

Comparison of the Effect of Milk Booster Drops and Acupressure on the Milk Volume of Mothers with Premature Infants: A Randomized Clinical Trial

Abstract

Background: Reducing the milk premature neonates receive threatens their lives and growth. Many studies have examined the effectiveness of milk booster drops and acupressure. This study aimed to compare the impact of milk booster drops and acupressure on milk volume in mothers with premature infants. **Materials and Methods:** This randomized clinical trial was performed in three Children's Specialized Hospitals of Mashhad, Iran, from June to November 2022. Fifty-four women with premature neonates were selected through convenience sampling and randomly assigned to milk booster ($n = 27$) and acupressure ($n = 27$) groups using permutation blocks. The milk booster group received 30 drops of milk booster drops three times and placebo point pressure for 2 weeks. The acupressure group also performed acupressure twice a day, for 10 min at points Stomach Meridian 16 (ST-16), PERICARDIUM-1 (PC-1), and Extra Point Head and Neck 3a (EX-HN3), and they also received placebo drops. The volume of milk expressed before the intervention on the 14 day of the intervention was measured using electric breast pumps. **Results:** There was no statistically significant difference in the volume of milk measured by mothers before the intervention in the two groups ($p = 0.699$). The mean (SD) of the mother's measured milk volume in the morning shift on the fourteenth day of the intervention in the milk-booster drop 31.85 (8.68) and acupressure group was 38.07 (9.38) cc ($p = 0.005$). **Conclusions:** Acupressure is more effective in increasing mothers' milk volume, so it is recommended that acupressure be taught to mothers in the neonatal intensive care units.

Keywords: Acupressure, intensive care units, milk, premature

Introduction

Breastfeeding is one of the policy priorities of most societies in the world. The World Health Organization recommends exclusive feeding with breast milk until the end of 6 months.^[1,2] Breast milk provides the best and most complete nourishment during the early months of birth. Nutrition is vital for the survival and growth of premature infants born before 37 weeks gestation.^[2] It is estimated that about 15 million premature infants are born in the world every year, but it is better to know that breast milk can prevent the death of 82,300 of these babies per year.^[3] A review conducted in 2020 revealed that Iran's exclusive breastfeeding rate up to six months was reported to be only 23.1%, falling significantly below the World Health Organization's (WHO's) recommended target. Despite the WHO's emphasis on exclusive breastfeeding for the

first 6 months and continued breastfeeding along with complementary feeding for up to 2 years, premature infants frequently experience reduced breastfeeding duration and exclusivity.^[4] One of the essential ways to reduce the mortality of these babies is exclusive breastfeeding. Exclusive breastfeeding in the first 6 months of life and continuing until one year of age can prevent the death of 1.3 million babies per year.^[5]

However, due to the hospitalization of premature infants in neonatal intensive care units, mothers often experience heightened exhaustion and stress, which can hinder the release of prolactin hormone and delay milk production.^[4] Consequently, breastfeeding initiation is typically delayed compared to mothers with full-term infants. Only 70% of mothers with premature infants between

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32 and 36 weeks and 63% with infants between 24 and 31 weeks-initiated breastfeeding within the first few hours after birth. This delay increases the risk of breastfeeding difficulties such as Growth failure, developmental delay, necrotizing enterocolitis, rapid hypoglycemia, late sepsis, and other life-threatening physical complications.^[6,7] Given that preterm newborns are susceptible to rapid drops in blood sugar levels, as well as conditions like necrotizing enterocolitis, respiratory distress, and aspiration, it becomes crucial to monitor the amount of milk these infants receive closely.^[6] Even a slight increase in breast milk intake during the first 14 days of life has reduced hospitalizations and the need for specialized treatments in premature infants throughout their first year.^[8]

A study reported that 43% of mothers seeking lactation counseling at the Mashhad clinic in 2022 had premature infants and were struggling with insufficient milk supply.^[9] In recent years, there has been a growing interest in using alternative and complementary approaches such as herbal remedies and acupressure to enhance milk production.^[8] Various medicinal plants have been identified for their potential to increase milk volume, including fenugreek, thistle, dill seed, fennel seed, Roman anise, black seed, five fingers, and garlic.^[10,11] One specific herbal combination called “Milk booster drops” contains a hydro-alcoholic extract of different plants, including 50% fennel extract, 20% cumin, 20% fenugreek, and 10% fennel extract. These plants are known for their phytoestrogen properties, which can stimulate milk secretion.^[12] One study found that after consuming fenugreek and fennel tea in the intervention group compared to the control group, there was a significant increase in the signs of breast milk sufficiency, including infant weight, head circumference, the number of wet diapers per day, the number of bowel movements, and the number of feeding times.^[13] The increase in milk production in mothers of infants with reduced milk production was not confirmed in a study conducted in Mashhad.^[14] It is worth noting that the American Academy of Medicine has not confirmed the efficacy of these herbs.^[15]

Another way to increase breast milk in premature babies is acupressure. Acupressure is a massage technique that originated in China and is used to maintain the body's balance and eliminate physiological disorders.^[16] A study reported that the acupressure at points Small Intestine1 (*SI1*), *ST18*, Conception Vessel17 (*CV17*), three times a day for 3 weeks, significantly increased in milk production in the acupressure group (70 Indonesian mothers) compared to the control group.^[17] Another study also reported that performing acupressure and back massage on 24 Indonesian primiparous mothers on the first day of delivery at three specific points by mothers was associated with an increase in milk volume.^[18]

As the importance of breastfeeding, especially premature babies, choosing the best method for breast milk production

is very important. Milk boosters are widely used in neonate intensive care units. However, numerous studies have evaluated the positive effectiveness of pressure on breast milk volume; therefore, the present study was conducted to compare the impact of Milk booster drops and acupressure on milk volume in mothers with premature infants.

Materials and Methods

This research is a randomized clinical trial (IRCT20220202053914N1) with a two-group, single-blind design. It was conducted on mothers with premature infants between 28 and 32 weeks, who were admitted to the special care department of one of the specialized hospitals affiliated with Mashhad University of Medical Sciences (Qaem, Imam Reza, and Akbar Children's Specialized Hospital) from June 2022 to November 2022. The inclusion criteria consisted of Gestational age between 28 and 32 weeks, Mother's desire to breastfeed, No smoking and drug use by the mother, Singleton pregnancy, Being on the third day after giving birth (at least 56 to at most 82 hours after giving birth), No history of severe and chronic disease or psychological diseases, Not using other treatment methods to increase milk supply, Absence of abnormalities in the baby, Oral-gastric or nasogastric feeding of the baby during 2 weeks of intervention. In the acupressure group, in addition to the above, Healthy skin in terms of acupressure, do not have a history of breast surgery, and No breast problems (congestion, mastitis, and breast abscess). Exclusion criteria included an Unwillingness to continue research, Hospitalization of the mother, taking drugs that affect breast milk (decreasing or increasing), Failure to perform acupressure at least one day or three times in a row, not consuming Milk booster drops at least one day or three times in a row. Based on the previous studies conducted by Ahmad *et al.* (2020) and Peila *et al.* (2015),^[19,20] and considering an average formula for two separate populations, a 5% error rate, and a test power of 90%, 25 participants were required in each group. Accounting for a potential attrition rate of 20%, the final sample size was determined to be 30 participants per group. The participants in this study were 60 breastfeeding mothers with premature infants, who met the inclusion criteria. They were placed in two groups through random allocation (quadruple permutation block). The samples were randomly assigned to either A or B groups using permuted blocks with a block size of four. In this method, all possible blocks of four (AABB, ABAB, ABBA, BBAA, BAAB, BABA) are listed (it should be noted that the assignment of the two groups is done randomly). Each permutation is assigned a number from 1 to 6, then the numbers 1 to 6 are randomly placed together. By writing the related permutations sequentially, the selection order in each of the two groups is determined. Then, to conceal the sequence allocation, they were recorded on small sheets of paper and placed in sealed envelopes. Based on the order

of arrival of the research units with the inclusion criteria, the envelopes were opened in order, and the assigned group was revealed. If the first block, for example, ABAB, were selected, the first person would be assigned to group A and the second person to group B, and this process continued until all samples were allocated. Thirty mothers were placed in the Milk booster drops group, and 30 people were placed in the acupressure group. Finally, in the Milk booster drops group, one person was excluded from the study due to the baby's death, one person due to unwillingness to continue the research, and one person did not use Milk booster drops for two consecutive days. In the acupressure group, one person was excluded from the study due to the use of Milk booster capsules along with the acupressure intervention, one due to the death of the baby, and one due to unwillingness to continue the study. Finally, data analysis was performed on 54 research units (27 people from the Milk booster drops group and 27 people from the acupressure group) [Figure 1].

Before the intervention, various tools were utilized to gather information. These included the demographic form, the DASS-21 self-report questionnaire, and the Casadi social support questionnaire. The demographic form comprised questions about mother and infant characteristics and consisted of two sections. The first section focused on the participants, such as age, income, perceived social support, amount of sleep, and mental perception of breast milk volume; In contrast, the second section gathered maternal obstetric information and infant characteristics, including history of premature birth, breastfeeding history, breastfeeding problems, birth weight, and infant's well-being. Participants completed this questionnaire one day prior to the intervention. The DASS-21 is a validated instrument used to measure adverse mental states, including depression, anxiety, and stress in adults. It consists of 21 items divided into three self-reported scales.

Each scale contains seven elements rated on a Likert scale from 0 to 3. Scores for depression, anxiety, and stress are calculated by summing the scores of the relevant items. As the DASS-21 is a shorter version of the original 42-item DASS, the subscale scores must be multiplied by two to obtain the final score. Based on the manual, the resulting scores are classified as "normal, mild, moderate, severe, or extremely severe."^[21] The validity of the Persian version of this tool was determined in Mashhad. The reliability of the DASS-21 has been confirmed with Cronbach's alpha coefficients of 0.79 for anxiety, 0.80 for stress, and 0.72 for depression.^[22,23] A reliability coefficient of 0.8 was also confirmed in this study. Participants completed this questionnaire one day prior to the intervention. The social support questionnaire comprises seven questions, with responses scored as yes (two points), not sure (1 point), or no (0 points). The total scores range from 0 to 14, indicating poor (0–4), moderate (5–9), or good (10–14) social support. The validity of this questionnaire has been confirmed in Iran, and its reliability was established with an alpha coefficient of 0.7.^[23,24] Throughout the research period, the scale and electric shower valve accuracy were regularly tested. Data collection occurred on the 3rd, 7th, and 14th days following birth. Participants completed this questionnaire one day prior to the intervention.

Following approval from the university ethics committee and registration of the clinical study, and after obtaining informed consent from eligible participants on the day before the intervention (the third day after birth), the researcher provided comprehensive breastfeeding education to all participating mothers in the department. This education covered topics such as proper breastfeeding techniques, appropriate nursing postures, recommended frequency and duration of breastfeeding, and effective milk expression methods. The infants' weights were then measured using a digital scale in the ward and recorded

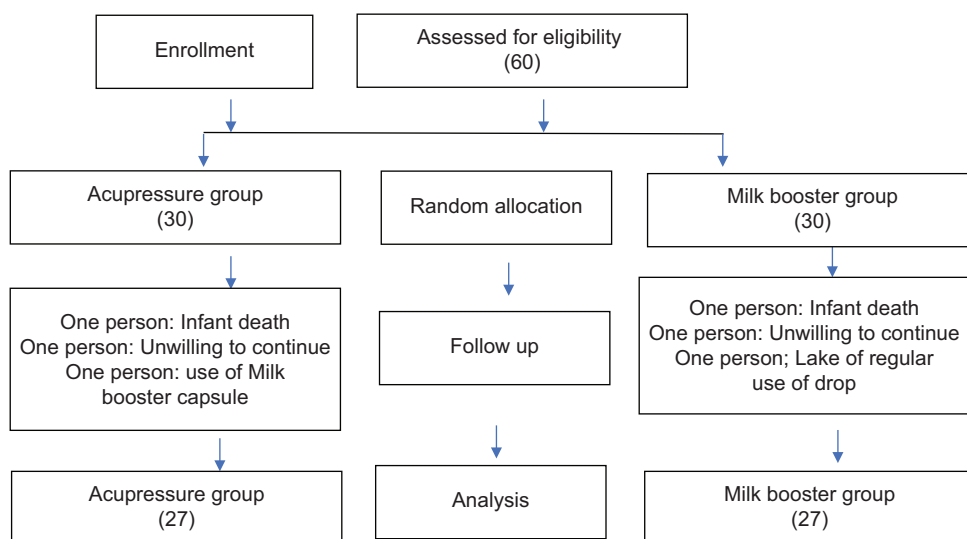


Figure 1: CONSORT flow chart of the study

in grams on the breastfeeding status evaluation form. To assess the volume of breast milk before the intervention, the researcher utilized an electric breast pump once in the morning shift in the mothers' resting room, 2 hours after their last milk expression. The pumping session lasted 15 min or until the last drop of milk was obtained, except for mothers, who did not produce any milk, for whom the procedure took 5 to 10 min. The amount of milk collected was documented on the breastfeeding evaluation form. The intervention commenced on the fourth day after childbirth. Mothers in the Milk booster drops group (with placebo point pressure) (Milk booster drops Chahargyaheh, manufactured by Goldaru Isfahan company) were instructed to take the medication three times a day after meals (breakfast, lunch, and dinner). They were advised to consume 30 drops mixed with half a glass of water each time for two weeks. Additionally, the researcher demonstrated the application of acupressure on specific areas and requested the mothers to perform acupressure sham and placebo points, namely Triple Warmer 14 (TW14) (located at the back of the shoulder joint), large Intestine 15 (LI15) (situated in front of the shoulder joint), and 24 (positioned in the midline of the front of the body, below the lower lip, in the mento labial groove). The mothers were instructed to apply acupressure twice daily, with a seven-hour interval between sessions, using their thumb pulp and exerting a pressure of three to four. Each session lasted 10 min, and this routine was followed for 2 weeks. To ensure proper pressure application, the mothers were advised to initially press their finger on the designated spot (using hypoallergenic glue) until they felt numbness, then reduce the pressure to a comfortable level, while applying pressure on the point. The researcher was present at the hospital every morning to address any questions from the mothers during the intervention and to evaluate their adherence to the intervention protocol. Additionally, the mothers received photographs of the acupressure points and instructions via internal messenger, and reminder SMS messages were sent every three days. On the seventh and 14th days of the intervention, the mothers visited the hospital in the morning, with a requirement to refrain from breastfeeding for 2 hours prior to the visit. An electric breast pump was used in the mothers' resting room to express the amount of breast milk secreted. The pumping session lasted for 15 min, or until the last drop of milk production, and for mothers who did not produce any milk, the process took 5 to 10 min. The researcher employed a 5 ml syringe to transfer the expressed milk from the graduated glass into customized milk storage bottles. The exact volume of milk, along with the baby's weight in grams and exclusive feeding status, was recorded in the relevant section of the breastfeeding status.

Acupressure group (acupressure with placebo drops): During the initial meeting on the third day following childbirth, the researcher provided instructions to mothers

in the acupressure group regarding the application of acupressure. They were advised to perform acupressure for 10 min twice daily, with a pressure of 3 to 4 kg, using the thumb pulp. The acupressure sessions were scheduled seven hours apart (at 8:00 and 15:00) and continued for 14 days. The designated pressure points included *ST-16* (located in the third intercostal space, parallel to the sternum and along the nipple), *ST-18* (situated in the fourth intercostal space, one thumb width lateral to the nipple), and *EX-HN3* (positioned between the eyebrows). Mothers were instructed to apply pressure to both the right and left sides of their bodies on the *ST-16* and *ST-18* points for 10 min, followed by an additional 2 min on the *EX-HN3* point between the brows. Additionally, participants in this group were requested to use placebo drops provided by the Goldaru Company, which were prepared to resemble and smell identical to Milk booster drops but lacked any beneficial components. Like the Milk booster drops group, mothers in this group received images of acupressure points and instructions via an internal messenger, accompanied by reminder text messages every 3 days. The researcher also ensured consistent attendance during the morning shift at the hospital to evaluate the optimal technique for performing acupressure. The researcher conducted milk volume measurements that mirrored the approach used in the milk booster drops group on the 7th and 14th days of the intervention. These measurements occurred 2 hours after the mother's last milking session, specifically during the morning shift. The researcher employed an electric breast pump to measure the volume of milk secreted over 15 min or until 1 min after the last drop of milk secretion (for instance, if milk secretion lasted 4 min, the pumping process continued until the fifth minute). In cases where mothers did not secrete any milk, this process was limited to 5 to 10 min. The data was analyzed using SPSS version 25, and a comparison between the two groups was conducted using the independent *t*-test and the Mann-Whitney test. In all cases, the hypotheses were two-sided, and statistical significance was determined by probability values less than 0.05.

Ethical consideration

The present study has an ethics code (IR.MUMS.NURSE.REC.1400.094) from the Ethics Committee of Mashhad University of Medical Sciences. All participants were briefed about the purpose of the research, confidentiality, and the right to withdraw from the study at any time without affecting their baby's treatment process. Written informed consent was obtained from all the study participants.

Results

The mean (SD) age of mothers in the Milk booster drops group was 29.67 (7.04) years, while in the acupressure group, it was 28.78 (7.13) ($p = 0.647$). Additionally, variables such as breastfeeding history, breastfeeding

problems, mental perception of milk volume, type of delivery, social support, and baby’s birth weight were similar in the Milk booster drops and acupressure groups, with no statistically significant differences [Table 1]. There were no statistically significant differences in breast milk volume between the two groups of participating mothers before and after the intervention on the seventh day. However, the mean (SD) of the mother’s measured milk volume in the morning shift on the fourteenth day of the intervention in the milk-booster drop was 31.85 (8.68) and 38.07 (9.38) cc in the acupressure group, the Mann-Whitney test revealed a statistically significant difference between the two groups regarding the volume of mother’s milk ($p = 0.005$) [Table 2].

Discussion

This is the first study to compare herbal galactagogues (Milk booster drop) with acupressure on breast milk volume in mothers with premature infants. Based on the current study’s findings, the milk volume in mothers in the acupressure group increased more than that in mothers using the milk-booster drops after 2 weeks. The Mann-Whitney test revealed a statistically significant difference between

the two groups regarding the volume of mother’s milk on the 14th day of the intervention ($p = 0.005$) [Table 2].

The results of a clinical study in Tehran indicate a 50% increase in milk volume in the acupressure group compared to the control group after 2 weeks. This study involved 60 mothers complaining of insufficient milk supply.^[25] In contrast, our study observed an increase of at least 20% (7mililitre in milk volume more than the Milk booster drops group). It should be noted that the infants in the Tehran study were full-term, and their control group did not receive milk boosters, but in the present study, one group received acupressure, and the other group used milk boosters. Milk booster drops in the present study and including mothers with premature infants born between 28–32 weeks gestation receiving oral-gastric or nasogastric feeding may explain this discrepancy. Sucking is a primary factor that stimulates breast milk production, and variables such as breastfeeding cessation and infants with low birth weight or preterm birth can reduce milk volume. Other factors that influence prolactin hormone release and milk secretion include the stress and fatigue experienced by mothers of preterm infants in the intensive care unit. Moreover, most mothers’ premature infants experience

Table 1: Comparison of demographic characteristics of the groups

Variable	Milk booster drops $n=27$	Acupressure $n=27$	Statistic	P
	M (SD) ^{s/n} (%) ^{ss}	M (SD) ^{s/n} (%) ^{ss}		
Mother’s age (years)	29.67 (7.04) ^s	28.78 (7.13) ^s	$t=52$	0.647*
A history of breastfeeding problems			$X^2=0.59$	0.704**
Yes	5 (18.51) ^{ss}	3 (11.11) ^{ss}		
No	22 (81.49) ^{ss}	24 (88.89) ^{ss}		
Mental perception of your milk’s volume			$X^2=1.97$	0.451**
Low	22 (81.51) ^{ss}	19 (70.37) ^{ss}		
Medium	5 (18.5) ^{ss}	6 (22.23) ^{ss}		
Much	0 (0.00) ^{ss}	2 (7.40) ^{ss}		
Average birth weight of infants (gram)	1437.96 (334.07) ^s	1428.15 (358.16) ^s		
History of breastfeeding			$X^2=0.07$	0.780**
Yes	17 (62.96) ^{ss}	16 (59.26) ^{ss}		
No	10 (37.04) ^{ss}	11 (40.74) ^{ss}		
Type of delivery				
Normal delivery	12 (44.45) ^{ss}	10 (37.03) ^{ss}		
Cesarean section	15 (55.55) ^{ss}	17 (62.97) ^{ss}		
Social support				
Poor (0–4)	0 (0.00) ^{ss}	2 (7.40) ^{ss}		
Middle (5–9)	5 (18.49) ^{ss}	6 (22.23) ^{ss}		
High (10–14)	22 (81.51) ^{ss}	19 (70.37) ^{ss}		

^sMean (Standard Deviation) ^{ss}Number (Percent) *Student’s t -test **chi-squared test

Table 2: Mean and standard deviation of milk volume the two groups before and after the intervention in the morning

Variable	Milk booster drops $n=27$	Acupressure $n=27$	Statistic	p
	M (SD)	M (SD)		
Before intervention (ml)	15.67 (8.97)	14.74 (8.41)	$t=0.38$	0.699*
The 7 th of intervention (ml)	23.89 (8.28)	27.00 (9.82)	$t=-1.25$	0.217**
14 th day of intervention (ml)	31.85 (8.68)	38.07 (9.38)	$z=0.78$	0.005**

*Student’s t -test ** Mann-Whitney test

delays in lactogenesis.^[26,27] Another potential factor contributing to the variation in effectiveness between these two studies is the difference in selected pressure points, which warrants further investigation.

Another study reported the effect of acupressure and relaxation on the milk volume of Indonesian primiparous mothers after 6 days. This study found that the acupressure group had a significantly higher breast milk volume on the seventh day than the control group. According to the researchers, acupressure and relaxation led to an average increase of 50% in milk volume for primiparous mothers.^[18] This variation in timing or amount of milk production could be attributed to factors such as infant prematurity, administration of placebo Milk booster drops, and differences in the selected pressure points between the two studies (large Intestine 14 CV17, Spleen 18, Spleen 6, ST36, ST18, ST16, ST15 were the selected points in our study). It is worth noting that in this study, acupressure was combined with relaxation techniques. While in our study, relaxation was not used.

In another study conducted in Indonesia, the increase in breast milk volume in the intervention group after 27 days and three times daily acupressure was reported to be greater than in the control group by 65%.^[17] It should be noted that the difference in duration of acupressure and the difference in age of the infants are the main differences that affect milk volume. Premature infants do not suck or have poor sucking, which significantly affects milk volume. Therefore, it is recommended that different pressure points for term and premature infants be compared in future studies. Furthermore, considering the mother's self-reported milk volume in the mentioned study could be influenced by the accuracy of the results. The results of our present study are considered highly accurate due to measurements taken with a graduated container of breast pump and the absence of breastfeeding in the infants.

Conclusion

Breastfeeding is vital for premature babies, so milk booster drops are widely used in intensive care units (NICU). Research findings show that acupressure is more effective in producing milk than milk booster drops in mothers with premature infants, and no side effects were reported from acupressure. Therefore, acupressure may be an effective and desirable method for milk production in the NICU, although more studies are recommended.

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Conflicts of interest

Nothing to declare.

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