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Examining the Effect of Earplugs, Eye Mask, and Earplugs + Eye Mask on the Sleep Quality in Intensive Care Patients: a Randomised Controlled Trial

Yoğun Bakım Hastalarında Kulak Tıkacı, Göz Maskesi ve Kulak Tıkacı + Göz Maskesi Uygulamasının Uyku Kalitesine Etkisinin İncelenmesi: Randomize Kontrollü Çalışma

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Abstract

Objective: Quality sleep, which plays an important role in the physical, cognitive, immunological, and psychosocial functions of patients, is imperative, especially for patients hospitalised in intensive care units (ICU) to recover from their critical illnesses.The aim of this study was to investigate the effect of earplugs (EP) and eye mask (EM) on sleep quality in ICU patients.

Materials and Methods: The sample of the study consisted of 120 patients hospitalised in the general ICU of Siirt State Hospital between July 2021-May 2022. Patients were divided into four groups as EP, EM, EP + EM and control group. Each patient in the related group wore EP, EM, and EP in combination with EM between 22:00-06:00 and was allowed to sleep in this way. Data were collected using the "patient description form" and "Richards Campbell Sleep Questionnaire (RCSQ)".

Results: According to that the dependent samples t-test performed for intra-group comparison, there was a statistically significant increase between pretest and post-test RCSQ mean scores of the patients in the EP, EM, and EP + EM groups (tEP=7,899, tEM=17,268, tEP + EM=9,381, p<0.001); whereas, there was no significant difference between pretest and post-test RCSQ mean scores of the patients in the control group (tC=1,084, p>0.05). Also, the first three factors that negatively affected the sleep quality of ICU patients were noise (71.6%), light (60.8%) and nursing interventions (49.1%).

Conclusion: The application of EM only was found to be the most effective nursing practice in enhancing the sleep quality of patients hospitalised in the ICU.

Keywords: Earplugs, eye mask, sleep quality, intensive care unit

Öz

Amaç: Hastaların fiziksel, bilişsel, immünolojik ve psikososyal işlevlerinde önemli rol oynayan kaliteli uyku, özellikle yoğun bakım hastalarının kritik hastalıklarından kurtulmaları için gereklidir. Bu çalışmanın amacı yoğun bakım hastalarına sadece kulak tıkacı (KT), sadece göz maskesi (GM) ve kulak tıkacı + göz maskesi (KT + GM) uygulamasının uyku kalitesine etkisini araştırmaktır.

Gereç ve Yöntem: Çalışmanın örneklemini Temmuz 2021-Mayıs 2022 tarihleri arasında Türkiye'de Siirt Devlet Hastanesi'nin genel yoğun bakım ünitesinde (YBÜ) yatan 120 hasta oluşturdu. Hastalar KT, GM, KT + GM ve kontrol grubu olmak üzere dört gruba ayrıldı. İlgili gruptaki her bir hastaya 22:00-06:00 saatleri arasında KT, GM ve KT + GM uygulandı ve bu şekilde uyumaları sağlandı. Veriler, "hasta tanıtım formu" ve "Richards Campbell Uyku Ölçeği (RCUÖ)" ile toplandı.

Bulgular: Grup içi karşılaştırma için yapılan bağımlı örneklemler t-testi sonucuna göre KT, GM ve KT + GM gruplarındaki hastaların ön test ve son test RCUÖ puan ortalamaları arasında istatistiksel olarak anlamlı bir artış olduğu (tKT=7.899, tGM=17.268, tKT + GM=9.381, p<0,001); kontrol grubundaki hastaların öntest ve sontest RCUÖ puan ortalamaları arasında ise anlamlı bir fark olmadığı bulundu (tK=1.084, p>0,05). Ayrıca, YBÜ hastalarının uyku kalitesini olumsuz etkileyen ilk üç faktörün gürültü (%71,6), ışık (%60,8) ve hemşirelik müdahalesi olduğu saptandı (%49,1).

Sonuç: Sadece GM uygulaması, yoğun bakım hastalarının uyku kalitesini artırmada en etkili hemşirelik uygulaması olarak saptandı.

Anahtar Kelimeler: Kulak tıkacı, göz maskesi, uyku kalitesi, yoğun bakım ünitesi.

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Introduction

Quality sleep, which takes a vital role in the physical, cognitive, immunological, and psychosocial functions of patients, is imperative, especially for patients hospitalised in intensive care units (ICU) to heal from their critical illnesses.[1] More than 50% of critically ill patients in the ICU suffer from sleep disturbances such as shortened total sleep time, interrupted sleep, and sleep deficiency.[2] It is known that sleep deprivation leads to sleep deficiency and poor sleep quality.[3] Sleep quality is vital for the healing process of patients who are treated and cared for in the ICU.[4] Bad sleep quality is mainly linked to immune system dysfunction, decreased resistance to infection as well as neurological consequences. Consequently, intensive care patients who lack quality sleep are likely to be hospitalised for a longer period and to die.[1] Therefore, it is critical to examine factors that can enhance the quality level of sleep for intensive care patients in order to improve their health and facilitate their recovery. Treatment and nursing practise in the ICU with significant noise sources such as equipment alarms, noisy staff chats, shriek of other patients, telephone calls and televisions cause decreased sleep quality in patients.[5,6] Another factor contributing to the insufficient sleep state of the ICU patients is the glossy light experienced at night. The body recognises that it needs to sleep at night since melatonin, a sleep hormone, is secreted only while the retina is exposed to low light. However, the illumination level of the indoor ceiling lights in the ICU is sufficient to disrupt the body's ability to produce melatonin.[1] The literature focuses particularly on the application of effect of earplugs (EP) and eye mask (EM) among non-pharmacological applications to enhance quality of sleep.[5] Many studies have determined that the application of EP alleviates the adverse effects of undesirable noise and enhances sleep quality in patients.[7-9] Also, the EM worn by patients at night effectively occlude excess light and facilitate the secretion of melatonin.[1,10] This may enhance the sleep quality of patients.[1] Randomised controlled trials using EM only showed that the sleep quality of patients enhanced.[11-13] Both randomised, controlled, and experimental studies using EP in combination with EM have also shown improved sleep quality.[14-24] From this point of view, it is observed that diminishing light, as well as noise and planning nursing practises before the patient sleeps are adjustments that increase patient comfort and enhance sleep quality.[25] Literature reviews have shown that wearing EP and EM in intensive care patients has positive outcomes on sleep quality.[1] Although the literature contains randomised controlled trials involving double and triple groups using the EP and the EM only in intensive care patients, a very limited number of related studies with four groups similar to the present study have been found. The goal of this investigation is comparing the effectiveness of applying the EP only, using the EM only as well as experiencing the EP and the EM together to the ICU patients and to incorporate these applications into routine nursing practises to enhance the quality of sleep.

Materials and Methods

Study Design

This study is a randomised controlled and single-centre trial. The study was registered on clinical trials (NCT05564351). The guidelines in the CONSORT list used for reporting randomised trials were followed.

Research Questions

Question 1: Is there any effect of using the EP, EM, and the EP + EM on sleep quality in intensive care patients?
Question 2: Is there any difference between the impact of making use of the EP, EM as well as the EP + EM on the sleep quality of the ICU patients?

Sample and Setting

The population consisted of 290 patients hospitalised in the general ICU of Siirt State Hospital in the Eastern Anatolia region of Türkiye between July 2021 and May 2022. A power analysis was done to find out the sample size of the study. A total of 108 patients (27 for each group) were calculated in four groups with a power of 80%, value of α=0.05 and an impact size of 0.50 in the G* Power 3.1.9.4 software. Each group had an additional three patients in case of data loss due to reasons such as withdrawal from the study and death. We focused on a total of 130 patients in our investigation: 30 patients were allocated to each group (Figure 1). A subtype of random sampling, which is known as the "complete (simple) random sampling", was used to reduce the possibility of selection bias resulting from sample selection phase. While randomising the patients, the website www.randomizer.org, which helps to generate random numbers in accordance with the criteria set to minimise the possibility of being influenced by each other, was used.

Inclusion Criteria

Our study consists of patients aged 18 and over, had no hearing impairment or visual impairment, could communicate verbally, were hospitalized in the general ICU for at least three days and agreed to be included in the analysis.[15,20,23]

Exclusion Criteria

Patients, who were unwilling to continue the study, had a visual analog scale score of seven or more, had a Glasgow Coma Scale score below 15, were taking sleeping pills or sedative drugs, were being treated with a diagnosis of sleep disorder, underwent mechanical ventilation therapy, had active ear or eye infections, and had diagnosed psychiatric illness were excluded.[15-26]

Data Collection

Questionnaires

Patient Descriptive Form: This form includes a total of seven questions about age, gender, marital condition, employment status, educational background, presence of chronic disease as well as factors affecting the sleep quality level in the ICU.

Richards-Campbell Sleep Questionnaire (RCSQ): This approach was constructed by Kathy C. Richards and it is a six-item scale that evaluates the depth of night-time sleep, latency of sleep state, frequency of awakenings, time to stay awake when woken up, quality of sleep as well as the ambient noise level. Scores in the range of (0.25) indicate the state of "very poor sleep" while scores in the range of (76,100) imply "very good sleep" case. A score increase calculated through the scale implies an enhancement in the sleep quality of patients. Özlü and Özer[27] adapted the RCSQ into Turkish and conducted its validity and reliability study. The Cronbach reliability coefficient of the scale is α=0.91. This finding shows that the scale is a highly reliable tool with internal consistency.[27] In our investigation, the Cronbach reliability parameter of the RCSQ was found to be α=0.94.

Instruments

Earplug: Developed by making use of the latest innovations in ergonomic design and heat-sensitive elastic materials, the minimalist-sized EP maximises sleep comfort with its soundproof feature.[23,28]

Eye Mask: The three-dimensional design fully grips the face and blocks the ambient light from catching the eyes. The black colour provides comfortable sleep by fully blocking the light. It comes in a disposable package and is sterile.[20,29]

Procedure

The researcher administered the "patient introduction form" to the patients on the first day with face-to-face interview technique and then administered the RCSQ as a pre-test to the patients in the ICU in the morning of the second day after their first night's sleep without any application.

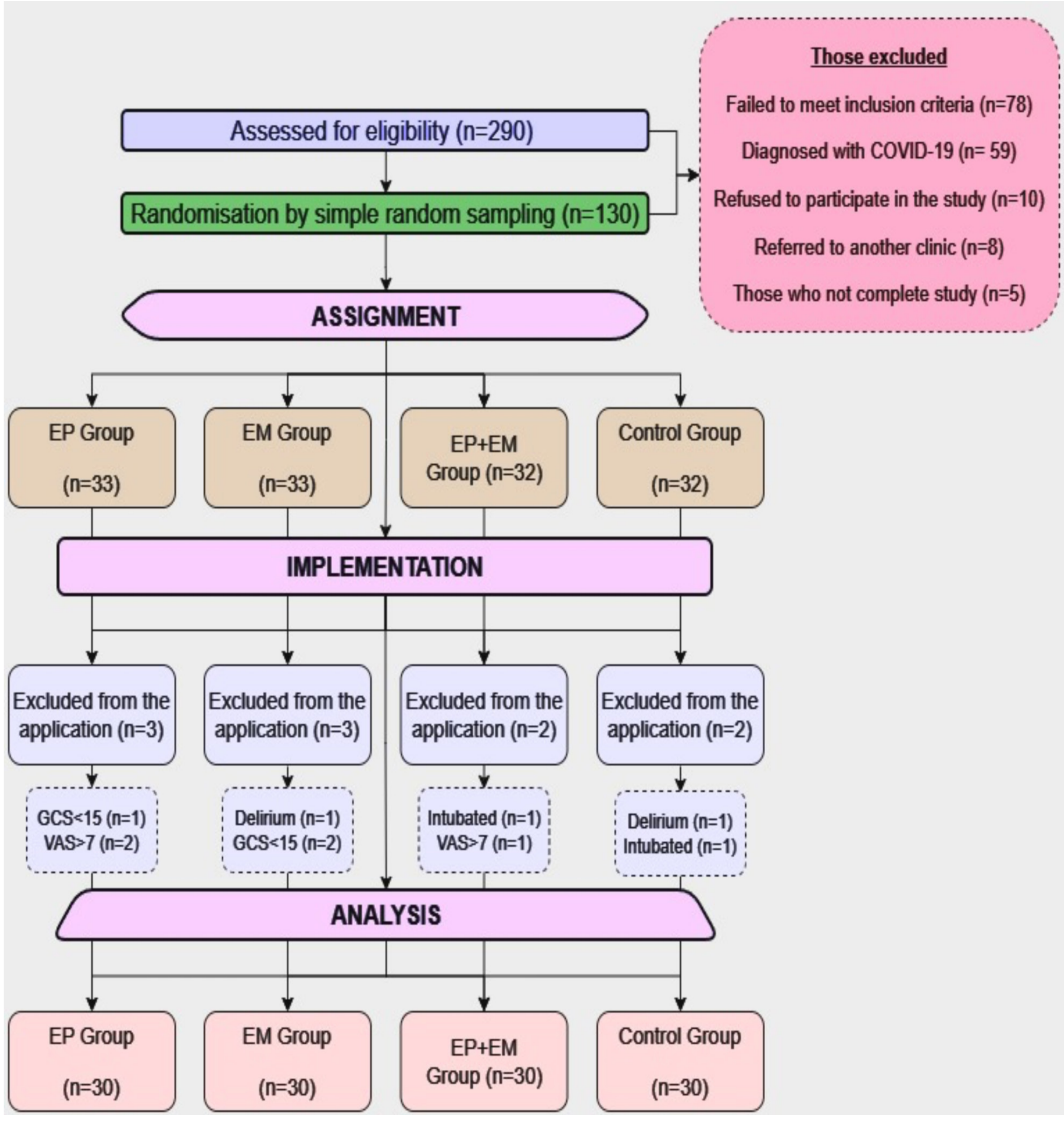

Figure 1. CONSORT flow chart of the study
EP: Earplug, EM: Eye mask, GCS: Glaskow Coma Scale, VAS: Visual Analog Scale

Treatment Group: In this study, the applications and the groups they are in have the same names and the corresponding instruments were applied by the researcher to the EP, EM and the EP + EM groups between 22:00-06:00 and the patients were allowed to sleep in this way. The researcher re-administered the RCSQ as a post-test in the morning of the third day after the second night's sleep of the patients in the ICU. Each patient in this group was followed up for three days.

Control Group: The corresponding members were allowed to sleep in the ICU without putting any EP or EM on. The researcher applied the RCSQ again as post-test on the morning of the third day of the second night's sleep of the patients in the ICU. Each patient in this group was followed up for three days.

Ethical Considerations

The ethical permission was received from the Scientific Research and Publication Ethics Committee of Gümüşhane University (approval number: 2021/1, dated: 04.02.2021) and institutional approcal was received from Siirt Provincial Health Directorate and Siirt Training and Research Hospital (approval number: E-71987595-604.02, dated: 22.06.2021) for the study. Patients who wanted to participate in the study were informed about the study and their consents were obtained. The Helsinki Declaration was followed at all stages of the study.

Statistical Analysis

We used the SPSS 27 to analyse the data in the study. The continuous datasets were shared as mean ± standard deviation and median, while the categorical ones were given as frequency and percentage. In comparison of differences between categorical variables according to groups, Pearson's chi-square was used in R x C tables where the rate of cells with 5 or more expected value or less than 5 expected value does not exceed 20%, and in R x C tables where the rate of cells with expected value below 5 exceeds 20%, Fisher Freeman Halton test was used. In order to decide on the analyses to be applied, the Kolmogorov-Smirnov approach was taken into account along with all scores for the assumption of normal distribution. Consequently, it was observed that the scores met the assumption of normal distribution, and therefore parametric tests were used while performing the analyses. In the analysis within groups, dependent samples t-test was used for pretest-post-test comparisons, and eta-squared (η^2) was used to calculate the effect size of the applications. In the analysis between groups, one-way analysis of variance (ANOVA) test was used for triple or more comparisons, Tukey's was used for homogeneously distributed data and Tamhane T2 test was taken into account for the data that did not indicate homogeneous distribution while carrying out multiple comparison tests. Test conclusions were appraised at the confidence interval of 95% and the significance level of $p<0.05$.

Results

While there was no statistically noteworthy difference between the patients in the EP, EM, EP + EM and control groups in terms of age, gender as well as marital status ($p>0.05$); a significant difference was found in terms of employment status and presence of chronic disease. In terms of education, the difference was found to be at the literate and middle school levels ($p<0.05$) (Table 1). The first three factors that influenced negatively the sleep quality level of the ICU patients were noise (71.6%), light (60.8%) and nursing interventions (49.1%) (Figure 2). As a result of the Dependent samples t-test performed for the within-group comparison, there was a statistically significant increase between the pre-test and the post-test RCSQ mean scores of the patients in the EP, EM, and the EP + EM groups ($p<0.001$); whereas, there was no substantial difference between the pre-test and the post-test RCSQ mean scores of the patients in the control group ($p>0.05$). When the effect size eta-squared calculation was examined, it was determined that the EP ($\eta^2=0.683$), EM ($\eta^2=0.911$) and the EP + EM ($\eta^2=0.752$) applications had a great effect on the increase in the RCSQ mean scores. After the post-test-pre-test procedure, the RCSQ score averages were compared with the significant results by one-way ANOVA test and the result was found to be significant. ($F=6.277$, $p<0.01$). According to the result of Tukey test included in the multiple comparison test, it was determined that the EM application was more effective than the EP and the EP + EM applications. As a result of the one-way ANOVA test performed for the inter-group comparison, it was found that the pretest RCSQ mean scores of the patients did not differ remarkably according to the group ($F=2.321$, $p>0.05$); the post-test RCSQ mean scores differed significantly according to the group ($F=27.426$, $p<0.001$). The results of the Tamhane T2 test, which was included in the multiple comparison test to determine which group caused the difference, revealed that the control group had the lowest RCSQ mean score; whereas, the RCSQ mean values of the EM group were higher than those of the EP + EM group (Table 2).

Discussion

When the factors affecting the sleep quality of the patients participating in the current study were examined, it was understood that top three factors were noise, light, and nursing interventions, similar to the literature.[11,12,21,30] A study conducted in the coronary ICU reported that the factors affecting sleep quality were light, noise, nursing interventions, and staff conversations working in the unit.[16] In the study conducted by Kavaklı[13] to assess effect of EM application, it was determined that the most frequent intensive care environment, noise and nursing interventions were the factors that impaired the sleep quality of the patients. These results revealed that noise and light were important parameters affecting sleep quality in ICU.[13,16,31] In the studies, it was determined that bright light and noise in the ICU harmed patients psychologically and physiologically.[9,32] When uninterrupted light is perceived by the brain during the night period of the day, it is related directly to the dark-light cycle. The brain interprets the relevant light as daytime and then the biological clock of the patient's body warns the pineal gland by sending signals to block the secretion of melatonin hormone.

Table 1. Descriptive characteristics of the patients (n=120)							
Variables		**EP group (n=30)**	**EM group (n=30)**	**EP + EM group (n=30)**	**Control group (n=30)**	**F**	**p**
Age ($\bar{x}$ ± SD) **Med.** (min.-max.)		57.66±12.68 58 (26-94)	58.66±12.28 63 (21-79)	51.30±16.19 51 (18-80)	52.83±10.63 48 (37-72)	2.263[a]	0.085
		n (%)*	**n (%)***	**n (%)***	**n (%)***	**χ2**	**p**
Gender	Woman Man	16 (53.3) 14 (46.7)	14 (46.7) 16 (53.3)	13 (43.3) 17 (56.7)	14 (46.7) 16 (53.3)	0.635[b]	0.888
Marital status	Married Single	29 (96.7) 1 (3.3)	27 (90.0) 3 (10.0)	23 (76.7) 7 (23.3)	26 (86.7) 4 (13.3)	5.399[c]	0.142
Working status	Yes No	5 (16.7) 25 (83.3)	8 (26.7) 22 (73.3)	14 (46.7) 16 (53.3)	13 (43.3) 17 (56.7)	8.100[b]	**0.044**
Education level	Literate Primary school Middle school High school University	15 (50.0) 5 (16.7) 1 (3.3) 7 (23.3) 2 (6.7)	16 (53.3) 4 (13.3) 0 (0.0) 6 (20.0) 4 (13.3)	8 (26.7) 7 (23.3) 5 (16.7) 7 (23.3) 3 (10.0)	2 (6.7) 9 (30.0) 7 (23.3) 7 (23.3) 5 (16.7)	28.032[c]	**0.003**
Chronic disease	Yes No	9 (30.0) 21 (70.0)	17 (56.7) 13 (43.4)	10 (33.3) 20 (66.7)	19 (63.3) 11 (36.7)	10.036[b]	**0.018**
Diagnosis of hospitalization in intensive care unit	Respiratory system diseases Cardiovascular system diseases Gastrointestinal system diseases Neurological diseases Urinary system diseases Others	11 (36.7) 2 (6.7) 3 (10.0) 5 (16.7) 2 (6.7) 7 (23.3)	11 (36.7) 5 (16.7) 4 (13.3) 2 (6.7) 4 (13.3) 4 (13.3)	8 (26.7) 1 (3.3) 1 (3.3) 3 (10.0) 3 (10.0) 14 (46.7)	5 (16.7) 14 (46.7) 0 (0.0) 4 (13.3) 0 (0.0) 7 (23.3)	35.412[c]	**0.000**

$\bar{x}$ ± SS: Arithmetic mean-standard deviation, Med.: Median, min.-max.: Minimum-maximum, *Column percentage was taken, [a]One way analysis of variance, [b]Pearson's chi-square test, [c]Fisher-Freeman-Halton test, EP: Earplugs, EM: Eye mask

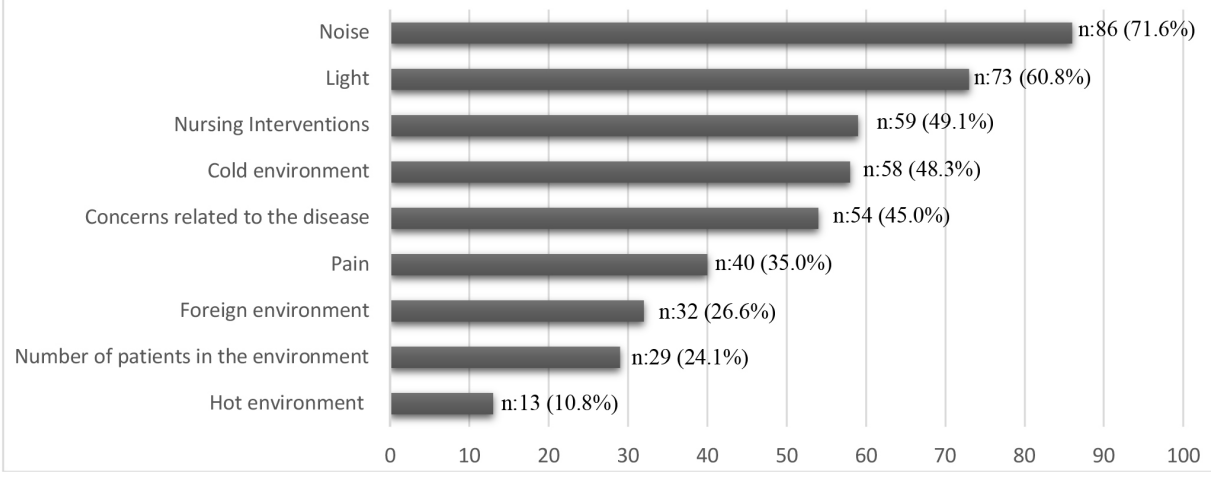

Figure 2. Factors affecting sleep quality of patients in the intensive care unit

Table 2. Comparison of RCSQ scores in ICU patients (n=120)						
Measurement	**EP group (n=30)**	**EM group (n=30)**	**EP + EM group (n=30)**	**Control group (n=30)**	**Between groups analysis****	**Comparing applications** (Post-test-pretest)**
	$\bar{x}$ ± **SS**	$\bar{x}$ ± **SS**	$\bar{x}$ ± **SS**	$\bar{x}$ ± **SS**		
Pre-test	47.37±8.42	46.50±5.24	45.27±10.20	39.67±20.45	F=2.321, p=0.079	F=6.277, **p=0.003** EM vs EP **(p=0.004)**, EM vs EP + EM **(p=0.022)**
Post-test	65.57±18.38	74.30±6.79	65.27±12.65	41.70±17.64	F=27.426, **p=0.000** EM vs C **(p=0.000[a])**, EM vs EP + EM **(p=0.007[a])**, EP vs C **(p=0.000[a])**, EP + EM vs C **(p=0.000[a])**	
Analysis within groups*	t=7.899, **p=0.000**	t=17.268, **p=0.000**	t=9.381, **p=0.000**	t=1.084, p=0.287		
η^2 Cohen's d Power Rating	0.683 1.442 0.99	0.683 1.442 0.99	0.683 1.442 0.99	0.752 1.713 0.99		

*Dependent groups t-test, **One-way analysis of variance, [a]Tamhane's T2 test; $\bar{x}$ ± SD, Arithmetic mean-standard deviation, C: Control group, vs.: And, RCSQ: Richards-Campbell Sleep Questionnaire, ICU: Intensive care units, EP: Effect of earplugs, EM: Eye mask

On the other hand, darkness is provided while the patient wears the EM and thus the brain perceives this darkness as night period and give directions to the pineal gland to enhance the production level of the hormone melatonin, which allows it to maintain sleep.[15] The ICU, where this study was conducted, has an environment that adversely affects sleep quality due to the presence of intense lighting at head level on each patient, the side by side placement of beds in a small area, and the noise caused by staff and technological devices. Although the conclusions of the current investigation are compatible with similar studies, it has been determined that there are too many stimuli that are not suitable for sleep in the ICU.[16,24,31] In patients who are affected by these stimuli and suffer from sleep problems; It is thought that wearing EM and EP by nurses as an easy and affordable method may be effective in providing patients' sleep satisfaction and enhancing their quality of life. In the present study, the effect of three interventions (the EM only, EP only and the EP + EM) on the sleep quality of the patients in the ICU was evaluated carefully. It was concluded that all three interventions enhanced the sleep quality of the patients and the EM only application enhanced the sleep quality more than the other attempts. When the studies in literature are examined, one may see that the combined use of the EM and the EP on intensive care patients can be taken into acount to enhance their sleep quality.[8,15,19,22,24,33] In a study conducted by Risch[34] to evaluate how the EM and the EP use affected sleep quality in the surgical-neurology ICU, it was determined that the combined use of the EM and the EP enhanced sleep quality by reducing environmental factors. In the meta-analysis study conducted by Fang et al,[1] the authors stated that the EP and the EM applied to the adult patients hospitalised in the ICU have significant effects on their sleep quality, while the combined use of the EP and the EM has the largest effect size. However, in literature, some patients reported the feeling of uncomfortable, anxiety and even the claustrophobia after experiencing the combined of the EP and the EM.[35,36] In line with this information and based on our observations, we think that this was effective in the EP + EM group in our study. In their study, Khoddam et al.[37] evaluated the effect of EM and EP on sleep quality and reported that only the EM group experienced a sense of improved sleep quality compared to the EP only and the EP + EM groups. In their study, Babaii et al.[12] reported that the EM and the routine sleep care was applied to the intervention group while only the routine sleep care was applied to the control group, and then on the second and sixth days of hospital admission, sleep quality was evaluated with the Pittsburgh Sleep Quality Index. As a result of this analysis, they found that the EM can significantly improve the sleep quality of cardiac patients in the coronary ICU. The EM blocks light causes an increase in melatonin levels and improves sleep quality.[38] On the other hand, the EP limits the improvement of sleep quality as they have less effect on melatonin secretion and evoke unpleasant sensations.[1] However, after making use of the EP application, Menger et al.[39] determined in that the sleep quality was significantly different between patients staying in the postoperative care unit and control group. In another study on the cardiac surgical ICU, no significant difference was found between control and intervention groups (p>0.05).[8] While some of the studies in literature are similar to results of the present study, some others have yielded different results.[7,8,12,37,40] The reasons for this difference were thought to be patients' discomfort with the EP, differences in the selection of the sample group and individual factors.

Although most of sleep disorders can be treated using pharmacological methods in intensive care patients, the effectiveness of non-pharmacological methods (70-80%) has been proven by studies.[11,40-42] Methods such as the EM, EP and landscaping are used as non-pharmacological methods.[43] The use of EM and EP which recent nursing studies have focused on is one of the various strategies used to enhance sleep quality of patients and control environmental stimuli.[5,15]

Conclusion

According to the conclusions achieved via our investigation, the use of only EP, only EM and EP + EM have positive effects on the sleep quality of intensive care patients. Results of the present study revealed that only the use of EM was the most effective on the sleep quality level of intensive care patients among the groups, while the application of only EP was the least effective

Ethics

Ethics Committee Approval: The ethical permission was received from the Scientific Research and Publication Ethics Committee of Gümüşhane University (approval number: 2021/1, dated: 04.02.2021).
Informed Consent: Patients who wanted to participate in the study were informed about the study and their consents were obtained.

Footnotes

Authorship Contributions

Surgical and Medical Practices: H.T., Concept: A.K.S., H.T., S.H., Design: A.K.S., Data Collection or Processing: H.T., Analysis or Interpretation: E.Y., S.H. Literature Search: A.K.S., H.T., E.Y., S.H., Writing: A.K.S., H.T., E.Y., S.H.

Conflict of Interest: No conflict of interest was declared by the authors.
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