



# Effect of Eye Masks, Earplugs, and Quiet Time Protocol on Sleep Quality of Patients Admitted to the Cardiac Care Unit: A Clinical Trial Study

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Received 2019 October 09; Accepted 2019 October 09.

## Abstract

**Background:** There are several factors such as noise and light, which affect the sleep quality of patients admitted to the cardiac care unit (CCU) and cause sleep disorders in these individuals.

**Objectives:** The purpose of this study was to compare the impact of applying eye masks and earplugs as well as implementing the quiet time (QT) protocol on the sleep quality of patients hospitalized in the CCU of Ali Ibn Abi Talib Hospital in Zahedan.

**Methods:** This clinical trial was performed on 135 CCU patients. Subjects meeting the inclusion criteria were chosen through convenience sampling. The patients were divided into three groups (control, eye mask and earplugs, and QT protocol) and were matched in terms of background variables. The subjects were studied over three days after admission. On the first night, the patients' sleep quality was determined by the Verran and Snyder-Halpern Sleep Scale (VSH), and on the second and third nights, the interventions (eye mask and earplugs and QT protocol) were administered. The next day, as the post-test, patients' sleep quality was measured again. ANOVA test was used to determine and compare the mean sleep quality of the three groups, and the chi-square test was employed to compare the qualitative variables in the three groups.

**Results:** After the intervention, the mean score of sleep disturbance was significantly different between the control and the two experimental groups. Also, the mean score of sleep efficacy was higher in the eye mask and earplugs group than the other two groups, indicating a better sleep quality in this group.

**Conclusions:** As low-cost devices with no side effects, eye masks and earplugs can improve the quality of sleep in [CCU] patients, and nurses could utilize them to help reduce environmental factors, which disturb patients' sleep.

**Keywords:** Sleep Disturbance, Sleep Efficacy, CCU, Eye Mask, Earplugs, Quiet Time Protocol

## 1. Background

Cardiovascular diseases are chronic conditions that not only have a high mortality rate, but in the long run, due to their debilitating nature, cause some limitations in one's life. According to the World Health Organization, coronary artery disease accounted for 30% of deaths by 2013, and it remains the leading cause of post-cancer mortality by 2020 (1).

Patients with acute heart problems such as stroke or coronary heart disease are hospitalized in the CCU to receive special care. The basis of care in the CCU is to provide special conditions for the patient to have a complete rest and to reduce their cardiac activity. Despite defining such a task for the CCU, patients' who sleep in this unit may be

impaired for a variety of reasons, one of which concerns environmental factors (2). Sleep is a complex and dynamic physiological state, which is vital for survival. Sleep deprivation and disruption can lead to heightened sensitivity to pain, increased sympathetic activity and decreased parasympathetic activity of the heart, immune system dysfunction, alterations in endocrine and metabolic systems, increased heart rate, hypoxia, cardiac dysrhythmia, and hemodynamic instability (3).

Sleep disturbance in CCU patients depends on several factors, which could result in acute coronary syndrome and aggravate patient's status. In this regard, the physical environment of the patient is of particular importance. Noise and light are among the most common factors that interfere with patient's sleep schedule and are quite recur-

rent in patients admitted to the CCU (4). Noise can stimulate the cardiovascular system, increase gastric secretions, and trigger adrenal and pituitary glands. The adverse effects of this environmental factor can lead to irreversible complications and even increase mortality due to stroke. On the other hand, nocturnal light suppresses the secretion of sleep hormone (melatonin) and consequently disrupts the sleep cycle (5).

Additionally, there is evidence that insufficient sleep is a risk factor for heart attack. Several ways have been proposed to resolve patients' sleep problems, the most important of which is medication. While the effectiveness of non-drug treatments is slower than that of sedative-hypnotic drugs, they are more durable and have no side effects such as addiction. The effect of non-pharmacological treatments on improving sleep quality has been observed by numerous studies. The efficacy of these treatments has been reported to be 70% - 80% (6).

A lot of methods, such as reducing unnecessary patient care and categorizing patient care activities, have been tested to enhance patients' sleep quality. Recently, the emphasis has been on reducing noise and encouraging dimming lights at night, however, noise control is often impossible and certain lamps stay on for viewing and maintenance activities; therefore, using an eye mask and earplugs is one of the less expensive and easy ways in this regard. Reducing the effects of environmental factors, these devices may help patients with interrupted sleep (7). In the UK, Richardson et al., examined the effect of using eye masks and earplugs on the sleep quality of ICU patients. They observed the comfort associated with earplugs as well as the improvement of patients' sleep as a result of applying an eye mask (8). Scotto et al., addressed the effect of earplugs on the subjective experience of sleep in patients admitted to the CCU of the University of Akron, Ohio, US. By using the Verran-Snyder-Halpern Sleep Scale (VSH), the authors reported a significant improvement in the overall score of sleep satisfaction in the case group compared to the control group. As a result, they suggested applying earplugs as a low-invasive and inexpensive intervention for raising the quality of sleep (9). The study by Koo and Koh in Korea showed that the use of earplugs and eye masks could improve sleep in CCU patients (10). Based on Roy's adaptation model, human beings are biopsychological systems that adjust to their environmental changes via certain processes; according to this model, the role of the nurse is to promote patient adaptation and provide stimuli, which facilitate adaptation (11).

Meanwhile, hospitalization itself is a stressor. Patients admitted to the intensive care unit experience high levels of stress. It is estimated that 30% - 70% of [these] patients undergo severe physiological stress (12). Physiolog-

ical changes occur when a person is threatened by illness, trauma, or stress. Following stress, heart rate usually rises and the risk of arrhythmia increases. Some of the major physiological responses associated with stress are increased metabolic rate resulting in heightened body temperature, increased cardiac output and contractile power, followed by hypertension and increased heart rate and respiration. A systolic blood pressure exceeding 140 mmHg caused by stress and coupled with a decrease in pulse pressure could be indicative of a severe increase in peripheral vascular resistance and the risk of cerebral artery rupture as well as stroke (13). The vital signs of patients with heart problems change and these alterations could threaten the patient's life. On the other hand, controlling patients' hemodynamic status is a routine but essential ICU practice that provides immediate and accessible information about the patient's cardiovascular function and enables quick response to and treatment of acute potential problems (14). Currently, medications such as sedatives and painkillers are widely used to control patients' stress in the ICU. These drugs are costly and give rise to many adverse effects such as weakening the respiratory system and even death. Some studies have shown that continued use of sedative drugs delays the removal of patients from mechanical ventilation apparatus and increases patient care costs (15).

There is a growing emphasis on the use of complementary therapies in the health system, such that these treatments are referred to as a psychological factor helping patients cope with stressful circumstances (16). Applying eye masks and earplugs is one of the most effective non-pharmacological methods to improve sleep quality and physiological parameters in the CCU environment. Using these devices alongside providing a peaceful environment can be an effective way to regulate physiological parameters.

In fact, another effective non-drug technique to ameliorate sleep quality and physiological parameters in CCU could be administering the so-called quiet time (QT) protocol. Despite all the warnings about the adverse effects of sleep deprivation on ICU patients, many patients still have difficulty sleeping and resting (17). While most studies have only focused on noise and light modulation, it is crucial to implement effective protocols to modify other environmental factors as well. In a study in Taiwan, Lee et al., reported that enhancing environmental factors such as light and noise by nurses can affect the sleep quality of ICU patients and reduce their sleep disruption (18). In the United States, Martinez et al., found that reducing noise and light, not even as a protocol but generally, could have a positive impact on the sleep quality of ICU patients (19).

Therefore, it is necessary for nurses to use non-invasive,

simple, safe, and cost-effective techniques to calm the environment, both physically and physiologically, in order to modulate factors affecting patients' sleep quality and to improve and stabilize their physiological parameters (17).

## 2. Objectives

In this context, the present study compares the effect of implementing a quiet environment protocol on the quality of sleep and physiological parameters of CCU patients admitted to Ali Ibn Abi Talib Hospital in Zahedan.

## 3. Methods

This is a quasi-experimental study with a pre-test and post-test design conducted on three groups of eligible CCU patients. The study population consisted of all patients admitted to the CCU of Ali Ibn Abi Talib Hospital in Zahedan in 2017. Based on the study by Chamanzari et al., which is similar to the present research ( $S_1 = 59.04$ ,  $S_2 = 74.92$ ), the sample size was estimated at 30 for each group with a 95% confidence interval and 90% power (20). Since there were three groups, applying a factor of 1.4 obtained 42 members for each group. Considering the possibility of sample attrition, 45 individuals were chosen for each group (total = 135). The eligibility criteria included being over the age of 18 years, informed consent, awareness of time and place, recognizing people, understanding/speaking Persian, literacy and the ability to communicate verbally, scoring 13 or higher in terms of the level of consciousness (GCS), staying in CCU for more than four days, passing more than 24 hours of general anesthesia, ejection fraction equal to or greater than 25%, no hearing/visual impairment (blindness and hearing loss), not receiving sedative and opioid analgesia five hours before nocturnal sleep, no psychiatric disorder and medication to treat it (determined based on the statement of patient's family and medical records), no sleep disturbance such as apnea, narcolepsy, and chronic insomnia at the beginning of the study (determined via (previous) medical records), not working at night in the past one week, no drug addiction (determined based on the statement of the patient and his/her family), and no history of ICU hospitalization. The exclusion criteria, on the other hand, included withdrawal from the research, acute problems during hospitalization such as acute heart failure, pulmonary edema, or a reduction in the ejection fraction to less than 25%, death, decreased consciousness during the study, and daily sleep of more than two hours. Data were collected using a demographic form and a modified version of Verran and Snyder-Halpern Sleep Scale (VSH).

The demographic questionnaire included information such as age, gender, number of days the patient was hospitalized before the study, number of days the patient spent in the CCU before the study, diagnosis, and patients' sleeping hours at home.

VSH (1987) was designed to assess the mental response of hospitalized adults to sleep, in addition, it also measures one's perception of sleep the night before. It consists of eight items divided into two separate domains: sleep effectiveness and sleep disturbance. Each item is scored from zero to 100 (mm). Higher scores of sleep disorders and sleep effectiveness indicate more severe disturbance and better sleep, respectively. Consequently, it is not useful to calculate the sum of the two domains, as each one measures the individual's perception of sleep differently. Patients were studied in order of admission to the CCU. The subjects were divided into three groups after being matched in terms of background variables. The three groups were studied in the following order: control, eye mask and earplugs, and QT protocol groups.

Sequential sampling was used according to the conditions of the ward. First, the control group, then the eye mask and earplugs group, and finally the QT protocol group were determined. Specifically, eligible patients were selected using convenience sampling. After the first night of admission to the ward, the day after between nine and ten o'clock in the morning, patients' sleep quality was evaluated. On the second and third nights, the interventions were implemented separately in each group in the order mentioned above. On the morning of these two days, about nine to ten o'clock, patients' sleep quality was reassessed as a post-test. On the first night, no intervention was conducted for any of the three groups. The intervention started from the second night. ANOVA test was used to determine and compare the mean (sleep quality) of the three groups, and chi-square test was used to compare the qualitative variables in the three groups. A significance level of 0.05 was considered for all tests.

## 4. Results

In this study, 135 patients admitted to CCU were investigated in three groups (45 members each). Based on the results, 53% and 47% of participants in the control group were male and female, respectively. In the QT protocol group, 64% and 36% of the participants were respectively male and female. Also, 56% and 44% of patients in the eye mask and earplugs group were male and female, respectively. The mean age of the control, QT protocol, and eye mask and earplugs groups were 55, 52.5, and 56 years, respectively. In the control group, 18% of participants were illiterate and 82% had various educational backgrounds.

In the QT protocol group, 13% of subjects were illiterate and the remaining 87% were literate. Furthermore, the eye mask and earplugs group was predominantly literate (82%) and just 18% of participants had no literacy. In terms of marital status, in the control group, 44% of the participants were single and 56% were married. In the QT protocol group, 47% of the patients were single and 53% were married. Also, in the eye mask and earplugs group, 64% of patients were married and the remaining 36% were single. Statistical results showed that the three groups were matched in terms of age, gender, education, marital status, ethnicity, and history of hospitalization (Table 1).

The results of the ANOVA test displayed no significant difference in the mean scores of sleep disturbance in the three study groups before the intervention ( $P = 0.95$ ), yet a significant difference occurred in terms of sleep disturbance between these groups after the intervention ( $P = 0.001$ ). Similarly, ad hoc tests showed a significant difference after the intervention between the control and eye mask and earplugs groups; QT protocol and eye mask and earplugs groups; as well as the QT protocol and control groups ( $P = 0.001$ ) (Table 2).

Based on the results of ANOVA test, the mean score of sleep efficacy was not significantly different in the three groups before the intervention ( $P = 0.99$ ); but these groups differed significantly with regard to their sleep efficacy after the intervention ( $P = 0.02$ ). However, Tukey's post hoc test suggested that sleep efficacy after the intervention was significantly different only between the control and eye mask and earplugs groups ( $P = 0.002$ ) (Table 3).

## 5. Discussion

The results showed that the control group had poor sleep quality. The results of many years of nursing research have consistently substantiated that hospitalized patients experience different degrees of decline in sleep quality, varying between 50%, 60%, 65%, and 74.6% based on four studies (21). There is ample evidence showing that 30% - 80% of patients admitted to the CCU develop sleep disorders (22, 23), and several studies have reported poor levels of sleep quality in these individuals (24). Some studies have even suggested a potential association between sleep deprivation, poor quality of sleep, and increased mortality (25). In this regard, Dines-Kalinowski observed that 56% of CCU patients suffer from sleep disorders (26). The results of the present research confirmed that patients' sleep quality improved after applying earplugs and using eye masks. This positive influence was found in the case of both sleep disturbance and sleep efficacy, as the former decreased and the latter increased. Comparing sleep quality between the two intervention groups revealed a signif-

icantly better status in the eye mask and earplugs group than in the group receiving the QT protocol. This is consistent with the results of the studies of Richardson et al., Koo and Koh, and Hu et al. (8, 10, 27). Similar to the present study, Richardson et al., in the UK, reported that the use of eye mask enhanced patients' sleep (7). Scotto et al., explored the impact of using earplugs on the subjective experience of sleep in patients hospitalized at the CCU of the University of Akron, Ohio, US. Using VSH, they saw a significant improvement in the total score of sleep satisfaction in the case group as opposed to the control group. Thus, they recommended this low-invasive and inexpensive intervention for raising patients' sleep quality (9). The results [of the present study] established that earplugs and eye masks could improve sleep in CCU patients. In one study that was designed by Arab et al., 2013, sleep quality increased significantly in patients using eye mask and earplugs, however, earplugs were more efficient (2).

Moreover, the results of the present study exhibited that implementing the QT protocol positively influences the sleep quality of hospitalized patients. Zolfaghari et al., reported that adjustment of environmental factors significantly boosted the sleep quality of the intervention group compared to the control group (28). This suggestion is in line with the present study. However, the QT protocol in the above study was administered generally and only on a single day, whereas in the current research, in addition to light and noise, therapeutic and diagnostic measures were also removed as much as possible. Even so, it is evident that adjustment of environmental factors disturbing sleep can improve the sleep quality of CCU patients (28).

Understanding the concept of sleep and the outcomes of sleep deprivation is a fundamental step in care planning. Nurses play a central role in assessing patients' sleep patterns and helping them meet their sleep and rest requirements (29). Given the vital importance of sleep for patients, especially those admitted to the CCU, lack of adequate attention to this basic need, the adverse effects of sleep deprivation, and the fact that sufficient sleep improves the patient's general condition and leads to timely discharge, it is necessary to develop practical yet simple and cost-effective solutions to promote sleep quality in these patients (5).

### 5.1. Conclusions

According to results of this study, using eye masks and earplugs as well as QT protocol improve sleep quality. Thus, improving sleep quality by means of such non-drug methods are less costly and have less side effects in comparison to pharmacological interventions. These interventions can be easily applied in clinical setting and nurses can apply them to improve patients comfort.

**Table 1.** Demographic Characteristics of the Subjects in the Study Groups<sup>a</sup>

Variable	Group			Result
	Control	QT Protocol	Eye Mask and Earplugs	
<b>Gender</b>				0.52 <sup>b</sup>
Male	24 (53)	29 (29)	25 (64)	
Female	21 (47)	16 (16)	20 (36)	
Total	45 (100)	45 (100)	45 (100)	
<b>Age, y</b>	55.1 ± 7.7	52.5 ± 6.9	55.8 ± 6.8	0.83 <sup>c</sup>
<b>Education</b>				0.35 <sup>b</sup>
Illiterate	8 (18)	6 (13)	8 (18)	
Literate	37 (82)	39 (87)	37 (82)	
Total	45 (100)	45 (100)	45 (100)	
<b>Marital status</b>				0.67 <sup>b</sup>
Single	20 (44)	21 (47)	16 (36)	
Married	25 (56)	24 (53)	29 (64)	
Total	45 (100)	45 (100)	45 (100)	
<b>Occupational status</b>				0.67 <sup>b</sup>
Employed	16 (36)	14 (31)	18 (40)	
Unemployed	29 (64)	31 (69)	27 (60)	
Total	45 (100)	45 (100)	45 (100)	

<sup>a</sup>Values are expressed as mean ± SD or No. (%).<sup>b</sup>Chi-square.<sup>c</sup>ANOVA.**Table 2.** Comparison of the Mean and Standard Deviation of Sleep Disturbance in the Study Groups Before and After the Intervention

Group	Before Intervention	After Intervention
Control	211.38 ± 86.19	214.38 ± 65.19
QT protocol	212.36 ± 67.64	178.34 ± 88.72
Eye mask and earplugs	210.39 ± 22.34	132.28 ± 04.98
ANOVA result	P = 0.95	P = 0.001

**Table 3.** Comparison of the Mean and Standard Deviation of Sleep Efficacy in the Study Groups Before and After the Intervention

Group	Before Intervention	After Intervention
Control	75.81 ± 27.01	108.83 ± 29.78
QT protocol	75.55 ± 24.82	120.22 ± 32.71
Eye mask and earplugs	75.45 ± 39.44	127.95 ± 33.93
ANOVA result	P = 0.99	P = 0.02

## Footnotes

**Authors' Contribution:** Constructing an idea or hypothesis for research and/or manuscript: Fatemaeh Khodadadi and Ebrahim Ebrahimi Tabas; helping the design of the study: Hamed Sarani and Farshid Saeedinezhad; collection and analysis of data, and writing the primary draft of the article: Fatemaeh Khodadadi; supervision of the study design and the composing of the article, review-

ing the article before submission, verifying the analytical method: Ebrahim Ebrahimi Tabas; revising of the article: Hamed Sarani; statistical analysis of the data, and the interpretation of the result: Hamed Sarani and Farshid Saeedinezhad; writing and editing the article, taking responsibility in logical interpretation, and presentation of the results: Mozghan Jahantigh. All authors discussed the results and contributed to the final manuscript.

**Clinical Trial Registration Code:** 20170130032293N3.

**Conflict of Interests:** The authors declare no conflict of interests in this study.

**Ethical Approval:** This study was approved by the Ethical Committee of Zahedan University of Medical Sciences (IR.Zaums.REC.1396.120).

**Funding/Support:** This study was funded by Zahedan University of Medical Sciences.

**Patient Consent:** All participants gave consent. All individuals were free to participate or to withdraw from the study. All data and results were anonymous.

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