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Effectiveness of a theory-based educational intervention on enhancing milk donation behavior: a cluster randomized controlled trial

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Abstract

Background This study aims to assess the impact of an educational intervention based on the theory of planned behavior (TPB) on breastfeeding mothers' knowledge, attitude, subjective norms, perceived behavioral control regarding donor human milk (DHM), intention to donate milk and milk donation behavior.

Method This cluster randomized controlled trial (CRT) was performed on 67 breastfeeding mothers (intervention, $n=33$; control, $n=34$) in health centers affiliated to Tehran University of Medical Sciences (TUMS) from April 2023 to October 2023. Four weekly 60-min educational sessions were conducted based on the TPB through lectures, group discussions, psychodrama method, videos and pictures display for mothers in the intervention group, while the control group received only routine care. The data collection tool was a researcher-made questionnaire based on the TPB. It assessed breastfeeding mothers' knowledge, attitudes, subjective norms, perceived behavioral control regarding milk donation, intention to donate milk, and actual milk donation behavior. The questionnaire was completed by participants in both groups before, immediately and three months after the intervention.

Results The findings indicated that both the intervention and control groups were similar in terms of demographic and obstetrics variables. Additionally, before the intervention, there were no significant differences between the two groups regarding knowledge ($P=0.552$), attitude ($P=0.734$), subjective norms ($P=0.813$), perceived behavioral control ($P=0.453$), intention to donate milk ($P=0.476$) and actual milk donation behavior ($P=0.105$). However, the intervention group showed significant improvements in the mean score of noted variables immediately and three months after the intervention ($P<0.05$). Moreover, regarding the frequency of milk donations, three months after the intervention, eight mothers in the intervention group had donated milk, whereas none of the mothers in the control group had done so ($P=0.002$).

Conclusion Our findings showed that the TPB-based educational intervention significantly enhanced milk donation behavior among breastfeeding mothers. Given that donor mothers are crucial for the establishment and sustainability of human milk banks (HMBs), such programs should be implemented to increase milk donation rates and support the development of HMBs.

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Keywords Milk banks, Donor milk, Breastfeeding, Breast milk, Newborn, Health education, Iran

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Background

When maternal breast milk, the most suitable form of nutrition for all infants, especially those with low birth weight (LBW), is not available, donor human milk (DHM) from human milk banks (HMBs) serves as the preferred alternative to formula, as it reduces the risk of necrotizing enterocolitis and other infections during neonatal hospitalization [1]. However, in some settings, particularly in developing countries, the service provided by HMBs is not widely known among breastfeeding mothers [2, 3]. This lack of awareness results in a low number of milk donors, which fails to meet the demand for DHM.

HMBs are widely available globally with more than 750 HMBs in 66 countries with a growing trend of establishing these HMBs in developing countries [4]. Although fewer than 20 HMBs have been established in the Middle East, Iran is the leading country in the region with a total of 12 HMBs. The first HMB in Iran was established in Tabriz in 2016. Since then, the country has expanded its HMB network to 10 cities (Tabriz, Tehran, Mashhad, Kermanshah, Shiraz, Isfahan, Yazd, Ahvaz, Kerman, and Zahedan) [5, 6].

Human milk donation, a tradition that dates back to ancient times in Iran, when wet nursing was a common practice, is now a modern HMB with more scientific and ethical standards. It is influenced by Islamic culture and values, such as the concept of milk kinship, which establishes a bond between the wet nurse, the child, and their families. According to this concept, the wet nurse and the child become relatives by milk, and they are prohibited from marrying each other [7]. Some mothers today may still hold concerns about milk kinship, impacting their decision to donate or receive DHM. However, according to Islamic laws, DHM available in HMBs does not create milk kinship [3, 8, 9].

A study on Iranian breastfeeding mothers' knowledge and attitudes towards DHM showed that only 12.8% of participants had heard about HMBs. In this study, mothers had limited knowledge but relatively positive attitudes towards DHM. Besides, 65% of mothers expressed concerns about milk kinship and indicated that due to the possibility of future marriages between children who receive DHM and the donor mother's children, they do not donate their breast milk or accept DHM. Furthermore, 94.3% of mothers reported that they should obtain their husband's consent before taking DHM [3].

Increasing the number of donors and improving the knowledge and awareness of breastfeeding mothers about DHM are crucial challenges for HMBs. These challenges require targeted strategies that address factors influencing milk donation behavior across various settings [10].

Studies have shown that interventions based on theoretical frameworks are more effective than those without in improving health-related behaviors [11]. In recent years, TPB was used as a useful framework in improving and understanding breastfeeding-related behaviors like milk donation [12–14]. This theory comprises domains which predict behavioral intention or an individual's tendency to perform a desired behavior. Based on the TPB, the factors that can affect women's decisions to donate their milk are their attitude towards sharing their milk with other infants, their subjective norms, which are the expectations and opinions of their significant others, such as partner, family and friends on milk donation, and their perceived behavioral control, which is the perception that they can control milk donation behavior [12, 15]. Addressing these factors is expected to improve milk donation behavior and increase the number of volunteer mothers donating breast milk.

In a study on the role of psychosocial factors in predicting milk donation behavior, breastfeeding mothers' attitude, subjective norm, and self-efficacy were positively associated with the intention to donate breast milk [15]. Moreover, in a Brazilian study, 46% of the donors indicated that encouragement by health professionals, family and friends was an influencing factor in their milk donation decision [16]. Additionally, in a descriptive study, women who donated their milk to a HMB expressed their confidence and ability to donate their milk, revealing the influence of control beliefs on their milk donation experience [12]. In another study, the main factors that encouraged milk donation were a desire to help other babies, altruism and having a surplus of breast milk. However, the main barriers were worries about cultural and religious rules and lack of knowledge about HMB [17].

Despite numerous studies exploring the factors influencing breast milk donation across various countries, including Iran [5, 10], none have specifically examined milk donation as a voluntary health behavior that can be enhanced and promoted through a structured intervention focusing on the local socio-cultural beliefs regarding DHM. Based on the literature review, despite the effectiveness of TPB-based programs in improving voluntary health behaviors, no study has been conducted on improving milk donation behavior using this theory. Thus, this study used a TPB-based intervention and aimed to determine the effectiveness of an educational intervention based on the TPB on the knowledge, attitude, subjective norms, perceived behavioral control, and intention to donate breast milk as well as the actual donation behavior of breastfeeding mothers who could be potential future donors.

Methods

This trial adhered to the CONSORT 2010 statement, with a specific focus on the extension for cluster randomized trials [18]. The protocol article of this study has been published [19].

Study design and setting

This study was a CRT with two groups (intervention and control) conducted at the health centers affiliated to Tehran University of Medical Sciences (TUMS) from April 2023 to October 2023. In this study, the unit of randomization was the health centers, with each health center considered as a cluster.

TUMS provides primary health care services to five districts (10, 11, 16, 17 and 19) out of 22 in Tehran city (the capita of Iran). These districts have a large population of breastfeeding mothers from south Tehran who regularly attend these health centers for their postpartum visits, infants' vaccination, screening or growth monitoring. We excluded district 19 from our study because its health centers lacked the facilities for holding in-person classes and had a low number of Iranian breastfeeding mothers. We randomly selected eight health centers from the remaining four districts and assigned four centers to the intervention group and four centers to the control group by simple randomization using computer-generated randomization. We enrolled ten participants from each health center (Fig. 1).

Participants and sample size

Eligible participants were breastfeeding mothers who resided in Tehran, and had given birth within the past year, and had enough breast milk for their own baby with a doctor's or midwife's approval based on the infant's biometric indicators, and neither the mothers nor their infants had any serious medical or mental conditions, such as chronic illnesses, severe infections, psychiatric disorders or any

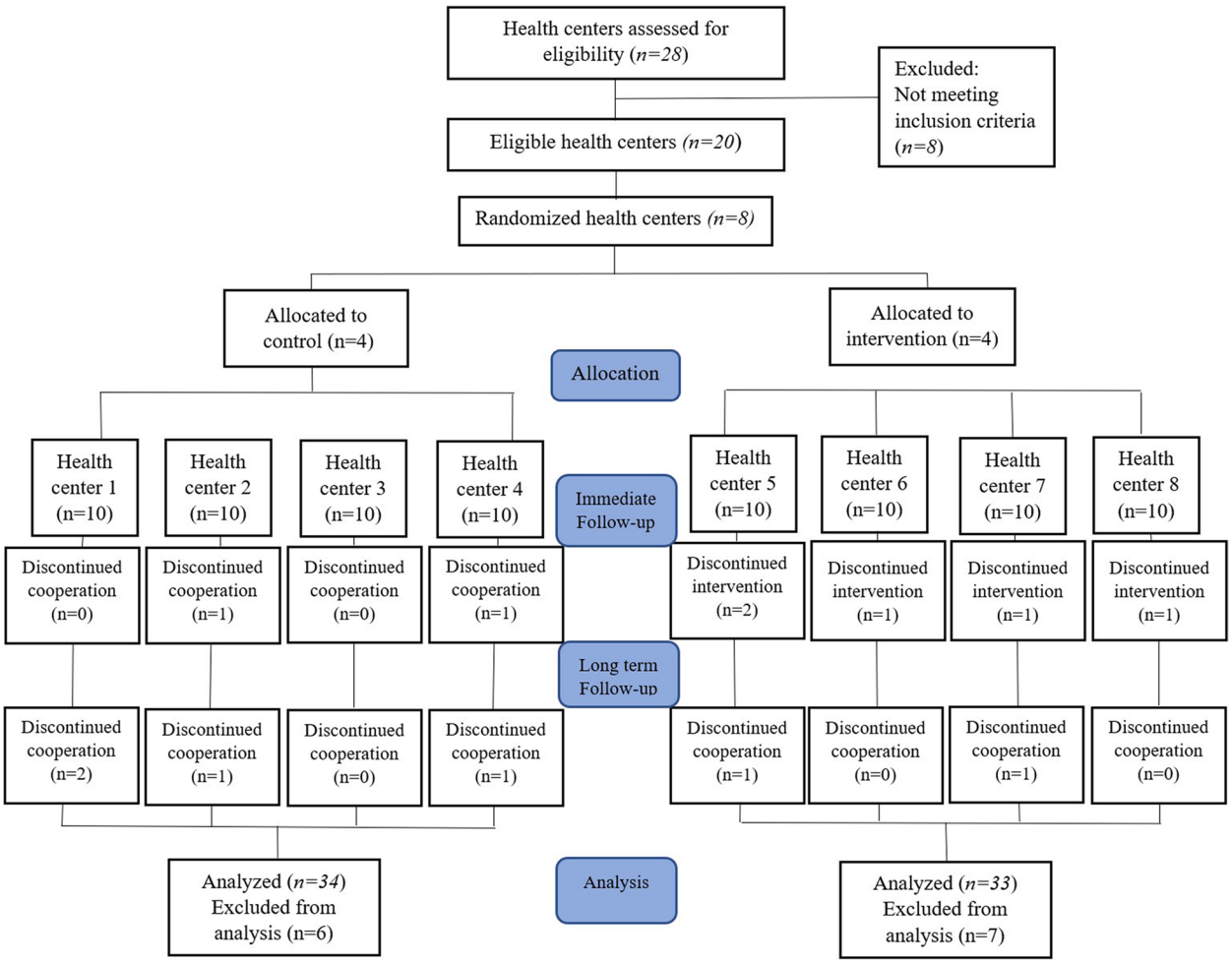

Fig. 1 Trial flowchart

condition that could compromise the health of the mother or infant.

The exclusion criteria were: not participating in more than one session of the educational intervention, breastfeeding cessation, loss of baby, and completing less than 80% of the questionnaire.

Breastfeeding mothers who met the inclusion criteria were selected by convenience sampling in each health center. After explaining the study protocol, the researcher obtained informed consent from the interested participants. The participants then completed a pretest questionnaire that collected demographic information and assessed their milk donation behavior based on TPB.

Our outcomes were the changes that occurred in TPB components. Therefore, using the following formula, to achieve a power of 95% with a 95% confidence interval, and a standard deviation ranging from 3.17 to 3.21, based on the findings of the similar study (considering a difference of 3 points in the average perceived behavioral control scores before and after the intervention) [20], the sample size was estimated at 30, and then allowing for 30% attrition to account for the possible loss of breastfeeding mothers because they might be busy with their infants and discontinue their participation, 40 samples were estimated for each group to ensures a reliable comparison between the intervention and control groups.

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 (s_1^2 + s_2^2)}{(\overline{x}_1 - \overline{x}_2)^2}$$

Procedures and intervention

The intervention group participated in a four-week educational intervention (60-min weekly sessions) based on the TPB. The researcher asked mothers to attend educational sessions at the patient education units of the intervention health centers. Text messages and phone calls were used to remind the mothers to be punctual for each session and to notify them of the time and date of the educational sessions. The educational courses were conducted as three courses per health center to minimize sample loss and increase the feasibility of the face-to-face sessions for the mothers. The 10 mothers in each intervention health center were divided into three groups: two groups of three participants and one group of four participants.

The attendance of the mothers in each course was recorded so that a makeup session could be arranged with the mothers of another course in the same health center in case of their absence. Since there were three sessions on the same topic every week so mothers could choose one by themselves if they could not attend the session of their course. However, five mothers from the intervention group who missed more than one training session were excluded from the study (Fig. 1).

The control group only received the routine care. The sessions included lectures, group discussions, psychodrama method, videos and pictures display, question and answer (Table 1). Mothers also received pamphlets and educational booklets that contained the content of all the sessions.

Table 1 The educational sessions based on the TPB

Session	Purpose	Educational content	Method
1	Increasing the knowledge and improving the attitude of mothers towards the DHM and HMBs	-The importance of breast milk -The definition, importance and history of DHM and HMBs	-Lecture and group discussion
2	Addressing the role of subjective norms in mothers' milk donation behavior	-The summary of the content of the previous session -Breastfeeding mothers' reasons and motivations for milk donation -The indications of using DHM for babies -The rules of DHM in Islam -The role of husbands and family members in donating breast milk to the HMB	-Lecture and group discussion -Two volunteer mothers were asked to express their subjective norms related to milk donation using psychodrama method. Then, the researcher guided their responses and addressed their concerns about their family and friends' opinions on their milk donation decision
3	Addressing the role of perceived behavioral control in mothers' milk donation behavior	-The summary of the content of the previous session -Donors' criteria -Milk donation contraindications -Working process and cost of milk banks -The status of milk banks in Tehran	-Lecture and group discussion -Pictures and videos of the local HMB were displayed to illustrate the practical aspects of milk donation
4	Addressing the behavioral intention and explaining how to implement the behavior of milk donation	-The summary of the content of the previous session -Breastmilk expression, collecting, and storing mother's milk -The procedures of sending milk to the HMB	-Lecture and group discussion -Practical demonstration of expressing breast milk by hand and pump -Motivating mothers and assuring them of their capability to donate milk

The participants in the control group did not receive any training; they just completed the questionnaires at three stages. However, to adhere to research ethics, after the study was completed, the mothers in the control group were also given the study's booklets and pamphlets.

Outcomes

Our primary outcome was the observed changes in milk donation behavior among breastfeeding mothers. The secondary outcomes included enhancements in breastfeeding mothers' knowledge, attitude, subjective norms, perceived behavioral control regarding DHM and HMBs, and their intention to donate milk.

Data collection tool

The data collection tool was a researcher-made questionnaire consisting of two sections including demographic and obstetrics information and TPB domains. The first section included 21 questions covering demographic and obstetrics information. The second section consisted of 10 questions related to the knowledge of DHM and HMBs, with multiple-choice scale (each correct answer earned one score, while incorrect answers received zero scores, resulting in a minimum total score of 0 and a maximum of 10). There were 12 questions on attitude toward DHM and HMBs using a 5-point Likert scale from strongly disagree (score 1) to strongly agree (score 5) (three of the questions were reverse-scored) with a minimum total score of 12 and a maximum of 60. There were 7 questions on subjective norms about DHM and HMBs using a 5-point Likert scale from strongly disagree (score 5) to strongly agree (score 1) (two of the questions were reverse-scored) with a minimum total score of 7 and a maximum of 35. There were 7 questions on perceived behavioral control in milk donation with a 5-point Likert scale from never (score 1) to always (score 5) (two of the questions were reverse-scored) with a minimum total score of 7 and a maximum of 35. There were 7 questions on the intention to donate milk using a 5-point Likert scale from never (score 1) to always (score 5) with a minimum total score of 7 and a maximum of 35 and the last part of the questionnaire included 3 questions on breastmilk donation including "I donated my breast milk in the last six months" with yes or no scale, "How many times did you donate your milk to the milk bank in the last six months?" and "I will follow hygiene tips if I want to donate my breast milk" with a 5-point Likert scale from never to always.

To validate the data collection tool, qualitative and quantitative content validity, using the Content Validity Ratio (CVR), and Content Validity Index (CVI), and face validity were assessed. To do this, the designed questionnaire was provided to 15 faculty members specializing in neonatology, gynecology, midwifery, reproductive health, health education and health promotion. Some items were revised to enhance clarity, simplicity, and comprehensibility based on the experts' suggestions. After that, to conduct face validity, the revised questionnaire was provided to 10 breastfeeding mothers who were not part of the study sample. They were asked to express their opinions on the appearance of the questionnaire, its simplicity, and the comprehensibility of the items. Based on their feedback, necessary changes were made to the wording of the items.

To determine the reliability of the questionnaire, test–retest method was used. The data were analyzed using SPSS software, and the Pearson correlation coefficient for the questions was calculated, which was 0.969 ($P < 0.001$) for the entire questionnaire. The correlation coefficient for each construct based on the test–retest method was also calculated, and these were acceptable coefficients. Also, the internal consistency of the questionnaire was assessed using Cronbach's alpha, which was 0.931 for the entire questionnaire and ranged from 0.703 to 0.953 for each construct.

Participants in both the intervention and control groups completed this researcher-made questionnaire through self-reporting before, immediately and three months after the intervention. To ensure complete and precise data collection, mothers were thoroughly briefed on how to complete the questionnaires accurately, and this process was closely monitored by the research team to promptly resolve any issues or discrepancies.

Data analysis

Data analysis was performed using SPSS software version 25. Descriptive analysis was used to report baseline demographic and obstetric characteristics. The Kolmogorov–Smirnov test was used to check the normal distribution of the data. For comparing quantitative variables with a normal distribution between two groups, the independent sample t-test was used, while the Mann–Whitney test was applied for quantitative variables that did not follow a normal distribution. Friedman's test was used to compare quantitative variables that did not have a normal distribution across three measurements. For pairwise comparisons in significant cases, the Wilcoxon and McNemar's tests were applied. The chi-square test or Fisher's exact test was used to compare qualitative variables between groups. The significance level for all tests was considered 0.05.

Results

The demographic and obstetric characteristics of the participants (intervention, $n=33$; control, $n=34$) are detailed in Table 2. Initial analysis showed no statistically significant differences in the baseline characteristics, including demographic and obstetric variables, the mean score of knowledge, and the TPB components (attitude, subjective norms, perceived behavioral control, intention to donate milk, and milk donation behavior), between the intervention and control groups (Tables 4 and 5). Moreover, the two groups did not have a statistically significant difference in terms of whether they had heard about milk donation or not, and the source of their prior information (Table 3).

Tables 4 and 5 present the follow-up assessment results. The findings indicate that immediately and three months after the intervention, the mean score of knowledge and TPB components significantly improved in

Table 2 Comparison of demographic and obstetrics characteristics between intervention and control groups

Group Variable		Intervention ($N=33$) n (%)	Control ($N=34$) n (%)	*p*-value
Age (year)	< 25	7 (21.2)	4 (11.8)	0.514[a]
	25_30	8 (24.2)	11 (32.4)	
	31_35	15 (45.5)	15 (44.1)	
	36_40	3 (9.1)	3 (8.8)	
	> 40	0 (0)	1 (2.9)	
	Mean ± Standard deviation	30.24 ± 4.89	31 ± 4.56	
Education	≤ High school	4 (12.1)	3 (8.8)	0.143[b]
	Diploma	18 (54.5)	13 (38.2)	
	University degree	11 (33.3)	18 (52.9)	
Employment	Housewife	31 (93.9)	29 (85.3)	0.427[b]
	Employed	2 (6.1)	5 (14.7)	
Household income	Poor	4 (12.1)	5 (14.7)	1.000[b]
	Acceptable	29 (87.9)	29 (85.3)	
Number of children in the household	1	13 (39.4)	18 (52.9)	0.478[c]
	2	18 (54.5)	12 (35.3)	
	≥ 3	2 (6.1)	4 (11.7)	
Parity	Primiparous	13 (39.4)	18 (52.9)	0.363[c]
	Multiparous	20 (60.6)	16 (47.1)	
Mode of delivery	Vaginal	10 (30.3)	10 (29.4)	0.936[d]
	Cesarean	23 (69.7)	24 (70.6)	
Sex of the infant	Female	17 (51.5)	15 (44.1)	0.544[d]
	Male	16 (48.5)	19 (55.9)	
Gestational age of the infant (weeks)	< 37	3 (9.1)	5 (14.7)	0.873[c]
	≥ 37	30 (90.9)	29 (85.3)	
Age of the infant (months)	< 2	30 (90.9)	25 (73.5)	0.328[c]
	≥ 2	3 (9.1)	9 (26.4)	
Previous breastfeeding experience	Yes	20 (60.6)	15 (44.1)	0.177[d]
	No	13 (39.4)	19 (55.9)	
Mother's perception of her breast milk supply	Low	4 (12.1)	2 (5.9)	0.743[b]
	Medium	21 (63.6)	24 (70.6)	
	High	8 (24.2)	8 (23.5)	
History of blood donation	Yes	1 (3)	2 (5.9)	1.000[b]
	No	32 (97)	32 (94.1)	

[a] Independent sample t-test

[b] Fisher exact test

[c] Mann-Whitney test

[d] Chi-square test

Table 3 Participants' prior information on milk donation

Group		Intervention (*N* = 33) n (%)	Control (*N* = 34) n (%)	*p*-value
Had heard about milk donation	Yes	7 (21.2)	8 (23.5)	0.820[a]
	No	26 (78.8)	26 (76.5)	
Information source	Internet	4 (57.1)	2 (25)	0.363[b]
	Health care professionals	2 (28.6)	2 (25)	
	Pamphlets	1 (14.3)	4 (50)	

[a] Chi-square

[b] Fisher exact test

Table 4 Comparison of the milk donation knowledge and TPB constructs between intervention and control groups

Variable	Time	Intervention group (*N* = 33)		Control group (*N* = 34)		*p*-value
		Mean	SD	Mean	SD	
Knowledge	Before intervention	6.18	1.66	6.44	1.87	0.552[a]
	Immediately after intervention	9.45	0.83	6.38	2.06	< 0.001[b]
	3 months after intervention	9.67	0.69	6.53	1.94	< 0.001[b]
	P-value	< 0.001[c]		0.781[c]		
Attitude	Before intervention	47.36	7.29	46.68	9.05	0.734[a]
	Immediately after intervention	57.88	2.34	46.88	8.19	< 0.001[b]
	3 months after intervention	57.42	2.8	47.12	8.73	< 0.001[b]
	P-value	< 0.001[c]		0.783[c]		
Subjective norms	Before intervention	22.58	4.95	22.88	5.59	0.813[a]
	Immediately after intervention	30.58	4.16	22.21	5.16	< 0.001[b]
	3 months after intervention	31.27	4.86	22.21	5.25	< 0.001[b]
	P-value	< 0.001[c]		0.147[c]		
Perceived behavioral control	Before intervention	21.06	5.31	20.15	4.56	0.453[a]
	Immediately after intervention	29.94	4.68	19.44	4.06	< 0.001[b]
	3 months after intervention	30.03	4.66	19.35	4.26	< 0.001[b]
	P-value	< 0.001[c]		0.092[c]		
Intention to donate milk	Before intervention	16.7	6.27	15.56	6.68	0.476[a]
	Immediately after intervention	28.24	6.56	15.82	6.57	< 0.001[b]
	3 months after intervention	28.03	6.71	15.24	5.93	< 0.001[b]
	P-value	< 0.001[c]		0.858[c]		

[a] Independent t-test

[b] Mann-Whitney test

[c] Friedman test

the intervention group. Furthermore, the mean score of knowledge and TPB components in the intervention group showed statistically significant differences before, immediately, and three months after the intervention. No significant changes were observed in the control group over the same periods.

According to the results of McNemar's test, which compared compliance with hygiene tips during milk donation at different times, in the intervention group, the number of mothers who had chosen the option "always" to the item "I will follow hygiene tips if I want to donate my breast milk" before the intervention (54.5%) and immediately after the intervention (97%) ($P < 0.001$), and before the intervention (54.5%) and three months after the intervention (100%) ($p < 0.001$) had statistically significant difference. In the control group, the frequency of mothers who had chosen the "always" option for compliance with hygiene tips during milk donation before the intervention (73.5%) and immediately after intervention (55.9%) had no statistically significant difference, however, before the intervention (73.5%) and three months after the intervention (47.1%), the number of mothers

Table 5 Comparison of milk donation behavior between intervention and control group

Variable		Intervention group (*N* = 33) n (%)	Control group (*N* = 34) n (%)	*p*-value
Record of milk donation before intervention	Yes	0 (0)	0 (0)	-
	No	33 (100)	34 (100)	
Record of milk donation immediately after intervention	Yes	3 (9.1)	0 (0)	0.114[a]
	No	30 (90.9)	34 (100)	
Record of milk donation 3 months after intervention	Yes	8 (24.2)	0 (0)	0.002[a]
	No	25 (75.8)	34 (100)	
"I will follow hygiene tips if I want to donate my breast milk" before intervention	Always	18 (54.5)	25 (73.5)	0.105[b]
	The rest of options	15 (45.5)	9 (26.5)	
"I will follow hygiene tips if I want to donate my breast milk" immediately after intervention	Always	32 (97)	19 (55.9)	< 0.001[b]
	The rest of options	1 (3)	15 (44.1)	
"I will follow hygiene tips if I want to donate my breast milk" 12 weeks after intervention	Always	33 (100)	16 (47.1)	< 0.001[b]
	The rest of options	0 (0)	18 (52.9)	

[a] Fisher exact test

[b] Chi-square test

who had chosen the "always" option had decreased significantly ($P = 0.04$).

Additionally, regarding the frequency of milk donations immediately after the intervention in the intervention group, among the three mothers who had donated milk, one person (33.3%) donated milk once and two people (66.7%) had donated milk twice. Three months after the intervention in the intervention group, among the eight mothers who had donated milk, four people (50%) had donated milk once, three people (37.5%) had donated milk twice and one person (12.5%) had donated milk three times.

Discussion

This study aimed to evaluate the impact of an educational intervention based on the TPB on milk donation behavior among breastfeeding mothers.

The findings of this study revealed that, in the intervention group, milk donation behavior including the number of milk donors and adherence to hygiene tips during milk donation significantly differed from that of the control group after the intervention. This demonstrates the effectiveness of the educational intervention based on the TPB in enhancing milk donation behavior and increasing the number of milk donors. Such improvements can significantly boost the availability of DHM, which is essential for infant health.

Furthermore, the study revealed a decline over time in the number of mothers in the control group selecting the "always" option for the item "I will follow hygiene tips if I want to donate my breast milk." This decrease likely resulted from the lack of education on hygiene tips and the absence of improvement in their behavioral intention to donate milk both immediately and three months after the intervention. These findings emphasize the importance of educational programs in boosting milk donation behavior, as routine information alone was not enough. Consistent with this research, Hu et al. found that an intervention based on the TPB improved re-donation rates among nonregular blood donors [21]. Since milk donation, like blood or organ donation, is an altruistic act, the alignment of this study's results with our research in increasing the number of donors suggests that the TPB is effective in promoting and enhancing donation-related behaviors.

Additionally, in the study by Sivanandan et al., after implementing a quality improvement intervention to promote voluntary milk donation by mothers in a hospital in India, the number of milk donors increased from 223 to 259 per month. However, this increase was not statistically significant ($p = 0.12$) [22]. This could be due to the fact that, on average, only 15% of mothers who gave birth in that hospital donated milk, and most mothers with their healthy newborns, who could potentially be milk donors, were discharged within 24 h after delivery, giving them no chance to donate. Therefore, designing interventions in clinics, health centers, and other outpatient settings, where healthy mothers frequently and regularly visit for maternal and child health services, may prove more successful in attracting milk donors compared to inpatient hospital wards.

According to the TPB, several factors can influence milk donation behavior. The results of this study demonstrated a significant improvement in the mean score of knowledge, attitude, subjective norms, perceived behavioral control, and intention to donate milk in the intervention group immediately and three months after the intervention. Conversely, no significant differences were observed in these constructs within the control group.

In the present study, before the educational intervention, breastfeeding mothers' knowledge regarding DHM and HMBs was moderate in both the intervention and control groups. This finding was consistent with previous similar studies conducted by Tu et al. [23], Zhang et al. [24], and Tian et al. [25]. This could be attributed to the lack of programs aimed at promoting milk donation and informing mothers about the nature of milk donation and the existence of HMBs in Iran and among the studied populations, which affects their level of awareness and knowledge.

In the study by Garegrat et al., it was found that one of the reasons of the low number of milk donors was the lack of knowledge among the stakeholders about milk donation and HMBs. Addressing this issue, their quality improvement initiative successfully enhanced DHM collection [26]. Our study showed that the educational intervention effectively increased breastfeeding mothers' knowledge about DHM and HMBs. According to Garegrat et al., we anticipated that the increased knowledge would improve milk donation behavior. This expectation was confirmed by the significant increase in the number of milk donors in our study.

The results showed that, before the educational intervention, mothers in both the intervention and control groups had a relatively good attitude towards DHM and HMBs. In the study by Varer Akpinar et al., which aimed to examine women's attitudes towards HMBs in Turkey, it was found that housewives and women with more children had a more positive attitude towards DHM and HMBs. This might be because they have more experience and spend more time breastfeeding and taking care of their children [27]. Similarly, in the study by Hosseinzadeh et al. in Iran, 90.5% of the mothers were housewives, and the average attitude score of the participants towards milk donation was reported to be relatively favorable [3]. Likewise, our study also showed that most mothers in both the intervention and control groups were housewives, which could influence their attitude towards DHM and HMBs.

The study by Zamahlubi et al. found that participants with a positive attitude were nearly five times more likely to have a sufficient knowledge score on DHM compared to those with a negative attitude ($p=0.003$) [28]. In the study by Hosseinzadeh et al., a direct relationship was also found between knowledge and attitudes regarding DHM ($p<0.001$) [3]. These findings were consistent with the results of our study. In the present study, we observed that mothers in the intervention group showed a significant improvement in their attitudes towards DHM and HMBs immediately and three months after the intervention. In contrast, the control group did not show such changes. This suggests that educational interventions are effective in enhancing the knowledge, attitudes, and behaviors of breastfeeding mothers regarding DHM. Therefore, organizing educational sessions can simultaneously improve mothers' knowledge and attitudes towards DHM and HMBs.

In this study, prior to the intervention, the average score of subjective norms was moderate in both the intervention and control groups. However, in the study by Wattanasit et al. conducted in Thailand, the average score of mothers' subjective norms regarding DHM was relatively high [29]. The variation in the average subjective norms score between this study and the present study may be attributed to the social, cultural, and religious differences among the populations of mothers examined in the two studies. For instance, in the study by Wattanasit et al., the majority of participating mothers were Buddhist, while in our study, all mothers were Muslim. The issue of milk kinship in Islam could be a significant factor contributing to the concerns of Muslim mothers regarding the use of DHM for infant feeding. Therefore, given the effectiveness of the educational intervention in enhancing the subjective norms of Muslim mothers in the present study, it is recommended that similar educational efforts be extended to mothers in other countries with diverse cultural and religious backgrounds to address their concerns regarding DHM.

Shepherd et al. found that women are more likely to intend to donate milk to HMB if they believe they have the capability to do so [15]. Additionally, in the study by Mathias et al., addressing barriers to milk donation, such as reducing costs and the time required for milk donation and improving transportation and milk collection services to facilitate donors, was emphasized as factors that are effective in the acceptance and promotion of milk donation [30]. These findings suggest that mothers' self-efficacy, along with their awareness of factors that either prevent or facilitate milk donation, significantly influences their decision to donate milk.

In the present study, the educational intervention included discussions on facilitating factors and barriers to milk donation, as well as strategies to overcome these barriers, which affect mothers' perceived behavioral control over milk donation. The results showed that immediately and three months after the intervention, the perceived behavioral control of mothers in the

intervention group was significantly higher than that of the control group. Therefore, it can be concluded that the educational intervention was effective in enhancing the perceived behavioral control of breastfeeding mothers regarding milk donation.

In the present study, before the intervention, mothers in both groups did not have a high behavioral intention to donate milk. Similarly, in the study by Ergin et al. in Turkey, only 19.1% of mothers were willing to donate their milk to an HMB [31]. In contrast, in the study by Tu et al. in China, a relatively high percentage of breastfeeding mothers visiting health centers (73.4%) were willing to donate their milk to an HMB [23]. In another study by Smyk et al. in Poland, 84.77% of women were willing to donate their milk [32]. The differences in mothers' intentions to donate milk observed in these studies are likely attributable to a variety of ethical, cultural, religious, and social factors. For instance, Turkey shares more cultural and religious similarities with Iran than with China and Poland. This similarity may result in comparable perceived barriers to milk donation in Turkey and Iran, consequently leading to moderate or low intentions among breastfeeding mothers in these countries to donate milk.

The findings of the present study showed that immediately and three months after the educational intervention, mothers' behavioral intention to donate milk in the intervention group increased significantly compared to the control group. Based on the results of the present study, and considering that previous research has demonstrated that intention is a strong predictor of prospective behavior, it is recommended to implement educational interventions that align with the cultural and social values of mothers in various societies. Using the TPB to address different constructs influencing behavior can effectively enhance mothers' willingness to donate milk.

Regarding the mothers' breastfeeding history, in our study, 60.6% of mothers in the intervention group and 44.1% in the control group had a history of breastfeeding. The higher prevalence of breastfeeding history in the intervention group may be attributed to the fact that mothers with prior breastfeeding experience and an understanding of its benefits are more inclined to engage in interventions aimed at promoting breastfeeding. Consequently, these mothers were more likely to attend the educational sessions included in this study.

It is noteworthy that 52.9% of mothers in the control group were primiparous, compared to 39.4% in the intervention group. Therefore, it was expected that more mothers in the intervention group would report a history of breastfeeding. However, the statistical analysis results showed that these differences between the intervention and control groups were not statistically significant, indicating that the two groups were homogeneous in terms of breastfeeding history and parity (Table 2).

In terms of prior exposure to information on milk donation, the majority of mothers (77.6%) had not previously heard about milk donation. Similarly, in the study by Hosseinzadeh et al. on Iranian breastfeeding mothers' knowledge and attitude towards DHM, 87.2% of the participants reported that they had not heard about HMB [3]. This could be attributed to the relatively recent introduction of HMB in Iran, along with the availability of formula as an acceptable and feasible alternative for mothers to feed their infants.

Strengths and limitations

One of the strengths of this study is the use of the TPB to design the intervention which enhanced its effectiveness. Examining milk donation behavior within this theoretical framework added to the study's robustness and filled a gap in existing knowledge. Furthermore, the CRT method enabled us to increase the variety of participants by selecting eight different health centers (four intervention and four control) while also minimizing the risk of contamination between mothers in the intervention and control groups.

Besides, this study makes a significant contribution by addressing a crucial gap in the literature on improving milk donation behavior, particularly within the Iranian context. Unlike previous studies, our research focuses specifically on Iranian mothers, considering their unique cultural and social values.

One limitation of this study was the follow-up period for the mothers. Given that exclusive breastfeeding typically lasts for six months, and many mothers due to cultural and educational influences continue breastfeeding until their infants are two years old, and considering that breast milk donation is possible until the infant reaches one year of age, future studies could benefit from a longer follow-up period to better assess the impact of educational interventions on milk donation behavior.

In addition, in the present study, mothers were asked to retrospectively self-report the frequency of their milk donations, which may have introduced recall bias. Therefore, future studies should consider using alternative methods to self-reporting for tracking the frequency of milk donations by mothers, such as obtaining data directly from HMBs.

Conclusion

The results of the present study demonstrated that the TPB-based educational intervention significantly improved breastfeeding mothers' knowledge, attitudes, subjective norms, perceived behavioral control, intention to donate milk, and actual milk donation behavior. Given

that donor mothers are crucial for the establishment and sustainability of HMBs, and taking into account the strengths and limitations of our study, it is recommended that future research implements and designs programs that fit the cultural context of mothers in different communities and countries to enhance milk donation rates and support the establishment of HMBs.

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Authors' contributions
SSS, MM, AK and VGS participated in conceptualization and methodology. FS participated in investigation, gathered data and drafted the manuscript. SSS, MM and FS were involved in the development of the study tool. AK and FS analyzed and interpreted data. SSS and MM supervised the research process. SSS, MM and FS were involved in critical revision and review and edit of the manuscript. All authors read and approved the final manuscript.

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Data availability
The data that were used and analyzed in this study can be obtained from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
This study obtained ethical approval from the Research Ethics Committees of the School of Nursing and Midwifery & Rehabilitation at Tehran University of Medical Sciences (IR.TUMS.FNM.REC.1401.150). The participants had received written informed consent forms and had been informed about the study objectives, risks, and benefits. The anonymity and confidentiality of the participants' characteristics had been ensured during the recruitment process. The participants were given the right to leave the research at any time, and they were promised to have access to the study results.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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