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RESEARCH ARTICLE

The effects of eye masks and earplugs on sleep quality, anxiety, fear, and vital signs in patients in an intensive care unit: A randomised controlled study

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Summary

In intensive care units, environmental factors like loud noises and bright lights can cause fear, anxiety, changes in vital signs, and sleep disturbances. The aim of this study was to find out how using earplugs and eye masks during the night affected sleep quality, anxiety, fear, and vital signs of patients in an intensive care unit. A total of 70 patients, 35 in the intervention and 35 in the control group, were included in this randomised controlled study. While the patients in the intervention group were provided with earplugs and eye masks for 3 nights in addition to their routine care, only routine care was given to the patients in the control group. The 'Introductory Information Form', 'Visual Analogue Scale-Fear (VAS-F)', 'Visual Analogue Scale-Anxiety (VAS-A)', 'Vital Signs Monitoring Form', and 'Richards-Campbell Sleep Questionnaire' were used for data collection. It was found that the mean scores of VAS-F, VAS-A, heart rate, diastolic and systolic blood pressure of the intervention group decreased significantly after the intervention, while their sleep quality increased significantly. In this study, it was found that using earplugs and eye masks for patients in an intensive care unit during the night was effective in improving patients' sleep quality and reducing fear, anxiety, and problems in vital signs.

KEYWORDS
anxiety, earplug, eye mask, fear, intensive care, sleep quality, vital signs

1 | INTRODUCTION

Patients in intensive care units (ICUs) are in a restricted environment, bound to equipment for treatment and monitoring for 24 h. Therefore, they are exposed to physical factors such as sound, light, cold-hot room temperature, frequent care, and participation in treatment activities (Güngör, 2015). Patients also experience emotional problems and high levels of anxiety due to being away from their families in the ICU, seeing the treatment and interventions for other patients, and being dependent on the treatment and caregivers (Kol & Dikmen, 2018).

Anxiety can be defined as the unpleasant distress experienced by all individuals at certain periods of their lives, accompanied by various physiological symptoms (Engin, 2014). It can be seen that patients in ICUs experience fear of death, deterioration of body integrity, pain, and anxiety due to invasive interventions. Therefore, anxiety in the ICU is of great importance due to its interaction with health problems (Azizpour et al., 2017). The frequency of anxiety in individuals with health problems may be 6%–10%, this rate may increase to 20% in hospitalised patients, and 70%–80% in ICU patients (Hare et al., 2014). Anxiety and fear about the seriousness of their current illness are common in ICU patients and these feelings are often

The manuscript, or a part thereof, has not been published or submitted for publication elsewhere. Clinical trial registration was done (ClinicalTrials.gov. identifier: NCT05451186). The CONSORT checklist for randomised controlled trials was used in this study.

reinforced by the ICU environment (Zigmond & Snaith, 1983). Vital signs consisting of heart rate, body temperature, blood pressure, and respiratory rate are the main indicators that reflect the health status of the individual (Temel, 2013). They are data that determine the physiological state of the body and the presence and level of disease (Sapra et al., 2021). In addition to the evaluation of health, vital signs also evaluate patient's response to psychological and physiological stress, as a result of surgical and medical interventions and nursing interventions (Stevenson et al., 2016). An increase is seen in heart rate (Craven et al., 1992; Boyko et al., 2017) and blood pressure (Muntner et al., 2019) in the presence of conditions such as pain, fear, anger, and anxiety that cause sympathetic nervous system activation. In addition, respiratory rate and depth increase in situations that increase the stress level in the individual, such as pain, anxiety, infection, fever (Boyko et al., 2017).

There are many factors that cause sleeplessness in ICU patients. These are environmental factors such as pain, anxiety, uncomfortable position, care activities, treatment, ventilator, medication, noise, light, and odour. The treatment and care applied in ICUs cause the patients' night sleep to be interrupted, circadian rhythm disorder, and patients to sleep less than normal (Beltrami et al., 2015). Problems such as decreased removal of neurotoxic waste products due to insufficient sleep, higher inflammatory cytokines, deteriorated immune system, delirium, longer ICU stays, and coronary heart diseases can be seen. In addition, due to the deterioration of sleep quality in ICUs, patients may experience sleep-related problems even after discharge (approximately 6–12 months; Ivusich, 2019). Noise and light, which are environmental factors, are the most important factors in the deterioration of sleep quality and circadian rhythm in ICUs (Hu et al., 2010). In the literature, noise is reported to be the most common factor causing sleep deprivation at rates ranging from 17% to 94% (Çakır et al., 2016). Factors that cause noise can be listed as monitors, ventilators, infusion pumps, the sounds of the working personnel, telephone, and the sounds from other inpatients (Azimian et al., 2019; Azizpour et al., 2017). According to the World Health Organization (WHO) guide, noise level in hospitals should not exceed a maximum of 40 dB during the day and 30 dB at night (Kol & Dikmen, 2018). In previous studies conducted in ICUs, the noise level was found to increase up to 60–80 dB (Locihová et al., 2018). Pharmacological and non-pharmacological interventions can be used to prevent sleep deprivation in the ICU (Obanor et al., 2021). It is much easier, more economical, and safer to apply non-pharmacological methods such as music therapy, aromatherapy, massage, planning nursing practices, and changing environmental factors when compared with pharmacological methods (Karimi et al., 2021). Another method used to improve sleep quality using eye masks and earplugs. With the use of eye masks and earplugs, sleep problems can be prevented by changing the patients' perceptions of the environment (Koçak & Arslan, 2020).

It has been reported that in reducing noise and controlling light, eye mask and earplug use may be better than other interventions (Karimi et al., 2021). In order to increase sleep quality, nurses should determine and implement the appropriate nursing intervention for the patient who has sleep problems. Eye mask and earplug use is one of the effective and independent nursing interventions (Hu et al., 2015; Huang et al., 2015; Koçak & Arslan, 2021). When the literature was examined, no study investigating fear, anxiety, vital signs, and sleep quality together in ICU patients could be found. For this reason, this study was conducted to examine the effects of using earplugs and eye masks during the night on sleep quality, anxiety, fear, and vital signs of ICU patients. It is thought that the results would contribute to the literature and this practice could reduce the duration of hospital stay by reducing the care process and other symptoms of the patients, thus reducing the workload of the nurses who care for their patients and increase the quality of care by providing a positive approach to treatment and care.

2 | METHODS

2.1 | Design

This study was carried out as a randomised controlled experimental study. The study was carried out in the Coronary ICU (CICU) of Elazığ Fethi Sekin City Hospital between June and November 2022. The CICU accepts an average of 95 patients a month. There are 13 beds in the CICU and patients stay 2–5 days on average. There are no patients followed up with mechanical ventilator in the CICU. This unit has been serving with six doctors for 4 years. There are also four nurses, a secretary and two assistant health personnel per shift. There is a window inside the CICU and the curtains are always closed. White, fluorescent light illuminates the environment continuously throughout the day and night. Noise from ventilation, monitors and personnel result in a very high sound level.

2.2 | Participants and sample

Patients with a diagnosis of heart failure who were hospitalised in the CICU of Elazig Fethi Sekin City Hospital between June and November 2022 formed the study population. The sample group consisted of 70 patients who met the inclusion criteria and who agreed to participate in the study between these dates. In the post hoc power analysis using the G-Power 3.1.9.4 program, the effect size of the study was determined to be 0.89 at 90% power and 0.05 significance level, and the sample size was found to be sufficient (Çapık, 2014). The number of patients reached between these dates was 80. Since 10 of the patients did not meet the research criteria, 35 patients were included in the intervention group and 35 patients in the control group, and the study was completed with a total of 70 patients (Figure 1).

2.2.1 | Inclusion and exclusion criteria

Inclusion criteria were: aged ≥18 years, New York Heart Association (NYHA) functional Class II and III, not having received any general anaesthesia for the previous 24 h, not having received any sedative medications or opioids for the past 24 h, not having a verbal communication disability (hearing and speaking), absence of pain, not having a previously diagnosed sleep disorder, not having psychiatric problems, not having a

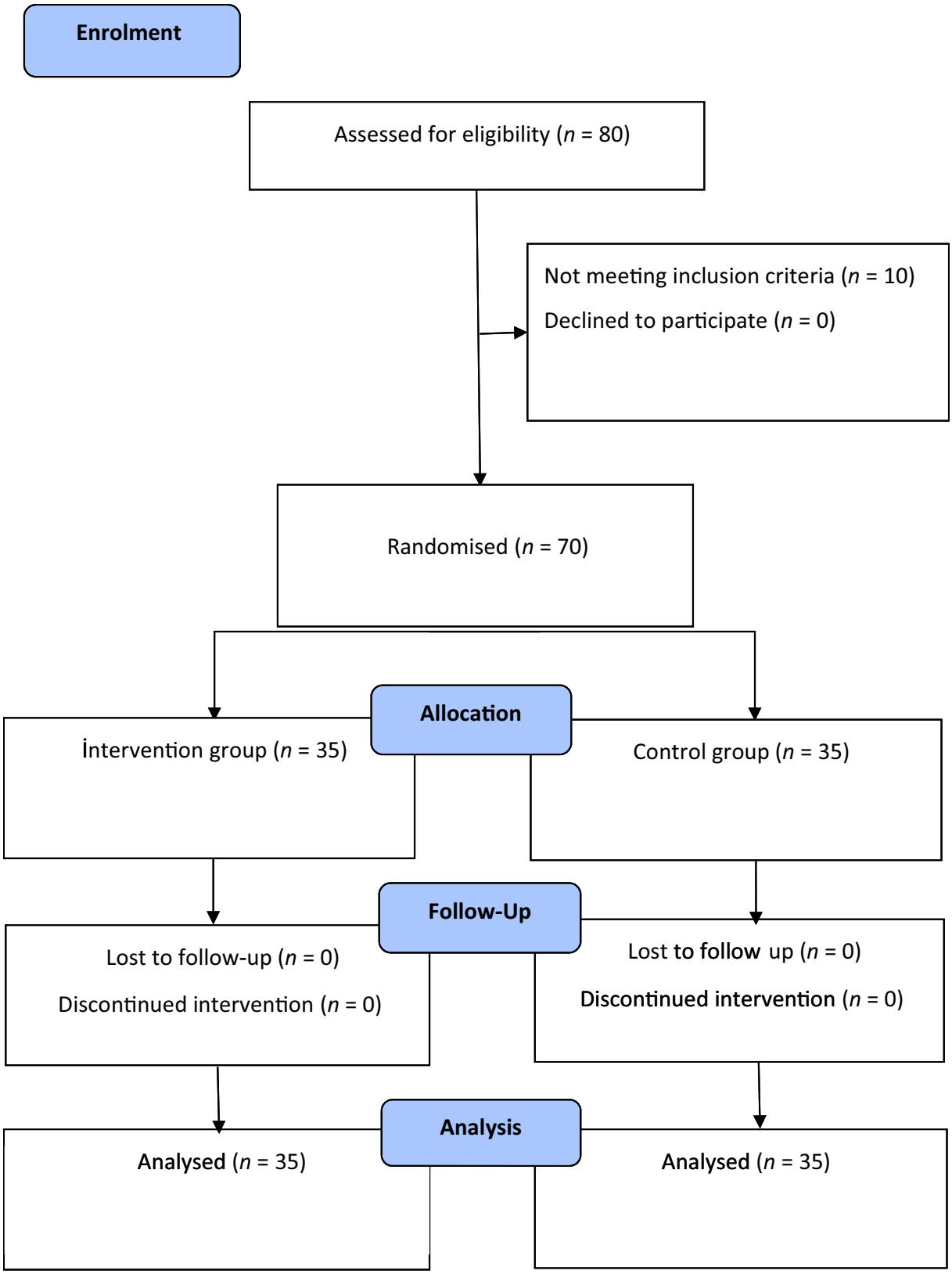

FIGURE 1 Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram.

cognitive problem, being healthy enough to put on and take off earplugs independently, in addition to wearing an eye mask and removing it when necessary, and continuing to be hospitalised for at least 3 days.

Exclusion criteria were: being diagnosed with delirium (Intensive Care Delirium Screening Checklist score ≥5), unconscious (Glasgow Coma Scale score <13), presence of additional chronic diseases,

having consumed coffee, alcohol and hypnotic drugs at least 12 h before the study, patients whose condition suddenly worsened, those who could not use earplugs and eye masks effectively at night, those who voluntarily withdrew from the study and were transferred from the CICU. All patients sent to another unit were excluded.

2.2.2 | Randomisation

The number of individuals in the intervention and control groups were equally randomised (1:1 ratio). The researcher assigned patients to the groups with the help of a computerised randomisation program (https://www.randomizer.org/). Randomisation was carried out using the closed envelope method. Patients in the intervention group were coded as '1' and patients in the control group were coded as '2', randomised up to 70. If the individual meets the inclusion and exclusion criteria of the study, the envelopes presented in a mixed way by a person who was excluded from the study were extended and asked to choose one randomly from among them, and in the opened envelope, it was determined which group the patient would be included in. The study adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Figure 1).

2.3 | Outcome measurements

The researcher used the 'Descriptive Information Form', the 'Visual Analogue Scale-Fear (VAS-F)', 'Visual Analogue Scale-Anxiety (VAS-A)', 'Vital Signs Monitoring Form' and 'Richards-Campbell Sleep Questionnaire (RCUQ)' to collect the research data.

2.3.1 | Descriptive Information Form

There are 13 questions in this form prepared by the researcher including age, gender, marital status, educational status, working status, income status, the state of living alone, the state of smoking, drinking alcohol, presence of another chronic disease, the state of having been hospitalised in ICU previously and the state of having received any intervention by health professionals during the night.

2.3.2 | Richards-Campbell Sleep Questionnaire

The RCSQ was developed by Richards (1987) to evaluate sleep perception. Özlü and Özer (2015) conducted the Turkish validity and reliability of the scale. The RCSQ is a six-item scale that assesses the depth of night sleep, the time to fall asleep, the frequency of waking, the time to stay awake after waking, the quality of sleep, and the noise level in the environment. Using the visual analogue scale technique, each item is evaluated on a scale between 0 and 100. A score between 0 and 25 indicates a very bad sleep, and a score between 76 and 100 indicates a very good sleep. Higher scores mean a higher sleep quality. The Cronbach's alpha value of the scale was found to be 0.91 (Özlü & Özer, 2015). In the present study, the Cronbach's alpha value was found as 0.86.

2.3.3 | Visual analogue scale-Anxiety (VAS-A)

Patients are asked to show the intensity of anxiety during activity or rest on a 10-cm horizontal line. The line has 0 at the beginning and 10 at the end, with 10 representing unbearable fear and 0 means no fear. The VAS is widely used in the evaluation of anxiety severity. While the patients mark the anxiety they have felt on this line, each point they have marked is measured in cm (Aslan, 2002).

2.3.4 | Visual Analogue Scale-Fear (VAS-F)

Patients are asked to show the intensity of fear during activity or rest on a 10-cm vertical or horizontal line. It has numbered shapes ranging between 1 and 10. The line has 0 at the beginning and 10 at the end. The 10 denotes unbearable fear and 0 means no fear. The VAS is frequently used in the evaluation of fear severity. While the patients mark the fear they have felt on this line, each point they have marked is measured in cm (Aslan, 2002).

2.3.5 | Vital Signs Monitoring Form

The researcher developed this form to record the body temperature, systolic-diastolic blood pressure, heart rate (pulse) of the patient who wore an eye mask or earphone at night.

2.4 | The materials used and their properties

2.4.1 | Eye mask

Medical device class phototherapy eye masks that were Conformité Européenne (CE) certified were used in the study. These masks, which are designed for use by adults, and which are made specifically with carbon materials, are tested at a radiation intensity of 450 nm and their transmittance is measured at 0.00. Three layers of material laminated to each other are used in the eye masks. The layer closest to the skin is made of cotton knitted fabric that can absorb sweat. The middle layer is supported by polyurethane anthracite foam that prevents light transmission. The top layer consists of raised (pile) polyamide fabric. Effective eye protection during UV treatment is possible with this eye mask. In addition, two rubber bands specially designed for face and head shape provide safe and easy use.

TABLE 1 Comparison of descriptive characteristics of intervention and control group patients ($n = 70$).

Variable		Groups, *n* (%)		Test value and significance
		Intervention	Control	
Gender	Female	11 (31.4)	18 (51.4)	$\chi^2 = 2.885$, $p = 0.089$
	Male	24 (68.6)	17 (48.6)	
Education status	Illiterate	7 (20)	15 (42.9)	$\chi^2 = 9.394$, $p = 0.052$
	Literate	16 (45.7)	17 (48.6)	
	Primary	9 (25.7)	2 (5.7)	
	Secondary	2 (5.7)	–	
	High school	1 (2.9)	1 (2.9)	
Marital status	Married	29 (82.9)	23(65.7)	$\chi^2 = 2.692$, $p = 0.101$
	Single	6 (17.1)	12 (34.3)	
Working status	Yes	2 (5.7)	3 (8.6)	$p = 1.000$
	No	33 (94.3)	32 (91.4)	
Income status	Little	34 (97.1)	94.3 (33.5)	$p = 1.000$
	Moderate	1 (2.9)	2 (5.7)	
Stage of disease	Stage 2	18 (51.4)	22 (62.9)	$\chi^2 = 0.933$, $p = 0.334$
	Stage 3	17 (48.6)	13 (37.1)	
Smoking status	Yes	4 (11.4)	6 (17.1)	$\chi^2 = 0.467$, $p = 0.495$
	No	31 (88.6)	29 (82.9)	
Using alcohol	Yes	–	1 (2.9)	$p = 1.000$
	No	35 (100)	34 (97.1)	
State of living alone	Yes	–	2 (5.7)	$p = 0.493$
	No	34 (100)	33 (94.3)	
Presence of another chronic disease	Yes	16 (45.7)	22 (62.9)	$\chi^2 = 2.072$, $p = 0.150$
	No	19 (54.3)	13 (37.1)	
Presence of previous intensive care history	Yes	11 (31.4)	16 (45.7)	$\chi^2 = 1.507$, $p = 0.220$
	No	24 (68.6)	19 (21.5)	
Intervention by health personnel during the day	Yes	35 (100)	35 (100)	–
Continuous variable, mean (SD)				
Age		65.40 (7.81)	66.71 (8.92)	$t = -0.656$, $p = 0.514$

Note: there is no χ^2 value when Fisher's exact test used.

2.4.2 | Ear plugs

Sleeping earplugs produced in accordance with the standards and health regulations set by the European Union and Australia were used. The earplugs, which fit well in the ear, do not protrude from the ear as they are produced from soft hypoallergenic elastic material, thus preventing any discomfort that may occur when the head touches the pillow. Perceived sound intensity can be reduced up to 30 dB with these earplugs.

2.5 | Intervention

Before starting the intervention, the light and noise amounts of CICU were examined by the Occupational Health Technical Services and randomly measured on two different days of the week (one public holiday and one non-holiday). Patients assigned randomly to the control and intervention groups were followed for 4 consecutive days (3 nights and 4 days). On the morning of the day after the patients were admitted to the CICU, a nurse working in the CICU (a nurse who is not one of the researchers) completed the Descriptive Information Form, RCSQ, VAS-F, VAS-A and Vital Signs Monitoring Form face-to-face for patients in both the intervention and control group. Intervention group patients were asked to use an eye mask and earplugs from 10:30 p.m. to 6:30 a.m. on the first, second, and third nights. They were allowed to remove their earplugs or eye masks for a short time when intervention or communication was needed. On the morning of Day 4, a nurse working in the CICU who was not one of the researchers met the patients face-to-face and completed the RCSQ, VAS-F, VAS-A and Vital Signs Monitoring Forms. In this process, the control group did not receive any intervention, and their routine care was performed.

2.6 | Statistical analysis

The Statistical Package for Social Sciences (SPSS) version 22.0 program was used to evaluate the data. In data analysis, in addition to numbers, percentages, means and standard deviations, Chi-square analysis was used in the comparison of demographic characteristics between the intervention and control group (categorical variables), the independent groups *t* test was used in the comparison of intervention and control group between groups, dependent *t* test was used in intragroup comparisons, kurtosis and skewness coefficients were used in the normality distribution analysis of data, and Cronbach's α coefficient was used in the determination of internal coefficient.

2.7 | Ethical considerations

Approval from Fırat University Non-Interventional Research Ethics Committee (2022/ 08-06), and official permission was obtained from the hospital where the application would be carried out. After informing the patients about the study, their verbal and written consents were obtained. The Helsinki Declaration of Human Rights was adhered to protect the individual rights.

TABLE 2 Comparison of Richards-Campbell Sleep Questionnaire, Visual Analogue Scale-Anxiety and Visual Analogue Scale-Fear mean scores of patients in the intervention and control groups within and between groups.

		Groups		
		Intervention	Control	Between groups t^a/p
RCSQ	Pre-intervention score, mean (SD)	32.70 (11.56)	35.76 (7.21)	$t = -1.325$, $p = 0.189$
	Post-intervention score, mean (SD)	44.54 (12.16)	25.85 (6.12)	$t = 8.119$, $p = 0.000$*
	Intragroup t^b/p	$t = -12.778$, $p = 0.000$*	$t = 11.959$, $p = 0.000$*	
VAS-A	Pre-intervention score, mean (SD)	3.57 (1.09)	3.48 (0.88)	$t = 0.360$, $p = 0.720$
	Post-intervention score, mean (SD)	2.65 (1.10)	4.02 (0.70)	$t = -6.167$, $p = 0.000$*
	Intragroup t^b/p	$t = 9.623$, $p = 0.000$*	$t = -5.729$, $p = 0.000$*	
VAS-F	Pre-intervention score, mean (SD)	3.48 (1.12)	3.54 (1.01)	$t = -0.224$, $p = 0.823$
	Post-intervention score, mean (SD)	2.57 (1.06)	4.08 (0.81)	$t = -6.671$, $p = 0.000$*
	Intragroup t^b/p	$t = -9.623$, $p = 0.000$*	$t = -5.729$, $p = 0.000$*	

Abbreviations: t^b, Dependent groups *t* test; t^a, Independent groups *t* test; RCSQ, Richards-Campbell Sleep Questionnaire; VAS-A, Visual Analogue Scale-Anxiety; VAS-F, Visual Analogue Scale-Fear.
*$p < 0.05$.

TABLE 3 Comparison of the mean scores of patients in the intervention and control groups on the Vital Signs Monitoring Form within and between groups.

		Groups		
		Intervention	Control	Between groups, t^a/p
Body temperature	Pre-intervention score, mean (SD)	36.47 (0.24)	36.50 (0.24)	$t = -0.593$, $p = 0.555$
	Post-intervention score, mean (SD)	36.38 (0.18)	36.52 (0.25)	$t = -2.663$, $p = 0.010$*
	Intragroup t^b/p	$t = -1.974$, $p = 0.057$	$t = -0.488$, $p = 0.629$	
Heart rate (pulse)	Pre-intervention score, mean (SD)	94.45 (14.06)	101.00 (14.15)	$t = -1.940$, $p = 0.057$
	Post-intervention score, mean (SD)	91.40 (10.87)	102.45 (12.83)	$t = -3.889$, $p = 0.000$*
	Intragroup t^b/p	$t = 2.662$, $p = 0.012$*	$t = -1.491$, $p = 0.145$	
Diastolic blood pressure	Pre-intervention score, mean (SD)	74.28 (10.08)	71.42 (12.16)	$t = 1.070$, $p = 0.288$
	Post-intervention score, mean (SD)	68.42 (8.64)	74.11 (11.16)	$t = -2.334$, $p = 0.023$*
	Intragroup t^b/p	$t = 3.802$, $p = 0.001$*	$t = -1.139$, $p = 0.263$	
Systolic blood pressure	Pre-intervention score, mean (SD)	133.14 (14.50)	131.71 (15.62)	$t = 0.396$, $p = 0.693$
	Post-intervention score, mean (SD)	125.14 (9.50)	135.14 (11.97)	$t = -3.869$, $p = 0.000$*
	Intragroup t^b/p	$t = -4.000$, $p = 0.000$*	$t = -1.827$, $p = 0.819$	

Abbreviations: t^a, independent groups *t* test; t^b, dependent groups *t* test.
*$p < 0.05$.

TABLE 4 Results of simple linear regression analysis conducted to determine the effects of eye mask and earplugs application on sleep, fear, anxiety, and vital signs.

	Model	Variable	*B*	Standard error	*β*	*t*	*p*	95% CI	
								Lower	Upper
Sleep	1	Constant	25.85	1.628		15.884	0.000*	22.609	29.105
		Eye mask and earplugs-Intervention	18.690	2.302	0.702	8.119	0.000*	14.097	23.284
	$R = 0.702$, $R^2 = 0.492$								
	$F_{(1,68)} = 65.915$, $p = 0.000$*								
Anxiety	1	Constant	4.029	0.157		25.618	0.000	3.715	4.342
		Eye mask and earplugs-Intervention	−1.371	0.222	−0.599	−6.167	0.000*	−1.815	−0.928
	$R = 0.599$, $R^2 = 0.359$								
	$F_{(1,68)} = 38.027$. $p = 0.000$*								
Fear	1	Constant	4.086	0.161		25.455	0.000*	3.765	4.406
		Eye mask and earplugs-Intervention	−1.514	0.227	−0.629	−6.671	0.000*	−1.967	−1.061
	$R = 0.629$, $R^2 = 0.396$								
	$F_{(1,68)} = 44.504$, $p = 0.000$*								
Pulse	1	Constant	102.457	2.011		50.959	0.000*	98.445	106.469
		Eye mask and earplugs-Intervention	−11.057	2.843	−0.427	−3.889	0.000*	−16.731	−5.383
	$R = 0.427$, $R^2 = 0.182$								
	$F_{(1,68)} = 15.122$, $p = 0.000$*								
Body temperature	1	Constant	36.526	0.037		982.445	0.000*	36.452	36.600
		Eye mask and earplugs-Intervention	−0.140	0.053	−0.307	−2.663	0.010*	−0.245	−0.035
	$R = 0.307$, $R^2 = 0.094$								
	$F_{(1,68)} = 7.090$, $p = 0.010$*								
Systolic blood pressure	1	Constant	135.143	1.827		73.950	0.000*	131.496	138.790
		Eye mask and earplugs-Intervention	−10.000	2.584	−0.425	−3.869	0.000*	−15.157	−4.843
	$R = 0.425$, $R^2 = 0.180$								
	$F_{(1,68)} = 14.971$, $p = 0.000$*								
Diastolic blood pressure	1	Constant	74.000	1.688		43.848	0.000*	70.632	77.368
		Eye mask and earplugs-Intervention	−5.571	2.387	−0.272	−2.334	0.023*	−10.334	−0.809
	$R = 0.272$, $R^2 = 0.074$								
	$F_{(1,68)} = 5.449$, $p = 0.023$*								

Abbreviations: CI, confidence interval.
*$p < 0.05$.

Clinical trial registration was done (ClinicalTrials.gov. identifier: NCT05451186).

3 | RESULTS

As can be seen in Table 1, the control and intervention groups were similar in terms of descriptive characteristics.

When the in-group comparison of the intervention and control groups was examined, pre-intervention RCSQ, VAS-A and VAS-F mean scores of the intervention and control groups were found to be significantly different after the intervention ($p < 0.05$). In terms of the differences between the groups, while there was no significant difference in pre-intervention mean scores of the RCSQ, VAS-A and VAS-F, a significant difference was found after the intervention (Table 2).

When the intragroup comparison of the intervention and control groups was examined in the study, while there was a significant difference in post-intervention mean scores of heart rate, diastolic blood pressure and systolic blood pressure of the intervention group before the intervention ($p < 0.05$), no significant difference was found in body temperature mean score ($p > 0.05$). In the control group, no significant difference was found in post-intervention mean scores of heart rate, diastolic blood pressure, body temperature and systolic blood pressure ($p > 0.05$). When the differences between the groups were examined, a significant difference was found after the intervention in the mean scores of body temperature, heart rate, diastolic blood pressure, and systolic blood pressure before the intervention ($p < 0.05$, Table 3).

Table 4 shows that the simple linear regression analysis performed to determine the effect of eye mask and earplug application on sleep, anxiety, fear, body temperature, pulse, diastolic and systolic blood pressure was statistically significant ($p < 0.05$). It can be seen that the application of an eye mask and earplugs affect the sleep quality of the patients positively, and the body temperature, pulse, fear, anxiety, diastolic and systolic blood pressure values negatively (Table 4, $p < 0.05$).

4 | DISCUSSION

Patients in ICUs who are critically ill experience an interrupted day/night routine, high levels of noise, and illness-related stress (Kol & Dikmen, 2018). Although the total sleep duration of the patients in the CICU is normal (7–9 h a day), there is an increase in the percentage of wakefulness and Stage 1 sleep, while there is a decrease in Stage 2, Stage 3, and rapid eye movement (REM) sleep. Compared to normal healthy people, arousal and alertness are significantly increased in ICU patients (Malik & Parthasarathy, 2014). ICU patients have up to 50% of their total sleep during the daytime (Boyko & Jennum, 2013). Treatment and care activities carried out at night in the ICU affect the patients sleep. In the ICU, patients are often adversely affected by night-time patient care. The frequency of these procedures causes patients to not be able to get adequate sleep time and rest adequately (Ritmala-Castren et al., 2015). Fear and anxiety also affect sleep negatively, and some ICU patients have reported being afraid of falling asleep because of the fear that they would not wake up again (Frisk & Nordström, 2003). Impaired immune function and associated susceptibility to disease and infection, decreased energy levels, delirium, delays in recovery, and impaired cognitive, respiratory, cardiac, and endocrine functions are linked to poor sleep quality. Sleep disorders are reported to be closely associated with mortality, infection rate and complications in critically ill patients. For this reason, quality sleep is important in critically ill patients (Wang et al., 2019). This study was conducted to find out how using earplugs and eye masks during the night affect sleep quality, anxiety, fear, and vital signs of ICU patients.

The intervention was found to cause a significant increase in sleep quality. It was found that earplugs and eye mask application improved sleep quality. In their study, Huang et al. (2015) found that worse subjective sleep quality was reported due to ICU noise and light, while sleep quality was significantly improved as a result of using earplugs and eye masks. In a study on the effects of earplug on sleep quality, Neyse et al. (2011) reported that using earplug improved sleep quality. Patients also stated that the use of earplugs decreased the consumption of sleeping pills and increased morning functions. Hu et al. (2015) investigated the effect of using earplugs and eye masks on sleep quality and melatonin levels in ICU patients and concluded that the use of earplugs and eye masks improved sleep and increased melatonin levels. In systematic reviews evaluating the short- and long-term benefits of eye masks and earplugs, they were found to have a positive effect on sleep quality (Fang et al., 2021; Locihová et al., 2018; Polat et al., 2022). In a different meta-analysis, it was reported that eye masks and earplugs provided a significant increase in total sleep time, sleep efficiency, REM time, and a significant decrease in awakening (Karimi et al., 2021). Different studies support the results of the study, reporting a positive effect of eye masks and earplugs on sleep quality (Dave et al., 2015; Hu et al., 2010; Koçak & Arslan, 2021). Melatonin is primarily released by the brain in response to darkness (Blask, 2009). As an important physiological sleep hormone, melatonin helps regulate the circadian rhythm and synchronise the sleep–wake cycle. Plasma levels begin to rise from mid-to-late evening, remain high for most of the night, and then fall in the early morning (Rzepka-Migut & Paprocka, 2020). Exposure to simulated ICU noise and light in healthy individuals inhibits both sleep and melatonin release (Hu et al., 2010). An eye mask reduces the exposure of the eyes to light, thus increases melatonin production (Hu et al., 2015; Huang et al., 2015). In addition, eye masks and earplugs can reduce sleep deprivation by changing the environmental perception of the patients (Hu et al., 2010). It has been stated that the use of earplugs and eye masks is a non-invasive, economical, and effective way to improve sleep quality in adult ICU patients (Polat et al., 2022).

A significant decrease was found in post-intervention fear and anxiety scores, and the application of earplugs and eye masks was found to be effective. There is no study similar to this study in the literature, and studies on the application of earplugs and eye masks to prevent the development of psychological problems in ICU patients are also very limited. Esfandiari et al. (2022) reported that the anxiety levels of patients using eye masks decreased compared to the control group. Demiray and Khorshid (2018) and Hu et al. (2015) found that the noise and light of the ICU caused higher anxiety levels and the use of earplugs and eye masks reduced the anxiety levels of the patients. When exposed to the noise and light of the ICU, acute noise triggers the stress response and high stress hormones (Leproult et al., 2001). Exposure to the noise and light of the simulated ICU in healthy individuals was reported to increase serum cortisol levels. It has been reported that the application of earplugs and eye masks reduces serum cortisol levels (Hu et al., 2010). Khoddam et al. (2022) found that eye masks and earplugs significantly reduced cortisol levels, which is known as the stress hormone. In their study, Azimian

et al. (2019) found that earplugs and eye masks were effective in preventing the development of post-traumatic stress. In another study, it was stated that earplug application affected stress levels of patients positively (Czaplik et al., 2016). Earplugs and eye masks were stated as a non-pharmacological intervention that can be used to manage psychological problems such as fear and anxiety (Azimian et al., 2019; Hu et al., 2015).

In this study, it was found that heart rate, systolic and diastolic blood pressure scores decreased significantly after the intervention. It was found that earplugs and eye mask application reduced the problems in vital signs. In the literature, studies on the application of earplugs and eye masks to prevent the development of problems in haemodynamic parameters in ICU patients are very limited. Esfandiari et al. (2022) reported that the haemodynamic parameters (heart rate and respiratory rate, systolic and diastolic blood pressure values) of patients using eye masks were better than the control group. In the studies of Demoule et al. (2017) and Koçak and Arslan (2021), an eye mask and earplugs were used for 1 night, and a decrease in heart rate was observed in vital signs, although not statistically significant in the experimental group. Lack of sleep can increase the activity of the sympathetic system, and this can cause conditions such as increased heart rate, blood pressure, myocardial oxygen demand, pain, anxiety, nervousness, and irritability in patients with heart disease (Neyse et al., 2011). It is thought that the increase in sleep quality in individuals contributes to the improvement of negative situations.

4.1 | Limitations

Several limitations can be listed for the study. First of all, it is a subjective evaluation of sleep quality, as objective evaluation of sleep quality cannot be achieved with polysomnography. The second limitation is the lack of determination of chronotypes (sleep–wake rhythms) that are thought to affect clinical outcomes. Methodological issues, such as small sample size, are other limitations of this study. Researchers and patients were not blinded; the data collector and data analyst were blinded. As the fifth limitation, patients with heart failure admitted to the CICU of only one hospital were evaluated; therefore, the results cannot be generalised.

5 | IMPLICATIONS FOR PRACTICE AND RECOMMENDATIONS

In ICUs, the risk of developing anxiety, fear and sleep disorders is increased in patients due to environmental factors like bright light and noise. Light and noise control is difficult in ICUs. However, the negative effects of sound and light can be reduced by using earplugs and eye masks. The results of the present study showed that the simple intervention of eye masks and earplugs can make a valuable contribution to reducing fear, anxiety, problems in vital signs, and improving sleep quality in ICU patients.

6 | CONCLUSION

In this study, a decrease in fear, anxiety, heart rate, systolic and diastolic blood pressure scores, and an improvement in sleep quality were observed after the intervention. The intervention was found to be effective in reducing fear, anxiety, problems in vital signs, and increasing sleep quality. Considering the present study results, it is recommended that this practical and economical non-pharmacological method should be used in hospitals to reduce fear, anxiety, problems in vital signs, and increase sleep quality in ICU patients, to make the use of eye masks and earplugs widespread in hospitals, to ensure that they are introduced to patients, and to be used at routinely determined hours. Studies with larger sample groups are recommended in order to increase awareness in the use of eye masks and earplugs and to evaluate their effectiveness based on evidence. It is also recommended to conduct studies with different non-pharmacological methods (such as morning bright light therapy) and on the potential of chronotherapeutics among critically ill patients.

AUTHOR CONTRIBUTIONS

Gülcan Bahcecioglu Turan: Conceptualisation, Methodology, Investigation, Writing—original draft, Writing—review and editing. Supervision Fatma Gürcan: Conceptualisation Investigation, Writing—original draft, Writing—review and editing, Supervision. Zülfünaz Özer: Conceptualisation, Investigation, Data curation, Writing—review and editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no financial interests in relation to the reported work.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author.

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