

Do Massage and Relaxation Music Therapy Increase Breast Milk Volume? A Meta-Analysis

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ABSTRACT

Background: Breast milk contains various nutrients that meet the needs of infants' growth and development. Furthermore, breast milk also contains various antibodies that will protect infants from viruses and bacteria to avoid infections and various diseases. Various conditions encountered by postpartum mothers often lead to stress and anxiety that generate a low milk supply, thus the infants do not get breast milk optimally. This study aims to discover the effect of massage and relaxation music therapy on breast milk volume.

Subjects and Method: The study used systematic review and meta-analysis using the PICO model. Population= postpartum mother, Intervention= massage and relaxation music therapy, Comparison= no massage and relaxation music therapy, and Outcome= breast milk volume. Article search was conducted in various databases, namely PubMed, BMC, ScienceDirect, ResearchGate, SpringerLink, and NCBI. The articles were collected in 1 month. The articles were published from 2012-2022. The keywords in this article search were "Massage AND Lactation" OR "Massage AND Milk Production" AND "Music AND Milk Production" OR "Relaxation AND Breastfeeding" AND "Randomized Controlled Trial". The inclusion criteria were full-text articles with an RCT study design, the correlation size used was mean and SD, and the articles were in English. The articles were analyzed using the RevMan 5.3 application.

Results: This study used 14 articles with sample populations from China, India, Indonesia, the United Kingdom, Iran, Malaysia, Thailand, and Turkey. The administration of massage had a positive effect 1.42 times more effective on the increase of breast milk volume compared to without massage (SMD= 1.42; CI 95%= 0.98 to 1.86; p<0.001). Relaxation music therapy can increase breast milk volume by 0.46 times compared to without relaxation music therapy (SMD= 0.46; 95% CI= 0.31 to 0.60; p<0.001).

Conclusion: Massage and relaxation music therapy have a positive effect on the increase of breast milk volume.

Keywords: massage, relaxation music therapy, breast milk volume, postpartum.

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BACKGROUND

Breast milk is a liquid produced by a mother's breast which is a source of food for babies with the content of perfect nutrients to meet the needs for nutrition that support the growth and development of infants from birth to 6 months of age without the need for additional complementary foods. Breast milk also contains hormones, and anti-body, anti-allergy, and anti-inflammatory agents (Arum and Widiyawati, 2019).

Infants who are not exclusively breastfed are more susceptible to diarrhea, acute respiratory infection, weight loss, malnutrition, low intelligence, decreased productivity, cognitive disorders, and social development. The global nutrition target is to increase exclusive breastfeeding in the first 6 months by at least 50% by 2025 (Getaneh et al., 2021).

Thirty seven of infants are exclusively breastfed globally (Jama et al., 2020). In Indonesia, 69.7% of infants are exclusively breastfed, with 3 provinces still below the target, namely Papua (11.9%), West Papua (21.4%), and West Sulawesi (27.8 %) (Kemenkes, 2022).

The importance of proper nutrition and stimulation in early life for short, mid, and long-term development of the human brain and cognitive, health, and well-being is well discovered. Breastfeeding is a vital element of optimal nutrition during the first 2 years of life because it can save lives, and improve infants' short-term and long-term health (Cordero and Escamilla, 2022).

Inadequate breast milk production is often an obstacle for breastfeeding mothers. An Indian study discovers that the main reason for the cessation of breastfeeding was generated by the inadequate secretion of breast milk. In another study, postpartum mothers often experience stress due to various issues such as lack of sleep, physical fatigue, hormonal changes, and anxiety in

taking care of infants, thus causing a decrease in breast milk production (Nuampa and Payakkaraung, 2021).

Massage is an effective and low-risk treatment for increasing breast milk secretion, reducing swelling, and facilitating breast milk secretion. Massage acts as an external stimulus that opens the milk ducts (Divya et al., 2016).

Massage is defined as the patterned manipulation of soft tissues and has a therapeutic purpose. Massage has a long history when it is traced back to ancient Egypt, China, and India. Almost all cultures have developed various massage techniques for healing and well-being (Ooi et al., 2018).

Massage is a touch technique in the form of friction, vibration, and pressure with various techniques and styles that arise from all over the world (Salarvand et al., 2021). Various types of massage that can be used to increase breast milk volume include Tui Na massage, Thai Traditional Massage, Breast Massage, and Oxytocin Massage (Leow et al., 2021).

Relaxation music therapy is a form of health therapy that uses music in overcoming various problems such as physical, psychological, cognitive, or individual social needs (Mappagerang et al., 2017).

Relaxation music therapy can increase breast milk volume, lower salivary cortisol levels, reduce stress, and maintain breast milk quality. Mothers who feel pain and stress, have chaotic thoughts, sadness, and lack of support and attention from the family and husband will inhibit oxytocin hormone and obstruct breast milk secretion. With the relaxation music therapy method, mothers will feel calm and relaxed, so that oxytocin hormone will be stimulated (Wulandari et al., 2020).

Music provides a relaxing effect and plays an important role in providing comfort by reducing the activity of the sympathetic

nervous system. Mothers who feel stressed by the production of breast milk can use pleasant relaxation techniques such as listening to music that can encourage the reflex of breast milk secretion (Widyantari et al., 2020).

A study by Munsittikul et al. (2022) has proven that massage can reduce breast pain and clear the clogged milk flow. Massage promotes the success of breastfeeding (Mahdizadeh-Shahri et al., 2021). Breast massage is effective in increasing lactation (Raju et al., 2018). Relaxation therapy improves the psychological state of mothers as well as increases breast milk production (Yu et al., 2019). Relaxation therapy using music can increase breast milk production (Widyantari et al., 2020). Massage and Music can increase breast milk production (Dağlı and Çelik, 2021).

Based on the background above, it is necessary to conduct a comprehensive study from various primary study sources on the effect of massage and relaxation music therapy on breast milk volume. Hence, the study is expected to prove the effect of massage and relaxation music therapy interventions on breast milk volume.

SUBJECTS AND METHOD

1. Study Design

It was a systematic review and meta-analysis study. The data were obtained from various databases, namely PubMed, BMC, Science-direct, ResearchGate, SpringerLink, and NCBI, published from 2012 to 2022. The keywords in this article search were "Massage AND Lactation" OR "Massage AND Milk Production" AND "Music AND Milk Production" OR "Relaxation AND Breastfeeding" AND "Randomized Controlled Trial".

2. Steps of Meta-Analysis

The meta-analysis was carried out in five steps as follows:

1. Formulate research questions in the PICO format (population, intervention, comparison, outcome).
2. Search for primary study articles from various electronic databases including Google Scholar, PubMed, and Science Direct and non-electronics.
3. Conduct screening and critical appraisal (Critical Appraisal) of primary research articles.
4. Perform data extraction and synthesize effect estimates into RevMan 5.3.
5. Interpret and conclude the results.

3. Inclusion Criteria

Full paper articles using Randomized Control Trial (RCT) study. The correlation effect used was the mean SD. The subject of the study was post-partum mothers. The interventions given were massage and relaxation music therapy. The outcome of the study was the volume of breast milk.

4. Exclusion Criteria

Articles published in languages other than English, articles before 2012, and articles not free access.

5. Operational Definition of Variables

Massage is a method of therapy by giving touch with various techniques that make mothers comfortable and stimulate blood flow that delivers stimulation from the breast to the brain and has an effect on the stimulation of breast milk production.

Relaxation Music Therapy is a therapeutic method using musical instruments that provide a relaxing effect on mothers that stimulates oxytocin hormone production which makes the mother comfortable and happy, in the end, it has an effect of stimulating breast milk production.

Breast milk volume is the quantity of milk that comes out of a mother's breast after obtaining massage and relaxation music therapy.

6. Instrument

The study was guided by a PRISMA flow-

chart and the quality assessment of the study articles using the Critical Appraisal Skill Program (CASP) Randomized Controlled Trial Standard Checklist (Table 2).

7. Data Analysis

The data of the study were processed using the Review Manager application (RevMan 5.3). In determining the measure of the correlation and data heterogeneity, this study used Forest plots and funnel plots.

RESULTS

The studies related to the effect of massage and relaxation music therapy on breast milk volume consists of 14 articles from 2 continents, namely Asia and Europe. Articles from Asia came from China, India, Indone-

sia, Iran, Malaysia, Thailand, and Turkey. The article from Europe was from England.

The initial search process obtained the results of 2,231 articles, after the process of removing the duplicated articles, 1,128 articles were obtained with 72 of them meeting the requirements for further full-text review. The full-text articles excluded for not meeting the inclusion criteria were 58 articles. Only 14 articles met the qualitative requirements which were divided into 2 categories according to independent variables namely massage and relaxation music therapy. The articles review process can be seen in the following figure 1. PRISMA flow diagram:

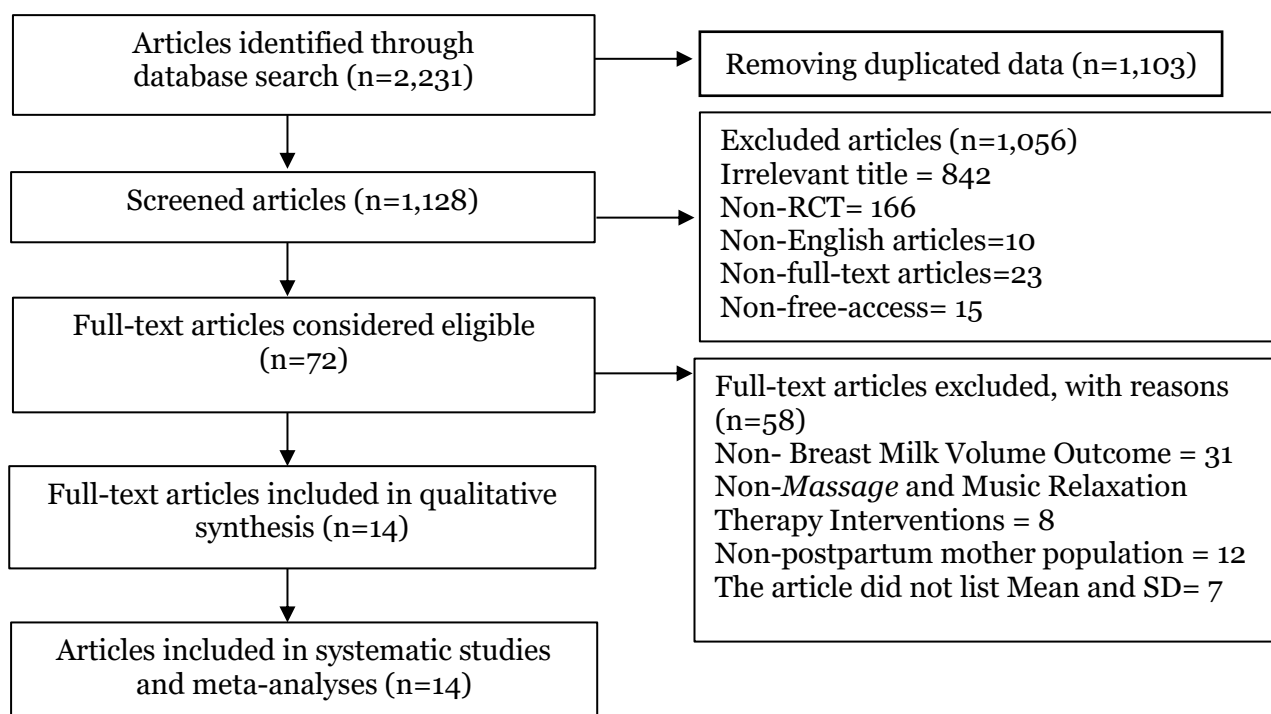


Figure 1. PRISMA flowchart diagram

Table 1 showed that a total of 14 primary studies articles on the effect of massage and relaxation music therapy on the volume of breast milk were included in the meta-analysis with varied study locations, namely China, India, Indonesia, England, Iran, Thailand, and Turkey. Similarities were

found in the study, namely, the study design used was a RCT, the subjects of the study were postpartum mothers, the interventions given were massage and relaxation music therapy, the comparison was without massage and relaxation music therapy, the minimum of intervention starting from the

first 24 hours postpartum. However, there was a difference in the number of samples used, i.e., the smallest number of samples was 16 and the largest was 152.

Table 3 shows that the mean value in

the massage intervention group was the highest recorded in the study of Sheng et al. 2021, namely 710.0 with SD= 128.6 and the lowest mean is in the study of Juan-Juan et al. (2012), namely 2.88 with SD= 1.171.



Figure 2. Map of Research Area

Table 1. Description of primary studies included to meta-analysis

Authors (years)	Country	Study Design	Sample		P	I	C	O
			I	C				
Juan-juan et al. (2012)	China	RCT	58	26	Postpartum mothers	Tui Na Massage	No massage	Breast milk Volume, prolactin level.
AK et al. (2015)	India	RCT	29	29	Postpartum mothers	Music therapy	No music	Breast milk Volume
Rahayuning sih et al. (2016)	Indonesia	RCT	30	60	Postpartum mothers	Breast care and oxytocin massage	No massage	Breast milk Volume
Kittithanesuan et al. (2017)	Thailand	RCT	152	152	Postpartum mothers	Music	No music	Breast milk Volume
Sari et al., (2017)	Indonesia	RCT	30	30	Postpartum mothers	Massage and hypno-breastfeeding.	No massage	Breast milk Volume, anxiety.
Dabas et al. (2019)	India	RCT	25	25	Postpartum mothers	Audio assisted relaxation technique	No audio relaxation	Stress, anxiety, breast milk Volume.
Lu et al. (2019)	China	RCT	40	40	Postpartum mothers	Acupoint Tui Na.	No massage	Breast temperature, breast milk volume.
Shukri et al. (2019)	Malaysia	RCT	33	31	Postpartum mothers	Relaxation therapy	No relaxation	Stress, anxiety, breast milk

Authors (years)	Country	Study Design	Sample		P	I	C	O
			I	C				
Varisoglu et al. (2020)	Turkey	RCT	22	22	Postpartum mothers	Listening to music	No listening to music	therapy volume, infants' behavior and growth
Sheng et al. (2021)	China	RCT	16	17	Postpartum mothers	Breast massage dan Acupoint stimulation.	No massage	Breast milk Volume
Khoonphet et al. (2022)	Thailand	RCT	21	21	Postpartum mothers	Thai traditional massage.	No massage	Breast milk Volume, reduced breast swelling.
Levene et al. (2022)	United Kingdom	RCT	66	66	Postpartum mothers	Relaxation	No Audio Relaxation	Breast milk volume, infants and maternal mental health.
Sefidhaji et al. (2022)	Iran	RCT	3	33	Postpartum mothers	Lullaby	No lullaby.	Volume, fat, total protein, and breast milk albumin concentration.
Septianingrum et al. (2022)	Indonesia	RCT	30	30	Postpartum mothers	Hypno-breast-feeding massage.	No massage	Anxiety, Breast milk Volume.

Table 2. Assessment of study quality using Critical Appraisal Skill Program (CASP) Randomized Controlled Trial Standard Checklist

Author (Year)	Question											Total score
	1	2	3	4	5	6	7	8	9	10	11	
Juan-juan et al. (2015)	2	2	2	2	2	2	2	2	2	2	2	22
AK et al. (2015)	2	2	2	0	2	2	2	2	2	2	2	20
Rahayuningsih et al. (2016)	2	2	2	0	2	2	2	2	2	2	2	20
Kittithanesuan et al. (2017)	2	2	2	0	2	2	2	2	2	2	2	20
Sariet al. (2017)	2	2	2	2	2	2	0	2	2	2	2	20
Dabas et al. (2019)	2	2	2	2	2	2	2	2	2	2	2	22
Lu et al. (2019)	2	2	2	2	2	2	2	2	2	2	2	22
Shukri et al. (2019)	2	2	2	2	2	2	2	2	2	2	2	22
Varisoglu et al. (2020)	2	2	2	2	2	2	2	2	2	2	2	22
Sheng et al. (2021)	2	2	2	2	2	2	2	2	2	2	2	22
Khoonphet et al. (2022)	2	2	2	2	2	2	2	2	2	2	2	22
Levene et al. (2022)	2	2	2	0	2	2	2	2	2	2	2	20
Sefidhaji et al. (2022)	2	2	2	2	2	2	2	2	2	2	2	22
Septianingrum et al. (2022)	2	2	2	0	2	2	2	2	2	2	2	20

Description of the question criteria:

- 1 = Does this study answer the question of the study?
- 2 = Is the participant's assignment for

intervention randomized?

- 3 = Are all participants who enter the study calculated into the conclusion?
- 4 = Is blinding implemented for patients,

- health workers, and researchers?
- 5 = Are the study groups similar at the beginning of the study?
- 6 = Regardless of intervention, does each study group obtain the same care or treatment?
- 7 = Are the effects of the intervention comprehensively reported?
- 8 = Is the accuracy of the estimated intervention reported?
- 9 = Do the benefits of the intervention outweigh the disadvantages and costs?

- 10 = Can the results be applied to your local population/ in your context?
- 11 = Did the intervention provide greater value to the people in your care than any intervention available?

Description of the answer score:

- 0 = No
- 1 = Hesitant
- 2 = Yes

1. The effect of massage on breast milk volume.

Table 3. Mean and SD values of intervention group and control group of primary studies meta-analysis

Authors (Years)	Mean		SD	
	Intervention	Control	Intervention	Control
Juan-juan et al. (2012)	2.88	1.50	1.171	0.583
Rahayuningsih et al. (2016)	17.57	1.58	9.70	1.69
Sari et al. (2017)	13.07	5.17	10.36	4.21
Lu et al. (2019)	51.25	5.68	48.51	10.05
Sheng et al. (2021)	710.0	499.4	128.6	160.1
Khoonphet et al. (2022)	14.05	9.29	3.40	3.96
Septianingrum et al. (2022)	15.37	9.00	7.61	4.81

The forest plot in figure 3 shows that there was a high heterogeneity across the primary studies ($I^2=76\%$; $p<0.001$) thus the analysis used a Random Effect Model. The administration of massage interventions was able to increase the volume of breast milk by 1.42 times compared to non-massage (SMD= 1.42; 95% CI= 0.98 to 1.86; $p<0.001$).

Figure 4 the plot funnel appeared to be asymmetrical between the right plot and the left plot, the distribution of the effect estimates was more on the left, which indicated the occurrence of a publication bias (overestimate). 5 plots were on the left with a standard error between 0.2 and 0.4, 1 plot was on the right with a standard error of 0.3, and 1 plot was parallel to the line.

a. Forest Plot

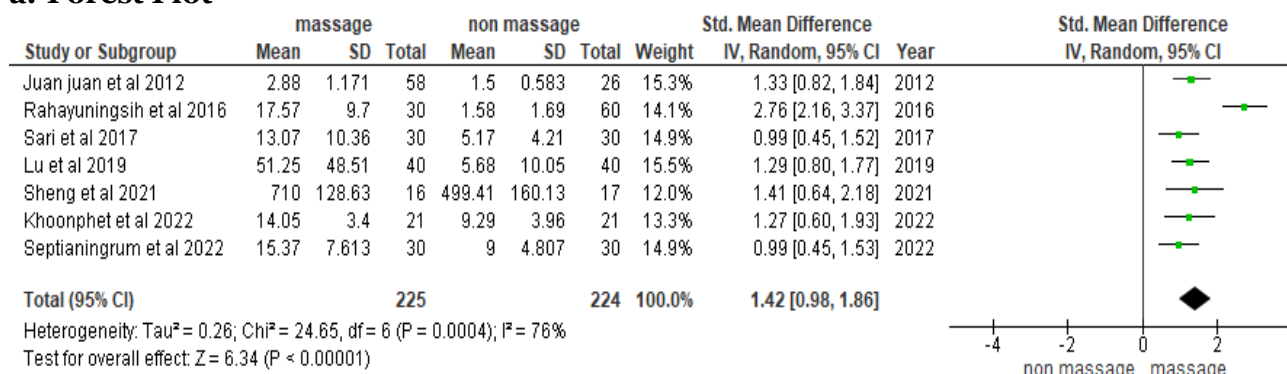


Figure 3. Forest plot of meta-analysis of the effect of massage toward breast milk volume.

b. Funnel Plot

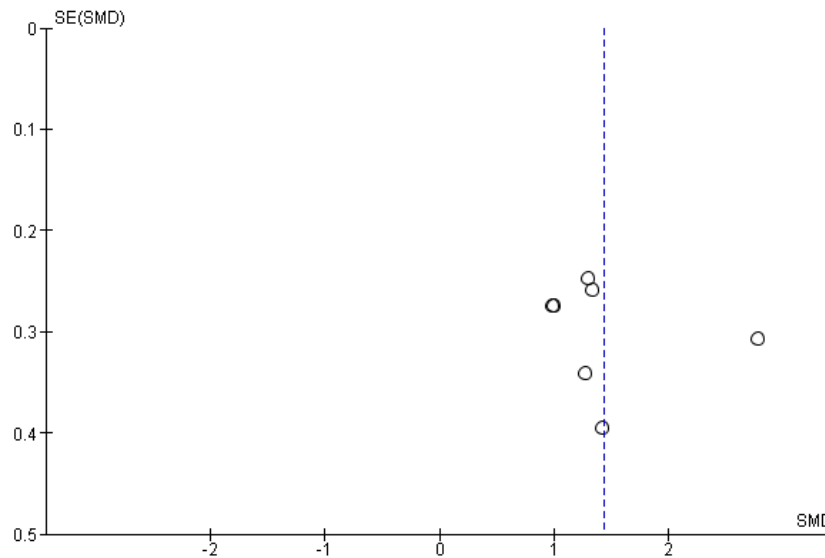


Figure 4. Funnel plot of meta-analysis of the effect of massage toward breast milk volume

2. The effect of relaxation music therapy on breast milk volume.

Table 4. Mean and SD values of intervention group and control group of primary studies meta-analysis.

Author (years)	Mean		SD	
	Intervention	Control	Intervention	Control
AK et al. (2015)	7.12	6.68	1.57	1.37
Kittithanesuan et al. (2017)	35.5	32.5	12.2	13.2
Dabas et al. (2019)	69.2	54.1	19.3	22.5
Shukri et al. (2019)	886.8	741.8	251	184
Varisoglu et al. (2020)	23.1	12.3	14.1	11.8
Levene et al. (2022)	825	670	300	300
Sefidhaji et al. (2022)	77.97	73.09	4.47	5.41

Table 4. The highest mean and SD values in the music intervention group were found in the study by Shukri et al. 2019, namely mean = 886.8 and SD = 251. Meanwhile,

the lowest mean and SD values are found in the study of Varisoglu et al. (2020), namely mean= 23.1 and SD= 14.1.

a. Forest Plot

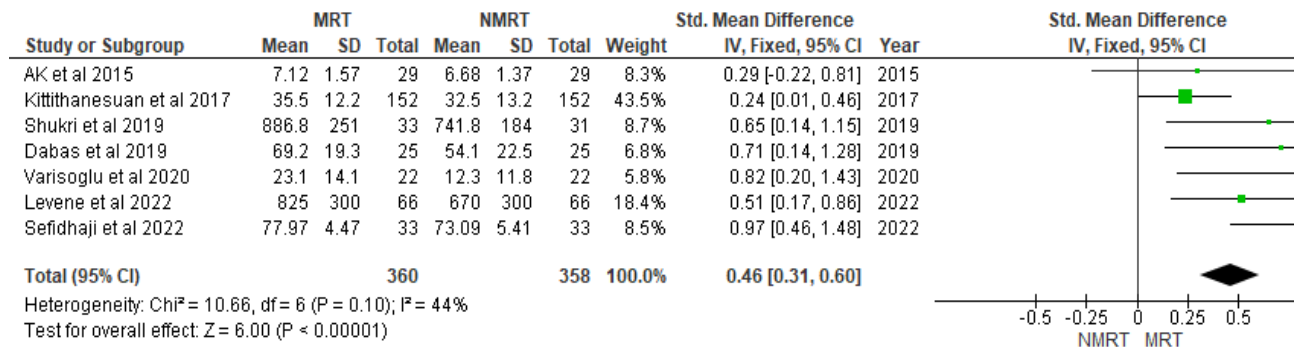


Figure 5. Forest plot of meta-analysis of the effect of relaxation music therapy toward breast milk volume.

Figure 5, the forest plot shows that there was a low heterogeneity across the primary studies ($I^2=44\%$; $p<0.001$) thus the analysis used a Fixed Effect Model (FEM). The intervention of relaxation music therapy was able to increase the volume of breast milk by 0.46 times compared to without relaxation music therapy (SMD= 0.46; 95% CI= 0.31 to 0.60; $p<0.001$).

b. Funnel Plot

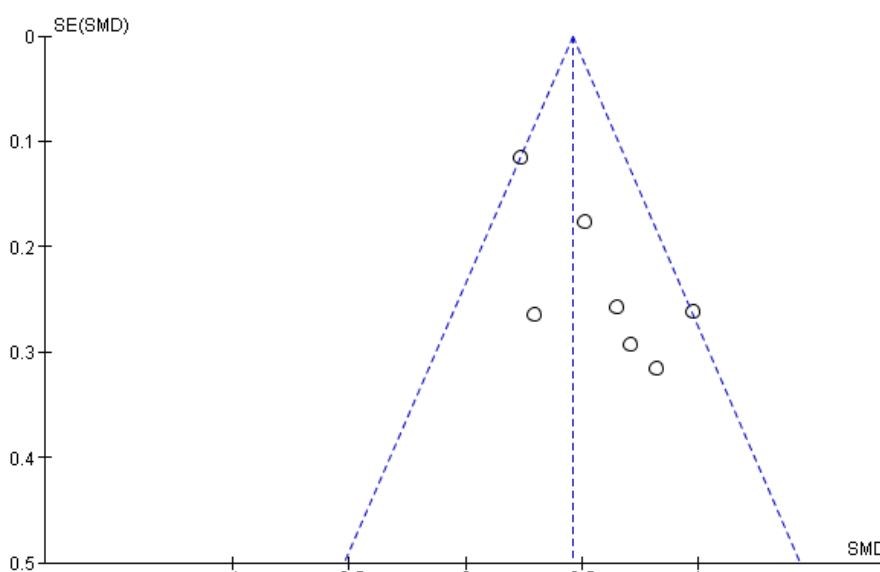


Figure 6. Funnel plot of meta-analysis of the effect of relaxation music therapy toward breast milk volume

DISCUSSION

Postpartum mothers often experience various conditions that make them uncomfortable, exhausted, stressed, anxious, and other conditions that make them psychologically disturbed hence it hinders oxytocin hormone stimulation and causes poor breast milk production, as a result, infants will have insufficient breast milk intake that encourages mothers to look for an alternative to formula milk which will interfere the breastfeeding process. Massage and relaxation music therapy will stimulate the brain to secrete oxytocin hormone which stimulates smooth muscles to contract and milk will flow toward the nipples.

The effect of massage on breast milk volume

Based on the results of the analysis of 7 primary studies on the effect of massage on the volume of breast milk included in systematic review and meta-analysis, it appeared the occurrence of high heterogeneity across the experiments ($I^2 = 76\%$; $p<0.001$) hence the analysis used a Random Effect Model. High heterogeneity was based on the occurrence of variations or diversity across the populations as seen from the different number of samples between the experimental group and the control group and the volume of breast milk that ranged differently.

The results of a meta-analysis of 7

primary studies related to the effect of massage on breast milk volume discovered that massage interventions increased breast milk volume higher than non-massage (SMD= 1.42; 95% CI= 0.98 to 1.86; $p < 0.001$). The 7 primary studies pointed to the significant value in the study of the effect of massage on the volume of breast milk. The significance value can be influenced by the number of samples between the intervention group and the control group which is nearly similar therefore the numbers of both proportions are relatively equal.

The results of this study are in line with a study conducted by Mahulette & Masini (2022) entitled "The Effectiveness of Oxytocin Massage with Breast Care Against Breast Milk Production in Post SC Mothers" with a population of postpartum mothers by SC of 44 respondents selected by random sampling. Oxytocin massage and breast care are administered to post-Sc mothers 2 times a day every morning and evening for 10 minutes. The intervention is carried out for 3 days and obtains significant results from the administration of oxytocin massage and breast care toward breast milk production.

One of the primary studies conducted by Chu et al. (2017) is reported in his article "The effect of breast massage at a different time in the early period after the cesarean section". The population used is 80 postpartum mothers by cesarean section randomly selected at a hospital in China's Shandong province, divided into four groups, with 20 patients each. The three groups obtain 3 breast massages every 24 hours starting from 2, 12, and 24 hours after cesarean section. The control group does not obtain breast massages. The result is administering massage starting from 2 hours after cesarean section is effective in improving the lactation status of maternity.

Breast massage provides various benefits in overcoming various conditions that

hinder the breastfeeding process such as breast swelling, breast pain, clogged ducts, and mastitis. A study conducted by Witt et al. (2016) "Therapeutic Breast Massage in Lactation for the Management of Engorgement, Plugged Ducts, and Mastitis" is performed on 42 mothers who experienced swelling, clogged ducts, and mastitis, evaluated within 12 weeks. The result is breast and nipple pain are significantly reduced with a mean= 3.90, SD= 2.40 in breast pain, mean= 2.10, SD=3 in nipple pain. The mastitis and clogged duct groups are significantly decreased after treatment ($P < 0.001$), and breast swelling is significantly decreased (mean=1.82, SD=1.6; $p < 0.010$).

Massage provides stimulation so that oxytocin hormones increases, provides the effect of relaxing tension, relieving stress, reducing discomfort, improving mood, and relaxing the body so that breast milk is well produced and easily comes out (Arisandi et al., 2022).

Massage provides rhythmic movements to the breasts, sensory information captured from the stimulation will be transmitted to the brain (Hanief et al., 2019), and the brain will deliver the information to the hypothalamus and prolactin-inhibiting hormone (PIH) cells. The hypothalamus will stimulate the posterior pituitary to secrete oxytocin hormone and the PIH cell will stimulate the anterior pituitary to release prolactin. If prolactin levels increase, breast milk production will increase. The oxytocin hormone secreted by the posterior pituitary will stimulate muscle cells to contract to secrete milk (Kania, 2018).

The effect of relaxation music therapy on breast milk volume

Analysis of 7 primary studies on the effect of massage on breast milk volume included in systematic review and meta-analysis showed low heterogeneity across the primary studies ($I^2 = 44\%$; $p < 0.001$) thus, the analysis used a

Fixed Effect Model (FEM). The intervention of relaxation music therapy was able to increase the volume of breast milk by 0.46 times compared to without relaxation music therapy (SMD= 0.46; 95% CI= 0.31 to 0.60; $p < 0.001$).

The result of this study is in line with a study conducted by Sowndarya et al. (2020) "Effect of Flute Music on Human Milk Production and Depression Among Lactating Mothers". The study is conducted using case-control method toward 60 postpartum mothers, 30 of them obtain musical interventions before breastfeeding and the other 30 without music. The intervention is performed during the first week of postpartum. The results show higher significance in the music group ($p < 0.001$) with mean= 31.30, SD=22.60 in the control group, and mean= 60.50, SD= 25.30 in the music group.

Another study conducted by Chawanpaiboon et al. (2021) "A Randomized Controlled Trial of the Effect of Music During Cesarean Sections and the Early Postpartum Period on Breastfeeding Rates" is conducted with a population of 555 pregnant women with a minimum gestational age of 37 weeks who will undergo a cesarean section. The results show that mothers who obtain musical intervention are better at breastfeeding with a duration of breastfeeding for 6 months is 39.7%, compared to the group without music intervention with a duration of breastfeeding is 6.2%.

A psychiatric study has indicated that relaxation therapy using music is effective in relieving anxiety and stress, encouraging the feeling of relaxation, and relieving depression. Relaxation music therapy helps overcome emotional problems by expressing feelings, changing the mood into a positive one, and helping to manage stress and anxiety (Larasati and Prihatanta, 2019).

When the sound produced by music enters the ear, it will generate an auditory

process. When the ear captures the sound wave, it can distinguish frequencies, then sends an information signal to the central nervous system, afterward it is delivered to the thalamus and flowed to the amygdala in the limbic system. The thalamus sends signals to the neo-cortex, while the amygdala sends signals to the hypothalamus (Hasanah et al., 2021). Relaxation signals and a feeling of calm from the effects of rhythm or musical sounds that reach the hypothalamus will stimulate the release of oxytocin hormone from the posterior pituitary gland (Sofiana, 2017).

The oxytocin hormone will stimulate muscle cells to contract to secrete milk. The contraction of these cells will express the produced milk out of the alveoli, flowing through the lactiferous ducts to the nipples (Mustika et al., 2018) . The secreting milk will empty the alveoli so that prolactin can enter and bind to receptors to produce milk (Wahyuni, 201).

The conclusion of the meta-analysis of the 14 randomized controlled trial studies in this study with 7 articles testing the effect of massage on breast milk volume and 7 other articles testing the effect of relaxation music therapy on breast milk volume, with sample populations originating from China, India, Indonesia, UK, Iran, Malaysia, Thailand, and Turkey indicates that both massage and relaxation music therapy interventions have positive effects on increasing breast milk volume. Massage increases breast milk volume by 1.42 times compared to no massage (SMD=1.42; 95% CI=0.98 to 1.86; $p < 0.001$) and relaxation music therapy increases breast milk volume by 0.46 times compared to no music relaxation (SMD= 0.46; 95% CI= 0.31 to 0.60; $p < 0.001$).

AUTHOR CONTRIBUTION

Sakinah was the major researcher who selected the topic, searched, collected, and

analyzed the study data. Eti Poncorini Pamungkasari and Hanung Prasetya were the supervisors in analyzing study data and preparing publications.

FUNDING AND SPONSORSHIP

This study is self-funded.

CONFLICT OF INTERESTS

There is no conflict of interest in this study.

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