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Original article

The effect of the 'M' Technique® massage on physiological parameters in preterm neonates: a randomized controlled trial study

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Abstract

Introduction: Preterm birth is one of the major health problems in developed and developing countries. The 'M' Technique® is a gentle, structured, stroking relaxation massage technique, which aims to reduce stress in preterm neonates in the Neonatal Intensive Care Unit (NICU) that cannot tolerate conventional massage techniques. Evidence consistently suggests that the 'M' Technique® is a safe non-medical intervention. The aim of this study was to examine the effect of the 'M' Technique® on physiological parameters of preterm neonates admitted to the NICU.

Methods: This study is a randomized controlled trial conducted on preterm neonates at a Level III NICU, affiliated to Iran University of Medical Sciences, from February 2018 to May 2019 in Tehran, Iran. The convenience sampling method was used. Physiological parameters were measured 5 minutes before, during and then 10 minutes after each intervention for 2 weeks. Data were analyzed using SPSS® version 23 for Windows® (SPSS Inc., Chicago, IL, USA).

Results: The findings showed there was no statistically significant difference between groups in heart rate, respiratory rate and oxygen saturation before intervention on the 1st day ($p = 0.868$, $p = 0.399$ and $p = 0.677$, respectively), but a statistically significant difference was observed during and after the intervention in heart rate ($p = 0.011$ and $p < 0.001$, respectively), respiratory rate

($p < 0.001$ and $p < 0.001$, respectively) and oxygen saturation ($p = 0.002$ and $p = 0.001$, respectively) in the same day. These results were repeated in the 7th and 14th days, too.

Conclusion: The use of 7-minute 'M' Technique® for preterm neonates has a positive effect on physiological parameters and improves physiologic stability.

Keywords

'M' Technique®, physiological parameters, preterm neonate, Neonatal Intensive Care Unit.

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Introduction

Preterm birth is one of the major health problems in both developed and developing countries [1]. Improvement in neonatal care has increased the number of preterm neonates who survive [2, 3]. Preterm neonates do not receive somatic stimulation produced by contact of the skin with amniotic fluid and uterine wall. This contact leads to proper growth and improved neurodevelopmental function in the neonates [4].

Preterm neonates in the Neonatal Intensive Care Unit (NICU) are exposed to stressful and noxious stimuli such as light, sound, and therapeutic procedures that may lead to cognitive impairment, problems in learning and social behavior, increased medical costs and longer hospital stay [5-8]. Therefore, finding a way to reduce stress responses in preterm neonates hospitalized in NICUs is of great importance [9]. Stress responses in preterm neonates occur in autonomic and behavioral systems. In the autonomic system, the physiological responses are reflected in heart rate, oxygen saturation, respiratory rate, blood pressure, and skin color [3]. Neonates express adaptation to their environment through changes in physiological parameters such as heart rate, tonicity, oxygen level, blood pressure, skin color and temperature [10].

One way to achieve these goals is to use tactile stimulation massage in a preterm neonate [11, 12]. Massage therapy is the systematic application of tactile stimulation that is performed in various ways and stimulates sensory receptors [13, 14]. Massage can be in the form of touching, stroking, friction, stretching, compression, and passive movement of the joints [15, 16]. Neonatal massage is one of the important supportive interventions if it is based on the neonate's behaviors and is aimed at reducing infant stress and optimizing the infant's sensory experience to improve long-term development [17]. Researchers have studied many types of comforting or relaxing touch techniques. These techniques include therapeutic touch [18] and gentle human touch (GHT), which is a type of massage without stroking or massaging [19, 20].

Recently, according to development in conventional massage techniques, a method for these babies was introduced by Dr. Jane Buckle, the so-called "'M' Technique®" [21]. This technique does not require changing the neonate's position and is based on the neonate's behavioral response. Each movement and sequence consists of a number of movements with specific pattern, pressure, and speed that are easily learned and applied in clinical practice and research [22, 23].

In order to provide quality care for infants and their families, a multidisciplinary team that is professional, responsive, and can effectively communicate with the families is needed [24]. Neonatal nurses are in a unique position [25] and, therefore, play an important role in enhancing the developmental environment of the infant as well as performing therapeutic interventions to ensure their optimal development [26]. The aim of this randomized controlled trial was to examine the effect of the 'M' Technique® on physiologic parameters in preterm neonates admitted to NICUs.

Method

This study was a randomized controlled trial conducted on preterm neonates admitted to Level III NICU of Iran University of Medical Sciences from February 2018 to May 2019 in Tehran, Iran. In this study, the following hypotheses were tested:

1. during and 10 minutes after the intervention, heart rate and respiratory rate would be lower in experimental than control group on the 1st, 7th and 14th days of the intervention;

2. during and 10 minutes after the intervention, oxygen saturation would be higher in experimental than control group on the 1st, 7th and 14th days of the intervention.

After the Ethics Committee of Iran University of Medical Sciences approved the study (IR.IUMS.REC 1395.29974), the researcher entered the research setting. A total of 75 preterm neonates were recruited in this study based on the following inclusion criteria: below 37 weeks of gestational age and birth weight between 800-2,500 g. Neonates were excluded if they had an endotracheal tube, congenital anomalies, seizures diagnosis, chest tube, intracranial hemorrhage higher than grade II, septic shock, respiratory failure (e.g., supplemental FiO_2 requirement > 80%), persistent tachycardia and persistent bradycardia. After selecting the samples, the objectives of the study were explained to the parents of the neonates and in case of their satisfaction for their neonates to participate in the study, written consent was obtained. Demographic information, including infant's gender, birth weight, gestational age, corrected age, type of delivery, Apgar at 1 and 5 minutes, were recorded by the researcher. Then, random allocation sequencing was used to determine the experimental and control group members. Using block randomization, neonates were placed in the experimental and control groups. Random allocation can be made in blocks in order to keep the sizes of treatment groups similar. Thus, first, a block size (size 4) was determined by the researcher. After determining the block size, all possible combinations of assignments within the block (i.e., equal number for all groups within the block) were calculated. The blocks were then randomly selected and assigned in groups: 32 neonates were allocated to the 'M' Technique® group and 32 neonates were allocated to the control group, so the number of analyzed neonates was 64. The steps of the study are shown in **Fig. 1**.

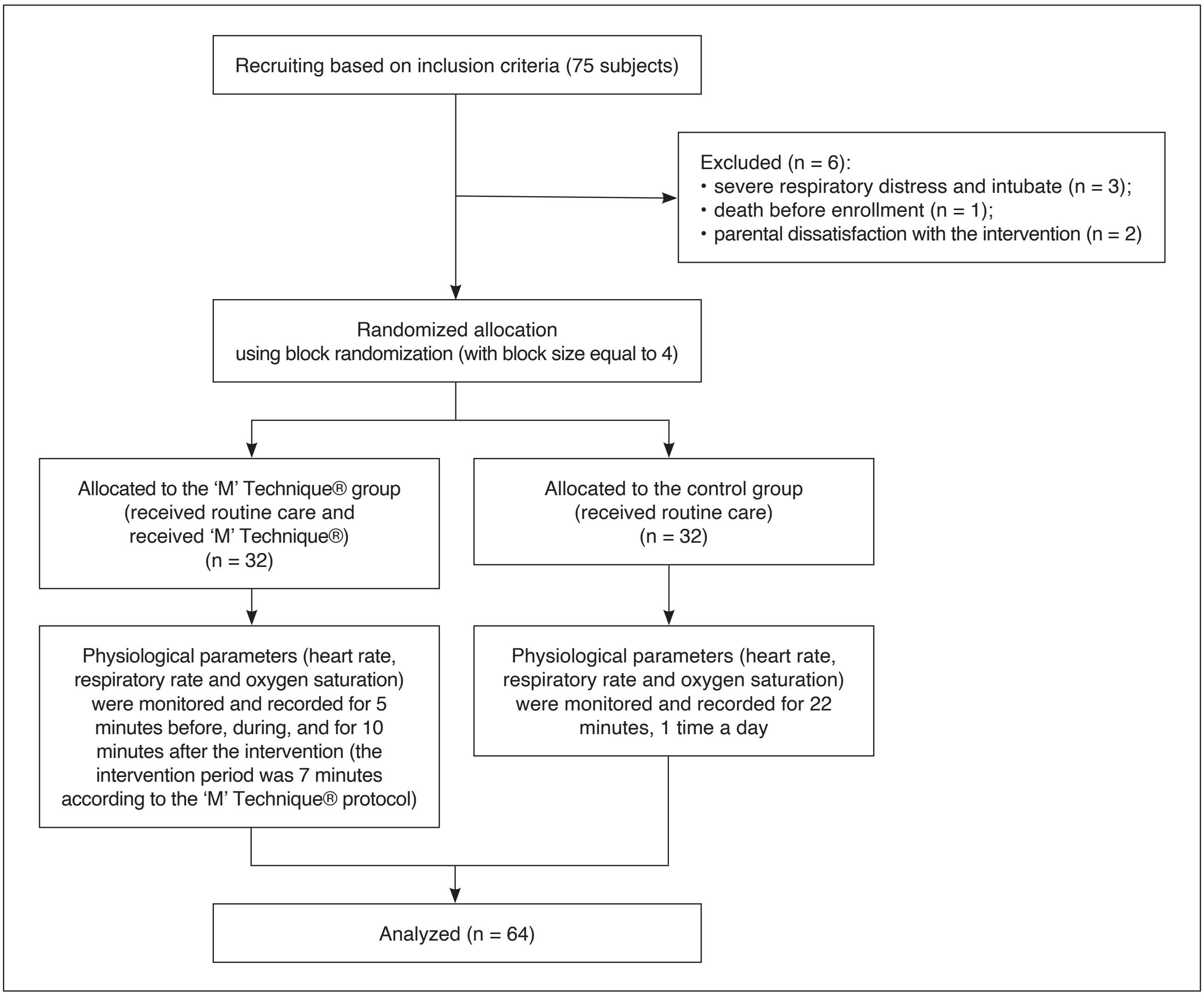

Figure 1. The steps of the study.

All neonates in the control and experimental group received routine developmental care in the NICU, such as skin-to-skin contact, parental presence, positional support and sleep cycle care. In addition to the care provided, the experimental group received an ‘M’ Technique® based protocol. None of the neonates received any procedures or handling for at least 15 minutes before data collection, because handling may have affected the physiological parameters of the neonates [27]. Cardiovascular monitoring was performed for all neonates in the control and experimental groups. The heart rate, respiratory rate and oxygen saturation percentage were recorded from neonatal pulse oximetry by a nurse/researcher. Neonatal pulse oximetry (Philips IntelliVue MX700 bedside patient monitor) was used to measure physiological parameters. This pulse oximetry tool is regularly calibrated according to the manufacturer’s standards. Data on physiological parameters (heart rate, respiratory rate and oxygen saturation) of the experimental group were monitored and recorded for 5 minutes before, during, and for 10 minutes after the intervention. The intervention period was 7 minutes according to the ‘M’ Technique® protocol. Each intervention session was performed from 8 a.m. to 2 p.m. based on the clinical condition and readiness of the neonate. In cases where any symptom of physiological distress (which included an increase in heart rate of more than 200 beats per minute for 15 seconds, or an oxygen saturation of less than 80% over 30 seconds) was observed in the neonates, the intervention was stopped. The physiological parameters in the control group were monitored and recorded for 22 minutes, once a day, under similar conditions to which the experimental group was exposed except for the intervention.

Study protocol

The ‘M’ Technique® was first developed by Dr. Jane Buckle as a relaxation touch technique in neonates after craniofacial surgery [21] and then it was used in very preterm neonates [17, 28]. The ‘M’ Technique® is a structured stroking relaxation massage technique that aims to reduce stress in premature neonates who cannot tolerate conventional massage techniques [22, 23]. The timing of the ‘M’ Technique® should be based on the medical status of each neonate. Generally, it should be done at least 1.5 to 2 hours after feeding [28]. After thoroughly examining the neonate and making sure that the baby is a candidate for massage, the neonatal nurse puts the neonate in prone position with extremities in flexed position. The baseline data is recorded. The investigator warms his hands; one hand is cupped and the other supports the baby’s head and extremities. Stroking begins with the third and fourth finger pads of both hands with a pressure of 3 (on a scale of 1 to 10), which are rhythmic and stepwise. Each stroke is repeated 3 times. The total duration of this technique is 7 minutes (approximately 20 seconds per pressure). The technique ends with a touch and support and is performed slowly [28]. In this study, the intervention was continued for 2 weeks.

Training

The ‘M’ Technique® protocol was extracted from 3 previous studies [17, 21, 28]. Prior to starting the study, the educational DVD film about how to perform this method [29] was made available to all members of the research team including 4 members, one of whom is a neonatal nurse practitioner that has an infant massage certification, and another member who is a neonatologist and a member of the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) in Iran and is also an expert in reading preterm neonate cues. Then ‘M’ Technique® training sessions were held. At first, all members of the research team watched an educational DVD film and a discussion was held on how it should be performed. Then, for 2 months before starting the study, training sessions were held 3 days a week, and in these sessions, the members of the research team performed massage on the manikin based on the ‘M’ Technique® method.

Data analysis

Statistical analysis was done by SPSS® version 23 for Windows® (SPSS Inc., Chicago, IL, USA). Descriptive statistics are presented as frequency, percentage, mean, standard deviation, minimum and maximum to show a general picture of participants’ characteristics. The data were checked for normality of distribution. Inferential statistics, including chi-square, two-way repeated measure ANOVA, repeated measure ANOVA and independent-t test, were used to compare the data between groups.

Results

Demographic characteristics

As shown in **Tab. 1**, 64 neonates (32 in each group) entered the study. Before the intervention,

Table 1. Demographic characteristics of neonates.

Variable		Groups				p-value
		Control group (n = 32)		Experimental group (n = 32)		
		Mean ± SD or frequency (%)	Min-max	Mean ± SD or frequency (%)	Min-max	
Delivery type	Caesarean	28 (87.5%)	-	25 (78.1%)	-	0.320
	Normal vaginal delivery	4 (12.5%)		7 (21.9%)		
Sex	Male	14 (45.2%)	-	17 (53.1%)	-	0.453
	Female	18 (56.2%)		15 (46.9%)		
Birth weight (g)		1,855.62 ± 445.66	1,100-2,900	1,787.43 ± 416.55	970-2,600	0.532
Gestational age (week)		31.6 ± 1.66	28.4-35	31.02 ± 1.68	28-34.2	0.184
Corrected age (week)		33.82 ± 1.92	30.4-37.2	34.26 ± 1.54	31.2-37	0.315
Apgar 1		7.28 ± 1.05	5-9	7.25 ± 1.41	3-9	0.921
Apgar 5		9.21 ±1.49	8-10	9.4 ± 1.71	8-10	0.225

there were no statistically significant differences between groups in terms of gender, birth weight, gestational age, corrected age, delivery type, Apgar 1 and Apgar 5.

Two-way repeated measure ANOVA was used to evaluate the overall effect of the intervention and repeated measure ANOVA was used to evaluate the effect of the intervention on each day on heart rate, respiratory rate and oxygen saturation.

Heart rate

The heart rate of neonates is shown in **Tab. 2**. Two-way repeated measure ANOVA was used to evaluate the overall effect of the intervention on heart rate. Results showed that the effect of intervention time was not significant ($p = 0.903$) but the effect of group ($p = 0.001$) was significant.

After the evaluation of the intervention effect on each day, the results showed that on the 1st day, the effect of time ($p < 0.001$) and the effect of group ($p = 0.022$) were significant. Therefore, independent t-test was used on this day to compare the two groups. It was shown that before the intervention, the two groups did not have a statistically significant difference ($p = 0.868$), but during ($p = 0.011$) and after ($p < 0.001$) the intervention this difference was significant and the heart rate in the intervention group was significantly lower than the control group.

On the 7th and 14th days, the effect of time ($p < 0.001$) and the effect of group ($p = 0.003$) were significant, similarly. Therefore, we compared the two groups and the results showed that before the intervention the two groups did not have a statistically significant difference on the 7th ($p = 0.498$) and 14th ($p = 0.555$) days, but during ($p < 0.001$) and after the intervention on the 7th ($p = 0.003$) and 14th ($p < 0.001$) days this difference was significant and the heart rate in the intervention group was significantly lower than the control group. The heart rate of the two groups at different times is depicted in **Fig. 2**.

Respiratory rate

As shown in **Tab. 3**, the results showed that the effect of intervention time on the respiratory rate was not significant ($p = 0.219$) but the effect of group ($p < 0.001$) was significant.

Then the effect of the intervention on each day was evaluated, which showed that, on the 1st and 7th days, the time effect ($p < 0.001$) and the group effect ($p < 0.001$) were significant. Therefore, we compared the two groups and the results showed that before the intervention there was no significant statistical difference between them in the 1st ($p = 0.399$) and 7th ($p = 0.744$) days, but during ($p < 0.001$) and after ($p < 0.001$) the intervention the respiratory rate was significantly lower in the intervention group than the control group in both days.

On the 14th day, the time effect ($p = 0.011$) and the group effect ($p < 0.001$) were significant. Therefore, independent t-test was used to compare the two groups and the results showed that before the intervention they did not have a statistically significant difference ($p = 0.861$), but during ($p < 0.001$) and after the intervention ($p < 0.001$) this difference was significant and the respiratory rate was lower in the intervention group than the control group. The respiratory rate of the two groups at different times is depicted in **Fig. 3**.

Table 2. The heart rate of neonates.

Time		Groups		Repeated measure ANOVA		Independent-t
		Control group (n = 32)	Experimental group (n = 32)	Group	Time	p-value
		Mean ± SD	Mean ± SD	P(η^2)	P(η^2)	
1st day	Before	128.84 ± 12.73	129.34 ± 11.19	0.022 (0.081)	< 0.001 (0.209)	0.868
	Within	129.43 ± 12.50	121.40 ± 12.01			0.011
	After	131.81 ± 11.67	119.15 ± 11.68			< 0.001
7th day	Before	130.71 ± 11.67	128.62 ± 12.88	0.003 (0.136)	< 0.001 (0.324)	0.498
	Within	132.81 ± 10.04	117.90 ± 11.16			< 0.001
	After	129.37 ± 11.18	120.28 ± 12.33			0.003
14th day	Before	128.81 ± 11.56	130.65 ± 13.22	0.003 (0.132)	< 0.001 (0.192)	0.555
	Within	131.75 ± 11.09	120.03 ± 11.05			< 0.001
	After	133.28 ± 11.55	118.34 ± 10.91			< 0.001
Two-way repeated measure ANOVA P(η^2)	Group	0.001 (0.154)		-		
	Time	0.903 (0.002)				
	Time * Group	0.726 (0.005)				

η^2 = partial eta-squared. Effect sizes: 0.01 = small; 0.06 = moderate; 0.14 = large.

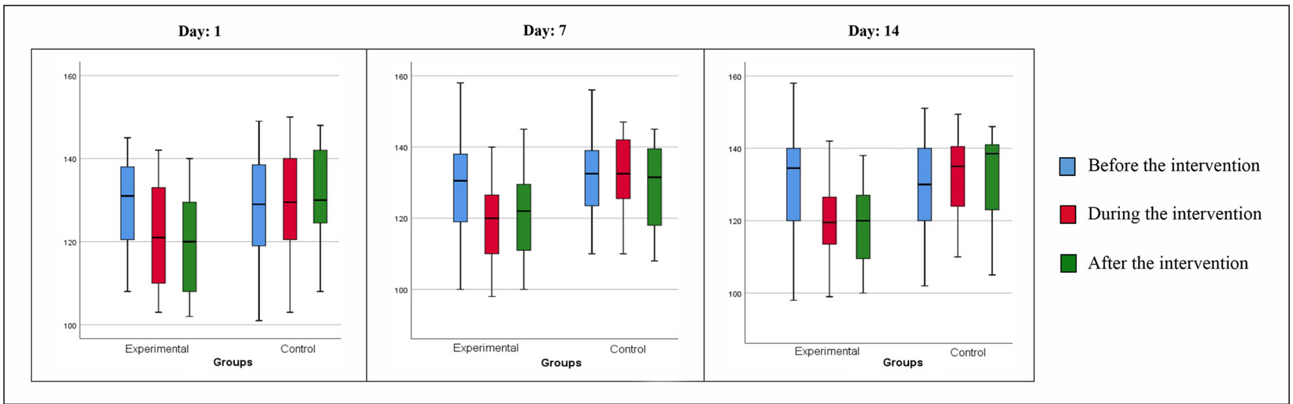

Figure 2. The heart rate of the two groups at different times.

Table 3. The respiratory rate of neonates.

Time		Groups		Repeated measure ANOVA		Independent-t
		Control group (n = 32)	Experimental group (n = 32)	Group	Time	p-value
		Mean ± SD	Mean ± SD	P(η^2)	P(η^2)	
1st day	Before	51.25 ± 5.48	49.96 ± 5.13	< 0.001 (0.263)	< 0.001 (0.360)	0.399
	Within	52.25 ± 5.43	43.46 ± 6.00			< 0.001
	After	52.71 ± 6.21	43.34 ± 6.19			< 0.001
7th day	Before	50.06 ± 6.05	50.53 ± 5.36	< 0.001 (0.238)	< 0.001 (0.377)	0.744
	Within	52.53 ± 5.87	42.46 ± 4.73			< 0.001
	After	50.68 ± 6.08	43.06 ± 5.11			< 0.001
14th day	Before	50.03 ± 5.55	50.28 ± 5.83	< 0.001 (0.185)	0.011 (0.071)	0.861
	Within	51.84 ± 4.78	46.46 ± 5.66			< 0.001
	After	53.28 ± 5.04	44.53 ± 4.87			< 0.001
Two-way repeated measure ANOVA P(η^2)	Group	< 0.001 (0.317)		-		
	Time	0.219 (0.024)				
	Time * Group	0.386 (0.015)				

η^2 = partial eta-squared. Effect sizes: 0.01 = small; 0.06 = moderate; 0.14 = large.

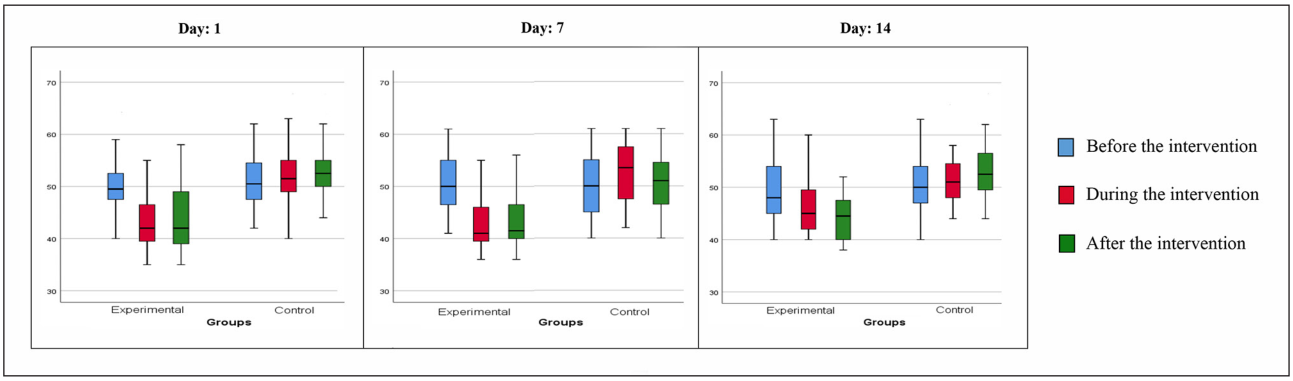

Figure 3. The respiratory rate of the two groups at different times.

Oxygen saturation

As shown in **Tab. 4**, the overall effect of the intervention on oxygen saturation was evaluated; results showed that the effect of the intervention time was not significant (p = 0.359) but the effect of the group (p = 0.002) was significant.

Repeated measure ANOVA was used to evaluate the effect of intervention on each day. The results showed that on the 1st day the effect of time (p < 0.001) and the effect of group (p = 0.011) were significant. Therefore, we compared the two groups and the results showed that before the intervention the two groups did not have a statistically significant difference (p = 0.677), but during (p = 0.002) and after (p = 0.001) the intervention these differences were significant and in the intervention group the oxygen saturation was significantly higher than the control group.

On the 7th day, the effect of time (p = 0.006) and the effect of group (p = 0.007) were significant. Therefore, independent t-test was used to compare the two groups and the results showed that before the intervention there was no significant statistical difference between the two groups (p = 0.746), but during (p < 0.001) and after (p = 0.002) the intervention these differences were significant and in the intervention group the oxygen saturation was significantly higher than the control group.

On the 14th day, the time effect (p = 0.007) and the group effect (p = 0.025) were significant. Therefore, independent t-test was used on this day to compare the two groups and the results showed that there was no significant statistical difference before the intervention (p = 0.805), but during (p = 0.008) and after (p = 0.001) the intervention the differences were significant and the oxygen saturation in the intervention group was significantly higher than the control group. The oxygen saturation of the control and experimental groups at different times is shown in **Fig. 4**.

Table 4. The oxygen saturation of neonates.

Time		Groups		Repeated measure ANOVA		Independent-t
		Control group (n = 32)	Experimental group (n = 32)	Group	Time	p-value
		Mean ± SD	Mean ± SD	P(η^2)	P(η^2)	
1st day	Before	95.34 ± 3.17	95.68 ± 3.38	0.011 (0.099)	< 0.001 (0.118)	0.677
	Within	95.28 ± 3.12	97.71 ± 2.85			0.002
	After	95.15 ± 3.41	97.96 ± 2.94			0.001
7th day	Before	95.34 ± 2.92	95.59 ± 3.21	0.007 (0.110)	0.006 (0.080)	0.746
	Within	94.93 ± 3.45	97.78 ± 2.53			< 0.001
	After	95.21 ± 3.13	97.53 ± 2.66			0.002
14th day	Before	95.28 ± 2.58	95.12 ± 2.47	0.025 (0.078)	0.007 (0.077)	0.805
	Within	95.06 ± 2.57	96.84 ± 2.64			0.008
	After	94.87 ± 2.51	97.06 ± 2.50			0.001
Two-way repeated measure ANOVA P(η^2)	Group	0.002 (0.148)		-		
	Time	0.359 (0.016)				
	Time * Group	0.648 (0.007)				

η^2 = partial eta-squared. Effect sizes: 0.01 = small; 0.06 = moderate; 0.14 = large.

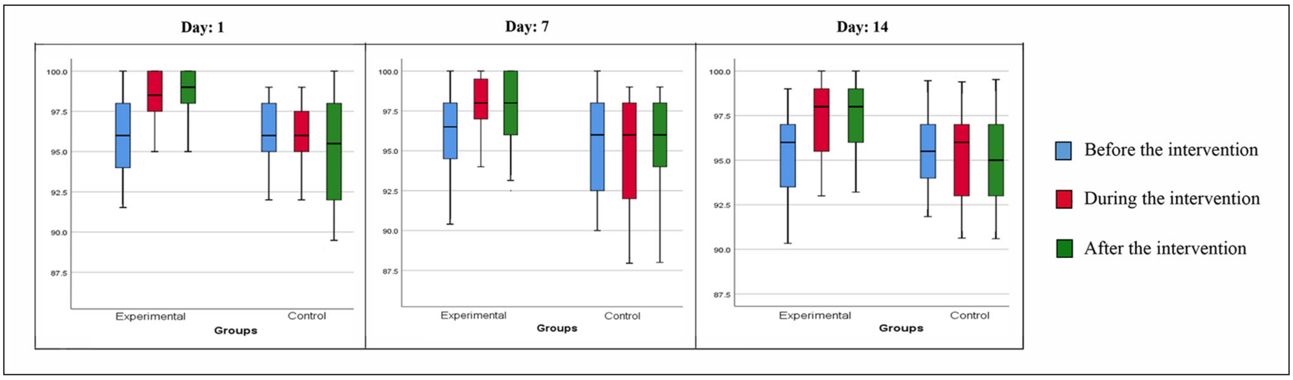

Figure 4. The oxygen saturation of the two groups at different times.

Discussion

The aim of the present study was to examine the effect of the 'M' Technique® on physiological parameters in preterm neonates hospitalized in NICUs. Based on our knowledge, this study is the first study to investigate the effects of the 'M' Technique® on physiological parameters of preterm neonates in Iran. However, two studies by Smith et al. have specifically focused on the 'M' Technique® in very preterm infants in the USA [17, 28]. Researchers are trying to promote the development of preterm infants with positive stimuli in NICUs [30]. One of these interventions is massage therapy. In developing countries, financial and human resources to care for premature babies are limited [31]. This approach can be used as an effective and cost-effective approach that is easily applicable [30].

Monitoring of physiological responses is an important component to ensure safety of preterm neonates. Today, few studies have examined physiological data (heart rate, respiratory rate, oxygen saturation) during massage in preterm neonates [32]. If massage therapy is beneficial in physiological regulation, massage therapy based on polyvagal theory in premature neonates will increase the function of the vagus and regulate and coordinate heart rate and respiration [33]. A study by Epstein found that physiological responses to stress in preterm infants lead to increased heart rate, less oxygen saturation, weight loss, and rapid respiratory rate [34].

The results of this study showed that performing the 'M' Technique® during and after the intervention can lead to a decrease in heart rate and respiratory rate and an increase in oxygen saturation, thereby, providing physiological stability in the preterm neonates. There was also a statistically significant difference between groups in all measured parameters. This result agrees with the results of the Smith et al.'s studies investigating the effects of the 'M' Technique® on very preterm infants [17, 28]. A study by Elsagh et al., which examined the effects of neonatal massage with a prone position in preterm infants on heart rate and oxygen saturation, showed that the heart rate had decreased, SaO_2 increased and the infant had become more relaxed [35]. In the Lee's study that examined tactile and kinesthetic stimulation on physiological and behavioral responses in infants under 36 weeks of age, the results showed that, although there were no significant differences in heart rate and oxygen saturation after massage, in the experimental group, the means of heart rate were lower (within the normal range) and the means of oxygen saturation were higher (within the normal range) after massage [27]. In a study by Modrcin-Talbott et al., results showed that GHT in medically fragile preterm infants had no adverse and stress effects, although it did not alter heart rate and oxygen saturation and there were no significant effects for either heart rate or oxygen saturation [20]. In the study of Harrison et al., which examined GHT in neonates with 27-33 weeks of gestational age for 10 minutes and 3 times daily, the results showed there was no statistically significant difference in heart rate and oxygen saturation at baseline and 10 minutes post touch [36]. Mathai et al.'s study also showed that during the tactile-kinesthetic stimulation the change in heart rate was significantly greater in the experimental group. However, there were no changes in other physiological parameters (e.g., respiratory rate, temperature, or oxygen saturation) [37]. In the other study carried out by Jabraeili et al. in Iran, with the aim of studying the effect of skin massage on physiological parameters of preterm infants, the results showed that there is a significant statistical difference between the mean scores of respiratory rate changes between the skin massage with olive oil group and the control group, so that the mean score on the 10th day after the intervention was 41.47 ± 5.22 and 50.24 ± 7.8 for the massage with olive oil and control groups, respectively. The study concluded that infant massage has no negative impact on physiological parameters [38].

Due to the discrepancy in the results, studies are necessary in view of the fact that the underlying physiological mechanisms and evolutionary benefits of massage are not well understood [39-41]. According to the results of the present study and the studies of Smith et al., it seems that the 'M' Technique®, which includes gentle and structured stroking on preterm infants, may have a favorable effect on physiological parameters and relaxation of preterm infants. Of course, more studies with larger numbers and broader age groups are needed. In the end, Korner asked the question precisely: "Who is stimulating, what kind of stimulation, how much, what intervals, at what postconceptional age and for what purposes?" [20].

Limitations

The most important strengths of this study were its good design, randomization, the use of an expert research team at all stages of research and massage in the presence of all of these neonatal specialists to prevent possible injury to the neonate. One of the limitations of this study was the prolongation of the study due to the need for a large sample to increase study power. Another limitation of this study was that the researchers who were collecting and recording data during the massage were aware of the purpose of the study and so blinding was not possible in this study.

Conclusion

The results of our study showed that the use of 7-minute 'M' Technique® for preterm neonates had a positive effect on physiological parameters and improved physiologic stability of preterm neonates. Evidence in this study showed that the 'M' Technique® can be used as a simple, effective and safe non-medical intervention that can be provided to preterm neonates by NICU nurses. Also, this study provided us with valuable information for future studies.

Implications for future research

Future research with a larger sample size is needed to replicate these findings and to further evaluate the efficacy of the 'M' Technique® intervention among preterm infants. Also, other research can be done with a longitudinal design to examine the post-NICU period, as well, because the parents are the main caregivers of premature neonates who become discharged. Thus, studying the 'M' Technique® effect performed by their parents will be useful. The effect of the 'M' Technique® on attachment between preterm neonates and their parents can also be examined. Comparative studies between the 'M' Technique® and other massage methods in preterm neonates should also be undertaken.

Declaration of interest

The Authors declare no conflict of interest in this study.

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