REVIEW ARTICLE

REVISTA ENFERMAGEM ATUAL IN DERME

EFFECT OF FOOT REFLEXOLOGY ON LACTATION: PILOT STUDY OF A RANDOMIZED CLINICAL TRIAL

EFEITO DA REFLEXOLOGIA PODAL NA LACTAÇÃO: ESTUDO PILOTO DE UM ENSAIO CLÍNICO RANDOMIZADO

EFECTO DE LA REFLEXOLOGÍA PODAL EN LA LACTANCIA: ESTUDIO PILOTO DE UN ENSAYO CLÍNICO ALEATORIZADO

[1]Maria Bertilla Lutterbach Riker Branco
[2]Valdecyr Herdy Alves
[3]Diego Pereira Rodrigues
[4]Hugo Henrique Kegler dos Santos
[5]Karina Yuriko Yaginuma
[6]Audrey Vidal Pereira
[7]Bianca Dargam Gomes Vieira
[8]Andre Guayanaz Lauriano

[1]Nurse. PhD in Healthcare Sciences. Universidade Federal do Fluminense, Niterói/RJ, Brazil. E-mail: bertillariker@yahoo.com.br. ORCID: https://orcid.org/0000-0002-5117-644XX.
[2]Nurse. PhD in Nursing. Full Professor. Universidade Federal Fluminense, Niterói/RJ, Brazil. E-mail: herdyalves@yahoo.com.br. ORCID: https://orcid.org/0000-0001-8671-5063.
[3]Nurse. PhD in Healthcare Sciences. Adjunct Professor. Universidade Federal Fluminense, Niterói/RJ, Brazil. E-mail: diego.pereira.rodrigues@gmail.com. ORCID: https://orcid.org/0000-0001-8383-7663
[4]Bachelor's degree in Mathematics. PhD in Statistics. Adjunct Professor. Universidade Federal Fluminense, Niterói/RJ, Brazil. E-mail: santos.hk@ufrgs.br. ORCID: https://orcid.org/0000-0003-0350-2594
[5]Statistician. PhD in Statistics. Adjunct Professor. Universidade Federal Fluminense, Niterói/RJ, Brazil. E-mail: karinayuriko@id.uff.br. ORCID: https://orcid.org/0000-0001-5731-0841
[6]Nurse. PhD by Escola Nacional de Saúde Pública, FioCruz. Associate Professor. Universidade Federal Fluminense, Niterói/RJ, Brazil. Email: avpereira@id.uff.br. ORCID: https://orcid.org/0000-0002-6570-9016
[7]Nurse. PhD in Nursing. Adjunct Professor. Universidade Federal Fluminense, Niterói/RJ, Brazil. E-mail: dargam_bianca@id.uff.br. ORCID: https://orcid.org/0000-0002-0734-3685.
[8]Nurse. Master's degree in Nursing. Human Milk Bank at Antonio Pedro University Hospital, Fluminense Federal University, Niterói/RJ, Brazil. Email: andreguayanaz@gmail.com. ORCID: https://orcid.org/0009-0007-3466-3434

ABSTRACT
Objective: to assess the effect of foot reflexology for lactation stimulation on women/mothers with babies admitted to a Neonatal Intensive Care Unit according to the measurement of breast milk flow before and after the intervention, and to compare breast milk flow according to the intervention and control groups. **Method:** a pilot study of a Randomized Clinical Trial, using an intervention design with repeated measures between two groups: control and intervention. The study setting was two public hospitals and one private maternity hospital in Metropolitan Region II of the state of Rio de Janeiro**. Results:** sixteen women/mothers with babies admitted to a Neonatal Intensive Care Unit took part, and there were no differences in breast milk flow in the two groups. **Conclusion:** there were no statistically significant differences between the two groups, but foot reflexology for lactation stimulation has been shown to improve breast milk flow.
Keywords: Women; Breast Feeding; Complementary Therapies; Infant, Premature.

RESUMEN
Objetivo: evaluar el efecto de la reflexología podal para la estimulación de la lactancia en mujeres/madres con bebés ingresados en la Unidad de Cuidados Intensivos Neonatales según la medición del flujo de leche materna antes y después de la intervención, y comparar el flujo de leche materna según los grupos de intervención y control. **Método:** estudio piloto de un Ensayo Clínico Aleatorizado, utilizando un diseño de intervención de medidas repetidas entre dos grupos: control e intervención. El escenario del estudio fueron dos hospitales públicos y una maternidad privada de la Región Metropolitana II del estado de Rio de Janeiro. **Resultados:** participaron 16 mujeres/madres con bebés ingresados en la Unidad de Cuidados Intensivos Neonatales y no hubo diferencias en el flujo de leche materna en los dos grupos. **Conclusión:** no hubo diferencias estadísticamente significativas entre los dos grupos, pero se demostró que la reflexología podal para estimulación de la lactancia mejora el flujo de leche materna.
Palabras clave: Mujeres; Lactancia Materna; Terapias Complementarias; Recién Nacido Prematuro.

RESUMO
Objetivo: avaliar o efeito da reflexologia podal para estímulo de lactação em mulheres/mães com bebês internados em Unidade de Terapia Intensiva Neonatal de acordo com a mensuração da vazão do leite materno antes e depois da intervenção, e comparar a vazão do leite materno segundo os grupos de intervenção e controle. **Método:** estudo piloto de Ensaio Clínico Randomizado, utilizando-se um desenho de intervenções com medidas repetidas entre dois grupos: controle e intervenção. O cenário do estudo foram dois hospitais da rede pública e um hospital maternidade da rede privada da Região Metropolitana II do estado do Rio de Janeiro. **Resultados:** participaram 16 mulheres/mães com bebês internados em Unidade de Terapia Intensiva Neonatal, e não houve diferenças na vazão do leite materno nos dois grupos. **Conclusão:** não houve diferenças estatísticas significativas entre os dois grupos, porém a reflexologia podal para estímulo de lactação demonstrou dar indícios na melhora da vazão do leite materno.
Palavras-chave: Mulheres; Aleitamento Materno; Terapias Complementares; Recém-Nascido Prematuro.

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INTRODUCTION

Low human milk production is a phenomenon that occurs in many women/mothers of premature babies in the postpartum period[1]. Human milk is considered the gold standard food, especially for premature babies who depend on immune reinforcement to overcome the disorders of prematurity[2]. It is estimated that every year 340 thousand premature or low-weight Brazilian babies are born in the country, which corresponds to 12% of the total number of live births[3].

Although breastfeeding is one of the most important strategies in reducing neonatal and infant mortality, many women/mothers in the postnatal period notice a sharp decrease in human milk volume shortly after the lactation phase called lactogenesis II[4]. This phenomenon of low milk production is due to several factors, including the stressful experience of mother-baby separation, infant feeding methods that do not promote breastfeeding, maternal illnesses, altered behavior of women/mothers, insufficient healthcare professionals' knowledge and skills, and the need for logistical support for mothers to breastfeed[5].

While the need for adequate nutritional support for premature babies depends on the provision of breast milk, it is not always possible to meet this need. Improving breast milk production is a challenge faced by healthcare professionals, because not everyone is prepared to manage low human milk production, and even those who are prepared are not always able to overcome it. Integrative and Complementary Practices (ICPs) are a very effective alternative resource, as shown in some studies[6].

The ICP chosen for the development of this pilot study was foot reflexology (FR), which has studies shown to improve lactation in women/mothers in the postpartum period with low breast milk production[1,6-9]. FR is a practice that has principles that in the feet there is a microsystem with points that correspond to the entire system of organs in the human body, which, as they are stimulated or toned, respond and restore their functionality and balance[10].

Although there are a greater number of publications of studies regarding FR in health conditions other than breastfeeding, there are studies using different methodologies that demonstrate its benefits. One of them, an Indian researcher, identifies[9] studies that support improved lactation through FR application, in addition to clinical trials that indicate an improvement in postpartum conditions related to pain and breastfeeding conditions[6].

The study hypotheses were that FR has no effect on women/mothers of babies admitted to the Neonatal Intensive Care Unit (NICU) regarding breast milk flow; and auriculotherapy and FR have an effect on women/mothers of babies admitted to the NICU regarding breast milk flow.

Thus, this study aimed to assess the effect of FR to stimulate lactation in women/mothers with babies admitted to the NICU according to the measurement of breast milk flow rate before

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and after the intervention, and to compare breast milk flow rate according to the groups with confounding variables.

METHODS

This pilot randomized clinical trial assesses an intervention (FR for lactation stimulation) and its effects on breast milk flow rate in postpartum women who have not yet initiated breastfeeding. Two interventions were employed. The allocation ratio was 1:1 for FR group (FRG), with stimulation of specific points for lactation, representing the intervention group, and the control group (CG).

The study was developed in a municipality in the state of Rio de Janeiro, in three hospital units for maternal and child care and with a NICU, two of which were in the public sector of the Brazilian Health System, and one in the private sector, which made it possible to cover populations of different socioeconomic strata.

Research participants were recruited from the NICUs of these health units. Initially, 40 women/mothers agreed to participate in the study by signing the Informed Consent Form. They had their newborns admitted to the NICUs of these three hospitals. These participants could not have initiated breastfeeding; they were initially required to be on the 10th day or from the 10th to the 20th day postpartum; they could not have thromboembolic diseases; or have skin problems or anatomical alterations in the feet.

The study was developed with data collection over 12 consecutive days from the moment the participant entered the research. FRG underwent three interventions on alternate days, on the 3rd, 6th and 9th days, when FR was applied for stimulation and lactation, CG and FRG received a Medela manual breast pump and guidance on maintaining lactation with systematic milking at least six times a day. All participants completed diaries recording the number, duration, and volumes collected. At the end of data collection, participants returned and returned the diary and manual breast pump to the researcher. To form groups, each participant was randomly assigned their corresponding group number at the time they entered the study. Data collection took place between January 15, 2019, and February 17, 2020.

Sample size depends on the acceptable significance level, the power of the test, and the effect size. The significance level is defined as the probability of rejecting the null hypothesis because it is true[11]. Typically, values of 1%, 5%, or 10% are used. Test power is defined as the probability of rejecting the null hypothesis given that it is false, i.e., the probability of making the correct decision when the null hypothesis is false. Effect size is defined as the magnitude of the difference between the means of CG and the intervention group. The effect size is generally unknown and must be determined from previous studies or preliminary samples.

To calculate the sample size, we used a significance level of 5% and a power of 90%. To determine the effect size, we used the flow

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observations on the 5th day of collection as a preliminary sample, and observed an effect size of 1.61. Based on these values, the required sample size for each group (control and intervention) was 7.4 individuals.

The expected outcome was an increase in breast milk flow rate (volume/time) compared with the flow rate in the first 48 hours before the interventions began and the last 48 hours after the last intervention (on day 12). Participants were considered to be included in the study starting on day 10 postpartum, limited to day 20 postpartum (they entered the study up to day 14). The main intervention was FR to stimulate lactation in FRG. In CG, the expected outcome was milk flow rate maintenance in the first 48 hours compared with the last 48 hours.

RESULTS

Only 16 women/mothers managed to reach the end, while the others interrupted data collection for various reasons, including the death of a fetus and having started breastfeeding before the end of data collection.

Table 1 - Independent control variables. Niterói, RJ, Brazil, 2020

Age of study participants: age range from 18 to 25 years: two participated					
Age in years	18 to 25	26 to 30	31 to 35	36 to 40	41 to 43
Number of participants	2	2	5	5	2
Distribution of CG and FRG participants over time in terms of number of days postpartum when participants entered the research					
Number of days		10th	11th	13th	14th
Number of FRG participants		5	1	1	2
Number of CG participants		4	2	1	0
Distribution of CG and FRG participants according to self-reported skin color, declared marital status and level of education					
Color					
White		Black		Brown	
Total: 6 (37.5%)		Total: 7 (43.75%)		Total: 3 (18.75%)	
CG: 0 (0%) FRG: 2 (12.5%)		CG: 4 (25%) FRG: 4 (25%)		CG: 3 (18.75%) FRG: 3 (18.75%)	
Marital status					
Married			Single		
Total: 12 (75%)			Total: 4 (25%)		

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CG: 5 (31.25%) FRG: 5 (31.25%)	CG: 2 (12.5%) FRG: 4 (25%)

Teaching			
Incomplete elementary school	High school	Undergraduate degree	Graduate degree
Total: 1 (6.25%)	Total 8 (50%)	Total: 6 (37.5%)	Total: 1 (6.25%)
CG: 0 (0%) FRG: 2 (12.5%)	CG: 3 (18.75) FRG: 4 (25%)	CG: 3 (18.75%) FRG: 3 (18.75%)	CG: 1 (6.25%) FRG: 0 (0%)

Study participant family income			
Unit / Family income (minimum wage)	Maternity hospital Private (number of participants)	State general hospital (number of participants)	University hospital (number of participants)
0	1 (6.25%)		
1		2 (12.5%)	1 (6.25%)
2	1 (6.25%)	2 (12.5%)	1 (6.25%)
3			
6	1 (6.25%)		
7	1 (6.25%)		
9	1 (6.25%)		
10	2 (12.5%)		
16	1 (6.25%)		

NICU for baby admission		
State general hospital	Private maternity	University hospital
3 (18.17%)	10 (62.5%)	3 (18.17%)
CG: 1 (6.25%) FRG: 2 (12.5%)	CG: 5 (31.25%) FRG: 5 (31.25%)	CG: 1 (6.25%) FRG: 2 (12.5%)

Gestational age at birth	
Gestational age	Total
26 to 28 weeks	7
29 to 31 weeks	6
32 to 35 weeks	3

Legend: CG - control group; FRG - foot reflexology group; NICU - Neonatal Intensive Care Unit.

Table 2 shows that, on most days, the mean CG flow rate is higher than that of FRG. Considering the standard deviation, the opposite behavior is observed. It is worth noting that, on

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some days, there is a lack of flow records for some women/mothers, particularly on days 11 and 12.

Table 2 - Milk production statistics collected by participants over the 12 days of the study. Niterói, RJ, Brazil, 2020

Group	Flow rate	Minimum	1st quartile	Median	3rd quartile	Maximum	Mean	SD
FRG and CG	Total	6	103.8	190	303.8	1160	263.3	233.83
	Mean	0.039	1.159	2.016	3.478	11.176	2.388	1.655
FRG	Total	6	85	120	430	840	241.9	215.98
	Mean	0.039	0.625	1.478	3.836	11.176	2.230	1.971
CG	Total	35	155	208	252.5	1160	291	253.87
	Mean	0.950	1.824	2.211	3.052	6.500	2.593	1.098

Legend: CG - control group; FRG - foot reflexology group; SD - standard deviation.

Table 3 - Milk flow rate statistics collected by participants over the 12 days of the study. Niterói, RJ, Brazil, 2020

Group	Flow rate	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12
FRG	Mean	2.228	1.663	2.470	2.761	2.156	2.777	1.972	2.051	2.177	2.198	2.502	1.456
	Standard deviation	2.342	1.623	2.024	3.440	1.666	2.450	1.552	1.661	1.639	1.630	2.085	0.854
	Missing values	0	1	0	0	0	0	0	1	1	1	3	4
CG	Mean	2.321	2.871	2.857	2.889	2.782	2.663	2.616	2.313	2.769	2.252	2.118	2.294
	Standard deviation	0.759	1.376	1.289	1.750	1.085	0.895	1.126	1.155	0.971	1.277	0.623	0.374
	Missing values	0	0	0	0	0	0	0	1	1	1	2	3

Legend: CG - control group; FRG - foot reflexology group.

In Figure 1, which presents the boxplots of the flow rate variable for each day, it can be seen that there is greater data variation in FRG than in CG.

The procedures with the groups were based on the "Standard Care for Mothers with Babies Admitted to the NICU" standard care protocol, which states that basic guidelines for stimulating lactation by emptying the breasts should be performed at least six times a day. Women/mothers can collect milk following strict protocols for milk collection, storage, and transportation in a cold chain to the Human Milk Bank for donation or for consumption by a hospitalized child.

FRG underwent three FR interventions to stimulate lactation on days 3, 6, and 9 of data collection. The figure below highlights the discrepancy in the dispersion of milk volumes collected in FRG.

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Figure 1 - Day-by-day comparative boxplot. Niterói, RJ, Brazil, 2020

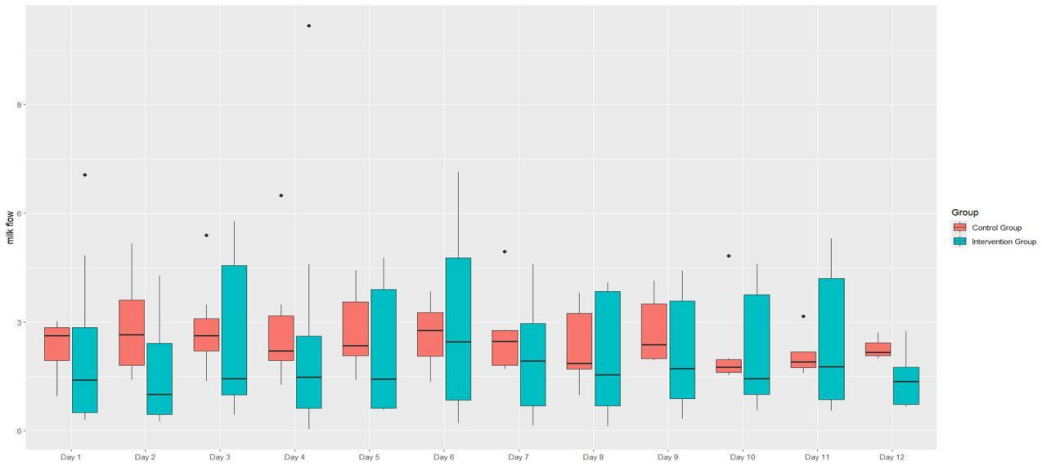

Table 4 - Difference between the mean daily flow rates. Niterói, RJ, Brazil, 2020

Day 1	Day 2	Day 3	Day 4
-0.093	-1.208	-0.387	-0.129
Day 5	Day 6	Day 7	Day 8
-0.626	0.114	-0.644	-0.261
Day 9	Day 10	Day 11	Day 12
-0.592	-0.054	0.384	-0.838

Observing the values found, it can be seen that, only on days 6 and 11, the mean value of the intervention group was higher than the mean value of CG.

To perform the hypothesis test, the days before the interventions were compared with the days after. For the pre-intervention days, we used days 1 and 2, and for the post-intervention days, we used days 5 (48 hours after the 1st intervention), 8 (48 hours after the 2nd intervention), and 11 (48 hours after the 3rd intervention) of FRG.

Due to the verification of the normality of the observations through the Shapiro-Wilk test with 5% significance, paired t-test was used to compare the pre-intervention mean flow and the post-intervention mean flow.

Table 5 - Tests of means within the foot reflexology group (intervention). Niterói, RJ, Brazil, 2020

Group	**Variables**	**p-value**	**Result**
Intervention	Days 2 and 11	<0.01	Different means

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Intervention	Days 1 and 11	0.03228	Different means at the 5% level
Intervention	Days 2 and 5	0.03856	Different means at the 5% level
Intervention	Days 2 and 8	0.0903	Equal means
Intervention	Days 1 and 5	0.1720	Equal means
Intervention	Days 1 and 8	0.2039	Equal means

Table 4 shows that, at a significance level of 5%, there was a significant difference between pre- and post-intervention on the 5th and 11th days. On the 8th day, no evidence of a difference between the means was found.

The same assessment was performed on CG. The tests showed that there was no significant change in the mean flow rate over time. Table 5 presents the results of paired t-tests.

Table 6 - Test results within the control group. Niterói, RJ, Brazil, 2020

Group	**Variables**	**p-value**	**Result**
Control	Days 2 and 11	0.8086	Equal means
Control	Dia 1 and11	0.9722	Equal means
Control	Days 2 and 5	0.7700	Equal means
Control	Days 1 and 5	0.1805	Equal means
Control	Days 2 and 8	0.5353	Equal means
Control	Days 1 and 8	0.8681	Equal means

Table 6 presents the results of the tests performed to compare the mean FRG flow rate and the mean CG flow rate for each of the first 11 days. Day 12 was disregarded due to the high number of missing values.

The hypothesis test applied was t-test for the means of two independent populations with different variances. For all days, the results show no significant differences between the FRG and CG means.

Table 7 - Mean tests between the control and foot reflexology groups. Niterói, RJ, Brazil, 2020

Day	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
p-value	0.913	0.143	0.649	0.924	0.380	0.900	0.352	0.735	0.416	0.946	0.683

DISCUSSION

We worked with women/mothers who did not initiate breastfeeding between 22 and 26 days postpartum. Therefore, physiologically, milk production in these women was somewhat reduced compared to the peak production, in the lactogenesis phase II, which begins between 30 and 40 hours after delivery[4].

The profile of the 16 study participants is similar to that of the 60% who dropped out. One of the reasons for discontinuing data collection can be identified as family income, where

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discrepancies between the public and private sectors are evident in the survey's adherence and completion criteria.

Added to this is the parental stress caused by children's hospitalization in the NICU, which is one of the many reasons that make it difficult to effectively form a bond with children, a fact observed when babies are more premature, have low weight and are in a more serious condition[13].

Still within the lack of follow-up of this research, all participants had their children with a gestational age of less than 35 weeks, with the majority at 30 weeks (Table 1). This had a direct influence on all levels of breast milk production, given both the physiological conditions of premature births and the stressful conditions these women/mothers experienced.

Furthermore, it was identified that the perception of insufficient breast milk by nursing mothers, the stress of their children's hospitalization in a NICU, the time of data collection and economic factors were indicative of weaknesses for the follow-up in the study, highlighting, mainly, the social vulnerability, which permeated the population of women/mothers.

Breast milk flow goes beyond its production. It is conditioned by several indicators, and is associated with economic and environmental factors, such as the type of support received by the nursing mother, stress, coexistence with the baby's father, educational level, gestational age at birth, and ethnicity[14], as well as physiological and emotional conditions, which affect its flow, facilitating or inhibiting lactation.

Based on these guidelines, the support provided by state and private maternal and child care units proved ineffective in preparing these women for lactation maintenance. Among the challenges presented was the restriction on their operation, which should encourage women/mothers to collect samples at defined times and freely, 24 hours a day[15]. Free access for women/mothers to spaces reserved for the collection and storage of breast milk should also support and promote breastfeeding, which benefits from improving breast milk flow in these women.

Internal stressors in breastfeeding include: women's adverse perception; inadequate biological conditions of women and children; body image; and the conflicting maternal role. External stressors include: inadequate space; absent or ineffective organizational systems for protection, promotion, and support; and family and social authority opposed to breastfeeding[16].

The support of children's hospitalization institution is essential to improve women's lactation conditions and milk flow, which lasts for a long time and requires professional care and support to maintain it[14-15]. In addition to these actions, others can promote the well-being of these women, such as FR, an intervention that begins with the goal of relaxing users and then develops specific stimuli that the intervention aims to achieve. Thus, maternal and child health

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units are jointly responsible for maintaining lactation and milk flow for women/mothers of premature babies who are temporarily unable to breastfeed.

Participants' ages ranged from 18 to 43 years old; 64.5% of the entire sample presented were between 31 and 40 years old; and only one participant was under 20 years old, which represents 6.25% (Table 1). Considering the age factor, 50% of participants were considered at obstetric risk.

The predominant gestational age at birth was less than 30 weeks, with a range from 26 to 35 weeks (Table 1). Regarding preterm birth conditions, between 22 and 34 weeks, mammogenesis may or may not be sufficiently complete for full lactation. Furthermore, placental lactogenic hormone influences mammary gland development. For women, premature termination of pregnancy does not contribute to full lactation and physiological flow conditions[4].

Preterm births are well-recognized as a high-risk factor for fetal hospitalization in a NICU and a higher chance of delayed initiation of breastfeeding[17]. Furthermore, mothers of premature babies face unique challenges arising from the prematurity situation, in addition to the stress inherent in an event involving an uncertain outcome[14]. These factors do not contribute to the practice of breastfeeding, as they are affected by the time that, the longer it takes to start, the lower the chances of success, making the conditions for milk production and breast milk flow even more difficult[17]. It is important to note that the baby's sucking on the mother's breast (breastfeeding) is the best stimulus for the production and breast milk flow, as it contains all the forms of neuronal stimuli necessary for the release of milk-producing and -excreting hormones.

The age of the women/mothers did not appear to influence lactation. However, in births with gestational ages below 35 weeks, there were repercussions on lactation conditions and milk flow rate, due to the lactation physiology of mothers of premature infants. FR developed in this study addressed the challenge of late lactation and lack of stimuli for milk production, proving to be a strategy to improve lactation conditions and milk flow rate in women/mothers unable to breastfeed.

Less than half of the sample of participants who had a cesarean section (68%) represented the total number of vaginal deliveries (32%). The cesarean rate in the public sector was 25% in this study, while in the private sector, it was 90%.

Different types of delivery affect lactation, as various factors, such as hormonal surges at the end of labor and the use of medications during labor, such as anesthetics and blood loss, can delay the second stage of lactogenesis[4,17].

Cesarean sections or forceps deliveries are recognized as factors that contribute to delayed lactogenesis II, in addition to the use of anesthetic medications during the surgical

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procedure. Another correlated finding is the delayed initiation of breastfeeding after the newborn's first 24 hours of life. Being separated from the baby soon after birth due to admission to the NICU, among other factors such as postpartum pain, makes it difficult for the mother to care for her child, and there are pathological conditions that require significant blood loss during delivery. All of these factors compromise breast milk flow[17].

Another important factor for the increase in breast milk flow is the safety conditions regarding the treatment of hospitalized children, ease of access to the hospitalization unit, practices promoted by the institution to maintain lactation, encouragement of parental visits, and a serene and easy-to-communicate environment[17-18].

Premature birth, whether eutocic or dystocic, has implications for breast milk flow. Delivery conditions, obstetric risks, and the separation of mother and child after birth due to hospitalization in a NICU are aggravating factors that will affect lactation and breast milk flow.

FR is a way to minimize the deleterious effects of late lactation through an intervention that promotes both relaxation and stimulation of lactation in women/mothers unable to breastfeed.

Studies using similar methodologies and the use of FR to assess lactation conditions in women show a variety of intervention techniques and varying interval times between applications, as there is no consensus on the minimum and maximum intervals between applications. These intervals range from a minimum of eight hours between applications for three days to a maximum of 48 hours for seven days[19-23].

FR applications can be spaced at varying times, and responses can last up to weeks after a single application. The more severe and chronic the cases, the greater the number of interventions required to achieve a cure or balance[24].

In this study, the time between interventions was 48 hours, similar to the maximum interval time between interventions in other studies. Here, the first intervention occurred 48 hours after the participant's inclusion in the study, as the study aimed to assess breast milk flow rate before and after FR to stimulate lactation, supporting its validity as a strategy for improving breast milk flow rate. Thus, the records of collection volumes and times were the data, recorded in the participant's diary, necessary for assessing flow rate before the first intervention. Just like the records of breast milk collected by the participants over 12 days and three interventions, it was possible to assess that there were positive effects on breast milk flow rate.

The results were analyzed up to the 11th day, as 48 hours after the last intervention (9th day) were considered the "after" assessment period. On the 12th day, the participant continued recording the collections until the time the research material was delivered. These final recordings served to continue stimulating lactation in these women after the research was completed.

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Initially, the milk volume collected in CG was higher. However, it showed a tendency to decrease over time, even considering the stimulation of breast emptying. Despite the volume fluctuations within this group, CG was expected to have a behavior of constant milk volumes over time, since breast emptying would be sufficient to maintain lactation. This data can be seen more clearly in the last three days of Figure 1, where the statistical test of CG's breast milk flow rate showed no differences from the means when comparing the 1st, 2nd, 5th, 8th, and 11th days, as shown in Table 5. Considering this result, it is understood that CG maintained lactation through the stimulation of breast emptying without showing an increase in breast milk flow rate. When comparing the same days that FRG mean flow tests were performed in CG, it can be seen that the means were the same on the days before and after in this group.

The milk production collected indicates differences between the two groups. Initially, regarding the values in the first quartile, representing the first 25% of values in ascending order, CG obtained a value equivalent to twice that of FRG. The first 50% of the values are represented by the median, resulting in a slightly smaller difference when comparing the two groups. However, CG still maintained its superiority over FRG. In the third quartile, representing 75% of the values, the difference between the groups reverses, indicating that CG value represents 58% of FRG volume. FRG expresses having higher mean flow rates, but these values are dispersed in the figure.

When observing Figure 1 of the mean breast milk flow rate of the two groups, a different behavior of FRG is observed, evidencing greater dispersion of milk volumes.

When comparing the mean breast milk flow rate within the groups, FRG showed statistically significant differences on the compared days (1st and 11th, 2nd and 11th, 2nd and 5th), considering a significance level of 5%, as shown in Table 14. Furthermore, on the 6th and 11th days of collection, when compared with CG and FRG groups, the means were positive for FRG, demonstrating the effects of the interventions. This indicates an improvement in breast milk flow rate in FRG participants, reaffirming that FR with lactation stimulation has an effect.

It is important to emphasize that these women/mothers are experiencing situations of extreme emotions, as their child may be progressing well, but at any moment their clinical condition can change.

Feelings such as anxiety, anguish, fear, helplessness, the desire to escape, the need to be with their child, and the need to care for them are unique coping reactions for each parent of a premature baby, as they permeate each parent's life story, the meaning of the baby in their lives, and personal and family plans[25]. Due to this vulnerability, emotional conditions play a significant role in breast milk flow rate performance, which contributes, in addition to

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FR intervention itself, to fluctuations in breast milk flow rate discrepancies.

Observing Figure 1, it can be stated that FR led to improved flow rate, even though the difference in the mean flow rates of human milk collected from the two study groups did not show a statistically significant difference.

This pilot study concluded that FR to stimulate lactation applied to mothers of premature infants born at less than 35 weeks' gestation who did not initiate breastfeeding until day 26 postpartum influenced breast milk flow rate when compared to mean pre- and post-intervention flow rates.

FR provided study participants with evidence of improved milk flow rate and milk production, which can be considered an incentive for breastfeeding.

In addition to clinical proof of its influence on lactation, it brings a broader scope to women's healthcare in the postpartum period and, more than that, in conditions of physical and emotional vulnerability due to hospitalization and the risks to children who cannot be breastfed.

In this way, FR has presented itself as a technology in nursing care to support the success of lactation in women/mothers, expressed in breast milk flow.

FINAL CONSIDERATIONS

Considering all the values presented, FR gives strong indications of positively influencing the lactation of women/mothers who did not start breastfeeding until the 26th day postpartum.

The intervention protocol developed and implemented in the study was able to stimulate milk production in women. Strategies like this can benefit women with low milk production by improving milk flow rates, encouraging longer breastfeeding in premature babies, reducing infant morbidity and mortality, and improving the lives of everyone involved in maternal and child healthcare.

Here, we highlighted suggestions for future research using the same method design, but with a larger number of interventions and samples. Furthermore, multicenter research would favor a profile more closely related to our population, effectively supporting this practice as an alternative for improving breast milk flow in women/mothers with compromised lactation.

This pilot study was limited in the number of samples, but it is suggested that, in the future, new research can be developed, with a greater number of interventions and larger samples, in different scenarios of our society for better assessment and verification of all the evidence presented.

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Authorship Contributions

Author 1 - Maria Bertilla Lutterbach Riker Branco Contributions: Study conception and design, data analysis and interpretation, final review with critical input on the manuscript.

Author 2 - Valdecyr Herdy Alves Contributions: Study conception and design, data analysis and interpretation, final review with critical input on the manuscript.

Author 3 - Diego Pereira Rodrigues Contributions: Study conception and design, data analysis and interpretation, final review with critical input on the manuscript.

Author 4 - Hugo Henrique Kegler dos Santos Contributions: Study conception and design, final review with critical input on the manuscript, and intellectual input on the manuscript.

Author 5 - Karina Yuriko Yaginuma Contributions: Final review with critical input on the manuscript and intellectual input on the manuscript.

Author 6 - Audrey Vidal Pereira Contributions: Study conception and design, and data analysis and interpretation.

Author 7 - Bianca Dargam Gomes Vieira Contributions: Final review with critical input and intellectual analysis of the manuscript.

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Declaration of Conflict of Interest
Nothing to declare.

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Orcid: https://orcid.org/0000-0003-0778-1447