

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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)

Phone

+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 unintervention 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,
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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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Shahid Fahmideh St., Hamadan University of Medical
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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Khodayar Oshvandi

Position

Associate professor

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Person responsible for updating data

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instructore

Latest degree

Master

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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