Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 Haghighatafshar

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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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
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54937-71649

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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

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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

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Nuclear Medicine department, Namazi Hospital, Namazi Square

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Nuclear medicine Specialist

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Specialist

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Person responsible for updating data

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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