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The effect of a noise and light-reducing hat on the comfort and physiologic parameters of the preterm neonates

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Abstract
Aim: This study was performed to evaluate the effect of hat that reduced noise and light on preterm neonatal comfort and physiologic parameters.
Material and Methods: This randomized controlled experimental study was conducted with 60 preterm newborns aged 32-37 weeks in a neonatal intensive care unit. The hat, which was developed by the researchers, was designed with and without a visor. The newborns were randomly divided into two groups (hat with a visor = 30 newborns, hat without a visor = 30 newborns). Each group also formed its own control group because all parameters in each group were measured before wearing the hat. The comfort of the newborns was evaluated using the "Premature Infant Comfort Scale." Heart rate, oxygen saturation, and respiratory rate were also measured.
Results: It was found that there was a highly significant difference in terms of mean comfort score, heart rate, oxygen saturation, and respiratory rate of preterm newborns in the groups after wearing the hat compared with before the hat ($p < 0.001$). There was no significant difference between the groups in terms of comfort score, heart rate, oxygen saturation, and respiratory rate ($p > 0.05$).
Discussion: The use of the noise and light-reducing hat positively affected the comfort and physiologic parameters of the preterm newborns.

Keywords
Comfort, Hat, Light, Noise, Preterm Newborn

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Introduction

Preterm newborns are exposed to high levels of noise and bright light during their stay in the neonatal intensive care unit (NICU) [1-3]. Noise and bright light are sources of stress for the newborn. Increasing stress in preterm newborns causes physiologic and behavioral reactions. They may have problems such as an increased heart rate and blood pressure, increased respiratory rate, decreased oxygen saturation, apnea, bradycardia, increased intracranial pressure, disturbances in sleep-wake pattern, hearing problems, changes in the transition period to oral nutrition, and weight loss. As a result, the comfort level of the preterm newborn decreased [1,3,4].

The American Academy of Pediatrics (AAP) recommends that the noise level in the NICU should be below 45 dBA during the day and 35 dBA at night [5]. However, in studies conducted in NICUs, it has been found that the noise level is well above the recommendations of the AAP [3,6,7]. Lighting is generally kept constant in NICUs, and this situation causes preterm newborns to be exposed to an excessive amount of light. Continuous illumination negatively affects the circadian rhythm of the newborn and causes disruption of the day/night cycle. The sleep quality of the newborn decreases, the duration of deep sleep decreases, and their growth and development, recovery, and hospital discharge processes are negatively affected [7,8]. However, attempts to reduce light and noise in NICUs can prevent these problems. These initiatives include regulation of the physical environment [9,10], use of double-walled incubators [11], incubator covers [12], training of healthcare professionals [6], earmuffs [13,14], light-stimulating decibel meters [15], cyclic lighting [8,16], and silent time applications [17,18]. These interventions reduce bright light and noise-induced stress behaviors in the preterm newborns hospitalized in NICUs, and their comfort levels increase accordingly. It is very important to evaluate and increase comfort in preterm newborns. NICU nurses should implement interventions to increase the comfort of preterm newborns [13,19,20]. Therefore, the aim of this study was to evaluate the effect of a hat developed to reduce noise and light on the comfort and physiologic parameters of the preterm newborn.

Material and Methods

Design

The study was conducted as a randomized controlled experiment designed to evaluate the effect of a hat that reduced noise and light on preterm newborn comfort and physiologic parameters.

Participants

The population of the study was composed of preterm newborns who were hospitalized to the NICU of a training and research hospital between October 2016 and March 2018 and who met the selection criteria. Power analysis was performed using the G*Power (9.1.3.2) program to determine the sample size. Cohen's effect size coefficients were used. Assuming that the effect size (d = 0.8) of the difference between the comfort level score of preterm newborns before and after using the hat use would be large, according to the calculation made with 5% alpha (two-sided) and 95% power, at least 23 newborns should be included in the study groups. With the suggestion of the statistician, considering that there might be losses during the working process, it was planned to include 30 newborns in each group. Since all parameters in each group were measured before using the hat, each group also formed its own control group. Numbers from 1 to 60 were randomly distributed to two groups through a computer program without repeating the number to determine which newborn would be in which group in the selection of the sample (available at: https://www.randomizer.org/) (Figure 1: Consort Flow Diagram).

The inclusion criteria for the study were as follows: newborns at 32-37 weeks of gestation and the appropriate gestational age (AGA), age 7 days to adapt to the external environment, not taking an analgesic 4 hours before that could affect their comfort, not receiving mechanical ventilation support, no hearing problems, and parental consent. The exclusion criteria were the presence of a congenital anomaly, sepsis or any infection.

Measures

Data were collected using a data collection form, an observation form, the Premature Infant Comfort Scale, pulse oximetry, a decibel meter, a lux meter, and the preterm noise and light-reducing hat. The data collection form developed by the researchers included some descriptive characteristics such as the newborn's sex, date of birth, gestational week, mode of delivery, weight and height at the time of the study. Observation form developed by the researchers included noise levels outside the incubator, light levels inside the incubator, physiologic parameters and comfort scale total score.

The Premature Infant Comfort Scale (PICS) is used to evaluate the comfort and pain of preterm newborns aged between ≥28 and ≤37 weeks in behavioral and psychological terms. It evaluates seven parameters: alertness, calmness/agitation, crying, physical movement, muscle tone, facial tension, and average heart rate. Each parameter is scored on a 5-point Likert-type scale from 1 to 5. High scores obtained from the scale indicate that the comfort level of the preterm newborn is low [21]. The Turkish validity and reliability study of the scale was conducted and the Cronbach alpha coefficient was found as 0.88 [19]. In our study, the Cronbach alpha coefficient was 0.65 before wearing the hat and 0.70 afterwards. The scale was scored by two independent observers, and the consistency between the mean scores was evaluated using the intraclass correlation coefficient (ICC) (two-way random effect model: consistency). It was found that there was a perfect fit between the comfort scores of the two observers (97.9% and 100%), ($p < .001$). Only the researcher's measurement results were used in the study analysis because the reliability level of the inter-observer measurement results was found to be high.

The preterm noise and light-reducing hat, developed by the researchers, is designed to protect the newborn from both sound and light. The hat had flaps to reduce noise, a visor to reduce light, and the hat was made of 100% cotton. There was a fiber in the flap part and a foldable visor in the front. Laces were not used on the hat due to the risk of choking, especially in preterm newborns (Figure 2). For this reason, the flap of the hat was created in three different sizes, taking into account the head circumference measurements, to cover the newborn's ear. The cotton fabric and fiber used were obtained from a manufacturer of baby clothing that has an international

guarantee certificate (Oeko-Tex Standard 100 certificate) to ensure that it did not contain any chemicals that might harm the newborn. The hat was tested by experts in the sound and lighting laboratories of X University Faculty of Engineering. The product received a "utility model" certificate from the Turkish Patent and Trademark Office (Registration Number: 2016/15262, Registration Date: 2017/05/22).

Procedure

Preparation phase: Descriptive information about preterm newborns was recorded in the data collection form. Working hours were ensured to be the same for all newborns so that the noise and light that the newborns were exposed to would be similar. Feeding, care, and treatment of the newborn were conducted by a NICU nurse between 08.00-08.30. The newborns were observed by the researcher between 09:00 and 11:30 AM. To ensure the stability of the newborns, observation was started half an hour after the care and treatment hours. Preterm newborns were placed in the supine position by nesting in the incubator at the time of the study. The intra-incubator light levels of newborns in both groups were measured.

Before wearing the hat: Preterm newborns were followed for one hour without a hat. No action was taken during the observation period. At the end of an hour, a video was recorded for 3 minutes just before donning the hat. Comfort levels were evaluated by watching the video recording independently by two observers. Physiologic parameters and noise levels were also recorded on video.

With the hat: Hats were put on the preterm newborns in both groups for 1 hour. No action was taken during the observation period. At the end of an hour, a video was recorded for 3 minutes while the neonate was wearing a hat. The comfort levels were evaluated independently by two observers by watching the video recording. Physiologic parameters and noise levels were also recorded on video.

Statistical Analysis

The SPSS (Statistical Package for the Social Sciences) 20.0 package program was used for data analysis. The results were evaluated at a 95% confidence interval, and the significance level was $p < .05$. When evaluating the data, the number, percentage, mean and standard deviation were given in descriptive statistics. Compatibility of numerical variables to normal distribution was evaluated using Skewness and Kurtosis. In testing the homogeneity of the descriptive characteristics of the groups, Yates's corrected Chi-square test and Pearson's Chi-square test were used for categorical variables and the independent samples t-test was used for numerical variables. Interobserver agreement of the Preterm Infant Comfort Scale scores was evaluated using Wilcoxon's signed-rank test and the ICC. The Mann-Whitney U test was used to compare the difference between the comfort scale mean scores of the hat groups with and without visors (for the differences between groups), and the t-test in independent groups was used to compare the averages of physiologic parameters. Wilcoxon's signed-rank test was used to compare the average scores of the premature newborns in each study group before and after wearing the hat (difference within the group), and the dependent group t-test was used to compare the averages of the physiologic parameters.

Ethical Considerations

Before data collection, ethics committee permission (IRB number: 148 Approval date: 15.07.2016) and institutional permission (No: 30965 date: 11.10.2016) were obtained. Verbal and written consent was obtained from the parents of the newborns included in the study.

Results

There was no significant difference between the groups in terms of descriptive characteristics, light and noise levels (Table 1, $p > 0.05$).

Comfort levels

Intragroup comparison: It was found that the average post-hat comfort score of preterm newborns in both groups with and without visors was found to be significantly lower than before wearing the hat (Table 2, $p < 0.001$).

Intergroup comparison: It was found that there was no significant difference between the groups in terms of average comfort scores before and after wearing the hat (Table 2; $p > 0.05$).

Physiologic measurements

Intragroup comparison: The mean heart rate and respiratory rate of the preterm newborns wearing hats with or without visors were found to be significantly lower than before wearing the hat. The average post-hat oxygen saturation of preterm newborns wearing a hat with or without visors was found to be significantly higher than before wearing the hat (Table 3, $p < 0.001$).

Intergroup comparison: It was found that there was no significant difference between the groups in terms of physiologic measurements before and after wearing the hat (Table 3, $p > 0.05$).

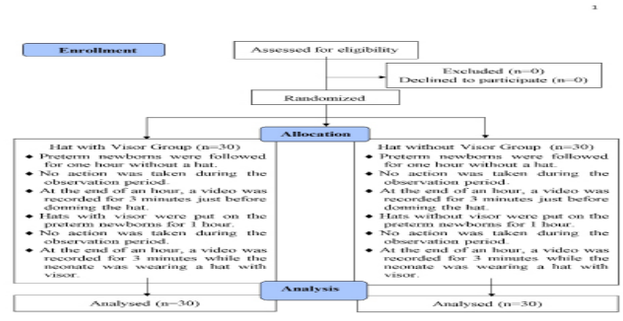


Figure 1. Consort flow diagram for this study



Figure 2. View of the hat with and without visor

Table 1. Comparison of descriptive characteristics, noise and light level of preterm newborns (n=60)

Features	Hat without visor (n=30) $\bar{x}$ ± SD	Hat with visor (n=30) $\bar{x}$ ± SD	t	p
Gestational age (week + day)	33.44 ± 1.23	33.23 ± 1.15	0.694	0.491
Postnatal age (week + day)	34.94 ± 1.11	34.69 ± 1.26	0.805	0.424
Weight (gr)	1993.17 ± 227.30	1965.00 ± 289.77	0.419	0.677
Height (cm)	44.63 ± 2.41	43.93 ± 2.70	1.058	0.294
Head circumference (cm)	31.73 ± 1.60	31.60±1.63	0.320	0.750
APGAR score (1th minute)	7.20 ± 0.41	7.17 ± 0.38	0.328	0.744
APGAR score (5 th minute)	8.20 ± 0.41	8.23 ± 0.43	0.308	0.759
Light level (lux/fc)	236.47 ± 104.95	241.30 ± 84.19	0.197	0.845
Noise level before wearing the hat (dB)	61.33 ± 1.47	61.83 ± 2.10	1.068	0.290
Noise level with the hat (dB)	62.17 ± 1.18	62.47 ± 1.80	0.765	0.448
	n (%)	n (%)	x^2	p
Delivery method				.
Vaginal	9 (30)	8 (26.7)	0.000	1.000[Y]
Caesarean	21 (70)	22 (73.3)		
Gender				
Female	15 (50)	13 (43.3)	0.067	0.796[Y]
Male	15 (50)	17 (56.7)		

t: Independent samples t-test, x^2: Pearson's Chi-square test. Y: Yates's corrected Chi-square test

Table 2. Comparison of the average score of the comfort scale of preterm newborns according to the group and time (n=60)

Measurement time	Hat without visor (n=30) $\bar{x}$ ± SD	Hat with visor (n=30) $\bar{x}$ ± SD	U	p	d / Power
Before wearing the hat	14.83 ± 1.34	14.93±1.60	438.0	0.854	0.07 / 0.06
With the hat	11.80 ± 1.16	11.67 ± 1.09	396.5	0.380	0.12 / 0.07
Z	4.768	4.694			
p	0.001	0.001			
d / Power	2.41 / 1.00	2.30 / 1.00			

U: Mann-Whitney U test, Z: Wilcoxon's signed-rank test, d: Cohen's d effect size / Power: post hoc power

Table 3. Comparison of the mean physiologic parameters of preterm newborns according to the group and time (n=60)

Physiologic Measurements	Measurement time	Hat without visor (n=30) ±SD	Hat with visor (n=30) ±SD	t*	p	d / Power
Heart Rate	Before wearing the hat	140.77±8.14	140.13±8.10	0.302	0.764	0.08 / 0.06
	With the hat	135.03±7.74	132.33±8.57	1.281	0.205	0.33 / 0.24
	t**	16.134	11.085			
	p	0.001	0.001			
	d / Power	0.72 / 0.97	0.93 / 1.00			
Oxygen Saturation	Before wearing the hat	96.60±1.94	96.93±1.44	0.756	0.453	0.19 / 0.11
	With the hat	97.90±1.47	98.00±1.29	0.280	0.780	0.07 / 0.06
	t**	8.963	6.440			
	p	0.001	0.001			
	d / Power	0.74 / 0.98	1.00 / 1.00			
Respiratory Rate	Before wearing the hat	49.97±4.66	50.73±4.87	0.623	0.536	0.16 / 0.09
	With the hat	47.70±4.59	48.03±4.92	0.271	0.787	0.07 / 0.06
	t**	15.000	10.807			
	p	0.001	0.001			
	d / Power	0.49 / 0.74	0.05 / 0.83			

*t: Independent samples t-test, **t: Dependent group t-test, d: Cohen's d effect size / Power: post hoc power

Discussion

In the NICU, preterm newborns are exposed to high levels of noise and lighting. In this study, the average noise level outside the incubator was found as 61 dBA before the test and 62 dBA after the test in both groups. In studies measuring noise levels in NICUs, ambient noise levels were found as 60 dBA by Parra et al. [3], 64 dBA by Garrido et al. [22], and 59 dBA by Varvara et al. [7]. Considering our study and other studies, it was determined that the noise levels outside the incubator in the NICU were higher than the level recommended by the AAP. In this study, the average light level inside the incubator was found as 236 lux in the group with the hat with a visor and 241 lux in the group with the hat without a visor. Similar to our study, Varvara et al. [7] found the average light level as 204 lux in their study between 8:00 and 12:00 AM in the NICU. Engwall et al. [23] found the ambient light level at the lowest level was 2 lux and the highest was 615 lux for any intervention in the NICU. As a result of noise and uncontrolled lighting, preterm newborns have physiologic and behavioral reactions due to increased stress [2]. In this study, a hat was developed to reduce the noise and light, which the preterm newborns were exposed to in our NICU. It was observed that the use of hats in preterm newborns was effective in increasing comfort and regulating physiologic parameters.

It was determined that the comfort level of preterm newborns wearing hats with and without visors was significantly greater after wearing the hat (1 hour after the hat was worn) than before (just before the hat was worn). However, there was no significant difference between the groups in terms of comfort levels. It was thought that the increase in comfort level was due to the reduction of noise and light due to wearing the hat, the reduction of the stress experienced by the newborns due to not being touched during observation, and the intact sleep-wake cycle of the newborns. Stokes et al. [20] found that playing music to premature newborns increased their comfort levels. In the study by Kahraman et al. [13], comfort levels in premature newborns in earmuffs, those listening to white noise, and those hearing their mother's voice were significantly higher than the control group during heel prick. Parallel to these studies, it was proven that the hat, which reduced noise and light, was an effective alternative method for increasing the comfort of preterm babies.

In this study, preterm newborns in the groups with hats with and without visors had lower heart and respiratory rates, and higher mean oxygen saturation after wearing the hat. However, there was no significant difference between the groups in terms of physiologic parameters. Considering these findings, it was seen that the use of hats was effective in reducing heart and respiratory rates and in increasing oxygen saturation. Similar to our study, Khalesi et al. [14] found that newborns who wore earmuffs had significantly lower heart rates and higher oxygen saturations than newborns who did not. In their study, Cardoso et al. [24] found that newborns had lower oxygen saturation and higher heart rates when the noise was highest (61 dBA) compared with when the noise was lowest (58 dBA). These results showed that as the noise and light levels to which the preterm newborns were exposed in the NICU decreased, newborns experienced less stress, and as a result, the physiologic parameters were positively affected.

Limitations

In the study, the noise level and the physiologic parameters of the neonates were evaluated in a single instant. The average of the one-hour follow-up was not calculated, which may have affected the comfort level of the newborns.

Conclusion

It was found that the hat developed to reduce noise and light increased the comfort levels of preterm newborns and was effective in the regulation of physiologic parameters. The hat can be used as one of the initiatives to increase comfort in premature newborns hospitalized in NICUs. Nurses working in NICUs are recommended to evaluate the comfort level of newborns and to plan interventions to increase comfort.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

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