

A randomized interventional study to promote milk secretion during mother–baby separation based on the health belief model

A consort compliant

Yi Liu, MD^{a,c}, Jianrong Yao, BD^{a,c}, Xinghui Liu, PhD^{a,c}, Biru Luo, PhD^{b,c,*}, Xiufang Zhao, PhD^{b,c,*}

Abstract

Background Breast milk is the most important nutrition for premature babies, but mothers of premature infants have difficulty in initiating and sustaining lactation. Breastfeeding infants who are separated with mothers have decreased morbidity. Nevertheless, such decrease is limited due to insufficient milk supply resulting from mother–baby separation during lac.

Objective To evaluate the effect of intervention methods based on the health belief model on promoting the secretion of milk among mothers who were separated with their babies.

Methods In this prospective, randomized controlled clinical trial, we enrolled 260 separation mothers between September 26, 2016 and March 7, 2017, in a 3rd-grade women and children hospital of Chengdu. The mothers all had cesarean delivery and were randomized into 2 groups: the intervention group (educated by investigators based on the health belief) and the control group (routinely educated by obstetric nurses). Data on the onset of lactation and the milk volume during 3 days postpartum were collected. The breast swelling rate within 3 days postpartum and the exclusive breastfeeding rate at 42 days postpartum were compared. The psychologic scores of separation maternal in both groups were assessed with State-Trait Anxiety Inventory at the 3rd day postpartum.

Results Compared with the control group, the intervention group had significantly earlier lactation time ($P < .01$), significantly larger milk volume ($P < .01$) during 24, 24 to 48, and 48 to 72 hours, and significantly lower psychologic scores ($P < .01$) at the 3rd-day postpartum.

The onset of lactation among mothers who initiated milk expression within 1 hour after childbirth were earlier than those who initiated milk expression between 1 and 6 hours ($P < .01$); the milk volume within 24-hour postpartum did not differ significantly between the 2 groups ($P > .05$). However, the milk volume of the early-expression group (<1 hour) was significantly higher than that of the late-expression group (1–6 hours) during 24 to 48 and 48 to 72 hours ($P < .05$).

The breast swelling rate of separation mothers within 3 days postpartum in the intervention group was lower than that in the control group ($P < .05$). The exclusive breastfeeding rate of mothers in the intervention group was significantly higher than that in the control group (59% vs 35%; $P < .01$) at 42 days postpartum.

Conclusion Nursing intervention based on the health belief model can stimulate milk secretion in mothers who were separated with their babies.

Abbreviations: 95% CI = 95% confidence interval, HBM = health belief model, NEC = necrotizing enterocolitis, NICU = neonatal intensive care unit, RCT = randomized controlled trial.

Keywords: lactation, maternal, milk expression, mother–baby separation, nursing intervention

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YL and BL contributed equally to this work.

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^a Department of Obstetrics, ^b Department of Nursing, West China Second University Hospital, Sichuan University, ^c Key Laboratory of Birth Defects and Related Diseases of Women and Children [Sichuan University], Ministry of Education, China.

* Correspondence: Biru Luo, No 20, Section 3, Renmin Nanlu, Chengdu, Sichuan 610041, China (e-mail: 284270778@qq.com).

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1. Introduction

Newborns are sent to Neonatal Intensive Care Unit (NICU) and separated with mothers due to various reasons, such as premature birth, low birth weight, infection, asphyxia, hypoglycemia, jaundice, and other high risk factors.^[1–4] Establishing milk supply among mothers who were separated with baby early after childbirth is challenging and crucial,^[5] and the provision of human milk is an important component of the premature infant care plan.^[6] Because the infants' gastrointestinal and immunologic systems are immature, breast milk is vital to them in that it contains immunoglobulins, nucleotides, hormones, and bioactive peptides and can thus provide numerous nutrients and vast benefits to the infants.^[7] Such benefits include a decreased incidence of necrotizing enterocolitis (NEC), feeding intolerance, and late-onset sepsis,^[7–9] as well as improved neurodevelopmental outcomes and decreased length of hospital stay.^[10] For mothers, the absence of breastfeeding is associated with increased

risks of breast cancer, ovarian cancer, diabetes, hypertension, and myocardial infarction.^[11,12] However, the separation mothers are more likely to struggle with the initiation and maintenance of a sufficient breast milk secretion than those mothers whose babies stay with them,^[9] with a high risk of breastfeeding failure.^[13] An insufficient breast milk secretion is one of the major barriers that compromise breastfeeding in infants who were separated with mothers. It is recommended that breast milk expression should be initiated within 6 hours after childbirth, 8 to 12 times per day.^[14]

As a matter of fact, however, numerous separation mothers are struggling with delayed lactogenesis II and inadequate milk volumes; but previous studies were mainly focused on maternal health education, breast care and psychologic intervention during mother–baby separation with small sample size and inadequate theoretical basis. To address these issues, we conducted a randomized controlled trial (RCT) study to determine the effects of education and support intervention on lactation outcomes among mothers who were separated with their babies. Intervention study was based on the health belief model (HBM).

The HBM was proposed by Hochbaum firstly in 1958. It emphasized that health cognition plays a key role in behavior change of individuals, by helping individuals aware of the current factors that affect health could enhance their health beliefs, and take the appropriate health behavior ultimately.^[15]

2. Patients and methods

A RCT was carried out in a third-grade women and children hospital of Chengdu between September 26, 2016 and March 7, 2017. Ethical approval was granted by the Institutional Review Board of West China Second University Hospital, Sichuan University, and written informed consent was obtained before enrollment of the participants into the study.

2.1. Sample size estimation

Using the formula of group comparison, the sample size was estimated according to the milk volume of separation mothers in the study performed by Luo et al.^[16] Given an α -error of 5% and power of 80%, a sample size of 130 was required in each group. Given the attrition rate of 10%, 286 mothers had to be included in the study, who were divided into 2 equal groups of 143 patients each. Finally, a total of 260 separation mothers completed follow-up, 130 cases in each group (Flow Diagram).

2.2. Participants

About 260 mothers who had gone through cesarean delivery and aged 18 years or above were eligible and were randomized into the intervention group and the control group. The mothers with following situations would be excluded: infants were dead; had sexually transmitted diseases such as human immunodeficiency virus and syphilis; had a history of breast surgery, breast disease, seriously sunken nipple; were too ill to express milk (such as severe postpartum hemorrhage, etc.) or suffering from mental illness which made it difficult for them to cooperate with the researchers; and used drugs that affect lactation (such as some specific antibiotics, sedatives, diuretics) during pregnancy or puerperium.

2.3. Randomization

Randomization was conducted using the computer-generated random sequence number. Each separation mother was assigned to one of the 2 groups. Allocation conducted with opaque sealed

envelopes, and we used parallel study design with allocation ratio 1:1. The nurses, the separation mothers and family members were blinded to the group assignment but the investigators were not. Our RCT was registered in the Chinese Cochrane Centre.

2.4. Intervention

The control group was routinely educated by obstetric nurses while the intervention group was educated by the investigators based on the results of investigation and HBM. In our previous investigation study, multiple linear regression results suggested that the mode of delivery, 1st time nipple stimulation, milking times during 24 hours and mother's daily diet were the independent influencing factors of milk secretion during mother–baby separation. Therefore, in the intervention group, all participants were given a health education handbook developed according to the HBM. The mothers were encouraged to begin the 1st expression within 1 hour after cesarean delivery; however, the initiation of milk expression depended on mothers' condition, which means that the milk expression could only be done when the mothers felt comfortable with doing it. Before the onset of lactation, all participants in both groups expressed breast milk exclusively by hand, and their milking times are fewer than 3 per day. Then, the participants were asked to switch to double pumping with a hospital-grade electric breast pump (Medela, Inc, McHenry, IL). Participants were instructed to use the breast pump and advised to express milk for 20 to 30 minutes every 2 to 3 hours and to maintain 8 to 12 times per day. Data were documented with regard to the frequency, time, and method of milk expression. Milk volume from each expression was measured by using digital containers (± 1 mL), and when the milk amount was less than 1 mL, a sterile syringe was used to measure the volume accurately. Milk amount was measured daily for the first 3 days, the 24-hour milk volume was measured by adding up the volumes of each expression (Table 1)

Finally, the psychologic scores of separation maternal in both groups were assessed with State-Trait Anxiety Inventory. STAI is a self-assessment scale, which is suitable for group investigation. The reliability structural validity test of the scale showed that the correlation coefficient S-AI of the test–retest score is 0.88 and the T-AI is 0.90. The correlation coefficient between S-AI and T-AI score is 0.84 in the initial test and 0.77 in the retest.^[17] It was implemented by hand out the State-Trait Anxiety questionnaire to mothers in both groups on the third day after childbirth.

2.5. Statistical analysis

All obtained data were entered into the Epidata software by double entry. Descriptive analyses were performed using SPSS version 21.0 software (IBM, Armonk, NY). Univariate comparisons of independent data were performed with Student *t* or the Mann–Whitney *U* test for continuous variables and the Chi-squared or Fisher exact test for categorical variables. $P < .05$ was considered statistically significant.

3. Results

3.1. Sample characteristics

Characteristics of mothers are summarized (Table 2). The 2 groups did not differ in maternal age, education, occupation, family per monthly income, maternal history, gestational age, or pregnancy complications ($P > .05$). The HBM is showed in Figure 1.

Table 1**Multivariate analysis of factors associated with milk volume in separation mother.**

Factors	Beta		Wald	T	P	95% CI	
	B	SE				Lower	Upper
Constant	-0.263	91.179		-0.003	.998	-180.676	180.150
Dietary status	-23.000	11.339	-0.157	-2.028	.041	-45.429	-0.571
Milking times in 24h	36.115	16.707	0.207	2.162	.033	3.057	69.173
Milking method	-0.796	6.410	-0.011	-0.124	.901	-13.479	11.887
Hot compress	10.426	11.298	0.071	0.923	.358	-11.928	32.780
Massage	5.340	11.555	0.033	0.462	.645	-17.523	28.203
First time of nipple stimulation	-21.466	11.742	-0.147	-1.828	.049	-44.700	1.767
Nipple type	3.271	11.382	0.020	0.287	.774	-19.250	25.792
Confidence in breastfeeding	-7.247	11.086	-0.048	-0.654	.514	-29.182	14.688
Tolerance of pain	-3.799	10.168	-0.037	-0.374	.709	-23.918	16.320
State score	-0.126	1.248	-0.011	-0.101	.920	-2.595	2.343
Trait score	1.629	1.819	0.073	0.896	.372	-1.970	5.228
Rest time in 24h	14.357	9.270	0.126	1.549	.124	-3.984	32.699
Take souping	-14.772	11.518	-0.099	-1.282	.202	-37.563	8.019
Delivery	37.529	13.831	0.228	2.713	.008	10.163	64.896
Each milking time	10.851	8.906	0.101	1.218	.225	-6.771	28.472
Milking time at night	12.918	12.137	0.088	1.064	.289	-11.096	36.933
Acquire degree of knowledge	-1.292	11.287	-0.009	-0.114	.909	-23.626	21.041

3.2. Comparison of lactation time within 3 days postpartum, milk volume, and psychologic state between 2 groups

Compared with the control group, the intervention group had significantly earlier lactation time ($P < .01$) and significantly higher milk volume during 24, 24 to 48, and 48 to 72 hours ($P < .01$). The psychologic scores of the intervention group were significantly lower than that of the control group ($P < .01$) in 3 days postpartum (Tables 3 and 4).

3.3. Comparison of lactation time, milk volume within 3 days postpartum between the early milk expression group (<1 hour) and late milk expression group (1–6 hours) in intervention group

The onset of lactation among mothers who initiated milk expression within 1 hour after birth was earlier than the mothers who did it between 1 and 6 hours ($P < .01$); the milk volume in 24 hours of postpartum did not differ significantly between these 2

Table 2**Comparison of social demographic data of 2 groups.**

Variables	Total number	Intervention group		Control group		χ^2	P
		Number	%	Number	%		
Age, y							
18–34	215	106	40.8	109	41.9	0.242	.623
≥35	45	24	9.2	21	8.1		
Educational level						1.210	.750
Junior high	4	1	0.4	3	1.2		
Senior high	27	13	5.0	14	5.4		
College	91	45	17.3	46	17.7		
University	138	71	27.3	67	25.8		
Profession						2.102	.906
Technical	30	15	5.8	15	5.8		
Institutions	83	43	16.5	40	15.4		
Staff	116	58	22.3	58	22.3		
Worker	1	1	0.4	0	0		
Unit	9	3	1.2	6	2.3		
Unemployed	21	10	3.8	11	4.2		
Income						4.098	.204
2001–3000	12	2	0.8	10	3.8		
3001–4000	92	50	19.2	42	16.2		
>4000	156	78	30.0	78	30.0		
Complications						0.143	.705
No	153	78	30.0	75	28.8		
Yes	107	52	20.0	55	21.2		
Relatives						1.862	.172
No	131	71	27.3	60	23.1		
Yes	129	59	22.7	70	26.9		
Maternal history						0.669	.413
Primipara	184	89	34.2	95	36.5		
Multipara	76	41	15.8	35	13.5		
Gestational week						0.754	.385
<37	221	108	41.5	113	43.5		
37–42	39	22	8.5	17	6.5		

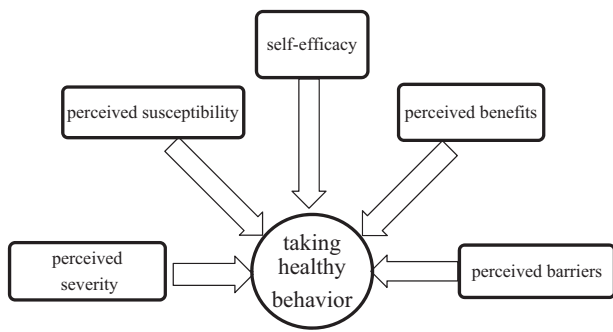


Figure 1. The health belief model emphasized that health cognition plays a key role in behavior change of individual, by helping individuals aware of the current factors that affect health could enhance their health beliefs, and take the appropriate health behavior ultimately.

Table 3
Comparison of lactation time (onset) and milk volume between 2 groups.

Group	Number	Lactation time	Milk volume during 3 days		
			24 h	24–48 h	48–72 h
Intervention	130	6.0 ± 3.3	4.9 ± 3.2	22.9 ± 6.3	49.5 ± 10.1
Control	130	10.2 ± 4.6	2.6 ± 2.3	16.3 ± 6.4	33.1 ± 8.2
<i>t</i>		-8.600	6.422	8.322	14.248
<i>P</i>		.000	.000	.001	.000

Table 4
Comparison of psychologic state between 2 groups.

Group	Number	State score	Trait score
Intervention	130	34.7 ± 4.7	31.8 ± 2.9
Control	130	38.7 ± 3.7	33.8 ± 1.9
<i>T</i>		-7.681	-6.542
<i>P</i>		.000	.000

groups ($P > .05$). However, the milk volume of the early milk expression group (<1 hour) was higher than that of the late milk expression group (1–6 hours) during 24 to 48 and 48 to 72 hours ($P < .05$) (Table 5).

3.4. Comparison of breast swelling rate in 3 days postpartum and exclusive breastfeeding rate in 42 days postpartum between 2 groups

Compared to the control group, the intervention group had a significantly lower breast swelling rate within 3 days postpartum

Table 5
Comparison of lactation time and milk volume within 3 days postpartum between the early milking mothers (<1 hour) and the late milking mothers (1–6 hours) in the intervention group.

Milking time	Number	Lactation time	Milk volume within 3 days		
			24 h	24–48 h	48–72 h
<1 h	31	2.4 ± 1.8	5.6 ± 1.8	25.7 ± 4.5	54.0 ± 6.8
1–6 h	99	7.0 ± 2.8	4.6 ± 3.6	22.0 ± 6.6	48.0 ± 10.6
<i>T</i>		-8.570	1.407	2.984	2.954
<i>P</i>		.000	.162	.003	.004

($P < .05$) but a significantly higher exclusive breastfeeding rate (59% vs 35%; $P < .01$).

4. Discussion

In this prospective, randomized, controlled study, the HBM was used to promote the breastfeeding behavior of separated mothers for the 1st time. The HBM holds that whether the individual adopts healthy behaviors mainly depends on the following factors: perceived susceptibility; perceived severity, perceived benefits, and perceived barriers and self-efficacy. It emphasizes that health cognition plays a key role in behavior change of the individual. Following this philosophy, our intervention measures focused on helping individuals become aware of the current factors that affect lactation and breastfeeding. In the intervention group, we have strengthened the theory of breastfeeding for separation mothers, and provided operational guidance at the same time. These efforts ultimately improved the behavioral compliance of maternal behavior greatly.

4.1. Nursing intervention based on the HBM can promote milk secretion

4.1.1. Nursing intervention based on HBM can advance the initiation time of lactation and increase milk volume. In the present study, the initiation time of milk expression was much earlier than the control group (2.0 ± 1.2 hours vs 7.1 ± 3.5 hours) and larger milk volume throughout the first 3 days postpartum. A previous study has shown that initiating milk expression within 6 hours after delivery is associated with higher milk production later on.^[18] Luo found in 2012 that initiating milk expression within 2 hours after birth can significantly increase the amount of lactation.^[19] Also in 2012, 1 pilot study demonstrated that initiating milk expression within 1 hour after delivery was more effective than between 2 and 6 hours,^[20] and could produce more milk at 1 to 3 weeks after delivery among mothers of infants having very low birth weight.^[7] But there were no study in previous focused on the mothers of cesarean delivery, which were associated with the delay of lactogenesis stage II,^[21] low pumping frequency, and lower milk volume.^[6] So, our study focused on the cesarean delivery mothers. In the study, stratification analysis was performed in intervention group for exploring the effect of early milk expression (within 1 hour), and the early milk expressing group with high milk volume. Our results are consistent with results of previous studies, We concluded from the study that beginning milk expression within 1 hour would lead to the early secretion of prolactin, which resulted from the early initiation. In addition, the number of milking sessions in the intervention group was larger than that in the control group at each period of time. It was found that increasing the number of milking could promote the prolactin secrete persistently and help keep it at a high level, thus facilitating the maintenance of

Table 6

Comparison of breast swelling rate within 3 days postpartum and exclusive breastfeeding rate within 42 days postpartum between 2 groups.

Variables	Number	Intervention		Control		χ^2	P
		Number	%	Number	%		
Breast swelling (\geq II)	69	24	9.2	45	17.3	8.700	.005
Exclusive breastfeeding rate at 42 days postpartum	123	77	29.6	46	17.7	14.828	.000

lactation. Early initiation of milk expression and frequent milk removal are important factors on the development of adequate milk supply among mothers separated with infants,^[5] which are associated with higher milk production later on.^[18] This indicates that we should encourage separation mothers to express milk as soon as possible.

4.1.2. Nursing interventions based on HBM can improve the diet of separation mothers after childbirth, and increase milk volume. Studies have confirmed that providing dietary guidance to mothers who were separated with their babies can meet the nutritional needs of the mothers and maintain and promote lactation.^[22] It is generally recommended for mothers to fast before and after cesarean section and began to eat a small amount of food after the intestine movement restores and anal exhaust is done, liquid first, semi-liquid next, and general food in the end.^[23] This means that the intake of mothers after cesarean section cannot guarantee nutritional needs, which inhibit the secretion of milk. In this study, we provided diet and exercise guidance to separation mothers based on the HBM and instructed the mothers to exercise on bed after assessing their postpartum physical conditions for promoting intestinal peristalsis, increasing appetite, and promoting the secretion of milk indirectly (Table 6).

4.1.3. Nursing interventions based on HBM can relieve anxiety. In the state of mother–baby separation, the inability to perform the mother’s role caused anxiety and depression, which leads to a series of changes in the mother’s endocrine glandular regulation and central nervous system, and finally inhibits milk secretion.^[22] In the present study, the psychologic status and traits scores in the intervention group were lower than those of the control group. We found that psychologic intervention could reduce the negative emotions of the mother and indirectly promote milk secretion. Effective communication can enhance mothers’ confidence of breastfeeding.^[24] In the study, we actively talked with separation mothers in the intervention group to learn about their psychologic needs and then provided them with psychologic support accordingly. At the same time, we encouraged family members to help the new mother express and store milk. A study has found that the husband’s company and coordination could help the mother to go through this particular period in a more positive way.^[25] In addition, mother–baby separation will lead to decrease of breastfeeding compliance.^[26] In this study, we provided information support for mothers in the intervention group, informing them of the health condition and treatment progress of the newborns to meet their psychologic needs, which further alleviated the maternal anxiety.

4.2. Nursing interventions based on HBM can promote breastfeeding

4.2.1. Nursing interventions based on HBM can reduce the incidence of breast swelling and pain. In this study, the incidence of breast swelling in the intervention group was lower

than that in the control group within 3 days postpartum, suggesting that breast nursing such as breast massage and heat treatment can help clear the obstruction of the breast tubes and thus prevent or alleviate breast swelling and pain, and ultimately promote breastfeeding.

4.2.2. Intervention based on HBM can improve exclusive breastfeeding rate at 42 days postpartum. The results showed that the measures based on the HBM in the intervention group can improve the exclusive breastfeeding rate at 42 days postpartum. Studies performed by Sullivan et al suggested that exclusive breastfeeding can reduce the incidence of NEC by 77% among premature infants,^[27] and enhance the feeding tolerance of newborns.^[28] It can be concluded that exclusive breastfeeding is essential for the infants who are separated with their mothers. In 2013, He et al intervened to the separation mothers based on the clinical nursing pathway. The results showed that exclusive breastfeeding rates at 42 days postpartum were 57% in the intervention group and 38% in the control group. In our study, exclusive breastfeeding rates at 42 days postpartum were 59% in the intervention group, significantly higher than that in the control group (35%). Compared with the study of He et al, our study excluded the separation mothers of natural delivery, which confirmed the fact that health education based on the HBM could promote the breastfeeding behavior of separation mothers that had cesarean section better.

4.3. Limitations

Our study has several limitations. First, although the 2 groups of mothers were assigned to different rooms randomly by the investigator, the outcomes may have been contaminated by the communication between family members of these mothers because they could move freely around the ward. Second, it remains controversial over the effect of simultaneous or sequential milk expression on improving milk volume. This study was intended to compare the differences between the 2 models of milk expression, but the participants did not adopt a fixed method of expression, which resulted in incomparable data. Third, we did not collect the separation time of each case, which is likely to affect the rate of exclusive breastfeeding within 42 days postpartum.

5. Conclusion

In this prospective, randomized, controlled study, we measured the impact of initiation of milk expression within 1 hour on milk volume and breastfeeding behavior. Nursing intervention based on the HBM is an effective intervention model for separation mothers who choose cesarean section, and it is essential for promoting milk secretion and breastfeeding. Although the medical professionals at the Obstetric Department are aware of mothers’ difficulties and the importance of the volume of milk

obtained, little has been studied regarding the conditions most conducive to milk expression. So, future research should pay more attention to this aspect.

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Author contributions

BRL assisted YL and JRY on formulating the research questions, designing the study and supervising the quality of this manuscript. This intervention was performed by YL, data were collected by YL and JRY, manuscripts were written by YL, and was revised by JRY and BRL.

Conceptualization: Yi Liu, Xinghui Liu, Xiufang Zhao.

Data curation: Yi Liu.

Formal analysis: Yi Liu.

Funding acquisition: Yi Liu.

Investigation: Yi Liu.

Methodology: Yi Liu.

Project administration: biru Luo, Xinghui Liu.

Resources: Jianrong Yao.

Software: Yi Liu.

Supervision: Biru Luo, Jianrong Yao.

Validation: Yi Liu.

Writing – original draft: Yi Liu.

Writing – review & editing: Yi Liu.

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