

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### To Assess the Effect of Binaural Beats on Stress and Motion Artifact in Patients Underwent Nuclear Imaging

#### Protocol summary

##### Study aim

To Assess the Effect of Binaural Beats on Stress and Motion Artifact in Patients Underwent Myocardial Perfusion Imaging

##### Design

Controlled Clinical Trial with Parallel Groups, Phase 3, Design of 267 Patients

##### Settings and conduct

This prospective study comprised 267 patients from April to October 2017 which were divided into three groups: Group I: patients who listened to the music with binaural beat; Group II: patients who listened to the music intervention and Group III: control group.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Intermediate Probability of Coronary Artery Disease According to Framingham Risk Score  
Exclusion Criteria: Arrhythmia; Hearing Problems; History of Epilepsy

##### Intervention groups

Group I: patients who listened to the music with binaural beat; Group II: patients who listened to the music intervention and Group III: control group.

##### Main outcome variables

stress , heart rate , motion artifact

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140514017684N9**  
Registration date: **2021-06-06, 1400/03/16**  
Registration timing: **retrospective**

Last update: **2021-06-06, 1400/03/16**

Update count: **0**

##### Registration date

2021-06-06, 1400/03/16

#### Registrant information

##### Name

Mahdi Haghghatafshar

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4835

##### Email address

afsharm@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Shiraz university of medical science, Vice chancellor for research

#### Expected recruitment start date

2017-10-02, 1396/07/10

#### Expected recruitment end date

2017-12-21, 1396/09/30

#### Actual recruitment start date

2017-05-10, 1396/02/20

#### Actual recruitment end date

2017-09-21, 1396/06/30

#### Trial completion date

2017-09-21, 1396/06/30

#### Scientific title

To Assess the Effect of Binaural Beats on Stress and Motion Artifact in Patients Underwent Nuclear Imaging

#### Public title

The Effect of Binaural Beats on Patients Anxiety and Motion Artifacts

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Intermediate Probability of Coronary Artery Disease According to Framingham Risk Score The Patients

Underwent Myocardial Perfusion Imaging

**Exclusion criteria:**

Arrhythmia Hearing Problems History of Epilepsy

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

Actual sample size reached: **267**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**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 Shiraz University of Medical Sciences

**Street address**

Nuclear Medicine department, Namazi Hospital, Namazi Square

**City**

Shiraz

**Province**

Fars

**Postal code**

7193711351

**Approval date**

2017-09-23, 1396/07/01

**Ethics committee reference number**

1396-01-95-15022

**Health conditions studied**

1

**Description of health condition studied**

cardiovascular

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Measuring heart rate

**Timepoint**

Before and after intervention of Imaging

**Method of measurement**

Heart rate monitor

2

**Description**

Motion Artifact

**Timepoint**

During Imaging

**Method of measurement**

Visually

**Secondary outcomes**

1

**Description**

Depression Anxiety Stress

**Timepoint**

Before and after intervention

**Method of measurement**

DASS questionnaire

**Intervention groups**

1

**Description**

Playing Music with Binaural Beats (Frequency Difference Between the Waves Entering the Left and Right Ear) with Headphone During Imaging, Just 3 min Before Imaging, Headphones Were Located in Both Ears of the Patients Until the End of Imaging (Average 15 min)

**Category**

Diagnosis

2

**Description**

Playing Music with Headphone During Imaging, Just 3 min Before Imaging, Headphones Were Located in Both Ears of the Patients Until the End of Imaging (Average 15 min)

**Category**

Diagnosis

3

**Description**

Without any Music With or Without Binaural Beats

**Category**

Diagnosis

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Al-Zahra hospital

**Full name of responsible person**

Nuclear medicine and molecular imaging research center

**Street address**

Siboye Ave

**City**

Shiraz

**Province**

Fars

**Postal code**

54937-71649

**Phone**

+98 71 3738 0283

**Fax**

+98 71 3738 0283

**Email**

hfcmanager@sums.ac.ir

**Web page address**

<http://hfhc.sums.ac.ir/>

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shiraz university of medical science, Vice chancellor for research

**Full name of responsible person**

Dr. seyed Basir Hashemi

**Street address**

Central building of Shiraz University of Medical Science, Karimkhan-e Zand Boulevard

**City**

Shiraz

**Province**

Fars

**Postal code**

71937-11351

**Phone**

+98 71 3235 7282

**Email**

vcrdep@sums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz university of medical science, Vice chancellor for research

**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**

Shiraz university of medical science

**Full name of responsible person**

Nuclear medicine and molecular imaging research center

**Position**

Expert of the center

**Latest degree**

Master

**Other areas of specialty/work**

Nuclear Medicine

**Street address**

Nuclear Medicine department, Namazi Hospital, Namazi Square

**City**

Shiraz

**Province**

Fars

**Postal code**

11351-71937

**Phone**

+98 71 3612 5330

**Fax****Email**

nmmirc@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz university of medical science

**Full name of responsible person**

Nuclear medicine and molecular imaging research center

**Position**

Nuclear medicine Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Nuclear Medicine

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Nuclear Medicine department, Namazi Hospital, Namazi Square

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

all data

### When the data will become available and for how long

1 year after publish of article

### To whom data/document is available

all researchers

### Under which criteria data/document could be used

without any limitation

### From where data/document is obtainable

Dr. Mahdi Haghighatafshar email: afsharm@sums.ac.ir

### What processes are involved for a request to access data/document

after sending email

### Comments

## Person responsible for updating data

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Mahdi Haghighatafshar

#### Position

Nuclear medicine Specialist

#### Latest degree

Specialist

#### Other areas of specialty/work

Nuclear Medicine

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