

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of white noise versus control group on sleep quality and delirium in patients after coronary artery bypass graft surgery: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of white noise versus control group on sleep quality and delirium in patients after coronary artery bypass graft surgery

Design

This is a randomized clinical trial, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients undergoing coronary artery bypass graft surgery hospitalized in the Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 40 to 70 years; Undergoing coronary artery bypass graft surgery; Literate; Full consciousness and ability of adequate hearing; Hemodynamic stability; Having a sleep disorder; Exclusion criteria: Having delirium; Suffering from neurological diseases

Intervention groups

Intervention group: Routine treatment and care after surgery plus white sound (rain sound) in the range of 50 to 60 dB for 30 minutes through mobile headphones for three nights Control group: Just routine treatment and care after surgery

Main outcome variables

Primary outcome: Delirium, sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N405**

Registration date: **2021-10-29, 1400/08/07**

Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**

Update count: **0**

Registration date

2021-10-29, 1400/08/07

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of white noise versus control group on sleep quality and delirium in patients after coronary artery

bypass graft surgery: a randomized clinical trial

Public title
Effect of white noise versus control group on sleep quality and delirium in patients after coronary artery bypass graft surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 40 to 70 years; Undergoing coronary artery bypass graft surgery; Literate; Full consciousness and ability of adequate hearing; Hemodynamic stability; Having a sleep disorder;
Exclusion criteria:
Having delirium; Suffering from neurological diseases

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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

Vice-chancellor for Research and Technology,

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-10-18, 1400/07/26

Ethics committee reference number

IR.UMSHA.REC.1400.555

Health conditions studied

1

Description of health condition studied

Coronary artery bypass graft surgery

ICD-10 code

I25.70

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris

Primary outcomes

1

Description

Delirium

Timepoint

Before the intervention and 3 days after that

Method of measurement

Using Delirium Observation Screening (DOS) Questionnaire

2

Description

Sleep quality

Timepoint

Before the intervention and 3 days after that

Method of measurement

Using Saint Mary Hospital Sleep Questionnaire (SMHSQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment and care after surgery plus white sound (rain sound) in the range of 50 to 60 dB for 30 minutes through mobile headphones for three nights

Category

Treatment - Other

2

Description

Control group: Just routine treatment and care after surgery

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital

Full name of responsible person

Fatemeh Malekipour

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

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Phone

+98 81 3838 1740

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Fatemehmalekipour324@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Malekipour

Position

Student of Nursery

Latest degree

Master

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

Zahra Khalili

Position

MSc in Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

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Email

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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