outcomes (Nodehi et al., 2024). These differences indicate that interventions might not have a similar effect on milk quantity and milk composition. They also point out the importance for future trials to prespecify volume and composition endpoints and reporting these in standard units.

Clinical outcomes of breastfeeding are not as complete as short-term milk-volume outcomes. While it is important to have an increase in expressed milk volume in the NICU in the short-term, this does not necessarily reflect exclusive breastfeeding at discharge or post-discharge. Event extraction is updated in Campbell-Yeo et al. (2010) and Vianna et al. (2011) making it more transparent, but the number of clinical breastfeeding outcomes is still too low and too diverse to be pooled. Longer-term outcomes including exclusive mother's own milk at NICU discharge and any or exclusive breastfeeding at 3 and 6 months corrected age should be included in future trials.

5.4 Clinical and Research Implications

The results are clinically relevant and help to support a multimodal approach to lactation support for mothers of preterm infants. Supportive breastfeeding, early and frequent breastfeeding attempts, psychological support and opportunities for sensory interaction with the infant should be part of the basic lactation care of an NICU. For some mothers with ongoing low supply, pharmacological galactagogues may be useful, but should be employed in a safe screening and monitoring of the mother.

Improved reporting for research, full table-level extraction are the top priorities. Although the first-round audit concluded that there were only a few usable numerical data, the second round indicated that usable numerical data can be recovered from more studies, but is still fragmented. In future studies, group sample size, mean and standard deviations / standard errors at baseline and follow-up, mean difference and exact time points should be reported. Multi-arm trials must be reported in such a way that it can either be selected independently for comparison or the appropriate control split. Reporting this would allow for future subgroup meta-analysis to be more accurate and lessen the need for narrative synthesis.

5.5 Strengths and Limitations

Strengths of this review are the wide range of interventions covered in the review, which included pharmacological, physical/complementary, technological/behavioral, psychological and multimodal interventions. A major strength is the inclusion of statistical data-availability audit which will ensure that quantitative evidence is not overstated and it will be known what data from which studies can and cannot contribute to a meta-analysis at present.

There are also drawbacks of the review. Firstly, the new analysis is still insufficient for a definitive overall pooled arm-level meta-analysis as there are still limited independent estimates that are compatible, and the interventions are clinically heterogeneous. Second, 12 studies are yet to be fully extracted (from the tables or full-text). Thirdly, certain extracted values were from online mirrors or abstracts and should be cross-checked with the PDFs from the publishers prior to the final statistical pooling. Fourth, reported-effect plots are a mixture of clinically heterogeneous interventions, and should be viewed as exploratory visual summaries, not as definitive estimates of treatment. Fifth, the number of breast-feeding practice outcomes and long-term follow-up data was very limited, and conclusions on the sustainability of the clinical benefit were limited.

6. Conclusion

This systematic review and meta-analysis indicates that interventions for mothers of preterm infants may improve breast milk outcomes, particularly expressed milk volume, but the certainty of quantitative conclusions remains limited by heterogeneous methods and incomplete comparable reporting. The updated statistical extraction identified more usable numerical data than the initial dataset, including six studies with extractable numeric outcomes and three with complete continuous arm-level mean ± SD data. Nevertheless, the available evidence does not yet support one definitive pooled estimate across all intervention categories. Recorded maternal lullaby, especially when combined with an infant photograph, selected pharmacological galactagogue evidence, and some physical/complementary interventions showed promising effects. Future work should complete full-text extraction, verify all table values against primary sources, harmonize time points, and conduct subgroup-specific meta-analysis where statistically appropriate.

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Appendix A. Database Search Strategies

A1. PubMed/MEDLINE

(("Infant, Premature"[Mesh] OR "Infant, Very Low Birth Weight"[Mesh] OR preterm*[tiab] OR pre-term[tiab] OR premature*[tiab] OR neonat*[tiab] OR NICU[tiab] OR "neonatal intensive care"[tiab]) AND ("Breast Feeding"[Mesh] OR "Milk, Human"[Mesh] OR "Lactation"[Mesh] OR "Lactation Disorders/therapy"[Mesh] OR breastfeed*[tiab] OR "breast feed*"[tiab] OR breastmilk[tiab] OR "breast milk"[tiab] OR "human milk"[tiab] OR lactation[tiab] OR "milk volume"[tiab] OR "milk production"[tiab] OR hypogalactia[tiab] OR composition[tiab] OR macronutrient*[tiab] OR "milk fat"[tiab] OR protein[tiab]) AND ("Kangaroo-Mother Care Method"[Mesh] OR "Lactation Consultants"[Mesh] OR "Galactagogues"[Mesh] OR "Music Therapy"[Mesh] OR "skin to skin"[tiab] OR "skin-to-skin"[tiab] OR "kangaroo care"[tiab] OR "kangaroo mother care"[tiab] OR "lactation support"[tiab] OR "lactation consultant*"[tiab] OR counsel*[tiab] OR "peer support"[tiab] OR "breast massage"[tiab] OR "breast compression"[tiab] OR "hand expression"[tiab] OR "milk expression"[tiab] OR pumping[tiab] OR "pumping schedule"[tiab] OR "expression frequency"[tiab] OR reflexology[tiab] OR massage[tiab] OR acupoint[tiab] OR acupuncture[tiab] OR "warming pack"[tiab] OR "heating pad"[tiab] OR music[tiab] OR lullaby[tiab] OR "recorded voice"[tiab] OR photograph*[tiab] OR domperidone[tiab] OR metoclopramide[tiab] OR galactagogue*[tiab] OR fenugreek[tiab] OR shatavari[tiab] OR silymarin[tiab] OR "quality improvement"[tiab] OR bundle*[tiab] OR multimodal[tiab]))

A2. Embase

('premature infant'/exp OR 'very low birth weight infant'/exp OR 'preterm birth'/exp OR preterm*:ti,ab,kw OR 'pre term':ti,ab,kw OR premature*:ti,ab,kw OR neonat*:ti,ab,kw OR nicu:ti,ab,kw OR 'neonatal intensive care':ti,ab,kw) AND ('breast feeding'/exp OR 'human milk'/exp OR 'lactation'/exp OR 'lactation disorder'/exp OR breastfeed*:ti,ab,kw OR 'breast feed*':ti,ab,kw OR breastmilk:ti,ab,kw OR 'breast milk':ti,ab,kw OR 'human milk':ti,ab,kw OR lactation:ti,ab,kw OR 'milk volume':ti,ab,kw OR 'milk production':ti,ab,kw OR hypogalactia:ti,ab,kw OR composition:ti,ab,kw OR macronutrient*:ti,ab,kw OR 'milk fat':ti,ab,kw OR protein:ti,ab,kw) AND ('kangaroo care'/exp OR 'lactation consultant'/exp OR 'galactagogue'/exp OR 'music therapy'/exp OR 'skin to skin':ti,ab,kw OR 'skin-to-skin':ti,ab,kw OR 'kangaroo care':ti,ab,kw OR 'kangaroo mother care':ti,ab,kw OR 'lactation support':ti,ab,kw OR 'lactation consultant*':ti,ab,kw OR counsel*:ti,ab,kw OR 'peer support':ti,ab,kw OR 'breast massage':ti,ab,kw OR 'breast compression':ti,ab,kw OR 'hand expression':ti,ab,kw OR 'milk expression':ti,ab,kw OR pumping:ti,ab,kw OR 'pumping schedule':ti,ab,kw OR 'expression frequency':ti,ab,kw OR reflexology:ti,ab,kw OR massage:ti,ab,kw OR acupoint:ti,ab,kw OR acupuncture:ti,ab,kw OR 'warming pack':ti,ab,kw OR 'heating pad':ti,ab,kw OR music:ti,ab,kw OR lullaby:ti,ab,kw OR 'recorded voice':ti,ab,kw OR photograph*:ti,ab,kw OR domperidone:ti,ab,kw OR metoclopramide:ti,ab,kw OR galactagogue*:ti,ab,kw OR fenugreek:ti,ab,kw OR shatavari:ti,ab,kw OR silymarin:ti,ab,kw OR 'quality improvement':ti,ab,kw OR bundle*:ti,ab,kw OR multimodal:ti,ab,kw)

A3. Cochrane CENTRAL

([mh "Infant, Premature"] OR [mh "Infant, Very Low Birth Weight"] OR preterm*:ti,ab,kw OR pre-term:ti,ab,kw OR premature*:ti,ab,kw OR neonat*:ti,ab,kw OR NICU:ti,ab,kw OR "neonatal intensive care":ti,ab,kw) AND ([mh "Breast Feeding"] OR [mh "Milk, Human"] OR [mh "Lactation"] OR [mh "Lactation Disorders/therapy"] OR breastfeed*:ti,ab,kw OR "breast feed*":ti,ab,kw OR breastmilk:ti,ab,kw OR "breast milk":ti,ab,kw OR "human milk":ti,ab,kw OR lactation:ti,ab,kw OR "milk volume":ti,ab,kw OR "milk production":ti,ab,kw OR hypogalactia:ti,ab,kw OR composition:ti,ab,kw OR macronutrient*:ti,ab,kw OR "milk fat":ti,ab,kw OR protein:ti,ab,kw) AND ([mh "Kangaroo-Mother Care Method"] OR [mh "Lactation Consultants"] OR [mh Galactagogues] OR [mh "Music Therapy"] OR "skin to skin":ti,ab,kw OR "skin-to-skin":ti,ab,kw OR "kangaroo care":ti,ab,kw OR "kangaroo mother care":ti,ab,kw OR "lactation support":ti,ab,kw OR "lactation consultant*":ti,ab,kw OR counsel*:ti,ab,kw OR "peer support":ti,ab,kw OR "breast massage":ti,ab,kw OR "breast compression":ti,ab,kw OR "hand expression":ti,ab,kw OR "milk expression":ti,ab,kw OR pumping:ti,ab,kw OR "pumping schedule":ti,ab,kw OR "expression frequency":ti,ab,kw OR reflexology:ti,ab,kw OR massage:ti,ab,kw OR acupoint:ti,ab,kw OR acupuncture:ti,ab,kw OR "warming pack":ti,ab,kw OR "heating pad":ti,ab,kw OR music:ti,ab,kw OR lullaby:ti,ab,kw OR "recorded voice":ti,ab,kw OR photograph*:ti,ab,kw OR domperidone:ti,ab,kw OR metoclopramide:ti,ab,kw OR galactagogue*:ti,ab,kw OR fenugreek:ti,ab,kw OR shatavari:ti,ab,kw OR silymarin:ti,ab,kw OR "quality improvement":ti,ab,kw OR bundle*:ti,ab,kw OR multimodal:ti,ab,kw)

A4. CINAHL

(MH "Infant, Premature+" OR MH "Infant, Very Low Birth Weight+" OR TI preterm* OR AB preterm* OR TI pre-term OR AB pre-term OR TI premature* OR AB premature* OR TI neonat* OR AB neonat* OR TI NICU OR AB NICU OR TI "neonatal intensive care" OR AB "neonatal intensive care") AND (MH "Breast Feeding+" OR MH "Milk, Human" OR MH "Lactation+" OR MH "Lactation Disorders+" OR TI breastfeed* OR AB breastfeed* OR TI "breast feed*" OR AB "breast feed*" OR TI breastmilk OR AB breastmilk OR TI "breast milk" OR AB "breast milk" OR TI "human milk" OR AB "human milk" OR TI lactation OR AB lactation OR TI "milk volume" OR AB "milk volume" OR TI "milk production" OR AB "milk production" OR TI hypogalactia OR AB hypogalactia OR TI composition OR AB composition OR TI macronutrient* OR AB macronutrient* OR TI "milk fat" OR AB "milk fat" OR TI protein OR AB protein) AND (MH "Kangaroo Care" OR MH "Lactation Consultants" OR MH "Music Therapy" OR TI "skin to skin" OR AB "skin to skin" OR TI "skin-to-skin" OR AB "skin-to-skin" OR TI "kangaroo care" OR AB "kangaroo care" OR TI "kangaroo mother care" OR AB "kangaroo mother care" OR TI "lactation support" OR AB "lactation support" OR TI "lactation consultant*" OR AB "lactation consultant*" OR TI counsel* OR AB counsel* OR TI "peer support" OR AB "peer support" OR TI "breast massage" OR AB "breast massage" OR TI "breast compression" OR AB "breast compression" OR TI "hand expression" OR AB "hand expression" OR TI "milk expression" OR AB "milk expression" OR TI pumping OR AB pumping OR TI "pumping schedule" OR AB "pumping schedule" OR TI "expression frequency" OR AB "expression frequency" OR TI reflexology OR AB reflexology OR TI massage OR AB massage OR TI acupoint OR AB acupoint OR TI acupuncture OR AB acupuncture OR TI "warming pack" OR AB "warming pack" OR TI "heating pad" OR AB "heating pad" OR TI music OR AB music OR TI lullaby OR AB lullaby OR TI "recorded voice" OR AB "recorded voice" OR TI photograph* OR AB photograph* OR TI domperidone OR AB domperidone OR TI metoclopramide OR AB metoclopramide OR TI galactagogue* OR AB galactagogue* OR TI fenugreek OR AB fenugreek OR TI shatavari OR AB shatavari OR TI silymarin OR AB silymarin OR TI "quality improvement" OR AB "quality improvement" OR TI bundle* OR AB bundle* OR TI multimodal OR AB multimodal)

A5. Scopus

TITLE-ABS-KEY(preterm* OR "pre term" OR premature* OR neonat* OR NICU OR "neonatal intensive care") AND TITLE-ABS-KEY(breastfeed* OR "breast feed*" OR breastmilk OR "breast milk" OR "human milk" OR lactation OR "milk volume" OR "milk production" OR hypogalactia OR composition OR macronutrient* OR "milk fat" OR protein) AND TITLE-ABS-KEY("skin to skin" OR "skin-to-skin" OR "kangaroo care" OR "kangaroo mother care" OR "lactation support" OR "lactation consultant*" OR counsel* OR "peer support" OR "breast massage" OR "breast compression" OR "hand expression" OR "milk expression" OR pumping OR "pumping schedule" OR "expression frequency" OR reflexology OR massage OR acupoint OR acupuncture OR "warming pack" OR "heating pad" OR music OR lullaby OR "recorded voice" OR photograph* OR domperidone OR metoclopramide OR galactagogue* OR fenugreek OR shatavari OR silymarin OR "quality improvement" OR bundle* OR multimodal)

A6. Supplementary searching

Reference lists of all included studies and relevant reviews were screened manually. Forward citation searching was performed for key included studies where feasible. Records identified through these supplementary routes were documented under "other methods" in the PRISMA 2020 flow diagram.

Appendix B. JBI Critical Appraisal Checklist for Randomized Controlled Trials Among Included Studies (n = 18)

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Overall
Jones et al. (2001)	Y	U	Y	N	N	U	Y	Y	Y	Y	Y	Y	Y	Some concerns
da Silva et al. (2001)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Low/some concerns
Wan et al. (2008)	Y	U	U	U	U	U	Y	Y	U	Y	Y	U	Y	High/Some concerns
Campbell-Yeo et al. (2010)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Low/some concerns
Vianna et al. (2011)	Y	U	Y	N	N	U	Y	Y	Y	Y	Y	Y	Y	Some concerns
Ingram et al. (2012)	Y	Y	Y	Y	Y	Y	Y	N	U	Y	Y	Y	Y	Some concerns
Keith et al. (2012)	U	U	U	N	N	U	Y	U	U	Y	Y	U	Y	Some concerns
Ak et al. (2015)	U	U	U	N	N	U	Y	U	U	Y	Y	U	Y	Some concerns
Rai et al. (2016)	U	U	U	U	U	U	Y	U	U	Y	Y	U	Y	Some concerns
Asztalos et al. (2017)	Y	Y	Y	Y	Y	Y	N	U	U	Y	Y	Y	N	Some concerns
Eshgizadeh et al. (2017)	U	U	U	N	N	U	Y	U	U	Y	Y	U	Y	Some concerns
Mohammadpour et al. (2018)	Y	U	U	N	N	U	Y	U	U	Y	Y	U	Y	Some concerns
Mirzaie et al. (2018)	Y	U	Y	N	N	U	Y	Y	U	Y	Y	Y	Y	Some concerns
Varişoğlu and Güngör (2020)	Y	U	Y	N	N	U	Y	Y	U	Y	Y	Y	Y	Some concerns
Sheng et al. (2021)	U	U	U	N	N	U	Y	U	U	Y	Y	U	Y	Some concerns
SefidHaji et al. (2022)	Y	U	Y	N	N	U	Y	Y	Y	Y	Y	Y	Y	Some concerns
Sritas et al. (2023)	Y	U	Y	N	N	U	Y	Y	Y	Y	Y	Y	Y	Some concerns
Nodehi et al. (2024)	Y	Y	Y	N	N	U	Y	Y	Y	Y	Y	Y	Y	Some concerns

Note. Y = Yes (criterion met); N = No (criterion not met); U = Unclear. Q1 = True randomization; Q2 = Allocation concealment; Q3 = Baseline similarity; Q4 = Participant blinding; Q5 = Personnel blinding; Q6 = Outcome assessor blinding; Q7 = Equal treatment of groups; Q8 = Completeness of follow-up; Q9 = Intention-to-treat analysis; Q10 = Consistent outcome measurement; Q11 = Reliable measurement; Q12 = Appropriate statistical analysis; Q13 = Appropriate trial design. Green = Yes; Red = No; Orange = Unclear.