Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of white noise on the quality of sleep and comfort of patients after open heart surgery.

Protocol summary

Study aim
Determine the effect of white noise on sleep quality of patients admitted to the intensive care unit after open heart surgery

Design
Randomized clinical trial with two groups and parallel

Settings and conduct
The present study is a quasi-experimental study that will be carried out at the Farshchian Heart Hospital of Hamadan with informed consent of the participants for participation in the research . In the intervention group, of three music considered (the sound of the waves, the sound of the river, the sound of the rain), The patient select one of them and music will be played for 30 minutes before sleep with a hands-free device with an intensity of 40-50 dB in three nights From 10:00 to 10:30 pm. At 7am the next day, the sleep quality questionnaire is completed for each person and every three nights. After the third night, the comfort questionnaire for the patient will be completed. In the control group, there is no intervention other than usual care for the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having hearing ability, Hemodynamic stability, Awareness of time and place and individuals, Patients admitted to the intensive care unit after open heart surgery Exclusion criteria: Addiction, hearing impairment

Intervention groups
Intervention: One of the three sounds of rain, ocean waves, rivers, patients will choose. These sounds will be played by handsfree for 30 minutes at 50-40 dB. Control: There will be no specific action other than routine care.

Main outcome variables
Quality of sleep, comfort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160110025929N20**
Registration date: **2019-02-22, 1397/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**
Update count: **0**

Registration date
2019-02-22, 1397/12/03

Registrant information

Name
Mehdi Molavi Vardanjani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3422 5056

Email address
m.molavi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-09-22, 1398/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of white noise on the quality of sleep and comfort of patients after open heart surgery.

Public title

Effect of white noise on the quality of sleep and comfort

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Awareness of time and place and individuals Hemodynamic stability Having hearing ability Patients admitted to the intensive care unit after open heart surgery

Exclusion criteria:

Addiction Hearing impairment

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the patients were registered according to the sample size (60) and according to the inclusion criteria, and using the blocking method (using a two-block method, two letters A and B with different permutations we place in blocks and randomly select 30 blocks and assign each block to 2 people) will be assigned to two groups

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.UMSHA.REC.1397.694

Health conditions studied

1

Description of health condition studied

coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Quality of sleep

Timepoint

Before and after the intervention for three nights

Method of measurement

Mary's Hospital Sleep Questionnaire

Secondary outcomes

1

Description

Patient comfort

Timepoint

Before and after the intervention for three nights

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: In the untervention group, of three music considered (the sound of the waves, the sound of the river, the sound of the rain), the patient select one of them and music will be played for 30 minutes before sleep with a hands-free device with an intensity of 40-50 dB in three nights From 10:00 to 10:30 pm.

Category

Other

2

Description

Control group: In the control group, there will not be done intervention other than routine care such as reducing environmental stimuli.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian heart center

Full name of responsible person
Khodayar Oshvandi

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Shahid Fahmideh St., Farschian heart center, Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeed Bashirian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Deputy of research and technology

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
Hamedan University of Medical Sciences

Full name of responsible person
Khodayar Oshvandi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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