Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

The effect of using blindfold, earmuff and quiet time protocol on sleep and physiological indices of patients admitted to CCU

Protocol summary

Study aim

The purpose of this study was to determine the effect of using blind fold, earplugs and quiet environment protocol on sleep quality and physiological characteristics of heart patients hospitalized in CCU.

Design

In this study, 135 eligible patients with heart disease who have been admitted to study at Ali ibn abitaleb Zahedan Hospital are selected. The participants are randomly divided into two groups of intervention and control.

Settings and conduct

This single-step clinical trial was conducted by simple sampling method with simple randomization, without blindness, with control group, on 135 cardiac patients admitted to CCU and at Ali ibn abi Talib Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Inclusion criteria: age over 18; informed consent to participate in the study; To know the time, place and persons, and acquaintance in Persian; ability to communicate verbally; being literate; level of consciousness equal to 13 or higher; length of hospitalization in the intensive care unit more than 4 days; more than 24 hours of general anesthesia; cardiac ejection fraction of 25% and higher than that; a lack of hearing and visual impairment (blindness and Deafness); Not receiving sedative and analgesics 5 hours before bed time ؛No symptoms of known psychiatric disorders and drug use to treat it, according to his family, and according to the patient's records ؛ not having sleep disorder such as sleep apnea narcolepsy, and chronic insomnia at the start of the study according to medical records and according to previous records ؛ Not having the history of night working during the past week ؛ No addiction to any drug according to the report of the patient and his family ؛ having no history of admission to ICU and Exclusion criteria: Cancellation of the continuation of the study ؛ the occurrence of acute problems during admission, such as acute heart failure or pulmonary edema, or reduction of ejection fraction less than 25%, the patient's death during the implementation of the plan؛ Consciousness reduction during the study ؛ A daily sleep more than 2 hours ؛ clearance before the 4th day of admission.

Intervention groups

Intervention groups include the blindfold-earplugs group and quiet time protocol group. In the first night, no intervention will be performed for any of the two groups, and the intervention will begin from the second night of admission.The blind fold and earplugs will be used in the first group and in the second group the environment will be made quiet, the physiological indexes will be recorded tomorrow and the sleep quality questionnaire will be completed.

Main outcome variables

In this study, the positive effects of using a quiet environment and tools such as blindfolds and earplugs are being studied to improve the quality of sleep and physiological indicators, and as a result, the improvement in the treatment of patients admitted to CCU is studied.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170130032293N3**
Registration date: **2017-12-25, 1396/10/04**
Registration timing: **prospective**

Last update: **2017-12-25, 1396/10/04**
Update count: **0**

Registration date

2017-12-25, 1396/10/04

Registrant information

Name

Hamed Sarani

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source
Deputy of Research of Zahedan University of Medical Sciences

Expected recruitment start date
2018-01-05, 1396/10/15

Expected recruitment end date
2018-02-04, 1396/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of using blindfold, earmuff and quiet time protocol on sleep and physiological indices of patients admitted to CCU

Public title
The effect of blindfold, earmuff and quiet time protocol on sleep and physiological indices in CCU patients.

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
older than 18 years consciously satisfy to participate in the experiment being aware of the time and the place and the individuals All heart patients admitted to CCU
Exclusion criteria:
Patients who are deaf and blind Patients with acute cardiac failure Patients with a ejection fraction of less than 25%

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomized study method is simple random. The method will be used to refer to the cc u section of the available samples.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
does not have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Sciences

Street address
Sistan and Balochistan Zahedan University of Medical Sciences

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
Iran

Approval date
2017-07-30, 1396/05/08

Ethics committee reference number
IR.ZAUMS.REC.1396.120

Health conditions studied

1

Description of health condition studied
Heart disease

ICD-10 code
I51.9

ICD-10 code description
Heart disease, unspecified

Primary outcomes

1

Description
sleep quality

Timepoint
Sleep quality questionnaire after the intervention on the next day at 9 to10 A.M will be completed by the Schneider Halpren Sleep Quality Inventory

Method of measurement
questionnaire

Secondary outcomes

1

Description
Physiological Indices
Timepoint
In the four nights of admission, the next days at the same time the sleep quality questionnaire are measured
Method of measurement
The blood pressure is measured by the automatic blood pressure meter in the semi-sitting position of the left hand and the heart rate is measured by the monitoring device and the number of respiration is measured by counting the number of chest movements in the human within one minute.

Intervention groups

1

Description
The intervention group 1: In this group, by using blindfold and earplugs instruments in a consecutive four nights and then using the sleep quality questionnaire, the patients will be measured and the physiological indices are also measured.
Category
Other

2

Description
The intervention group 2: In this group, the implementation of the protocol of the quiet environment and calming the section in a consecutive four nights and then patients will be measured by using the sleep quality questionnaire ,and physiological indicators are also measured.
Category
Other

3

Description
Control group: Routine care will be taken.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan University of Medical Sciences, Ali ibn-Abi Talib Hospital
Full name of responsible person
Fatemeh Khodadadi
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1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available