

Effect of Using Earmuffs on Physiological Parameters and Stress Levels of Premature Infants: A Randomised Controlled Trial

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ABSTRACT

Background: Earmuffs can be worn to reduce the noise exposure of premature infants. The results regarding the use of earmuffs to provide physiological stability and reduce the stress level in preterm infants are not precise. The present study aims to examine the effect of providing noise control using ear muffs on premature infants' physiological parameters and stress levels in the neonatal intensive care unit.

Methods: A prospective randomised controlled trial was conducted including 100 premature infants for a one-year-period. After randomisation, the infants included in the study were evaluated for two consecutive days and checked twice a day for a total of four times. The infants in the study group wore earmuffs twice a day, in the supine and prone positions. The infants in the control group were followed up without earmuffs.

Results: There was a statistically significant difference between the post-procedural stress scores of the study and control groups ($p < 0.05$). The stress scores of the infants in the study group were significantly lower than those in the control group. Two hours after wearing earmuffs on the first and second days, a statistically significant difference was found between the respiratory rates of the two groups, being significantly lower in the study group ($p = 0.003$).

Conclusion: According to the results of our study, using earmuffs in premature infants decreased the stress score and respiratory rate; however, this intervention did not affect other physiological parameters.

Keywords: Earmuff, Noise, Preterm infant, Physiological parameters, Stress

Introduction

Preterm infants in the neonatal intensive care unit may be exposed to undesirable but inevitable noise from human voices, alarms, telephones, and other sounds originating from the devices used in the neonatal intensive care unit (NICU) (1-5). Noise is described as unwanted, unpleasant, disturbing, and sometimes even harmful sound. Noise causes changes in the sleep-wake cycle and vital signs of infants, fluctuations in oxygen saturation, increase in systolic and diastolic blood pressure; thus, it may cause an increase in environmental stress (6-10). Noise can cause hypoxemia, apnea, and a decrease in the amount

of calories available for growth due to increased oxygen consumption and increased respiration and heart rate in preterm infants (3, 6, 7, 10, 11). Noise can reduce the infant's sleep time and prevent deep sleep. Exposure of infants to excessive noise can lead to severe and long-term health problems such as sleep disturbances and unwanted neurological and developmental effects (12, 13). The American Academy of Pediatrics (AAP) recommends that the sound level in the NICU should not exceed 45 decibels (dBA) (14). However, some studies have revealed that sound levels in NICUs exceed these limits (13, 15-17). In

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order to reduce the noise level that infants in the neonatal intensive care unit are exposed to, some precautions should be taken (2, 15, 18, 19).

The use of earmuffs in infants hospitalized in the NICU may be an effective method in reducing the negative consequences of excessive noise on the development of infants (12). However, study results examining the effect of earmuffs on preterm infants' physiological parameters are limited and contradictory (7, 19-22). Further, the results regarding the use of earmuffs in infants born at 28-32 weeks of gestation providing physiological stability and reducing the stress level are not precise (23). The earmuffs used in the previous studies are either completely enclosing the infants' ears or are inserted up to the turbinate inside the ear (7, 19-22, 24). Earmuffs that surround or are placed inside the ear may cause pain and discomfort to the infants. The use of earmuffs in this way may cause limitation of movement of the infant and make it difficult to change position. The earmuffs used should not adversely affect the infant's comfort and allow the continued care of the infant, including regular position changing. Using silicone earmuffs that are suitable for the infant's outer ear anatomy can prevent the premature infants from being exposed to ambient noise, stabilize the physiological findings, and decrease stress. None of the previous studies evaluated the effect of using earmuffs in different positions on infants. Changing the position of infants using earmuffs, ensuring that there is no increase in stress, and keeping the physiological parameters at the desired values are essential. The current study has focused on analyzing the effect of providing noise control by using silicone earmuffs in different positions on preterm infants' physiological parameters and stress levels in the NICU.

The purpose of the study was to examine the effects of noise control using silicone earmuffs in different positions on the physiological parameters and stress levels of premature infants hospitalized in the NICU. Our main aims throughout the study were to search for possible changes in physiological parameters and decrease in noise-induced stress level of preterm infants due to using silicone earmuffs. Secondly, we aimed to check whether position change was possible in infants wearing earmuffs.

Methods

This randomised controlled trial was conducted in the 2nd and 3rd level NICUs of a maternity and children's hospital. Total incubator

capacity is 28, with 7 incubators at the 3rd level and 15 incubators at the 2nd level. In this NICU, approximately 1250 infants are hospitalized each year.

The study was approved by the Non-interventional Clinical Research Ethics Committee of Adnan Menderes University Faculty of Nursing Clinical Research (Protocol no: 2020/203) and the relevant hospital. Written and oral informed consent was obtained from the parents of the infants.

The participants included in the study were hospitalized between 1 September 2021 and 31 August 2022. Premature infants with a birth weight of ≥ 1000 g and a 5th minute Apgar score of ≥ 9 were included in the study. We excluded infants with congenital anomalies, presence or suspicion of intracranial hemorrhage, receiving invasive mechanical ventilation support, and those with umbilical catheters and/or chest tubes. Infants with known or suspected hearing deficit, who were on anticonvulsant medication or sedation, who have undergone intensive phototherapy or exchange transfusion due to hemolytic disease, and who were born to mothers with substance abuse were excluded from the study. Infants who were discharged before 48 hours or who developed sepsis were excluded from the study.

A simple randomization procedure with a random numbers table was used to separate the infants into groups. Randomization was conducted by a researcher other than the researcher who collected the data.

For sample size calculation, first of all, the effect size was 0.7, taking into account the calculation (effect size < 0.2 weak, 0.5 medium strength, and 0.8 strong strength) developed by Cohen (1988) in calculating the sample size. The power analysis (Power=0.95; effect size [d] =0.7; alpha [α] =0.05) using G-power 3.1 software calculated it as 110 infants, n=55 in the control group and n=55 in the study group. A total of 10 infants, five infants in the study group (receiving invasive mechanical ventilatory support [n=4] and sepsis developed [n=1]) and five infants in the control group (receiving invasive mechanical ventilatory support [n=3] and umbilical catheter inserted [n=2]), were excluded from the study. The study was completed with 100 infants, n=50 in the study group and n=50 in the control group (Figure 1). As a result of the posthoc power analysis, it is found that for power = 0.84, effect size = 0.5 and $\alpha = 0.05$ for a total of 100 subjects.

As an intervention, a researcher (neonatal

nurse) working in the NICU randomly distributed

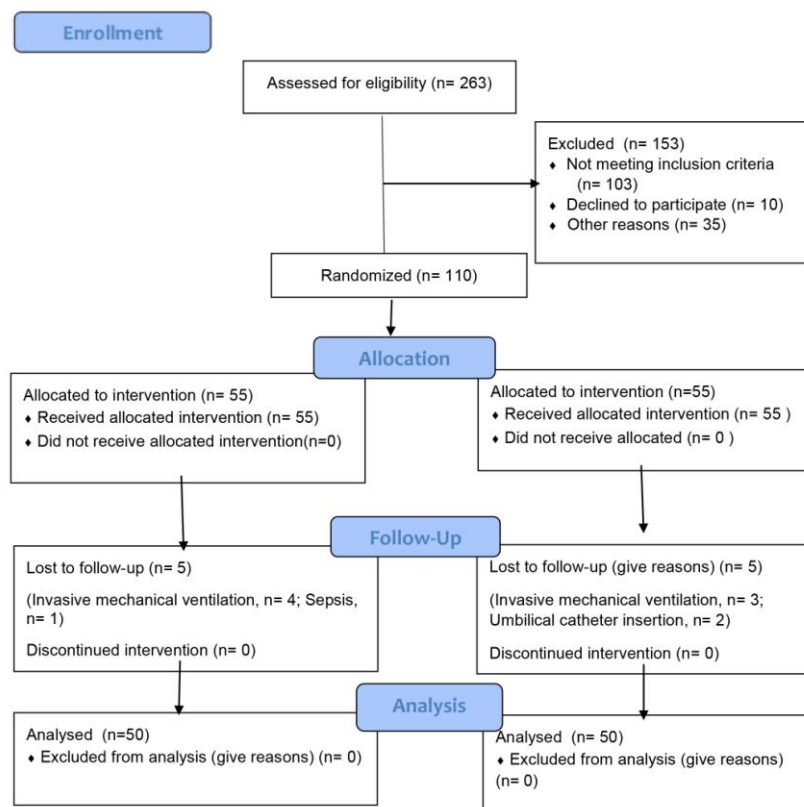


Figure 1. Consort Flow Diagram

infants to the study and control groups. All infants were followed up and evaluated for two consecutive days and twice a day for a total of four times.

In the study group, earmuffs were placed while the infants were in the supine position (morning, 09:00 am-11:00 am) and in the prone position (afternoon) for two hours twice a day. Heart rate, respiratory rate, oxygen saturation (SpO₂), systolic blood pressure, diastolic blood pressure, and stress scores were measured before each procedure (0. hour) and at the 2nd hour (2. hour) of the procedure. A suitable position was given to the infant before the procedure. Silicone earmuffs were shaped by hand, fitting the infant's external auditory meatus.

Before the earmuffs were placed (0. hour) in the morning, the infant's vital signs were recorded together with the stress score and ambient noise measurements. The silicone earmuffs were then inserted into the external auditory meatus, being positioned to cover the meatus completely. A net, covering the infants' head was placed over the earmuffs thus preventing the earmuffs from slipping out of the

ear. The infant was then placed supine. At the end of the 2nd hour, all the measurements and recordings were made again.

In the afternoon (03:00 pm-05:00 pm), procedures similar to morning intervention is repeated but this time, the infant is placed in the prone position. And again, at the end of the 2nd hour, all the measurements and recordings are made again. The purpose of this kind of application was to evaluate the effect of using earmuffs at different time periods and positions.

In the control group; no earmuffs were placed. Infants in the control group were kept in the supine position in the morning (09:00 am-11:00 am) and in the prone position in the afternoon (03:00 pm-05:00 pm) without extra intervention. Heart rate, respiratory rate, SpO₂, blood pressure (systolic and diastolic), stress scores, and ambient noise were measured and recorded at the similar time periods; at 09:00 am, 11:00 am, 03:00 pm and 05:00 pm.

In the study, the primary outcomes were differences in the infants' stress scores, heart rates, respiratory rates, SpO₂, and blood pressure. The bedside monitor and neonatal stress scale were used to get the preliminary results.

Demographic characteristics of the infants regarding their Apgar scores, feeding methods, status about the oxygen therapy and phototherapy, vital signs and neonatal stress scores were recorded.

The Neonatal Stress Scale had been developed to assess acute stress in preterm infants. The scale consists of eight subgroups and 24 items. Subgroups include facial expression, body-color, respiration, activity level, consolation, muscle tone, extremities and posture. Each item of the scale, in triple Likert type, is evaluated between 0-2 points. A minimum of 0 points and a maximum of 16 points are taken from the scale. As the score increases, the infant's stress level increases. Cronbach's alpha coefficient is between 0.65-0.81 (5).

The sound-meter (Extech SL130W Datasheet) was used to monitor the noise level inside the NICU. The values (dBA) measured with the sound meter were recorded once before the procedure and once in the 2nd hour after the procedure.

Statistical analysis

The data were analyzed using SPSS (Statistical Package for Social Sciences) 23.0 software. Descriptive statistical analyses (frequency, percentage, mean, standard deviation) were used to analyze the data, the Chi-square test was used in the analysis of categorical variables, and the student's t-test was used to compare the difference between the two groups. Kolmogorov Smirnov test of normality was used to determine whether the data were distributed following the normal distribution. Values at the $P < 0.05$ level were considered statistically significant.

Results

In this study, we could finally analyse data of totally 100 infants and the demographic characteristics were similar in between the two groups. The study and control groups were similar regarding their way of delivery, gender, resuscitation, oxygen intake and administration, receiving phototherapy, and method of feeding (Table 1).

Ambient noise levels in the environment were similar for the two groups ($p > 0.05$). In the morning measurements of the study group, mean value of the noise level in the NICU at the 0. hour was 55.05 ± 5.16 dBA and 53.39 ± 4.98 dBA at the 1. hour. In the control group, 0. hour mean value was 56.92 ± 4.57 dBA as the 1. hour was 54.94 ± 5.02 dBA in the morning. In the

afternoon measurements of ambient noise level of the study group was 54.91 ± 5.04 dBA at the 0. hour, 53.37 ± 4.98 dBA at the 1. hour; as these mean values of the control group were 54.37 ± 5.05 dBA at the 0 hour and 53.24 ± 4.07 dBA at the 1. hour.

First and second-day stress scores, respiratory rate, SPO₂, heart rate, systolic and diastolic blood pressures of the infants in the study and control groups were compared. There was no statistically significant difference between the groups on the first day in terms of SPO₂, heart rate, systolic and diastolic blood pressure values (Table 2). But there was a statistically significant difference between the first-day stress scores of the study and control groups ($p < 0.05$). The stress scores of the groups at the 0. and 2. hours in the morning and at the 2. hour in the afternoon were statistically different in the measurements made in the supine position in the morning and in the prone position in the afternoon (respectively, $p = 0.024$, $p = 0.008$, $p = 0.009$). The stress scores of the infants in the study group using earmuffs were lower than those of the infants in the control group (Table 2).

There was a statistically significant difference between the first-day respiratory rates of the study and control groups ($p < 0.05$). The respiratory rate values of the groups measured in the afternoon on the first day and in the second hour were statistically different ($p = 0.03$). The respiratory rate of the infants in the study group was lower than the respiratory rate of the infants in the control group (Table 2).

There was no statistically significant difference between the second day SpO₂, heart rate, systolic and diastolic blood pressures of the babies in the study and control groups ($p > 0.05$). There was a statistically significant difference between the stress scores measured in the morning on the second day of the infants in the study and control groups ($p < 0.05$). A statistically significant difference was observed between the infants in the study and control groups regarding stress scores measured at 0. and 2. hours in the morning and 2. hours in the afternoon on the second day (respectively, $p = 0.030$, $p = 0.006$, $p = 0.003$). A statistically significant difference was found between the groups regarding respiratory rate in the morning and afternoon on the second day ($p = 0.008$ and $p = 0.004$, respectively). After using earmuffs, the respiratory rate of the infants in the study group was lower than those in the control group (Table 2).

Table 1. Basic Demographic Characteristics and Clinical Features of the Infants

	Study group (n=50)		Control group (n=50)		Test* P value
	Mean	SD	Mean	SD	
Gestational age	33.42	2.62	33.12	2.78	t=0.554 p=0.581
Birth weight	2067.70	550.23	2145.66	664.47	t=-0.639 p=0.542
Apgar 1-min.	8.18	0.82	7.88	1.45	t=1.270 p=0.208
Apgar 5-min.	9.16	0.71	8.96	1.10	t=1.076 p=0.285
	n	%	n	%	χ ² Test** P value
Type of birth					
Vaginal	13	26.0	10	20.0	0.508
C-section	37	74.0	40	80.0	
Gender					
Girl	29	58.0	21	42.0	2.560
Male	21	42.0	29	58.0	
Performing resuscitation					
Yes	4	8.0	5	10.0	0.122
No	46	92.0	45	90.0	
O ₂ uptake (First day)					
Yes	10	20.0	11	22.0	0.060
No	40	80.0	39	78.0	
O ₂ uptake (Second day)					
Yes	8	16.0	12	24.0	1.000
No	42	84.0	38	76.0	
NIMV implementation					
Applied	6	12.0	10	20.0	1.190
Not applied	44	88.0	40	80.0	
Feeding Method (First day)					
Breast milk only	28	56.0	23	46.0	1.000
**Other	22	44.0	27	54.0	
Feeding Method (Second day)					
Breast milk only	29	58.0	31	62.0	0.167
***Other	21	42.0	19	38.0	
Receiving Phototherapy (First day)					
Yes	3	6.0	3	6.0	0.000
No	47	94.0	47	94.0	
Receiving Phototherapy (Second day)					
Yes	4	8.0	2	4.0	0.709
No	46	92.0	48	96.0	

*Independent Sample t-test **Chi-square test ***Other (Formula and breast milk or formula or parenteral nutrition)

Discussion

The present study revealed that the 2-hour stress levels of preterm infants who used earmuffs in the supine position (morning) and prone position (afternoon) were lower than infants without earmuffs. Even if 0-hour stress levels were higher in the control group in supine position, this difference is more precise in the 2-hour in supine position. In addition, the respiratory rates of preterm infants using earmuffs were lower than those of infants without earmuffs. This indicates that earmuffs contribute to the decrease in preterm infants' stress scores and respiratory rate. There was no difference in systolic and diastolic blood pressure values between the groups with and without earmuffs. Further, there was no significant difference between the SpO₂

and heart rate groups.

Stress can cause adverse physiological changes in preterm infants, significantly increased intracranial pressure, increased arterial blood pressure, apnea, and bradycardia (9, 10, 25). Previous studies show the relationship between earmuffs and physiological values such as heart rate, respiratory rate, arterial oxygen saturation, blood pressure, and body temperature, which vary under stress. However, there is no study examining the effect of earmuff use on the stress of preterm infants. In two studies, it was concluded that the heart and respiratory rates of the infants who used earmuffs were lower than those in the group without earmuffs (7, 20). In another study, the heart rate was decreased in infants who used earmuffs compared to infants

who did not use earmuffs, and the oxygen

Table 2. First and Second-day Neonatal Stress Scores and Physiological Parameters

Variable	Day 1			Day 2		
	Study group (n=50)	Control group (n=50)	Test* P value	Study group (n=50)	Control group (n=50)	Test* P value
	Mean ±SD	Mean ±SD		Mean ±SD	Mean ±SD	
In supine position						
Stress score (0. hour)	1.04±1.04	1.66±1.61	t=-2.280 p=0.024	0.88±0.89	1.36±1.30	t=-2.144 p=0.030
Stress score (2. hours)	0.60±0.85	1.20±1.34	t=-2.667 p=0.008	0.32±0.58	0.88±1.28	t=-2.798 p=0.006
Respiratory rate (0. hour)	50.66±2.33	50.92±3.48	t=-0.439 p=0.662	49.76±2.95	49.96±2.33	t=-0.375 p=0.709
Respiratory rate (2. hours)	51.32±3.80	52.44±4.06	t=-1.422 p=0.158	51.28±3.49	53.24±3.74	t=-2.706 p=0.008
SpO ₂ (0. hour)	96.38±6.91	97.28±2.22	t=-0.876 p=0.383	97.28±2.10	97.00±2.11	t=0.664 p=0.508
SpO ₂ (2. hours)	96.52±6.63	97.70±1.19	t=-1.238 p=0.219	97.12±1.82	97.40±1.87	t=-0.757 p=0.451
Heart rate (0. hour)	138.28±12.22	140.36±15.34	t=-0.749 p=0.455	139.36±11.23	139.46±13.86	t=-0.040 p=0.968
Heart rate (2. hours)	139.12±14.06	138.36±14.10	t=0.270 p=0.788	139.84±10.51	140.72±11.50	t=-0.399 p=0.691
Systolic BP (0. hour)	77.22±12.33	75.32±9.12	t=0.876 p=0.383	75.30±12.11	75.06±9.71	t=0.109 p=0.913
Systolic BP (2. hours)	77.06±11.64	73.20±10.07	t=1.772 p=0.079	74.32±9.96	74.72±9.19	t=-0.209 p=0.835
Diastolic BP (0. hour)	42.08±10.19	41.44±11.26	t=0.298 p=0.766	40.92±8.70	42.92±8.48	t=-1.164 p=0.247
Diastolic BP (2. hours)	43.78±9.71	43.34±8.75	t=0.238 p=0.812	42.22±8.70	43.14±8.50	t=-0.534 p=0.594
In prone position						
Stress score (0. hour)	0.82±0.96	1.12±1.28	t=1.3198 p=0.190	0.84±1.218	1.26±1.700	t=-1.420 p=0.159
Stress score (2. hours)	0.36±0.66	0.82±1.04	t=-2.631 p=0.009	0.26±0.751	0.82±1.101	t=-2.972 p=0.003
Respiratory rate (0. hour)	49.46±7.39	51.74±7.38	t=-1.543 p=0.126	50.32±3.139	49.90±7.517	t=0.365 p=0.716
Respiratory rate (2. hours)	50.76±4.15	53.32±7.47	t=-2.115 p=0.03	50.72±4.036	53.08±4.105	t=-2.899 p=0.004
SpO ₂ (0. hour)	97.12±2.28	97.38±2.09	t=-0.593 p=0.555	97.18±2.027	97.52±2.023	t=-0.840 p=0.403
SpO ₂ (2. hours)	97.18±1.76	97.46±1.79	t=-0.785 p=0.434	97.80±1.294	98.48±9.725	t=-0.490 p=0.625
Heart rate (0. hour)	138.80±13.55	137.28±15.14	t=0.529 p=0.598	139.10±12.620	140.44±14.837	t=-0.486 p=0.628
Heart rate (2. hours)	138.68±11.51	137.54±13.93	t=0.446 p=0.657	141.00±9.817	140.72±10.863	t=0.135 p=0.893
Systolic BP (0. hour)	75.24±11.204	76.88±10.856	t=-0.743 p=0.459	86.10±81.370	76.68±10.040	t=0.812 p=0.419
Systolic BP (2. hours)	73.26±9.856	75.82±9.473	t=-1.324 p=0.189	74.88±9.674	74.54±8.924	t=0.183 p=0.855
Diastolic BP (0. hour)	42.48±7.075	44.64±9.113	t=-1.324 p=0.189	39.94±9.162	42.60±9.752	t=-1.406 p=0.163
Diastolic BP (2. hours)	42.40±7.675	44.16±10.689	t=-0.946 p=0.347	43.12±8.287	41.52±7.841	t=0.992 p=0.324

*Student's t-test

saturation values were the same between the two groups (19). Another study showed that the heart rate, respiratory rate, blood pressure, oxygen saturation, and body temperature values were similar in infants with and without earmuffs (22). One study reported no difference between the diastolic blood pressure and pain scores of babies

with and without earmuffs. Nonetheless, heart rate, respiratory rate, and systolic blood pressure were lower, and oxygen saturation values were higher in infants using earmuffs. In the above studies examination, the researchers discussed the indirect effect of earmuffs on the stress state according to the changes made on the

physiological findings of the infant (heart rate, respiratory rate, blood pressure, oxygen saturation, and body temperature) (7, 20, 22). Again, according to studies, different results were obtained showing the effect of using earmuffs on physiological findings in different studies. These results may be challenging to explain the direct effect of earmuffs use on the infants' stress level. Therefore, the current study has responded to an essential need as it reveals the effect of earmuffs use on the stress levels of preterm infants.

The current study asserted that wearing earmuffs reduces the respiratory rate yet does not cause a significant change in vital signs such as heart rate, oxygen saturation, and blood pressure in infants. Similar to the present study's findings, some studies showed that using earmuffs in preterm infants exposed to noise decreased the respiratory rate; however, it was emphasized that it reduced heart rate, unlike the current study findings (26). Abujarir et al. demonstrated that placing earmuffs to the newborns hospitalized in the NICU reduces heart rate, systolic blood pressure, and oxygen requirement (21). Similar to the current study findings, some studies show that using earmuffs does not make a difference in the blood pressure of infants and some studies did not detect a difference in heart rate, respiratory rate, or SpO₂ values (7, 22, 27, 28). No changes were reported in the infants' physiological parameters (blood pressure, heart rate, SpO₂) in the study and control groups, except for the respiratory rate. Since the noise level of the NICU where the infants are followed is not very high and checked strictly by the NICU staff according to the local policies (minimum 53.39±4.98 dBA, highest 56.92±4.57 dBA), there is no significant difference between the noise values.

Changing the position of infants followed in the intensive care unit is essential for reasons such as neurodevelopmental outcomes and respiratory stability (29-32). In the literature review, no study was found investigating the effects of earmuff use on infants' physiological parameters and stress levels in different positions. In the current study, the stress scores and respiratory rate values of the infants in the supine position (morning) and prone position (afternoon) were found to be similar, showing that they can be used in both positions.

Limitations of the Study

There are some limitations in the present study. Infants receiving invasive mechanical ventilation support were not included in the

study. A significantly low proportion of infants with the gestational age of 28-32 weeks could be included in the study as most of the infants in this group were receiving invasive mechanical ventilatory support—so as a result, this limited obtaining the data of this mostly vulnerable group. There was a difference in infants' stress scores in the study and control groups before the earmuffs were placed on the first day in supine position. The difference continued after the earmuffs were placed. However, the difference between the stress scores before and after the earmuffs was more apparent in the study group. Besides, this difference in the basal stress scores were not observed in the prone position. Even so, 2. hour stress scores of the study group was significantly lower than the control group. So this result supported the possible benefit of earmuffs for decreasing infants' stress in the NICU. And at last, a fourth researcher collected the study data, and the researcher was not blinded. The researcher who collected the data was not blinded may have caused bias.

Conclusion

The present study deduces that using silicone earmuffs reduced the stress score of 28-37 weeks-old premature infants, decreased only the respiratory rate, yet did not affect other physiological findings (heart rate, SpO₂, systolic, and diastolic blood pressure). Silicone earmuffs can be used to reduce the stress level and regulate the respiratory rate of 28-37 weeks premature infants hospitalized in the NICU.

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Conflicts of interest

The authors declare that they have no conflict of interest.

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