**REVIEW ARTICLE** 



# The effectiveness of interventions using relaxation therapy to improve breastfeeding outcomes: A systematic review

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#### **Abstract**

Maternal psychological state is recognised to influence lactation success, largely by affecting milk ejection. Thus, increased psychological distress can disrupt milk flow and in the long-term, affect milk synthesis. Conversely, it is possible that milk ejection could be improved by using relaxation therapy during breastfeeding. We performed a systematic review to evaluate the effectiveness of interventions using relaxation therapy to improve breastfeeding outcomes and to assess the consequent impact(s) on infant growth and behaviour. A literature search was performed using the PRISMA guidelines where we included intervention studies (including nonrandomised controlled studies) using relaxation therapy in breastfeeding mothers during the post-natal period. Out of 147 identified records at the initial search, 5 studies were eligible, of which 3 were randomised controlled trials and 2 were nonrandomised or quasi-experimental studies. These studies were conducted in Europe, America, and India and included 311 mother-infant pairs, of which 64 infants were full-term and 247 were premature infants. Relaxation therapy was shown to increase milk yield in mothers of preterm infants in 2 randomised trials, however, the milk sampling protocol for these studies could be questioned. None of the studies investigated the consequent effects on infant outcomes. Overall, limited evidence was found on the effectiveness of relaxation therapy on breast milk composition and infant outcomes. Experimental studies with better standardisation of protocol and robust methodological design are needed to investigate the effectiveness of relaxation therapy on both breastfeeding and infant growth and behavioural outcomes.

# KEYWORDS

breastfeeding, breast milk, infant feeding, lactation, psychological state, relaxation therapy

#### 1 | INTRODUCTION

Many women experience situations or events throughout pregnancy, and the post-partum period that are perceived as stressful and which, if prolonged, could lead to chronic or severe psychological distress (Kingston, Tough, & Whitfield, 2012; Sparling, Henschke, Nesbitt, & Gabrysch, 2017). A systematic review on the prevalence of perinatal psychological distress reported a gradual increase in post-partum

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mood disorders in the first 3 months (Gaynes et al., 2005), with the prevalence of post-partum depression reported to be around 13% worldwide (Leahy-Warren, McCarthy, & Corcoran, 2012; O'Hara & Swain, 1996). Another systematic review indicated that infant distress in the first 3 months, such as colic and crying, was associated with maternal anxiety such as tiredness and fatigue especially among new mothers, which could, in turn, lead to maternal post-partum depression (Kurth, Kennedy, Spichiger, Hösli, & Zemp Stutz, 2011). However, because most studies are observational, the direction of causality cannot be established. For example, if a mother is stressed, this could lead to disengagement with her infant, which could result in an

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increase in infant crying or demand for care or feeds, further raising the maternal stress level.

Psychological distress in mothers and/or difficult behaviour in infants could influence infant feeding and development during early life (Dennis & McQueen, 2007; Kingston et al., 2012). This could occur either through effects on the breastfeeding process itself or by increased energy expenditure on crying in the infant so that less energy is available for growth, especially in the first 4 to 6 months when the infant depends solely on nutrition for growth (Wells & Davies, 1998). If this "stressed" mother-infant relationship is prolonged, it could lead to post-partum depression in the mother that might subsequently have detrimental effects on the mother's health and later infant development, including cognitive and socioemotional development (Kingston et al., 2012; Moehler, Brunner, Wiebel, Reck, & Resch, 2006). This is supported by studies reporting that mothers with psychological distress have difficulties in interacting with or responding to their infants including less contact or touching, being less sensitive to infant cues, and tending to have a negative perception towards infant signals (Field, 2010; Gonidakis, Rabavilas, Varsou, Kreatsas, & Christodoulou, 2008).

Among breastfeeding mothers, those with depressive symptoms tend to have low breastfeeding self-efficacy, defined as low confidence in their perceived ability to breastfeed their infant (Dennis, 2006), to be less sensitive in touching their infant, and more likely to have poor positioning of the infant during breastfeeding (Hart, Jackson, & Boylan, 2011; Shakespeare, Blake, & Garcia, 2004; Watkins, Meltzer-Brody, Zolnoun, & Stuebe, 2011). Human studies have reported that emotional distress in mothers inhibits the let-down reflex leading to disruption of milk flow and reduced milk volume or milk yield, hence affecting breastfeeding duration (Dewey, 2001; Hart et al., 2011; Lau, 2001; Stuebe, Grewen, & Meltzer-Brody, 2013; Ueda, Yokoyama, Irahara, & Aono, 1994). In addition, maternal psychological distress has also been associated with elevated maternal cortisol during the post-partum period (Rogers, Hughes, Tomlinson, & Blissett, 2016; Stuebe, Grewen, Pedersen, Propper, & Meltzer-Brody, 2012). This hormone has been suggested to interfere with the regulation of oxytocin and prolactin, which may influence breastfeeding frequency and duration (Groër, 2005; Stuebe et al., 2012). Hence, the combination of both depressive symptoms and difficulty in breastfeeding may eventually influence the duration of (exclusive) breastfeeding and affect breastfeeding success (Adedinsewo, Fleming, Steiner, Meaney, & Girard, 2013; Taveras et al., 2003; Watkins et al., 2011; Zanardo et al., 2009).

Because the let-down-reflex is affected by maternal psychological state, it has been hypothesised that milk ejection and/or synthesis could be improved by reducing maternal psychological distress (Newton & Newton, 1948; Ueda et al., 1994), potentially through the use of relaxation therapy (Fotiou, Siahanidou, Vlastarakos, Tavoulari, & Chrousos, 2017; Shukri, Wells, Mukhtar, Lee, & Fewtrell, 2017). Such an approach could potentially stimulate the let-down reflex resulting in more efficient milk ejection, especially when a mother intends or expects to breastfeed. Over a long period, this could help mothers to prolong breastfeeding duration, hence improving overall breastfeeding rates in a population (Fotiou et al., 2017). This is especially important given that breastfeeding rates worldwide are still below target levels (Victora et al., 2016),

## Key messages

- Our systematic review found few studies testing the hypothesis that the breastfeeding process could be improved by reducing maternal psychological distress or stimulating let-down-reflex by using relaxation.
- Two randomised controlled trials have shown that relaxation therapy improved milk supply, but overall evidence is inconclusive due to methodological limitations.
- More robust trials with larger sample size and standardised protocols including additional infant outcomes are suggested.
- This is especially among mothers with infants in the neonatal-intensive-care-unit who are most reliant on milk expression.

To further our understanding of the physiological aspects of breastfeeding, specifically milk synthesis and ejection, in this review, we investigate the effects of attempts to induce a more positive maternal psychological state on breastfeeding outcomes, focussing in particular on the direct effects of relaxation intervention therapy on milk volume and milk composition (including bioactive factors such as cortisol) that could be influenced by psychological state. In addition, we also investigate whether such interventions have consequent effect(s) on infant growth and behaviour. If successful, such therapies have the potential to help mothers who are likely to be more stressed during the post-partum period, for example, those with preterm infants. These mothers are often reliant on milk expression for long periods of time and are less likely to establish breastfeeding than mothers who deliver a healthy term infant (Bonet et al., 2011; Lee & Gould, 2009; Merewood, Brooks, Bauchner, MacAuley, & Mehta, 2006). Previous reviews on the effects of the relaxation therapy mainly involved patients in hospital (Kwekkeboom & Gretarsdottir, 2006; Pelekasis, Matsouka, & Koumarianou, 2016; van Dixhoorn & White, 2005), and to our knowledge, only one recent review has reported the effects of relaxation interventions in breastfeeding women (Fotiou et al., 2017). This review only included mothers of full-term infants, and their main focus was the influence on breastfeeding success including breastfeeding initiation and duration rates (Fotiou et al., 2017).

Our approach was to focus on the direct effects of relaxation therapy on breastfeeding outcomes (milk volume and composition), regardless of the infant's gestational age, as well as considering the consequent effects on infant outcomes as indicated above.

# 2 | METHODS

The literature search was conducted based on the PICOS (participants, interventions, comparators, outcomes, study design) model (Liberati et al., 2009) in order to match it closely with our research question: Does relaxation therapy (verbal protocol/ guided imaginary recording/

meditation/ music therapy) help to improve breastfeeding outcomes and are there any consequent effects on infant growth or behaviour?

# 2.1 | Eligibility criteria

Articles were eligible for inclusion in the review if they were full-text articles published in English that reported an experimental study design (including nonrandomised and quasi-experimental studies) testing the effectiveness of relaxation therapy on breastfeeding and/or infant outcomes. Therapy interventions included were limited to those that potentially have a positive effect on psychological state, termed mind stress-releasing therapy. Body stress-releasing therapy such as back massage was not included because the aim was to focus on the direct effects of the intervention in reducing maternal psychological distress during breastfeeding. Observational studies were excluded from the review because they cannot establish causal relationships between the intervention therapy and breastfeeding outcomes. Both primiparous and multiparous women and term and preterm infants were included.

#### 2.2 | Information sources

Databases that were used for the literature search were Embase, Medline, CINAHL Plus, Allied and Complementary Medicine Database, Web of Science, and the Cochrane Library. The publication date during the search was set from inception to August 2016.

# 2.3 | Search strategy

A comprehensive search strategy was conducted separately using both Medical Subject Heading (MeSH) terms and free text keywords at the initial search stage. The MeSH terms were also expanded to include all relevant subterms. Next, both searched results were combined to identify relevant articles. The first search included breastfeeding terms whereas the second search included the relaxation therapy terms as shown in Table 1. Next, both breastfeeding and relaxation therapy terms were combined to obtain the final set of articles.

Table 1 presents the search strategy used including the MeSH and keywords that were used for the literature search. The keywords and strategy used were applied similar for all selected databases.

# 2.4 | Study selection

The final search results were imported into EndNote X3, where duplicates were removed. Following the PRISMA guidelines, all titles were first screened, followed by review of the abstracts and full-text

by N. H. M. S. and M. F. in order to extract the data and assess the eligibility of the articles, as shown in Figure 1. The primary outcomes that were considered for the review were breastfeeding (breast milk volume or milk yield), breast milk macronutrient content (levels of fat, protein, and carbohydrate), breast milk energy content, and breast milk cortisol levels, and/or infant outcomes (infant growth including weight gain and body mass-index, and infant behaviour such as feeding, sleeping and crying duration, and temperament). The secondary outcomes were maternal psychological state during the lactation period and/or bioactive factors in breast milk other than cortisol. The randomised controlled trials (RCTs) that were included in this review were assessed for their quality using a critical appraisal tool for therapy articles by the Centre for Evidence-Based Medicine, University of Oxford (Centre for Evidence-Based Medicine University of Oxford, 2005).

#### 3 | RESULTS

Using the search strategy (Table 1), 147 references were identified, and all were exported into Endnote. As shown in Figure 1, after duplicates were removed, and titles and abstracts were screened based on the eligibility criteria, five articles were eligible to be included in the analysis. Of those five articles, three studies reported primary outcomes related to breastfeeding: milk yield and milk composition [either macronutrient (Feher et al., 1989; Keith et al., 2012) or cortisol levels (Ak, Lakshmanagowda, G. C. M. & Goturu, 2015)], and the other two presented data on the secondary outcomes: breast milk secretory IgA (Perez-Blasco et al., 2013) and maternal psychological state (O'Connor et al., 1998). None of the studies reported on infant growth or behaviour outcomes.

The studies included 311 mother–infant pairs, of which 64 infants were full-term and 247 were premature infants. Studies that presented the primary outcomes of breastfeeding only involved mothers of preterm infants (Ak et al., 2015; Feher et al., 1989; Keith et al., 2012) whereas the two studies that presented the secondary outcomes [maternal psychological state, (Perez-Blasco et al., 2013) and other bioactive factors in breast milk, (O'Connor et al., 1998)] only involved mothers of full-term infants. Three out of five studies were RCTs (Feher et al., 1989; Keith et al., 2012; Perez-Blasco et al., 2013). Three studies used a guided imagery recording or meditation as a relaxation therapy (Feher et al., 1989; O'Connor et al., 1998; Perez-Blasco et al., 2013); one study used music therapy (Ak et al., 2015), and only one study compared both guided imagery recordings and music therapy (Keith et al., 2012). Table 2 shows a detailed description of all studies including the length of relaxation therapy used and their results.

 TABLE 1
 Medical Subject Heading (MeSH) / keyword used for literature search

No.	Search strategy	Map term to subject heading (MeSH)	Keywords
1	MeSH or keywords (key findings for breastfeeding)	Breastfeeding, lactating, lactation, human milk, breast milk, breastfeed, and breastfed	Breastfeeding or "breast feeding" or breastfed or lactation or "breast milk" or "human milk"
2	MeSH or keywords (key findings for relaxation therapy)	Relaxation therapy, relaxation techniques, meditation, imagery, verbal protocol, guided imagery, and music therapy	Relaxation therapy or meditation or guided imagery or music therapy or verbal protocol
3	1 and 2 (combination both of key findings)		

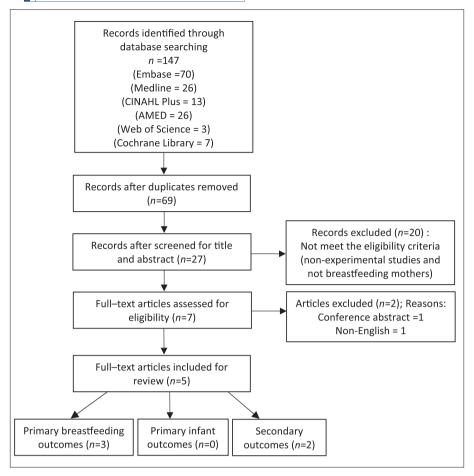


FIGURE 1 Flow diagram of data extraction

# 3.1 | Primary outcomes

Overall, our review identified only three studies investigating the effects of relaxation therapy on breastfeeding outcomes, in particular, breast milk yield and composition. Two RCTs (Feher et al., 1989; Keith et al., 2012) found that listening to relaxation therapy significantly increased milk yield by more than twofold compared to that of mothers in the control group; demonstrating a large effect size. A doseresponse effect was also reported showing a significant positive association between frequency of listening to the therapy and milk produced from a single pumping session (Feher et al., 1989). There was also a nonrandomised study (Ak et al., 2015) that claimed that listening to music therapy was effective in increasing the amount of milk expressed in the study population, but the difference in milk volume compared to the amount expressed while not listening to the therapy was very small (0.5 ml or a 7% difference) and unlikely to be clinically relevant. In terms of milk composition, one study (Keith et al., 2012) reported a significant increase in fat content in the breast milk of mothers in two of the intervention groups (Group D: Who received the imagery protocol only; and Group C: Who received the imagery protocol accompanied by visual images of the mother's infant) compared to the control group or the intervention group that received the voice protocol accompanied by lullabies (Group B; Keith et al., 2012). The authors suggested that the lullabies might have distracted the mothers from focussing on the guided imagery protocol and thus affected the milk produced during milk expression. The other RCT reported higher fat content in breast milk of mothers in the intervention group than the control group, but the difference was not significant (Feher et al., 1989).

# 3.2 | Secondary outcomes

One study reported the effect of the relaxation intervention on sIgA level (bioactive factor other than cortisol) in breast milk and found no significant difference between groups (O'Connor et al., 1998). They also found no significant differences in maternal stress, anxiety, and depression scores. Nevertheless, they reported a positive association between maternal stress and sIgA level at a later home visit. On the other hand, another two studies reported the effectiveness of the intervention in reducing maternal stress (Ak et al., 2015; Perez-Blasco et al., 2013) and anxiety (Perez-Blasco et al., 2013). In addition to reducing maternal stress, one RCT also reported the effectiveness of relaxation therapy in improving maternal psychological state shown by a higher score in overall maternal self-efficacy and mindfulness among intervention group mothers (Perez-Blasco et al., 2013).

# 3.3 | Intervention tools

Four studies that used a guided imagery recording or meditation as a relaxation therapy involved mothers practising a progressive muscle relaxation technique such as taking deep and rhythmic breaths. The duration of the voice protocol recording in these selected studies was as short as 12 min and as long as 20 min. The guided imagery in

 TABLE 2
 Summary of studies included in the review

				WILEY-	/Ia	ternal & Child Nutrition	
	Outcomes	Frequency of listening: 50% women listened to the tape >5 times before expressing a milk sample  Milk volume Intervention: 90.1 $\pm$ 60 ml;  Control: 55.4 $\pm$ 48.2 ml; 63% higher in the intervention group, $p$ < .05  Creamatocrit (fat) Intervention: 7.2 $\pm$ 2.9%;  Control: 6.8 $\pm$ 2.4%; $p$ > .05.  Dose—response: Milk volume and frequency of listening	Frequency of listening: Not reported Milk volume: Groups B, C, and D had significantly higher milk volume than the control group (A); $p < .05$ Creamatocrit (fat): Groups C and D had significantly higher fat content at Day 1-6, compared to A and B ( $p < .05$ )	Psychological state: Intervention group had significant higher reduction in anxiety and stress (p < .05) Self-efficacy, self-compassion, and mindfulness: All showed higher score in the intervention group (p < .05)	Outcomes	Frequency of listening: 4 days Milk volume music therapy: $7.12 \pm 1.6$ ml; non-music therapy: $6.68 \pm 1.4$ ml ( $p = .033$ ). Milk volume increase significantly from Day 1-4 during music therapy period ( $p = .024$ ) Salivary cortisol Music therapy: $3.31 \pm 3.5$ nmol/L; non-music therapy: $2.99 \pm 4.0$ nmol/L. Significant reduction was reported after music therapy period, $p = .001$ Stress level: Mean PSS score at Day 1 ( $42.4 \pm 3.3$ ) was significantly higher than at Day 4 ( $33.5 \pm 3.5$ ), $p = .01$ .	
	Sample collection / assessment	Milk volume: Volume of single expression at 1 week after enrolment Milk fat content: Creamatocrit	Milk volume: No. of times pumped and volume of milk produced Milk fat: Creamatocrit collection of 1 ml sample of composite breast milk of expressed milk, collected daily from Day 1 to 14, close to noon time	Only secondary outcomes: Psychological state (DASS 21), mindfulness and self-efficacy at baseline and end-point after 11 weeks	Sample collection or assessment	Milk volume: milk pumped for 15 min at Minute 15 of the therapy. Milk collection: Twice a day at around 11 AM and 4 PM (for 4 days).  Salivary cortisol: Before and after music therapy on the last day  Stress level using Perceived Stress Score (PSS) at Days 1 and 4	
	Methodology: Intervention tool / groups	Tool: A 20-min audio cassette tape based on relaxation and visual imagery techniques. Instruction: Listen once daily prior to BF for 7–13 days. Analysis: t test	Groups A: Control; B: Verbal protocol (12 min) + Iullabies; C: Verbal protocol + guitar music background + images of the infant D: Verbal protocol only Instruction: Use as often as possible while pumping milk for 14 days. Analysis: Repeated measure ANOVA.	Tool: 2–3 sessions of 10-min guided meditations Instruction: 2-hr session per week, for 8 weeks Analysis: ANCOVA	Methodology: Intervention tool or groups	Tool: a 30-min rendition of the raga flute song (music therapy) Instruction: Listen for 4 times within 4 days. Analysis: Paired t-test	
Neview	Participants	Urban USA, mothers of mixed parity (n = 55), breastfeeding Infant: Preterm infants in the NICU for at least 10 days	Urban USA, mothers of mixed parity (n = 162), breastfeeding Infant: Preterm infants (born before 38 weeks) in the NICU or critically ill	Urban—Valencia, Spain, mothers of mixed parity (n = 26), breastfeeding Infant: Healthy infants	Participants	Bangalore, India, parity was not mentioned, breastfeeding mothers (n = 30) Infant: Preterm infants (born before 34 weeks) in the NICU.	
Sullillally of studies illefuded ill tile review	Randomisation	Randomised: Method not stated	Random schedule	Randomised: Method not stated	Randomisation	Random permuted blocks for task. No control group	
IABLE 2 Sullillial y Ol	Study design	RCT: Feher, Berger, Johnson, and Wilde (1989)	RCT: Keith, Weaver, and Vogel (2012)	RCT: Perez-Blasco, Víguer, and Rodrigo (2013)	Study design	Quasi- experimental: Ak et al. (2015)	

(Continues)

		Frequency of listening: 36% of Group 1 practiced less than once, and 60% practice 1-2 times daily for 2 weeks after HV1 Milk slgA: No significant difference between groups at all HV. Psychological test: No significant difference between groups at all HV. Mothers who were stressed at HV2 (n = 14) had significant increase in slgA level at HV3 (+0.16 g/L), compared to those who were not stressed (n = 22); slgA (-0.09 g/L); p = .03.
	Outcomes	Frequency practiced 1–2 time Milk slgA: groups a Psychologi betweer were strisignificad (+0.16 g not street practice) p = .03.
	Sample collection / assessment	Milk collection: 10 ml breast milk sample at baseline (HV1), after 2 weeks (HV2) and after 6–8 weeks (HV3) Psychological state using SCL-90-R to measure overall stress, anxiety, and depression at HV 1–2
	Methodology: Intervention tool / groups	Groups 1) relaxation training and audiotaped; 2) conversation about life; 3) none Groups 2 and 3 received the relaxation audiotape after HV2 Instruction Group 1: Listen to the tape or perform the relaxation training twice daily for 2 weeks after HV1. Groups 2 and 3: Listen to the audiotape daily after HV2 Analysis: ANOVA
	Participants	Urban USA (Ohio), mothers of mixed parity (n = 38), breastfeeding Infant: Healthy infants
	Randomisation	Not randomised, no control group
TABLE 2 (Continued)	Study design	Nonrandomised, non-controlled: O'Connor, Schmidt, Carroll- Pankhurst, and Olness (1998)

RCT = randomised controlled trial; NICU = neonatal intensive care unit Note. HV = home visit; BF = breastfeeding; two RCTs (Feher et al., 1989; Keith et al., 2012) included descriptions of pleasant surroundings, positive and supportive messages about breastfeeding and mother-infant bonding, and all mothers in the intervention group received the same guided imagery recording. The only difference was the addition of lullabies or guitar songs to the recording and also the use of additional visual images of the mother's baby in two additional intervention groups in the study by Keith et al. (2012). Another two studies involved meditation to aid or stimulate relaxation in general (O'Connor et al., 1998; Perez-Blasco et al., 2013), of which one study had a well-planned meditation program of eight different sessions targeted to increase mindfulness and selfempowerment including maternal self-efficacy (Perez-Blasco et al., 2013). Whereas the other study (O'Connor et al., 1998) individualised the tape-recorded meditation according to maternal preference; thus, each mother received a different recording. Only one study used music therapy (without an accompanying verbal protocol), which was based on the raga played on the flute specifically designed for the Indian population in the study (Ak et al., 2015). All mothers were advised to listen to the therapy once daily, and the duration of use varied from 4 days to 8 weeks. Apart from neonatal intensive care unit-based studies (Feher et al., 1989; Keith et al., 2012), two studies involved mothers attending relaxation therapy sessions at the study centres (Ak et al., 2015; Perez-Blasco et al., 2013), and one study (O'Connor et al., 1998) involved a researcher performing relaxation training (meditation) during a home visit where it was audiotaped, and then mothers were asked to listen to the audiotape twice daily for the next 2 weeks. All RCTs reported that mothers in both intervention and control groups received standard post-natal care and breastfeeding support during the study period. In the non-RCTs, all mothers were reported to have received similar relaxation intervention therapy but at different time points. This should reduce potential confounding by extra post-natal care or breastfeeding support.

# Quality of the RCT studies

All three RCTs (Feher et al., 1989; Keith et al., 2012; Perez-Blasco et al., 2013) that were included in this review were assessed for their quality as they provided evidence for the primary outcomes. The limitations of the other two nonrandomised studies that provided evidence on the secondary outcomes are considered in the discussion section. One study (Keith et al., 2012) used a random schedule for randomisation whereas another two studies (Feher et al., 1989; Perez-Blasco et al., 2013) did not mention the method of randomisation; none of these studies indicated whether the randomisation was prepared by an independent person. All of the RCTs, however, indicated that both control and intervention groups were similar at baseline because there were no significant differences between groups in baseline characteristics. Apart from the intervention, all mothers in the studies were treated the same throughout the study period. The loss to follow-up or incomplete data (e.g., failure to collect milk samples) in these studies was around 20-25%, and none of the studies mentioned per-protocol analyses. Researchers and mothers involved in the RCTS were not blinded due to the nature of this behavioural therapy, and mothers in the control group were aware of the relaxation therapy treatment of the mothers in the intervention group. Therefore, there was a

possibility that mothers in the control group might seek similar therapy during the study period—and this concern was not acknowledged in any of the RCTs. The sample size of two RCTs (Feher et al., 1989; Keith et al., 2012) was adequate to detect hypothesised differences in the primary outcome(s) between groups and their effect sizes (mean differences) were also large. Another RCT had a very small sample size, and they were not able to detect differences in any of the primary outcome results (Perez-Blasco et al., 2013).

#### 4 | DISCUSSION

From this review, there is evidence from three studies suggesting that relaxation therapy may be effective in significantly increasing milk yield (Ak et al., 2015; Feher et al., 1989; Keith et al., 2012) and from one study suggesting that it may have beneficial effects on milk fat levels (Keith et al., 2012). However, the assessment of milk yield was different between studies. The RCT by Feher et al. (1989) compared the average milk volume of a single expression only at the end-point of data collection, whereas the RCT by Keith et al. (2012) compared the average daily milk volume expressed from Day 1 to 14 of data collection. In the non-RCT study by Ak et al. (2015), each mother was asked to express milk twice daily (morning and afternoon) for 4 days, and mothers were randomly assigned to listen to music therapy while expressing milk either during morning or afternoon sessions, and the milk volumes produced were compared daily from Day 1 to 4.

Because milk production may be highly variable throughout the lactation period, the result from the study by Keith et al. (2012) would be most convincing because the comparison was done daily for 14 consecutive days. However, assessing breast milk volume daily for 2 weeks would be less practical for a large sample study size. Hence, alternatively, milk sampling could be done at baseline, mid-point, and end-point of data collection, or once a week, depending on the duration of the intervention. The finding by Feher et al. (1989) on the other hand would be more convincing if the milk volume had also been assessed at baseline so that the increase in milk volume from baseline to end-point of data collection could have been calculated.

The milk sampling procedure that was used by Ak et al. (2015) could introduce potential bias because the milk production might be different during the morning and afternoon sessions (Kent et al., 2006), and if the mothers were assigned to listen to music therapy in the morning, there might be carry-over effect of the therapy during the afternoon session, because the music therapy might have influenced the maternal psychological state during the day. There are also other methodological issues with these studies with regards to milk collection. First, the studies did not define the stage of lactation when sample collection took place, which would be expected to influence the results for milk volume and composition, because milk production changes over the course of lactation, especially during the early stages (Hytten, 1954; Neville et al., 1991). Second, the studies did not provide information on the exclusivity of breastfeeding that may also affect milk yield (Hytten, 1954). Finally, it is not clear whether the milk collection procedure was standardised, for example, in terms of the time of the last feed or last pumping and the time of day; all of these factors can influence both milk volume and composition due to high variability of milk synthesis between mothers (Kent et al., 2006; Miller et al., 2013).

Most importantly, none of these studies measured the volume of milk that would be consumed by the infant if it suckled directly from the breast (milk intake). Although the study results are therefore relevant to mothers who feed their infant entirely on expressed milk, for example, mothers of preterm infants, they do not reveal whether a greater capacity to produce breast milk would lead to a larger ingestion of suckled breast milk. Nevertheless, both RCTs conducted in mothers of preterm infants (Feher et al., 1989; Keith et al., 2012) have shown positive effects of relaxation therapy on expressed milk volume, suggesting that relaxation therapy could be an effective intervention to help these mothers express milk. This is especially important as studies have reported that mothers of preterm or very low-birthweight infants are likely to have more problems in expressing milk or breastfeeding their infants and were also more likely to formula feed their infants during early life compared to mothers of healthy fullterm infants (Bonet et al., 2011; Lee & Gould, 2009; Merewood et al., 2006). The relaxation therapy tool is simple and cheap and can easily be used without hospital staff involvement.

With regard to fat content, neither of the RCTs (Feher et al., 1989; Keith et al., 2012) specified the milk sampling procedure and the methods used could be considered nonphysiological if samples were obtained on a single occasion by either mechanical or hand expression, because breast milk composition is highly variable (e.g., changes within a feed and across lactation). Thus, future studies should consider performing mid-feed, fore, or hindmilk sampling in order to assess breast milk composition, especially milk fat, given that the breast milk content is not static but changes within a feed and diurnally (Kent et al., 2006). In addition, for future studies, it would be desirable to use stable isotopes to estimate the energy transfer of breast milk and/or milk intake, as this method is physiological (suckled breast milk), non-invasive (unlike test-weighing, it does not interfere with the breastfeeding process), and is suited to studying infants in their normal home environment (da Costa et al., 2010). A study performed by Lucas, Ewing, Roberts, and Coward (1987) using this method reported lower metabolisable energy content of breast milk than that previously reported from expressed breast milk samples at Weeks 5 and 11, with figures of 57 and 61 kcal/100 ml, respectively.

Similarly, standardising the timing of sample collection is important when measuring cortisol levels in humans as the concentration changes throughout the day (Tu, Lupien, & Walker, 2005). Only one study investigated the effect of the relaxation therapy on maternal salivary cortisol, and it was measured only on the last day of the music therapy session. The authors concluded there was a reduction of cortisol levels after listening to the music therapy. However, the study was not randomised, and all mothers were exposed to the music therapy several times at different sessions, and therefore, although the sample collection was done on the last day, mothers that were assigned not to listen to the therapy might feel relaxed during breastfeeding because they had already been exposed to the therapy previously. There were also limitations in statistical power because the sample size of the study was small (n = 30). Therefore, future studies with better study design and a larger sample size are required to further investigate the effect of relaxation therapy on maternal salivary or milk cortisol.

One study found no effect of the relaxation intervention on both a milk bioactive factor (slgA) and maternal psychological state (O'Connor

et al., 1998). Similar to the Ak et al. (2015) study design, all mothers received the intervention at different time points, hence, all mothers were exposed to the relaxation therapy, and this may have had carry-over effects even at the point where they were not receiving therapy. Thus, the changes in breast milk composition and psychological state due to the effects of the intervention could not be ascertained between groups. Although Ak et al. (2015) found a significant reduction in maternal stress, their results were not convincing, as they compared maternal psychological state before and after the study period for all mothers, without having a control group. Thus, causality cannot be determined. The RCT of Perez-Blasco et al. (2013) reported an improvement of overall maternal psychological state: reduction in stress and anxiety and higher scores in self-efficacy, self-compassion, and mindfulness among mothers in the intervention group. However, because the intervention involved different meditation programmes during each session, they did not identify which program could have contributed the most or been most effective in reducing maternal distress or increasing mindfulness during the post-partum period.

In summary, there are limited studies and inconclusive evidence on the effectiveness of relaxation therapy on both primary and secondary outcomes considered in this review. This could partly reflect the fact that the literature search was limited to full-text articles published in English. The strongest evidence was for an effect in increasing milk volume expressed by mothers of preterm infants in two RCTs. Only one study found an effect on milk fat content. Two studies reported an effect on maternal stress. There are a number of plausible potential mechanisms for the observed effects of relaxation therapy on breast milk outcomes: (a) mothers who are more relaxed have better milk ejection, thus producing higher milk volume; and/or more hindmilk with higher fat concentration; (b) mothers who are more relaxed produce breast milk with altered composition in terms of macronutrients and, potentially, other bioactive factors. On the basis of the limited evidence in this review, the effects of the relaxation therapy on expressed milk volume in two RCTs is more consistent with the first suggested mechanism. However, both mechanisms should be investigated in future studies.

# 5 | CONCLUSION

All studies included in the review had limitations either relating to study design or the sample collection procedure. With regard to the intervention, mothers in the control group in all studies were aware of the availability of the relaxation tools that were used in the intervention group(s), and thus, there is the possibility that some mothers may have sought similar relaxation tools and used them during the study period. None of these studies acknowledged the potential influence of parity on breast milk outcomes or maternal psychological state, therefore, and this should be considered for future studies as a potential confounder, in addition to socio-economic status. Many of the studies had a small sample size and, due to a higher potential of selection bias (selecting breastfeeding mothers from higher social economic status for the study), it is important to acknowledge that it may not be appropriate to generalise the study results to all breastfeeding mothers from all socio-economic class; none of the studies addressed this issue.

Finally, none of the studies reported the effects of the relaxation therapy on infant growth or behaviour. Because improving maternal psychological state may affect breastfeeding outcomes, it is also important to ascertain the consequent effects on infant growth and behaviour. Certain components in breast milk or the production of different milk volumes as a result of intervention therapy could potentially influence infant appetite, breast milk intake through suckling at the breast, behaviour, and growth during infancy (Shukri et al., 2017). Hence, experimental studies with better standardised protocols and robust methodological design are needed to investigate the effectiveness of relaxation therapy on breastfeeding outcomes and the consequent effects on infant growth and behaviour. This work should include larger studies in mothers of preterm infants in whom simple relaxation interventions may have great potential for improving the success of milk expression and breastfeeding.

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#### **CONFLICTS OF INTEREST**

The authors declare that they have no conflicts of interest.

#### **CONTRIBUTIONS**

NHMS, MF, and JW proposed the idea and concept of this review. NHMS screened the title and compiled the searched, NHMS and MF screened the abstracts and full-text articles and assessed the quality of the method and data of the studies. NHMS led the review process and the writing, under the supervision of MF and JW, which MF led the editing process. NHMS, MF, and JW edited and approved the final manuscript.

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