

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 6119 2673

##### Email

moona.ballo@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Moona baloo

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1477893780

##### Phone

+98 21 2200 4355

##### Email

moona.ballo@yahoo.com

##### 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

##### Street address

5th floor, educational block 1, science and research  
unit, Islamic Azad University, Shohdai Hesarak Blvd,  
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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Moona ballo

**Position**

Special care nursing master's student

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Master

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

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**Email**

moona.ballo@yahoo.com

**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