

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of white noise on stress and hemodynamic indices of patients hospitalized in the cardiac intensive care unit

Protocol summary

Study aim

Determining the effect of white noise on stress and hemodynamic indicators of patients admitted to the cardiac intensive care unit

Design

Clinical trial with control group, with parallel groups, single-blind, simplified randomization, on 70 patients who were randomly assigned to CCU one and two. There is no difference in the patients of the two sections.

Settings and conduct

Patients hospitalized in two CCUs of Imam Khomeini Hospital in Tehran were divided into experimental and control groups by a simple random method. There is no difference between patients hospitalized in separate CCUs of this center. A blind strain was blinded participants. White noise was played at 50-60 dB for 30 minutes on the first day of hospitalization in the test group. Questionnaire and vital signs were recorded before and after playing the sound. In the control group, only routine care was applied, and the questionnaire and symptoms were recorded twice. Then the results of the groups were compared.

Participants/Inclusion and exclusion criteria

The age of 20 to 70 years and being aware of time and place and the ability to communicate verbally and not having a history of taking anti-anxiety drugs and patients who were hospitalized on the first day were the inclusion criteria. Exclusion criteria included, in case of prescription of anti-anxiety drugs and consciousness disorder and dissatisfaction, and patients who were transferred or discharged from the department before the start of the test.

Intervention groups

In the test group, white noise in the range of 50 to 60 dB was played for 30 minutes in the cardiac intensive care unit. The control group received routine care. In order to collect data, demographic profile questionnaires of patients, hemodynamic index registration checklist and DASS-21 were used.

Main outcome variables

Stress; heart rate; blood pressure; respiratory rate; Oxygen saturation percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220822055778N1**

Registration date: **2022-10-22, 1401/07/30**

Registration timing: **retrospective**

Last update: **2022-10-22, 1401/07/30**

Update count: **0**

Registration date

2022-10-22, 1401/07/30

Registrant information

Name

Moona Baloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 273 5386

Email address

moona.ballo@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-15, 1400/06/24

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

2021-09-15, 1400/06/24

Actual recruitment end date

2021-11-21, 1400/08/30
Trial completion date
 2021-11-21, 1400/08/30

Scientific title
 The effect of white noise on stress and hemodynamic indices of patients hospitalized in the cardiac intensive care unit

Public title
 The effect of white noise on stress and hemodynamic indices of patients admitted to the cardiac intensive care unit

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 20 to 70 years Aware of time and place The ability to communicate verbally Absence of hearing defects Not having a history of taking sedative and anti-anxiety drugs Patients who were hospitalized on the first day
Exclusion criteria:
 If sedative and anti-anxiety drugs are prescribed on the first day of hospitalization Impaired consciousness Dissatisfaction and unwillingness to continue cooperation Patients who were transferred or discharged from the department before the start of the test

Age
 From **20 years** old to **78 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **70**
 Actual sample size reached: **70**

Randomization (investigator's opinion)
 Randomized

Randomization description
 One CCU of the control group and one CCU of the intervention group were randomly selected. There is no difference and separation in any way among the patients hospitalized in each CCU. In a completely simple random manner, after the discharge of each patient, a new patient was admitted in any empty bed and entered the study.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 In this research environment, the CCUs were completely separate and distant. Consent to participate in the study was obtained from both groups before conducting the study. But the control group was not involved in the intervention group.

Placebo
 Not used

Assignment
 Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee Islamic Azad University of Medical Sciences, Tehran

Street address

5th floor, Educational Block 1, Ethics Committee of Islamic Azad University, Science and Research Unit, Shohday Hesarek Blvd., University Square, end of Shahid Sattari Highway

City

Tehran

Province

Tehran

Postal code

1477893855

Approval date

2021-02-21, 1399/12/03

Ethics committee reference number

IR.IAU.TMU.REC.1399.483

Health conditions studied

1

Description of health condition studied

Stress and patients hospitalized in cardiac intensive care unit with various heart diseases

ICD-10 code

I01.8

ICD-10 code description

Other acute rheumatic heart disease

Primary outcomes

1

Description

Stress score with DASS-21 questionnaire and measurement of hemodynamic indices

Timepoint

Measurement of stress and hemodynamic indicators on the first day of hospitalization And half an hour away from playing white noise

Method of measurement

Measuring stress with the DAS 21 questionnaire and measuring hemodynamic indicators with a central monitoring device connected to the patient Mark Saadat

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The effect of white noise on stress and hemodynamic indicators was measured during 30 minutes in the intervention group on the first day of hospitalization.

Category

Treatment - Other

2

Description

Control group: The control group received only usual care and no intervention. Stress and hemodynamic indices were measured twice on the first day of hospitalization for the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital affiliated to Tehran
University of Medical Sciences

Full name of responsible person

Moona baloo

Street address

Imam Khomeini Hospital Complex, Doctor Gharib
Street, Keshavarz Blvd

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1419733141

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Moona baloo

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5th floor, educational block 1, science and research
unit, Islamic Azad University, Shohdai Hesarak Blvd.,
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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Moona baloo

Position

Special care nursing master's student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

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Person responsible for updating data**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