Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The impact of music on patients undergoing myocardial perfusion imaging

Protocol summary

Study aim
Determining the effect of music on patients performing myocardial perfusion scan in the nuclear medicine ward of Farshchian Hospital in Hamadan

Design
A clinical trial with two arms parallel-group randomized trial, double-blind (blinded on outcome assessor and data analyser) and randomized on 60 patients whose randomization process is performed using the Balanced Block Randomization approach with a block size of four

Settings and conduct
The study will be performed on candidates for myocardial perfusion scan in the nuclear medicine ward of Farshchian Hospital in Hamedan. Blinding will be two-sided on outcome assessors and data analyzer. How to do it randomly among patients who have completed the consent form will be in the test process. The type of music is also considered traditional Iranian music.

Participants/Inclusion and exclusion criteria
The study population is also a candidate for myocardial perfusion scan. Inclusion criteria: 1. Age 25-79 years 2. Having informed consent and exclusion criteria also have hearing problems and inability to read and write and have mental disorders and diseases such as depression and anxiety disorders.

Intervention groups
In the control group, the steps of performing the heart myocardial perfusion scan test were performed routinely, and in the intervention group, in addition to the routine treatments of the desired test, traditional instrumental music was played through headphones during the stress test and imaging and stereo playback during the waiting period from The admission of the patient until the start of the diagnostic modality and the waiting time after the injection until the start of imaging are used.

Main outcome variables
Determining and comparing the mean score of anxiety and stress due to myocardial perfusion scan and parameters related to this test in patients in music therapy group and control group before and after the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220509054797N1**
Registration date: **2022-09-24, 1401/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-24, 1401/07/02**
Update count: **0**

Registration date
2022-09-24, 1401/07/02

Registrant information
Name
Zahra Shaghaghi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3838 1720
Email address
z.shaghaghi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-03-11, 1401/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The impact of music on patients undergoing myocardial perfusion imaging

Public title
The impact of music on patients undergoing myocardial perfusion imaging

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 25 and 79 years Referrals to the nuclear medicine department of Farshchian Hospital in Hamadan Candidate patients undergo myocardial perfusion scan

Exclusion criteria:
Having hearing problems Inability to read and write Having mental disorders and diseases

Age
From **25 years** old to **79 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
For this purpose, we will use the BalancedBlock Randomization method (block size=4). Random allocation software will be used for this purpose. At first, we prepare two sheets of paper. We write "Intervention" on one paper and "Control" on another. Mix the sheets together and place them in the desk drawer. With the referral of each of the eligible patients, one of the cards will be drawn randomly, and based on this drawn card, it will be assigned to one of the two groups. It should be noted that the drawn sheets will not be returned to the drawer until all four sheets have been removed. After all four sheets are drawn randomly, all the sheets are returned to the drawer and the above operation will be continued for the next four patients until the desired sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The outcome assessor is supposed to measure the outcome in two groups and will be blinded to the allocation of patients to the study groups. Moreover, the data analyzer will be unaware of treatment groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of hamedan university of medical sciences

Street address
Shahid Fahmideh Blvd

City
Hamedan

Province
Hamadan

Postal code
۶۵۱۷۸۳۸۷۳۶

Approval date
2022-03-05, 1400/12/14

Ethics committee reference number
IR.UMSHA.REC.1400.955

Health conditions studied

1

Description of health condition studied
Myocardial perfusion scan

ICD-10 code
**

ICD-10 code description
**

Primary outcomes

1

Description
Severity of phobia

Timepoint
Before and after the intervention

Method of measurement
questionnaire

2

Description
Stress

Timepoint
Measurements at the beginning and end of the test

Method of measurement
questionnaire

3

Description
Anxiety

Timepoint
Measurements at the beginning and end of the test

Method of measurement
questionnaire

4

Description
Exercise Test Distance
Timepoint
during exercise test
Method of measurement
exercise test information

5

Description
Heart Rate
Timepoint
during exercise test
Method of measurement
exercise test information

6

Description
Chronotropic Index
Timepoint
during exercise test
Method of measurement
Mathematical calculations and formulas

7

Description
Heart Rate Recovery Index
Timepoint
Before and after the intervention
Method of measurement
Mathematical calculations and formulas

8

Description
Reduce patient movement
Timepoint
Before and after the intervention
Method of measurement
Expert doctor's opinion

9

Description
Reduce shooting frequency
Timepoint
Before and after the intervention
Method of measurement
Expert doctor's opinion

Secondary outcomes

1

Description
blood pressure
Timepoint
Before and after the intervention
Method of measurement
Barometer

2

Description
Overall feeling of satisfaction
Timepoint
Before and after the intervention
Method of measurement
questionnaire

3

Description
Non-cardiac side effects of dipyridamole
Timepoint
Before and after the intervention
Method of measurement
questinnaire

4

Description
Quality of data collection (Checking the quality of the information obtained from the image)
Timepoint
Before and after the intervention
Method of measurement
Expert doctor's opinion

5

Description
double product
Timepoint
Before and after the intervention
Method of measurement
Mathematical calculations and formulas

Intervention groups

1

Description
Intervention group: Patients will listen to traditional music without words through headphones or stereo playback while performing myocardial perfusion scan tests (such as exercise test or imaging phase). In addition, the desired music will be played during the test and the patients' reaction to the music during the test will be evaluated through parameters such as heart rate, reduction of patient movement, reduction of imaging frequency and data quality. The target group will be exposed to listening to music during all stages of the procedure 1- Waiting time from the patient's admission to the start of the diagnostic modality (listening to music with stereo for 15 minutes from the beginning to the end of this stage) 2- Conducting a stress test (test Exercise (physical) - drug test) (listening to music with headphones for 10 minutes from the beginning to the

end of this phase) 3- waiting time after injection until the start of imaging (listening to music with stereo for 10 minutes) From the beginning to the end of this stage (4-imaging stage) (listening to music with headphones for 10 minutes from the beginning to the end of this stage).

Category

Other

2

Description

Control group: Control group: Patients referred to the nuclear medicine department for the perfusion scan test will routinely perform the desired tests. During the physical stress test stage, Exercise Test Distance, Heart Rate, Chronotropic Index, Double product and Heart Rate Recovery Index. During the drug stress test stage, the rate of occurrence of non-cardiac side effects of dipyridamole including headache, dizziness, flushing, chest pain and nausea for both The group is registered. Before performing the stress test, the drugs from beta-lactose and calcium channel blockers are stopped for 48 hours and nitrates for 24 hours. Patients are advised to fast at least 4 hours before. On the day of visit, resting electrocardiogram, blood pressure, and baseline heart rate are recorded, and then for candidate patients, a modality exercise test is performed with a treadmill and Bruce protocol. At the peak of stress or when the exercise test becomes positive, the radiopharmaceutical 99mTc-MIBI is injected and after ten to fifteen minutes, GATED-MPI imaging is performed using a Siemens dual-head gamma camera and using a LEHR collimator. If due to some reasons (old age, fracture, etc.) the patient cannot tolerate physical stress, the patient is a candidate for a pharmacological test. In this condition, the patient's resting electrocardiogram, blood pressure and heart rate are recorded. Then dipyridamole drug is administered during 4 minutes of infusion. During the infusion, the patient's heart rate is monitored, for this purpose, a 12-lead heart rate monitor is used, and the patient's blood pressure and heart rate are recorded at two-minute intervals. In addition, any patient complaints are recorded during this period. In the 6th minute (from the start of the infusion), the patient's blood pressure and heart rate are measured again, and the patient is also asked about the presence of seven different clinical symptoms (headache, dizziness, flushing, chest pain, and nausea). Then, the radiopharmaceutical is injected and an hour later imaging of the patient is done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Hospital Nuclear Medicine Center

Full name of responsible person
Maryam Alvandi

Street address
Shahid Fahmideh Blvd

City
Hamedan

Province
Hamadan

Postal code
6517839131

Phone
+98 81 3838 1740

Email
hcvc@umsha.ac.ir

Web page address
https://hcvc.umsha.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Reza Shokoohi

Street address
Shahid Fahmideh Blvd

City
Hamedan

Province
Hamadan

Postal code
۶۵۱۷۸۳۸۷۳۶

Phone
+98 81 3131 0000

Email
Info.research@umsha.ac.ir

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
Hamedan University of Medical Sciences

Full name of responsible person
Maryam Alvamdi

Position

Assistant Professor

Latest degree
Medical doctor

Other areas of specialty/work
Nuclear Medicine

Street address
Shahid Fahmideh Blvd

City
Hamedan

Province
Hamadan

Postal code
۶۵۱۷۸۳۸۷۳۶

Phone
+98 81 3131 0000

Email
maryamalvandi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Maryam Alvamdi

Position
Assistant Professor

Latest degree
Medical doctor

Other areas of specialty/work
Nuclear Medicine

Street address
Shahid Fahmideh Blvd

City
Hamedan

Province
Hamadan

Postal code
۶۵۱۷۸۳۸۷۳۶

Phone
+98 81 3131 0000

Email
maryamalvandi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Zahra Shaghaghi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nuclar pharmacy

Street address
Shahid Fahmideh- Hamadan-Iran

City
Hamadan

Province
Hamadan

Postal code
۶۵۱۷۸۳۸۷۳۶

Phone
+98 81 3838 1720

Fax
+98 81 3838 1686

Email
z.shaghaghi@umsha.ac.ir

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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Information can be shared

When the data will become available and for how long
After announcing the results

To whom data/document is available
Everyone

Under which criteria data/document could be used
Provided that the source of the information is mentioned

From where data/document is obtainable
Research team

What processes are involved for a request to access data/document
After the decision of the research team after the announcement to the team

Comments