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The Effect of Counseling and Sleep Mask Application in Coronary Intensive Care Patients on Sleep Quality and Anxiety: A Randomized Controlled Study

Koroner Yoğun Bakım Hastalarında Danışmanlık ve Uyku Maskesi Uygulamasının Uyku Kalitesi ve Anksiyete Üzerine Etkisi: Randomize Kontrollü Bir Çalışma

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Abstract

Objective: Patients in the coronary intensive care unit most of them have sleep problems. Intensive care nurses should regularly review patients' sleep patterns and identify strategies that promote sleep. Intensive care nurses are in a unique position to provide direct support to cardiac patients regarding physiological and psycho-social risk factors. The aim of this study is to investigate the effect of eye mask application and anxiety reduction counseling on sleep quality and anxiety in the coronary intensive care unit.

Materials and Methods: This is a single-center prospective randomized controlled clinical study. 50 patients in the intervention group were allowed to wear eye masks during sleep at night and counseling was provided to reduce their anxiety. 50 patients in the control group received routine cardiological treatment. Research data were evaluated with the Richards-Campbell Sleep Scale, the Hamilton Anxiety Rating Scale and the "Numeric Rating Scale". Data were analyzed using the statistical program SPSS (22.0).

Results: Sleep quality score (intervention group: 316.40±148.42, control group: 291.80±149.29) differed between the groups, but it was not statistically significant (t=0.826, p=0.411). However, the difference between the anxiety scores (intervention group: 11.44±8.74, control group: 15.38±10.49) was statistically significant (t=-2.040, p=0.044).

Conclusion: Eye mask application supported the sleep of the patients in the coronary intensive care unit and was recommended for patients who wanted to use an eye mask. Nurses were advised to answer and support their patients' questions through counseling.

Keywords: Patient, eye mask, counseling, sleep, anxiety

Öz

Amaç: Koroner yoğun bakım ünitesinde yatan hastaların büyük çoğunluğunda uyku sorunu vardır. Yoğun bakım hemşireleri, hastaların uyku örüntülerini düzenli olarak gözden geçirmeli, uykuyu teşvik eden stratejileri belirlemelidir. Yoğun bakım hemşireleri, fizyolojik ve psiko-sosyal risk faktörleri konusunda kalp hastalarına doğrudan destek sağlama açısından benzersiz bir konumdadır. Bu çalışmanın amacı, koroner yoğun bakım ünitesinde göz maskesi uygulamasının ve anksiyete azaltmaya yönelik verilen danışmanlığın uyku kalitesi ve anksiyete üzerine etkisini araştırmaktır.

Gereç ve Yöntem: Tek merkezli prospektif randomize kontrollü klinik bir çalışmadır. Müdahale grubundaki 50 hastanın gece uykusunda göz maskesi takmasına izin verildi ve kaygılarını azaltmak için danışmanlık sağlanmıştır. Kontrol grubu 50 hastanın rutin kardiyolojik tedavi alması sağlanmıştır. Araştırma verileri Richards-Campbell Uyku Ölçeği, Hamilton Anksiyete Derecelendirme Ölçeği ve "Sayısal Derecelendirme Ölçeği" ile değerlendirilmiştir. Veriler istatistiksel program SPSS (22.0) kullanılarak analiz edilmiştir.

Bulgular: Uyku kalitesi puanı (müdahale grubu: 316,40±148,42, kontrol grubu: 291,80±149,29) gruplar arasında farklıydı ancak istatistiksel olarak anlamlı bulunmamıştır (t=0,826, p=0,411). Ancak anksiyete puan ortalamaları arasındaki fark (müdahale grubu: 11,44±8,74, kontrol grubu: 15,38±10,49) istatistiksel olarak anlamlı çıkmıştır (t=-2,040, p=0,044).

Sonuç: Göz maskesi uygulaması hastaların koroner yoğun bakım ünitesinde uykularını ddesteklemiş, göz maskesi kullanmak isteyen hastalara önerilmiştir. Hemşirelere, hastalarının sorularını danışmanlık yoluyla yanıtlamaları ve desteklemeleri tavsiye edilmiştir.

Anahtar Kelimeler: Hasta, göz maskesi, danışmanlık, uyku, anksiyete

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Introduction

As one of the basic human needs, "sleeping" is as important as eating, resting, excretory system (1). Keeping the changes on the sleeping pattern and quality for a long time may lead to physiological and mental disorders (2). Sleep/wake cycle may become irregular in intensive care units (ICUs). Pharmacological interventions for sleep (analgesic, sedative and hypnotic agents) can both disrupt and induce sleep and have many adverse side effects in the intensive care population. The use of complementary and alternative medicine treatments to aid sleep has been explored, as drug interventions to improve sleep in ICU patients is a relatively new area of research, and despite the limitations of the studies included in the review, there is hope that some complementary and alternative medicine interventions may promote improvement in sleep quantity and for ICU patients. convincing evidence has been reported (3). Although it is widely known that sleep is reduced in the ICU, it is still unclear what interventions can effectively improve sleep in this setting. One review analyzed articles on pharmacological and non-pharmacological interventions to promote sleep in the ICU. According to the results; non-pharmacological interventions such as eye masks and earplugs, to reduce noise and lighting, and to regulate patient care have been shown to improve subjective and objective sleep quality, although the level of evidence is considered low. It has been reported that more high-quality studies are needed to strengthen the evidence base (4). Lack of sleep of sufficient quality and length in the ICU is an important factor affecting the quality of care provided. Saturation of sleep need is extremely problematic in many ways, especially because of the difficulty of assessing sleep quality. However, the literature agrees on the importance of non-pharmacological strategies used to induce sleep in ICUs (5). In another review written to summarize, clarify and evaluate what is known about the sleep of (ICU) patients; it has been concluded that various interventions such as earplugs, eye mask use, listening to light music, and reducing light and noise levels can be applied in the ICU to improve the sleep quality of the patients (6). Patients in the coronary care unit are also at risk for sleep deprivation. Sleep deprivation can be associated with increased blood pressure and heart rate, which increases the risk of developing cardiovascular problems in patients hospitalized in the coronary care unit. According to a randomized controlled study conducted to examine the effect of eye mask on sleep quality in heart patients; 60 patients were randomly divided into experimental and control groups. While the patients in the control group received routine care, the patients in the experimental group used routine care and an eye mask for the following three nights. after all; the use of eye masks has significantly improved sleep quality in heart patients. Therefore, it is recommended that patients use an eye mask with existing treatments to improve sleep quality (7). There is a study suggesting that sleep problems are quite common in critically ill patients (more than 50%) (8). Patients, staying in the coronary ICUs (CICUs), are hospitalized with the diagnosis of life threatening cardiac disease, thus being provided with medical care. Sleeping pattern of patients are negatively affected due to various reasons (noise, light, nursing interventions, fear, anxiety, pain and drugs, etc.) in CICUs. Solid lighting and noise interrupts the night-sleep of patients, while also increasing the anxiety level. Within this scope, the medical team professionals are to be more attentive to the patients for ensuring their resting and sleeping needs, and the nurses should routinely review the sleeping pattern of the patients during admission, as well as identifying strategies that encourage sleeping (9). The sleeping problems that the patients have are mostly treated with pharmacological methods. However, there are more practical and affordable methods to stimulate the patient's sleep. There are evidences in the literature stating that the use of sleep masks by the adult patients has a positive effect on the sleeping pattern. It is suggested to carry out more comprehensive studies on this matter in order to strengthen the evidence level (10-12). Cardiac patients experience immense anxiety due to medical procedures. Nurses are in a unique position in terms of providing direct support for cardiac patients concerning the physiological and psychosocial risk factors. Effective communication, meeting the requirements, as well as optimization of the treatment and care allow the patients to be motivated for getting better.Nurses may identify the fears and concerns of their patients by carrying out realistic tests in the beginning. Then, the consultancy for reducing the anxiety level of the patient will help controlling or preventing the anxiety. The objective of this study is to analyze the effect of consultancy, provided for the patients, with the aim to minimize their anxiety levels, along with the use of sleep masks, on the sleeping quality and anxiety level.

Materials and Methods

Research Design

This is single-center prospective randomized controlled clinical trial.

Setting and Data Collection

This study was conducted in Cardiology Clinic, CICU in University of Health Sciences Turkey, Gülhane Training and Research Hospital between January-May 2017.

Participants

The research population comprises of every patients, who were decided to be hospitalized in the training and research hospital, cardiology clinic, CICU. The sample size was calculated as a result of the pilot application of this study by using G*Power (13). So, the sample size was calculated using the averages of the Richards-Campbell Sleep Scale (RCAS) obtained from the results of 15 patients who used an eye band with a night time follow-up and 9 patients who did not use an eye band. The mean score of RCAS of the patients using eye masks in the intervention group was 50.1±20.9, and the mean score of the patients in the control group was 26.9±13.3. In the calculation made by using the type 1 error 0.01 and type 2 error 0.01 values, it was calculated that the sample number for each group should be at least 25 possible. In order to minimize the error of the study and

to increase the power of the research, it was considered that it would be appropriate for the sample to consist of 50 or more participants for each group. So, the sample consisted of 50 or more participants for each group. Patients who were decided to be hospitalized in University of Health Sciences Turkey, Gülhane Training and Research Hospital, Cardiology Clinic CICU were evaluated by the researcher and the patients who met the inclusion criteria of the study and accepted to participate in the study were included in the sample group.

Inclusion criteria: Being 25 years of age or older, communicating in Turkish, not having mental impairment that could interfere with communication, no history of previously diagnosed neurological and psychiatric diseases (dementia, psychosis, mental retardation, neuromuscular disease, head trauma, neurosurgery), palliative care unit at least one night stay (sample group patients were followed for the first 24 hours of hospitalization), hemodynamically stable, lack of visual and hearing impairment, not being mechanically ventilated and sedated, adequate functional capacity and willingness to participate in the study and signed. Informed consent needs to be provided. Patients having a diagnosed sleep disorder and using sedative drugs were not included in the study.

Exclusion criteria: The severity of the disease increases, the patient cannot speak due to pain or discomfort, the patient does not want to wear the eye mask regularly during the night (what is meant here; patients are warned not to remove their eye masks unless necessary during their night sleep, but there are patients who cannot adapt despite this), at the patient's own request. Withdraw from the study and transfer the patient to another department (11,14). The need for patients to wear eye masks and the possibility of patients removing them when they are awake during the night means they can achieve this control themselves (11). The suitable patients were informed concerning the research (both in verbal and written form), while discussing the doubted issues and answering the questions. The number of patients admitted to the CICU and evaluated for eligibility was 220. As shown in Figure 1, n=52 patients who refused to participate in the study, n=60 patients excluded for various reasons: Patients who did not want to use eye masks (n=31), under 25 years of age (n=9), diagnosed Alzheimer's or dementia patients (n=2), using sleeping medication (n=2), patients with hearing loss due to old age and who could not communicate (n=16). One hundred eight patients, meeting the sample criteria and accepting to participate in the research, were randomized in two groups: 54 as intervention group, 54 as the control group. Eight patients were removed out of the sample during the implementation phase of the research. The research was completed with 100 patients. Figure 1 shows a summary of the study design and flow diagram based on the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines (15). CONSORT checklist is shown as Supplementary File 1.

Instrumentation

Data collection form comprises of three sections.

Personal Information Questionnaire

The first part included Personal Information Questionnaire consisting of the descriptive characteristics and medical characteristics of the participants. Descriptive characteristics of the participants; it consisted of questions of age, gender, marriage, educational status, and occupation (Table 1). Medical characteristics of participants are; the patient's presenting medical complaint, medical diagnosis, chronic illnesses were questioned (Table 2).

Richards-Campbell Sleep Questionnaire (RCSQ)

RCSQ was used for measuring the sleeping quality of the patients. This is a questionnaire, comprising of 6 charter, analyzing the sleep-deepness, dozing off time, wake-up frequency, the duration of keeping awake after waking up, sleeping quality, along with the noise level in the respective environment. This questionnaire questions are evaluated on a chart of 0 to 100, with visual analog scale technique. A score between "0-25" indicates a very poor sleeping, while "76-100" indicates high quality of sleeping. Cronbach α value of the scale was found to be 0.82 (16). Translation of RCSQ into Turkish was performed by Ozlu and Ozer (17) in 2015. The sample group was selected among the patients, staying in ICU, in terms of validity and reliability study. Cronbach α value of the scale was found to be 0.86 in our study.

Hamilton Anxiety Rating Scale (HARS)

HARS was used to measure the anxiety severity of the patient. The evaluation is made between 0-4 points according to the symptom severity. There are 14 items in the HARS that evaluate the physical and psychic symptoms of anxiety. Fourteen items; it covers anxious mood, tension, fears, insomnia, intellectual (cognitive), depressive temperament, somatic (muscular), somatic (emotional), cardiovascular, respiratory, gastrointestinal symptoms, genitourinary symptoms, autonomic symptoms, and behaviors during the interview. The Turkish validity and reliability study of the scale was conducted by (18). Zero-5 points define no anxiety, 6-14 define minor anxiety, 15 points and above define major anxiety. In our study, the Cronbach α value of the scale was found to be 0.83.

Study Arms

Control monitoring of the patients was maintained for one day. The ICU personnel was requested to maintain the routine cardiologic care and procedures, and not attempting to perform any special procedure on control group patients. Sleeping quality and anxiety level of the patient group were analyzed with data collection tools during the day-time of the second day.

Intervention the researcher went up to the patient and introduced himself/herself, informing the patient about the objective and procedures of the research, as well as receiving the patient's consent. The consultancy scope for minimizing the anxiety level comprises of therapeutic communication, investigating the anxiety sources of the patient, ensuring the patient to be informed on his/her diseases as deemed required. Starting from the first encounter in the morning hours, the

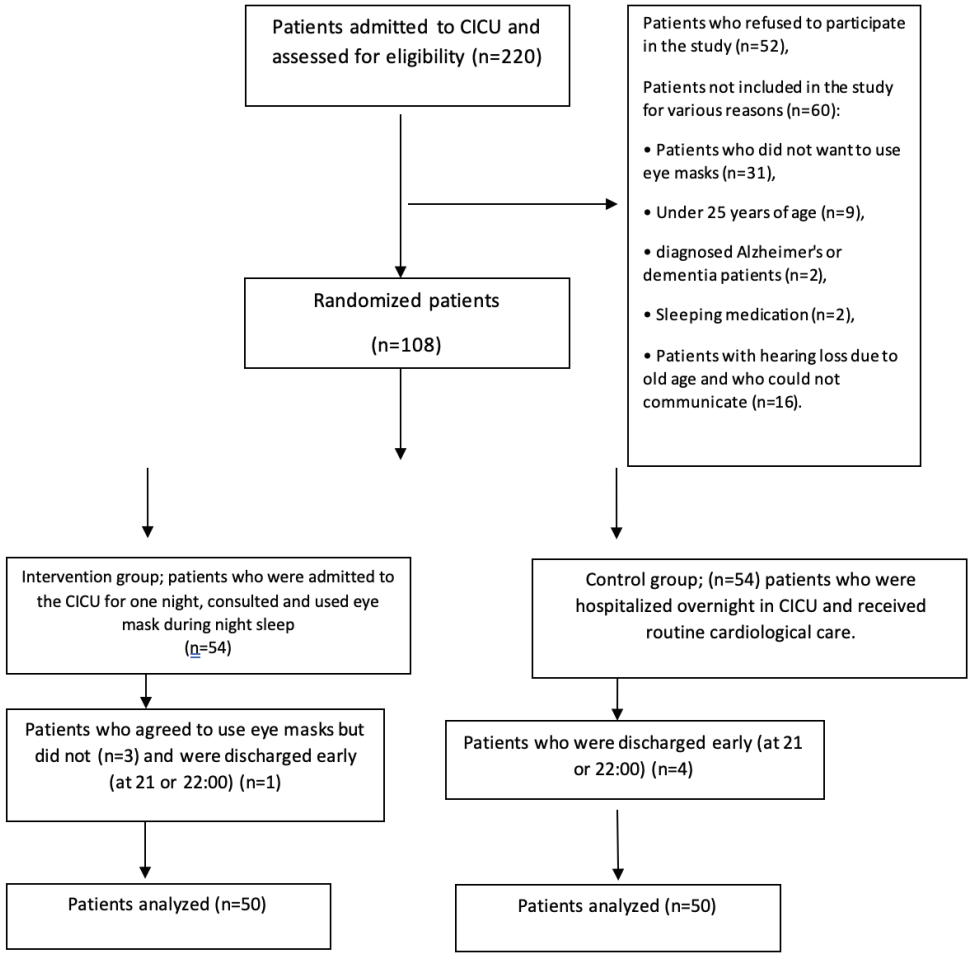

Figure 1. Consort diagram

patient was contacted via face-to-face interview method, by the patient bed for between 10 to 30 minutes. Consultancy services were kept to be provided for a few times during various period (10 minutes or more), when the patient was available in the afternoon. By 10:30 pm, the patient was asked if he/she had any questions before sleeping within the scope of the consultancy service. The patient was requested to wear a sleep mask from 10:30 pm until 06:30- 08:00 am, as well as being informed on how to use the mask. Nightshift nurse gave polite warnings on the use of sleep mask by the patient. Where the patients did not feel comfortable, they were allowed to remove the sleep mask, then wear it again. During the day-time of the second day, the feedbacks from the patient on his/her experience for the night before, sleeping quality, anxiety level were filled in the form by the researcher via data collection tools by face to face interview method. Adult phototherapy sleep mask was used in the research (18). Research implementation steps can be seen in Table 3.

The windows in CICU, which are not projected out, partially receive the day light. Fluorescence lamps are placed in the ceiling of ICU, which are on during the day time and night time, radiating white light. The fluorescents over the patient beds can be turned off by the patient, at will. The eye mask used in the research; are specially designed adult phototherapy eye masks (brand; UNIMAG) with carbon materials. It is generally used in newborn ICU, dermatology clinics and ultraviolet treatment rooms. It has CE certificate, is produced in medical device class, has been tested at 450 nanometer beam intensity and its transmittance is measured as "0.000". As sleeping glasses, it is made of 3 layers of material laminated to each other, and the part close to the skin is made of knitted cotton fabric for skin compatibility. Designed for face shape and head structure, with 2 elastic bands, it provides safe and easy use. It has a cotton-like texture that grips the skin and absorbs sweat. There is 1 sterile product in the bag and it is for single use (19). Research application Table is given in Table 3.

Randomisation Process

Computer randomization was performed after consent was obtained. A block randomization list for two groups was obtained by using web-based Random Allocation Software program (20). By using the list, each participant was randomly assigned to the control and the intervention groups.

Table 1. Descriptive characteristics of participants						
Features	**Intervention group (n=50)**		**Control group (n=50)**		**Test statistics**	**p value**
Age (average, SD)	56.78±15.44		59.54±10.73			
	n	**%**	**n**	**%**		
30-65 years old	32	64.0	36	72.0	0.735[b]	0.391
Over 65 years	18	36.0	14	28.0		
Gender						
Male	23	46.0	21	42.0	0.162[b]	0.687
Famale	27	54.0	29	58.0		
Marital status						
Single	9	18.0	8	16.0	0.071[b]	0.500
The married	41	82.0	42	84.0		
Education situation						
Primary education	17	34.0	23	46.0	3.057[a]	0.217
Secondary education	18	36.0	19	38.0		
University and above	15	30.0	8	16.0		
Job						
Officer	9	18.0	6	12.0	3.789[a]	0.284
Self-employment	1	2.0	4	8.0		
Retired	24	48.0	29	60.0		
Housewife	16	32.0	11	22.0		
Total						

[a]Fisher's exact test, [b]Pearson chi-square test, SD: Standard deviation

Table 2. Medical characteristics of participants						
Features	**Intervention group (n=50)**		**Control group (n=50)**		**Test statistics**	**p value**
	n	**%****	**n**	**%****		
Patient's complaint*						
Chest pain	29	55.8	23	44.2	1.442[b]	0.230
Palpitation	8	38.1	13	61.9	1.502[b]	0.220
Shortness of breath	9	42.9	12	57.1	0.542[b]	0.461
Pain in the back and arm	7	70.0	3	30.0	1.778[b]	0.182
Medical diagnosis						
Acute coronary syndrome	29	58.0	28	56.0	3.660[a]	0.599
Congestive heart failure	5	10.0	9	18.0		
Arrhythmia	13	26.0	11	22.0		
Chronic diseases						
Yes	33	66.0	43	81.0	2.486[b]	0.115
No	17	34.0	10	19.0		
Chronic diseases*						
Diabetes mellitus	11	42.3	15	57.7	0.832[b]	0.362
Hypertension	15	40.5	22	59.5	2.102[b]	0.147
Total						

*More than one answer to this question. Percentages are calculated from "n", **Column percentages have been taken, [a]Fisher's exact test, [b]Pearson chi-square test

Blinding

The principal investigator conducted the study, provided counseling services, and implemented data collection instruments. Voluntary participants that met the inclusion criteria were informed about the aim and scope of the study. After giving their consent, they were randomly allocated to the control and intervention groups by using the randomization list. An expert in statistics who did not take part in the implementation of the study conducted statistical analysis.

Table 3. Research application table		
Application time	**Intervention group (n=50)**	**Control group (n=50)**
First encounter with the patient		
09:00	- Patients were selected according to the inclusion criteria and randomly selected numbers were used in the study groups.	
First day interview with patient and night		
09:00-10:00	- Written and oral consent of the patients about the research, - Counseling services are provided to reduce anxiety.	- Written and verbal consent of the patients were obtained and no consultancy services were provided.
09:00-10:00	- The patient was informed about how to use the eye mask at night sleep and how to use it.	- Patients did not use eye mask.
13:30-14:30	- Counseling services are provided to reduce anxiety.	- Counseling services were not provided.
22:30	- Counseling services are provided to reduce anxiety.	- Counseling services were not provided.
22:30	- The patients were supported to wear an eye mask at 22:30 until 06:30-08:00 the following morning. - Routine cardiological nursing care has been given to patients by night nursing nurse*.	- Control group patients are provided to sleep during normal sleep hours*. - Routine cardiological nursing care has been given to patients by night nursing nurse*.
22:30-08:00	- The participants were allowed to remove the eyebrows for a short time (10 minutes or less at a time) and then to replace them again if needed.	- Control group patients are provided to sleep during normal sleep hours.
Second day and day follow-up with patient		
09:00-16:00	- The quality of sleep and the level of anxiety were evaluated by using data collection tools by face-to-face interview method.	- The quality of sleep and the level of anxiety were evaluated by using data collection tools by face-to-face interview method.

*Intensive care personnel were asked to continue their usual routine cardiological care practices during the research and not to undertake specific attempts to reduce light and noise

Table 4. Findings of the participants about the sleep experience						
Features	**Intervention group (n=50)**		**Control group (n=50)**		**Test statistics**	**p value**
	n	**%****	**n**	**%****		
Sleep problems of the participants						
Yes	37	74.0	33	66.0	0.762[b]	0.383
No	13	26.0	17	34.0		
The reasons why the participants could not sleep*						
Intensive care environment	14	56.0	11	44.0	0.480[b]	0.488
Noise	26	60.5	17	39.5	3.305[b]	0.090
Other patient voices	15	46.9	17	53.1	0.184[b]	0.668
The woken by Nurse	26	60.5	17	39.5	3.305[b]	0.069
He can not sleep	10	50.0	10	50.0	0.001[b]	1.000
Pain or discomfort during the night sleep						
Yes	19	38.0	16	32.0	0.396[b]	0.529
No	31	62.0	34	78.0		
Causes of pain or discomfort experienced by the participants during the night sleep*						
Pain in the groin placed in the stent	8	61.5	5	38.5	0.796[b]	0.372
Back pain	2	28.6	5	71.4	1.382[b]	0.240
To live in fear that "I cannot survive here"	2	50.0	2	50.0	<0.001[b]	1.000
Blood pressure elevation	2	50.0	4	66.7	0.709[b]	0.400

*More than one answer to this question. Percentages were taken over "n", **Milk percentages were used, [a]Fisher's exact test, [b]Pearson chi-square test

Table 5. Sleep quality and anxiety score average of participants after intervention				
	Intervention group (n=50)	Control group (n=50)	Test statistics	p value
	Mean ± SD	Mean ± SD		
RCSQ	316.40±148. 42	291.80±149. 29	t*=0.826	0.411
HARS	11.44±8.74	15.38±10.49	t*=-2.040	**0.044**
HARS psychic complaint	2.88±3.36	4.32±3.51	t*=-2.093	**0.039**
HARS somatic complaint	8.56±6.39	11.06±8.07	t*=-1.716	0.089
*Independent sample t-test, SD: Standard deviation, RCSQ: Richards-Campbell Sleep Questionnaire, HARS: Hamilton Anxiety Rating Scale				

Statistical Analysis

Data were collected during face-to-face interviews. We used IBM SPSS (Statistical Package for the Social Sciences) 22.0 software for data analysis. As descriptive statistics, number (n), percentage (%) were used for numerical variables and mean-standard deviation ($\bar{X}$ ± SD), median, and minimum-maximum (min-max) for categorical variables. Kolmogorov-Smirnov test was used to analyze the normality of the distribution of continuous variables. Non-parametric tests were used for the analysis of data without normal distribution. For inter-group comparison, we used Pearson's chi-square test for discrete variables and Independent Sample t-test, Mann-Whitney U tests for continuous variables. Wilcoxon t-test was used for intragroup analysis. A p-value of 0.05 was set for statistical significance.

Ethical Consideration

Ethical approval was obtained from the Ethical Committee of the Institution, where the study was carried out. The study was started after obtaining approval from the University of Health Sciences Turkey, Gülhane Health Sciences Institute Ethics Committee (decision no: 0000127, date: 23.02.2017). Institutional permission was obtained from the place where the research was conducted. Permission to use the scales used in the study was obtained.

Results

Baseline Characteristics

The average age regarding the descriptive characteristics of the patients is 58.16±13.30. The majority of the participants in the intervention group (64%) and control group (72%) were in the 30-65 age range. More than half of the participants in the intervention group (54%) and control group (58%) are women. The majority of the intervention and control group participants are married. There was no statistically significant difference between the groups in terms of socio-demographic characteristics (p>0.05) (Table 2). All patients gave more than one response to the complaint of presentation to CICU and reported the most complaint of chest pain. Other complaints of the patients; palpitations, shortness of breath, and pain radiating to the back and left arm. The medical diagnoses of the patients are mostly acute coronary syndrome, rhythm disturbance and congestive heart failure (CHF). The majority of both groups stated that they have chronic diseases. It has been reported that patients have the highest rate of diabetes mellitus (DM) and hypertension among chronic diseases with more than one response. There was no statistically significant difference between the groups in terms of the medical characteristics of the patients (p>0.05) (Table 3). The majority of the patients reported that they could not sleep at night in the CICU. The most common reasons for the participants not to sleep; noise and being awakened by the nurse, other patient sounds (cough, moaning, cell phone conversation sounds), intensive care environment and the inability to sleep. Less than half of the patients stated that they felt pain or discomfort during night sleep. In both groups, patients were mostly; reported that he was uncomfortable and unable to sleep due to pain in the groin area where the stent was placed, back pain, fear of "I cannot survive here" and increased blood pressure. the findings regarding the sleep experience of the participants are given in Table 4.

Main Outcomes

Sleep quality and anxiety score average of the participants is given in Table 5. In our study, sleep quality and anxiety data of the control and intervention groups, after the eye mask and counseling intervention, were analyzed. The sleep quality average score of the intervention group was higher than the control group, but the difference between the groups was not statistically significant (p=0.411). The mean anxiety score of the intervention group was lower than that of the control group, and the difference was statistically significant p=0.044) (p<0.05) (Table 5).

Secondary Outcomes

A correlation analysis was performed between the sleeping quality of the patients and anxiety scale score averages. A negative, moderate (r=-0.395) and statistically significant (p=0.005) correlation was found between the intervention group sleep quality and anxiety mean scores.

Discussion

In this randomized clinical study, CICU examined the effects of counseling and sleep mask use on inpatients to reduce anxiety on sleep quality and anxiety. In our study, in the majority of patients; middle-aged, female and married, chest pain complaints mostly, acute coronary syndrome, rhythm disorder and CHF, DM and hypertension among multiple chronic diseases were observed. There was no difference between the groups in terms of medical characteristics, and similar results were found in terms of socio-demographic data and medical characteristics in similar studies. The intensive care

environment is a significant source of stress for all patients, and it is a frightening and disturbing unit where negative experiences are experienced (7,21,22). The presence of chronic disease is among the important factors in the development of sleep problems. Continuous drug use in patients with chronic diseases, especially in the elderly, can also cause disruptions in sleep architecture and continuity (23). In our study, the majority of the patients said that CICU could not sleep at night, the most common causes were; noise and being awakened by the nurse, the presence of other patient voices (cough, groaning, cell phone talking sounds) and the intensive care environment. In the majority of patients in both groups; it has been reported that they experienced discomfort due to pain in the groin area where the stent was placed, back pain, fear of "I can't live here" and increased blood pressure, and they could not sleep. CICU patients experience serious anxiety and face sleep problems. However, it is thought that the sleep problems experienced are especially related to "the patient's being in the acute illness period and the severity of the underlying disease" (21). Achieving restorative sleep in the ICU is difficult for most patients. There are many hurdles to overcome to improve sleep patterns in critically ill patients. In our study, the sleep quality mean score of the intervention group in which eye mask was applied was higher than the control group among the patient groups, but the difference was not statistically significant. Similar results were found in the literature. In the current literature review analyzing the effects of non-pharmacological intervention types (earplugs and eye masks) on sleep quality/amount in the intensive care setting; despite the heterogeneity of the analyzed studies and some common methodological issues (sample size, design, selection and comparison of outcome parameters), earplugs and eye masks have been shown to have potential positive effects on ICU inpatient sleep quality and delirium incidence (5). Researchers such as Jones and Dawson (12), who reached similar results, found that critical intensive care patients had a better quality sleep experience with the help of earplugs and sleep masks, but their sleep was frequently interrupted (24). In a study aiming to evaluate the effect of using a combination of eye mask and earplugs on perceived sleep quality in patients admitted to the ICU, it was determined that the use of eye mask and earplugs and perceived sleep quality were significantly better than the participants in the control group (6). Sleep is an indispensable need for patients with CICU. A clinical study examined the effect of eye mask and earplug use on the sleep quality of patients with coronary heart disease (CHD), it is effective, feasible, cost-effective and widely available, using eye masks can significantly increase urinary melatonin levels helping to improve sleep quality. It has been reported that it is a material and can be used to improve CICU sleep of patients (15). In the study conducted to determine the sleep quality and fatigue levels of patients who underwent CICU angiography; it was determined that the sleep quality of the patients who underwent coronary angiography was adversely affected and their fatigue levels were high. It is recommended to make a nursing care plan for sleep hygiene and activity for these patients and to provide counseling. Individuals at risk should be monitored at regular intervals (25). Various levels of anxiety are experienced in every patient, but this situation is seen more strongly and frequently in heart patients. Anxiety disorders are associated with the onset and progression of heart disease and in many cases are associated with adverse cardiovascular outcomes, including mortality. Given the associations between anxiety disorders and poor heart health, timely and accurate identification and treatment of these conditions is extremely important. More studies are needed to determine whether interventions to treat anxiety disorders ultimately affect both psychiatric and cardiovascular health (26). Anxiety is present in all patients in varying degrees. Anxiety is common in coronary artery disease (CAD). Anxiety reduces the quality of life of patients who are at risk of having a heart attack at any time and increases the need for health services. CICU is an emotionally disturbing and anxiety-inducing environment where patients with serious heart diseases are hospitalized. In a study conducted to determine the intensive care experiences and anxiety and depression levels of patients receiving CICU medical treatment and nursing care, it was reported that all patients are at risk of experiencing anxiety and depression, and that patients may experience more negative experiences as the length of stay increases (27). In another study, it was found that patients with suspected heart disease, whose application procedures for angiography were completed, experienced significant anxiety and depression (28). The anxiety sensitivity of these patients with heart disease is related to cardiac events rather than psychological factors, that is, it is specific to the heart. In another study, the effect of patient education and counseling intervention on the quality of life in patients with CAD was investigated, and it was found that the education and counseling intervention provided to the patient increased the quality of life (29). In this context, similar results were obtained in our study, and the anxiety average of the intervention group was found to be lower after the counseling given to the patients. Anxiety is common in patients with CHD and can have adverse consequences. It has been reported that studies investigating the effects of anxiety on clinical outcomes such as acute cardiac events and death should be conducted and at the same time, it is necessary to determine the benefit of its treatment to patients (30).

Study Limitations

Anxiety level of both patient groups were not measured before intervention within the scope of the study. Normal sleeping habits of the patients, along with their sleep/wake cycles, are recognized to be within uncontrollable factors. The patients were monitored for only one night. Personal feedbacks from the patients were.

Conclusion

Majority of the patient groups reported to not having a good-night sleep, while mentioning the following as the most frequent reasons for being waken up: Noise, being waken up by the nurse, noises of other patients, and the intensive care environment. Patients, using sleep masks had a better night-

sleep. It is also suggested to establish an environment, where the patients have the opportunity to express their situations, as of the date of admission to CICU, as well as answering their questions and providing support for them, through the consultancy services to be provided by the nurses. It is suggested to carry out study, where the number of patients, staying in CICUs, and the application times are increased. In the future studies, it is suggested to carry out researches on different measures, which can be developed as oriented at not allowing the patients to be interrupted while sleeping, who stay in CICU. It is recommended to develop and establish CICUs in modular structure and technological architecture, supporting the sleeping of patients.

Ethics

Ethics Committee Approval: The study was started after obtaining approval from the University of Health Sciences Turkey, Gülhane Health Sciences Institute Ethics Committee (decision no: 0000127, date: 23.02.2017).
Informed Consent: Informed patient consent was obtained.
Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practice: Ö.K., Concept: Ö.K., G.G., H.C., Design: Ö.K., G.G., H.C., Data Collection or
Processing: Ö.K., Analysis or Interpretation: Ö.K., G.G., H.C., Literature Search: Ö.K., G.G., H.C., Writing: Ö.K., G.G., H.C.
Conflict of Interest: No conflict of interest was declared by the authors.
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Supplementary File 1.
CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/topic	Item no	Checklist item	Reported on page no
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5-6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	6
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	5-6
Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation Concealment Mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5-6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	6
	13b	For each group, losses and exclusions after randomisation, together with reasons	6
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5-6
	14b	Why the trial ended or was stopped	5-6
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10-11, 19-20
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10-11
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10-11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	10-11

Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	10-11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and if relevant, multiplicity of analyses	12-13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-13
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	None

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.