Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Fatemeh Malekipour
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Person responsible for updating data

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Professor of Epidemiology

Latest degree
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Other areas of specialty/work
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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