Study protocol

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Title: The Effects of White Noise for Adult Patients' Sleep Quality in Intensive Care Unit.

Background and objective: Sleep is one of the basic physiological needs for humans. According to the American National Sleep Foundation, the recommended sleep duration for adults (18-64 years old) is 7-9 hours per day, while for older adults (65 years and above), it is 7-8 hours per day (Hirshkowitz et al., 2015). However, sleep disturbances are common among intensive care unit (ICU) patients. It is estimated that more than half of ICU patients report experiencing sleep disorders during their stay (Blissitt, 2016). A study by McKinley et al. in 2012 tracked 164 critically ill patients, aged 18 and above, who were in the ICU for more than 48 hours and used a ventilator for more than 24 hours. The study found that one week after transferring out of the ICU, 50% of patients still reported moderate to severe sleep disturbances, and one-third continued to experience moderate to severe sleep disturbances 26 weeks after discharge. This indicates that sleep disorders not only occur during ICU admission but may also persist after discharge.

There are many factors contributing to sleep disorders in ICU patients,

including pain, light, and the severity of illness. Noise is one of the factors leading to sleep disturbances in critically ill patients (Pisani, 2015). According to the World Health Organization's recommendations, daytime environmental noise should be below 45 decibels, and nighttime sleep noise should be below 35 decibels (World Health Organization, 2010). However, ICUs are filled with the sounds of operating medical equipment and alarm signals due to treatment requirements. A study by Darbyshire & Young (2013) measured the noise levels in five adult ICUs and found that the noise level exceeded 45 decibels throughout the day, with the lowest noise level at 4 a.m. being 51 decibels, which is still higher than the WHO recommendation. Furthermore, noise levels exceeding 85 decibels occurred 16 times during the night. A 2007 study by Uğraş and Öztekin, which used a questionnaire to investigate the causes of sleep disturbances in patients in a neurosurgical ICU, found that 78.6% of the 84 patients reported sleep disturbances, and 57.6% of them attributed the disturbances to environmental noise. Sudden loud noises not only cause sleep interruptions but also increase the number of awakenings, leading to sleep disorders (Devlin et al., 2018; Reuter-Rice, 2020). Once sleep disturbances occur, they negatively affect the immune system, respiratory function, metabolic functions, and cardiovascular health, while also causing psychological stress and negative emotions (Reuter-Rice, 2020; Sterniczuk et

al., 2014). Over time, these disturbances affect the recovery of critically ill patients, leading to extended hospital stays, increased medical costs, and higher mortality rates (Altman et al., 2018; Pisani, 2015). Furthermore, sleep disorders can impair cognitive functions such as memory, attention, and reaction time, increasing the risk of delirium (Van et al., 2009). Thus, sleep issues in ICU patients require urgent attention.

Currently, the treatment of sleep disorders in ICU patients still primarily involves medication, but cognitive decline, drug tolerance, and drug dependence may lead to negative effects on sleep. Therefore, many international studies have explored non-pharmacological interventions to improve ICU patients' sleep, such as reducing light and noise stimuli, minimizing nighttime disturbances, or teaching relaxation techniques. Among these, white noise intervention is one approach to reduce light and sound stimulation. The purpose of white noise is to create a consistent sound with fixed frequencies and tones, which can raise the hearing threshold during nighttime sleep, reducing the frequency of being awakened by sudden loud noises, and thereby enhancing sleep quality through masking effects (Farokhnezhad Afshar et al., 2016).

White noise interventions have often used white or pink noise in research, typically targeting newborns, students, or healthy adults. For example, a study

on white noise in a cardiac ICU found that exposure to 40-50 decibel noise between 8-9 p.m. and 11 p.m.-12 a.m. for one hour each night for three days significantly improved sleep quality compared to the control group (Farokhnezhad Afshar et al., 2016). This suggests that the effectiveness of white noise interventions in improving ICU patients' sleep quality is inconsistent, possibly due to differences in the duration and timing of the intervention. Furthermore, sleep disturbances during the night in the ICU are unpredictable, and short intervention periods may not be sufficient to protect patients from sudden noise events that occur outside the intervention hours. Many studies on white noise in adult ICUs use the Pittsburgh Sleep Quality Index to measure sleep quality, which assesses sleep over the past month. However, since critically ill patients are in the acute phase and their ICU stay is usually short, the Pittsburgh Sleep Quality Index may not accurately reflect their sleep condition during their ICU stay. Additionally, individuals may have preferences for different types of white noise, making it difficult to standardize the type of noise used in interventions. Therefore, the purpose of this study is to explore the effectiveness of white noise interventions on sleep quality in adult ICU patients. The aim is to utilize this low-cost, easy-to-implement, and accessible measure to block out ICU noise and improve the sleep quality of critically ill patients in the ICU.

Method: The inclusion criteria of this study as follows: (a) age must be greater than or equal to 20 years old, (b) admitted to the ICU and have been intubated for at least 24 hours, (c) awareness of people, time, and place without hearing impairment., (d) be able to communicate in writing., (e) the Glasgow Coma Scale(GCS) score must be equal to or greater than 11(with a vocal response of 1 in the patient post-endotracheal tube placement). The exclusion criteria of this study as follows: (a)history of insomnia, Alzheimer's disease, or depression, (b) routine use of sedative-hypnotic drugs (opioids, benzodiazepines, non-benzodiazepines, antihistamines, and melatonin) before admission, (c) post-operation in the operating room before ICU admission, (d) intensive care delirium screening checklist(ICDSC) score of at least 4 or Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) positive.

Sample: The sample size for this study is calculated using G*Power 3.1, with an effect size set at 0.25 (Kotrlik & Williams, 2003), $\alpha = 0.05$, and power = 0.8. The minimum required sample size is 58 participants. In statistical analysis, a sample size of 30 is often considered the threshold for a large sample , the total sample size will be 60 participants, with 30 participants in the experimental group and 30 participants in the control group.

Study interventions

This study adopts a convenience sampling method and will be conducted

in the Fifth Department of Internal Medicine ICU at Kaohsiung Chang Gung Memorial Hospital. The study groups are set as follows: the white noise group will receive white noise intervention, while the conventional treatment group will receive standard care. The total sample size of 60 participants will be divided into 6 blocks of 10 participants each, with random assignment generated by a computer. Upon admission to the ICU, patients who meet the inclusion and exclusion criteria will be selected. The principal investigator will fully explain the study's purpose and procedures to the patients, and once informed consent is obtained, the recruitment process will begin. On the first day of enrollment, participants will complete a baseline assessment using the VAS sleep quality scale (T0). Random assignment will then allocate participants to either the Treat (white noise) group or the Control (standard care) group based on the generated block sequence.

For the white noise group, in addition to receiving standard care, white noise will be introduced from 11 p.m. to 6 a.m. the following morning. A noise-reducing sleep aid device will be placed at the corner of the bedside cabinet, and a decibel meter will be positioned near the patient's head. The volume of the noise-reducing sleep aid device will be controlled between 40-50 decibels. According to a study by Van et al. in 2009, up to 90% of delirium occurs on the third day of ICU admission, so the intervention will be applied

continuously for three nights. The control group will receive standard care. Both groups will complete the VAS sleep quality scale at 6 a.m. on the first day after intervention (T1), the third day (T2), and the fifth day (T3). The total number of assessments will be four, each taking approximately 5 minutes.

Outcome measurements:The Verran and Snyder-Halpern Sleep Scale (VSHSS) was initially developed by Snyder-Halpern & Verran in 1989 to measure the sleep quality of hospitalized patients from the previous night. The internal consistency reliability was found to be 0.82. The original scale consisted of four subscales: sleep fragmentation, sleep disturbance, effective sleep, and compensatory sleep. In 1996, Simpson et al. revised the scale to include three subscales: sleep disturbance, effective sleep, and compensatory sleep. Tranner et al. tested the scale in 2003 with 110 hospitalized and surgical patients, and the Cronbach's α values for the subscales of sleep disturbance, effective sleep, and compensatory sleep were 0.86, 0.80, and 0.63, respectively. In 2007, Fang and Wang translated this scale, and the Cronbach's α values for sleep disturbance, effective sleep, and compensatory sleep were 0.90, 0.72, and 0.64, respectively. The overall internal consistency was 0.84, and the Content Validity Index (CVI) was 1.0.

The scale consists of 15 items, each scored on a 0-100mm visual analog scale, where 0 represents the lowest score and 100 represents the highest. The

sleep disturbance section contains 7 items, with a total score range from 0 to 700. A lower score indicates more severe sleep disturbance. The effective sleep section contains 4 items, with a total score range from 0 to 400. A lower score indicates less effective sleep. The compensatory sleep section contains 4 items, with a total score range from 0 to 400. A lower score indicates a greater need for compensatory sleep. Since the original author of the scale has passed away, the version of the Verran and Snyder-Halpern Sleep Scale used in this study has been translated and authorized by the publisher.

Statistical Methods: Descriptive Statistics: Personal demographic data and disease characteristics of the study participants will be analyzed. Categorical variables will be presented as frequencies and percentages, while continuous variables will be expressed as means and standard deviations.

Inferential Statistics:Independent samples t-tests or chi-square tests will be used to compare the homogeneity of sleep quality and demographic data between the white noise group and the general care group before the intervention.

Independent samples t-tests will be used to compare the differences in sleep quality pre- and post-intervention between the white noise group and the general care group.

Generalized Estimating Equations (GEE) will be used to compare the

effects of the white noise group and the general care group under the factors of group, time, and the interaction between group and time.

Ethical considerations: Ensuring Non-Disclosure of Participants' Identity and Information: A research code will be used to represent each participant's identity during the study, ensuring that the participant's name, ID number, address, medical record number, or any other personal information will not be disclosed during the research process.

Confidentiality of Participant Data and Diagnosis: The research investigator will maintain confidentiality and carefully protect the privacy of participants' data. Before the study begins, participants will be informed that the questionnaires they complete and the data collected will be encoded and kept confidential, solely for the purposes of this study. These data will be securely stored in a locked cabinet by the principal investigator, and only the study team will have access to them. No external parties will have access to the data. After the study is completed, the data will be destroyed five years later and will not be retained. If at any point during the study a participant experiences discomfort, they have the right to withdraw at any time without affecting the treatment and rights they are entitled to.

Confidentiality in Publication of Results: If the study results are published, the identity of the participants will remain confidential. The researcher will

explain the study's purpose and procedures to participants before obtaining their consent and having them sign the informed consent form. In future academic publications, no identifying information such as the research institution or participant codes will be included.