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# The Effect of Neonate Multisensory Intervention on the Mental Health of Mothers with Preterm Neonates

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#### ABSTRACT

**Background & aim:** The admission of premature infants in NICU is a worrying experience for mothers. Therefore, early intervention is important. Multisensory intervention enhances mother-neonate interaction. This study aimed to investigate the effect of multisensory intervention on the mental health of mothers with preterm infants.

**Methods**: This quasi-experimental study was performed on 60 mothers of premature in Bojnourd, Iran, in 2021. The participants were selected using convenience sampling. Neonates of mothers in intervention group received multisensory stimulation twice daily for seven days and then for up to one month. Those in the control group received kangaroo care. Mothers of neonates completed the Goldberg Mental Health Questionnaire before one week and one month after the intervention. The data was analyzed by SPSS (version 16) using the independent sample t-test and Mann-Whitney U test.

**Results:** There difference between the mean score of mental health was not significant in the two study groups before the intervention (P=0.43). One week after the intervention, the mental health scores were significantly different between the control (27.10 $\pm$ 9.6) and intervention groups (44.97 $\pm$ 7.37) (P=0.001). Similarly, one month after the intervention, a significant difference was observed (16.30 $\pm$ 8.22 vs. 42.30 $\pm$ 6.41, P=0.001). Furthermore, one month after the intervention, the mean change of mental health score was also significant between control and intervention group (P=0.001), respectively.

**Conclusion:** Multisensory intervention had an effect on the mental health of mothers with premature infants. Therefore, this type of intervention is recommended for preterm neonates' mothers to promote their mental health.

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### Introduction

Premature birth is one of the biggest public health problems worldwide, accounting for 6%-10% and 15% of total births in high- and low-income countries, respectively (1). In Iran, according to the results of a meta-analysis published in 2017, the rate of preterm delivery is reported to be 10% (2). These neonates are two to three times more likely to have multiple physical complications than full-term newborns (3). In addition, the ward environment is

stressful for the mother due to the noise and equipment attached to the neonate (4). These factors cause great shock to parents, especially mothers when they are not physically, mentally, and emotionally prepared (5). Mothers respond to this stress in the form of sadness, hopelessness, guilt, anxiety, and mental health problems (6). Due to the stressful setting of the neonatal intensive care unit (NICU), mothers of premature neonates also suffer from mental

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health disorders (7). Based on the findings of mothers' research, distressing memories of the NICU may persist for up to six months after delivery and lead to traumatic stress disorders (8, 9). In anxious mothers, high cortisol is transmitted to the newborn through breast milk and causes physical psychological problems (10).Another psychological reaction that mothers experience is the onset of depressive symptoms (11). The rate of depression in mothers with premature neonates is almost double, about 21%- 28%, especially in the early postpartum period (12). According to the results of a study accomplished by Kammerer et al. (2009), 43% of mothers with postpartum depression suffer from insomnia, decreased energy, concentration, and appetite, as well as fatigue, feelings of worthlessness, and a lack of self-esteem (13).

The physical health of mothers with premature neonates is also affected by this crisis, as their constant presence on the newborn's bed restricts their ability to meet their physical needs. Many parents have experienced physical reactions. including insomnia, headache, stomach pain, tachycardia, loss of appetite, nausea, vomiting, fear, restlessness, and crying, because of their newborn's illness and hospitalization (14). The outcome of a previous research similarly showed that maternal psychological problems during the pre- and postpartum periods could predict the poor growth of the neonate (15). Therefore, it is essential to support such mothers through improvement of their mental health outcomes to facilitate mother-infant attachment (16).

Several techniques have been proposed to reduce worry and stress in mothers, such as maternal education in caring for premature newborns (17), emotional support of mothers kangaroo care training Multisensory intervention is a convenient and safe method for both the mother and the neonate, which, by focusing on the neonate, can affect the mother's mental health. This intervention contains auditory, tactile, visual, and vestibular (ATVV) stimulation. The intervention starts with the auditory stimulation of the baby through the mother's direct talk with the infant. After 30 sec, the mother massages the infant for 10 min in the flat position. After that, the baby is moved horizontally in the mother's arms for 5 min very gently. The duration of the intervention is 15 min, during which the mother tries to maintain eye contact with the baby (9). The consequences of using this type of intervention in most studies were focused on infants. In several research studies, multisensory stimulation has shown positive results in the evolutionary (18) and physiological domains, such as weight gain, reduction of neonatal stress levels, decrease in heart rate, and positive changes in behavior (19). However, a limited number of studies have focused on providing opportunities for motherinfant interaction or investigated the effects of this type of intervention on the psychological dimensions of mothers (20). In one study, performing multi-sensory care on mothers with premature babies indicated a reduction in mothers' depression (9).

The increase in the number of premature births and the tension and stress caused by neonatal hospitalization have led to maternal mental breakdowns (21). In this regard, nurses play a special role in creating lasting positive effects on the mother during their transition to motherhood and promoting their mental health (22). Thus, this study aimed to assess the effect of multisensory intervention on the mental health of mothers with preterm infants admitted to the NICU.

#### **Materials and Methods**

This quasi-experimental study was performed on mothers with preterm neonates (28-32 weeks gestation) admitted to the NICU of one Hospital in Bojnourd, Iran, in 2021. The sample size was determined at 14 cases in each group using the formula of "Determination of sample size based on mean and standard deviation comparison of the dependent variable in two populations" based on a pilot study and on the basis of the variable of the mental health score of mothers with premature infants. Finally, data analysis was performed on 60 subjects (n=30 in each group). In computing the minimum sample size, 95% confidence level and 80% test power was considered.

N=  $[(1.96 + 0.84)^2 \times (41.9^2 + 87.8^2)] / (38.32-73.42)^2$ 

The inclusion criteria for neonates were lacking congenital anomalies, the need for

invasive mechanical ventilation (ventilator), cerebral haemorrhage (grades 3 and 4), or the need for advanced resuscitation during hospitalization, as well as having a stable clinical condition (pink baby colour, body temperature of 36-37 degrees, and oxygen saturation of above 90%) and a five-minute Apgar score of above 7.

The eligible mothers were those without any known mental disorders or a history of drug substance or serious family problems based on self-declaration. On the other hand, the cases were excluded from the study if the neonate passed away, transferred to another hospital, or was discharged with personal consent before the completion of the intervention, as well as if any neonatal special medical conditions occurred (such as respiratory instability and a need for mechanical ventilation), if there was dissatisfaction to continue cooperation at any stage, stressful events occurred during the research (including the death of a loved one and the illness of the child), or the mother was absent for more than one day and did not perform the intervention more than three times in a month.

The main data collection instruments included a demographic questionnaire and Mental Health Questionnaire developed by Goldberg and Hillier in 1979. This item questionnaire-28 consist of four subscales, including physical symptoms (sentences 1-7), anxiety and sleep disorder symptoms (sentences 8-14), social functioning (sentences 15-21), and depression symptoms (sentences 22-28). The sentences are scored on a four-point Likert scale (0-3), resulting in a total range score of 0-84, with a lower score indicating better mental health (23). The validity and reliability of the Goldberg Mental Health Questionnaire have been proven in several studies. Validity of this questionnaire is often done using the factor analysis method, and as first reported by Goldberg (1979), the validity of this questionnaire was calculated through factor analysis resulting in four subscales were obtained: physical symptoms, anxiety and insomnia, social dysfunction and depression. Cronbach's alpha coefficient of this instrument was determined at 0.93 (24). This tool was translated by Taghavi and its validity was evaluated by content and external validity methods and its reliability based on three methods of retesting, splitting into two halves and Cronbach's alpha, which respectively, the reliability coefficients were obtained 0.93, 0.70 and 0.90 (25). Furthermore, in the current study, the reliability of the tool was obtained with Cronbach's alpha coefficient for each of the subscales and also for the overall score; The alpha coefficients for the physical, anxiety, social and depression dimensions of mothers' mental health were 0.72, 0.83, 0.81 and 0.87, and for the overall mental health score of mothers of premature babies, it was 0.79.

After obtaining the permission of the Ethics Committee of the Mashhad University of Medical Sciences, Mashhad, Iran, the researchers went conducted the study at to the NICU Bin Al-Huda of the mentioned Hospital. The study objectives were explained to eligible mothers, and informed consent was taking taken from the subjects to take part in the research. Afterward, the research sample was selected using convenience sampling from eligible mothers and neonates, and the demographic information questionnaire was completed. To prevent the exchange of information, first the control group and, subsequently, the experimental group entered the study. To conduct the multisensory intervention, first the mother washed her hands with soap and water, and then the neonate was placed on the infant bed. The intervention began with auditory stimulation, which was a fiveminute lullaby by the mother. Subsequently, gentle tactile stimulation was performed for five min. This part of the stimulation (tactile stimulation) was performed in such a way that five areas of the neonate's body were massaged 12 times consecutively, with each massage lasting five second. The massage started from the head and continued to the abdomen, chest, and arms from shoulders to wrists, and legs from thighs to knees. Afterward, the baby was put in the prone position, and their his/her back was massaged. Simultaneously, with the tactile stimulation of the massage, the visual stimulation was performed through the mother's direct eye contact with the neonate. Finally, to stimulate the vestibular, the mother hugged the baby and performed horizontal movements for five minute. The total duration of the intervention was 15 minute repeated twice a day (9). It was once performed around 10 in the morning when the baby was already visited so that the intervention did not interfere

with para clinical examinations (such as medication and blood sampling) and then at 4 or 5 in the afternoon.

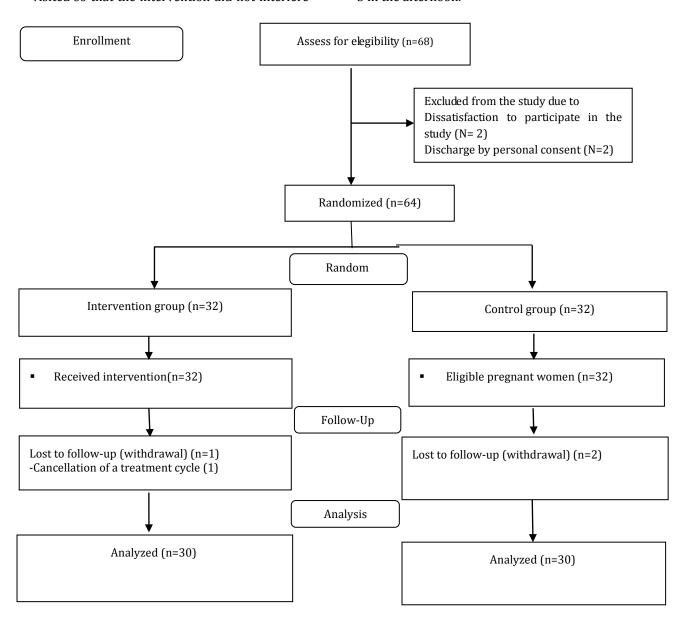


Figure 1. Flowchart of the study

The intervention was taught to the mother in simple language and face-to-face beside the neonate for 10 min. The researcher supervised the procedure daily during the first week to ensure the correct implementation of the intervention. Before the intervention, the

neonate was visited by a doctor to ensure that they were medically fit. All newborns were exposed to almost the same environmental conditions in terms of light and temperature (25-26°C). The neonate was then connected to a monitoring device (pulse oximetry) to be in a

physiologically stable position (i.e., pulse, respiration, and oxygen level). During each stage of the intervention, if physiological or behavioural changes, such as hiccupping, crying, and vomiting, were observed, the intervention was stopped for 10 min, and the next stage of the intervention began after the neonate was stabilized. This procedure was performed by the mother until the discharge of the newborn from the hospital and was administered on days 8-30 according to the previous procedure. The researcher supervised every three days in person (at the neonate's bed) during the hospitalization and by telephone discharge. In the control group, mothers took care of the baby, including breastfeeding, baby safety, changing positions, and kangaroo mother care according to the ward regulations. The Mental Health Questionnaire was filled out at the baseline and one week and also one month later than the intervention.

The data were then analyzed utilizing SPSS statistical software (version 16) after their

accuracy was ensured. The independent sample t-test or the Mann-Whitney U test was utilized to compare the scores of the mental health dimensions of mothers between groups. Due to the fact that the assessment of mental health scores was done on three occasions, the repeated measures analysis of variance or Friedman's analysis was also performed for intragroup comparison. A significance level of 0.05 was considered.

#### Results

The most frequency of the education level in the experimental and control groups was under the diploma, and most women in both groups were housewives. In terms of income level, 43.3% and 46.7% in the experimental and control groups had less than sufficient income, respectively. The type of delivery was mostly vaginal in both groups, and the mean fetal age of the neonates in both groups was about 30 weeks (Table 1).

**Table 1.** Socio-demographic characteristics of the participants

w '11	Intervention group	Control group	2 statistical tests	
Variables	N=30	n = 32		
	(Percent)	(Percent)		
Mother's Age (year), Mean (SD)	$30.60 \pm 7.43$	$7.24\pm29.70$	t= 0.79 p= 0.43*	
Gestational age(week), Mean (SD)	1.03±30.80	1.43±30.63	Z= 0.52 p= 0.86**	
Infant weight (gr), Mean (SD)	330.85±1680.33	401.24±1560.20	t= 1.26 p= 0.21*	
Mother's education				
High school	16 (53.3)	19 (63.3)	11 - 2.07	
Diploma	5 (16.7)	6 (20.0)	U = 3.07 P=0.38**	
University	9 (30.0)	5 (16.7)		
Mother's Job			$\chi 2 = 0.48$	
Housewife	24 (80.0)	26 (86.7)	γ2 -0.46 P=0.49***	
Employed	6 (20.0)	4 (13.3)	r-0.49	
Husband's Job				
Unemployed	0 (0.0)	1 (3.4)		
Worker	7 (23.3)	13 (43.3)	$\chi$ 2 =4.33 P=0.23***	
Employed	6 (20.0)	3 (10.0)		
Others	17 (56.7)	13 (43.3)		
Monthly income adequacy				
Adequate	5 (16.7)	2 (6.6)	U = 1.99 P=0.57**	
Somewhat adequate	12 (40.0)	14 (46.7)		
In adequate	13 (43.3)	14 (46.7)		
Type of delivery				
Natural	21 (70.0)	24 (80.0)	$\chi 2 = 1.11$	
Cesarean section	9 (30.0)	6 (20.0) P=0/64***		

Based on the results of statistical tests, the two groups were similar according to everyone

background and intervening variables. Moreover, the results of Kolmogorov-Smirnov and Shapiro-Wilk tests showed that all background and intervening variables in this study had a normal distribution.

Regarding between group comparison, there was no statistically significant difference between two groups in terms of mean total mental health score of mothers with preterm neonates at the beginning of admission (P=0.43). Nevertheless, based on the results of the independent t-test at the end of the first week a significant difference was observed between the two groups (P=0.001). Mann-Whitney nonparametric statistical testing also showed that there was a significant difference between the two groups of mothers with premature neonates at the end of the first month (P=0.001).

Regarding intragroup comparison, the results of repeated measures analysis of variance indicated that there was a significant

difference in the intervention group in terms of the total mental health score of mothers in the three stages of the baseline, end of the first week, and end of the first month (P=0.001). The result of the Bonferroni post hoc test showed that there was a significant difference between the time stages of the baseline and end of the first week (P=0.001). baseline and end of the first month, and end of the first week and end of the 1 month (P=0.001).Nonetheless, no significant difference was observed in terms of the total mental health score of mothers in the three stages of admission, the end of the first week, and the end of the first month in the control group (P=0.27). It was also revealed that the two groups of mothers with premature neonates had significant differences regarding the process of changes in the mentioned time stages (P=0.001) (Table 2).

**Table 2.** Comparison of mean scores of mental health before and after intervention

Mean score of	Control	Intervention	Intergroup	
mothers' mental	(n = 30)	(n = 30)	statistical	
health	Mean (SDa )	Mean (SDa )	tests	
Before intervention	46.63 ± 9.25	49.73±1	t= -0.79	
before intervention	40.03 ± 7.23	17.73±1	P= 0.43*	
After intervention	$44.97 \pm 7.37$	27.10±9.66	t=0.85	
(End 1 weak)	44.97 ± 7.37	27.10± 9.00	P=0.001*	
After intervention	42.30 ± 6.41	$16.30 \pm 8.22$	z= 13.66	
(End 1 month)	42.30 ± 0.41	10.30 ± 0.22	P=0001**	
The difference before				
the intervention and	6.14± 1.67-	12.21+21.97-	t= 8.14	
the end of the first		12.21_21.77	P=0.001*	
week				
The difference				
between the end of	4.84± 2.67-	5.63± 10.80-	t= 5.99	
the first week and the			P=0.001*	
end of the first month			E 110.45	
Analysis of variance	F- 0.62	F_ 127 41	F= 113.17	
with repeated	F= 9.63	F= 137.41	P= 0.001***	
measures	P= 0.37	P= 0.001	Interaction of	
			group and time	

<sup>\*</sup> Independent Samples t-Test

The results indicated that there was a statistically significant difference between the two groups after the intervention in all dimensions of mental health of mothers with preterm neonates (P=0.001). Based on the differences in scores of each dimension, the

most and the least effects of the intervention were associated to the anxiety and depression dimensions in the Mental Health Questionnaire, respectively (Table 3).

<sup>\*\*</sup> Mann-Whitney U test

<sup>\*\*\*</sup>Repeated Measures ANOVA

Table 3. Comparison mean scores of dimensions of mental health before and after intervention

Dimensions of mental health	Mean (SDa) Control group	Mean (SDa) Intervention group	Intergroup statistical tests	
Before				
intervention				
Physical health	11.57± 2.45	± 3/75 12.03	t=0.57	P= 0.57*
Anxiety	$14.33 \pm 2.88$	$\pm 5/75$ 12.05 1537 $\pm 3.80$	t=0.37 t=-1.19	p = 0.37
Social	$14.33\pm 2.66$ $13.43\pm 3.40$	$13.67 \pm 3.00$ $13.67 \pm 4.17$	t=0.24	-
Performance			t = 0.24 t = -0.83	P=0.61* P= 0.41*
Depression	$7.30\pm 2.53$	$8 \pm 3.89$	ι= -0.63	P= 0.41
After intervention				
(End of one weak)				
Physical health	$10.67 \pm 2.12$	$6.53\pm 2.74$	<b>-</b> ( <b>-</b> 2	D_0.001*
Anxiety			t= 6.53	P=0.001*
Social	$14/07 \pm 2.83$	$7.97 \pm 3.84$	t= 7.01	P=0.001*
Performance	$13.03 \pm 2.41$	8.17± 2.56	t= 7.50	P=0.001*
Depression	$7.20 \pm 1.79$	$4.43 \pm 2.78$	t= 4. 59	P=0.001*
After intervention				
(End of one month)				
Physical health	0.22 ± 1.41	2.47   2.20	44.54	D 0 0 0 1 **
Anxiety	$9.23 \pm 1.41$	$3.47 \pm 2.30$	z=11.71	P=0.001**
Social	$13.47 \pm 2.56$	$4.97 \pm 3.35$	t= 11.05	P=0.001*
Performance	$12.57 \pm 2.42$	$5.80 \pm 2.23$	z= 11.26	P=0.04**
Depression	$7.03 \pm 1.81$	$2.07 \pm 2.32$	z= 9.25	P=0.001**

<sup>\*</sup> Independent Samples t-Test

#### **Discussion**

This study was conducted to evaluate the effect of multisensory intervention on the mental health of mothers with preterm neonates. In the present study, the mean score of total mental health after the intervention was lower in the intervention group than in the control group, meaning that the multisensory intervention increased maternal mental health. In other words, multisensory intervention could promote all aspects of mental health in mothers with premature neonates.

This finding is consistent with the findings of several previous studies. A semi-experimental study was conducted by Derakhshani et al. (2022) on 80 mothers selected using the census technique in the NICU of Shahid Sadoughi Hospital, Yazd, Iran. The infants in the interventional group received multisensory stimulation twice a day, from the third to the sixth day. After the intervention, the overall stress level showed two groups had significant differences (P<0.001). Given that the greatest source of stress in mothers is the separation of the newborn from the mother and the loss of parental role, parental involvement in caring for

neonates through multisensory intervention can reduce stress in mothers (20).

A clinical trial was done by Mokaberian et al. (2016) to examine the efficacy of a period of tactile-motor stimulation on preterm neonates. In the mentioned study, the tactile-motor stimulation technique was performed on 40 neonates for 10 days, three times a day, for 20 min. The Spielberger questionnaire was used to measure anxiety. Accordingly, the mothers' level of anxiety in the exprimental group decreased significantly at the termination of intervention, compared to mothers in the control group (26). The results of the current study are aligned with those of the mentioned research, which can be attributed to the partial similarity between the interventions, namely neonatal massage, despite the differences in the tools of the two studies (8). In this regard, Grohl et al. stated that the use of massage therapy in early infancy for neonates admitted to the NICU can reduce the negative effects of maternal separation (27).

The study conducted by Lotfalipour et al. (2019) Showed that changes in the

<sup>\*\*</sup> Mann-Whitney U test

psychological dimension of mothers after doing infant massage were not significantly different from those who did not perform infant massage, but mothers in the massage group experienced less anxiety and fatigue (28). It seems that the reason for the discrepancy between the results of the mentioned research and our study is the type of intervention and the duration of the intervention. In the present study, multi-sensory stimulation was an intervention during which the mother, in addition to massaging the infant, stimulated the senses of touch, sight, hearing, and balance of the baby, while in the mentioned study, only one infant massage was done once a day for five days.

Part of the multisensory intervention is lullabying for the neonate, which has been shown to be effective in reducing maternal anxiety in several studies. The study carried out by Arnon et al. (2014) revealed that singing significantly reduced the anxiety of mothers with premature neonates during kangaroo care, compared to performing kangaroo care alone (29), which is similar with the findings of the current research, since singing in kangaroo care is highly similar to multi-sensory intervention, which is a combination of pleasant stimulation of the neonate's senses. Another study was carried out by Persico et al. (2017) to determine the effect of lullabies during pregnancy and after the mother-neonate emotional relationship, neonatal behaviors, and maternal stress. The findings of the mentioned research indicated that lullabies decreased crying, colic, and nocturnal awakening in neonates and decreased maternal stress. Moreover, the mother's lullabying improved mother-neonate communication and bonding (30).

Singing represents a multifaceted experience that combines auditory, visual, and vestibular stimuli (31). During maternal singing, episodes with longer face-to-face encounters between the mother and the neonate and more emotional states on the face were observed. Therefore, the neonate's consciousness increases with the mother's singing, and a stronger connection is established between them. In this respect, the mother feels more empowered to care for the neonate, and her stress and anxiety are reduced (32). On the other hand, inconsistent with the finding of the present study, the research done

by Holditch-Davis et al (2009) revealed that auditory and tactile atrial stimulation enhanced parental sensitivity; however, it did not significantly improve parent-neonate interactions (9). The reason for this discrepancy can be the small sample size in their research.

Based on the findings, the physical health dimension of mothers and the social performance dimension of mental improved in the intervention group. Palizwan et al (2014) achieved a similar result regarding the effect of kangaroo care on maternal mental health. In the mentioned study, the effect of kangaroo care on the general health status of postpartum mothers was investigated on 100 mothers with term neonates in Ahvaz, Iran, the using Goldberg General Questionnaire. The results revealed that skin-toskin contact between the mother and the neonate (i.e., kangaroo care) was effective in improving general health, including maternal physical health and social functioning (33). The advantage of multisensory intervention in kangaroo care is that according to the principles of developmental care, it is better to stimulate all the senses of neonates, including hearing, sight, and atrium, in a desirable way, which is achieved in this type of intervention (34).

The multisensory intervention also had an effect on the depression dimension of the mental health of mothers with premature infants and showed a meaningful reduction in this regard, compared to the control group. In a randomized clinical trial, Holditch-Davis et al. (2009) compared three groups (n=240), including one in which the mothers were encouraged to do skin-to-skin care, another in which the mothers were motivated to perform ATVV intervention, and the control group. It was determined that the mothers in the skinto-skin contact group experienced a faster reduction in anxiety, and those in the ATVV group experienced a significant decrease in depressive symptoms. Furthermore, the mothers experienced less parental stress in both the skin-to-skin contact and ATVV groups than in the control group (9), which is aligned with the results of the current study. Multisensory intervention allows the mother to have a pleasant and desirable interaction with her newborn and improves the mother's

mental state by strengthening her attachment and bond with the neonate (34). The results of the intragroup comparison indicated that mental health improved over time in the intervention group, indicating the effect of time due to more emotional communication between the mother and the neonate during the multisensory intervention even at home, which made mothers feel more qualified and less stressed. Considering that only mental health was investigated in the current study and mothers were followed up for up to one month after the intervention, it is suggested to implement further researches to evaluate the long-term effects of this intervention by following up for a longer period after discharge. It is also s recommended to inquiry the role of peer education in multisensory intervention and its effect on mothers' mental health.

One of the limitations of this research was that sometimes the mothers did not cooperate to perform the multisensory stimulation intervention due to fatigue and impatience. Consequently, it was tried to attract parents' attention and encourage them to cooperate in the research by informing them properly about the benefits of this intervention for their neonate and following up on the phone. Another limitation of this study was related to the psychological characteristics of the parents, which were beyond the control of the researcher.

#### Conclusion

The results of this research indicated that the efficacy of multisensory intervention on the mental health of mothers of premature infants. Since mothers are present without restrictions in the NICU and the mother's participation in the care of the baby in the family-centered care approach is emphasized, this type of intervention can be used as an easy and cost-free way to promote the mental health of premature neonates' mothers.

## **Declarations**

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## **Conflicts of interest**

Authors declared no conflicts of interest.

#### **Ethical Considerations**

Obtaining informed consent, obtaining permission to carry out work. Voluntary participation in research, confidentiality of information, were among the ethical considerations

#### Code of Ethics

This study was extracted from a thesis approved by the Mashhad University of Medical Sciences, Mashhad, Iran (IR.MUMS.NURSE.REC.1399.082 & IRCT code 20210127050152N1).

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#### **Authors' contributions**

A.N was a MSc student, supervised by N.R, and HR. B. contributed substantially in the study design. A.N. carried out the data collection N.R, and HR. B. conducted data analysis and interpretation. N.R. provided the first draft of the work. All authors have reviewed the manuscript critically. All authors have read and approved the final version of the manuscript.

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