

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of music therapy on anxiety level and Vital Signs of patients candidate for trans esophageal Echocardiography

Protocol summary

Summary

The aim of this study is to evaluate the effect of music on level of anxiety and vital signs of patients candidate for transesophageal echocardiography. In this study, conducting in Namazi and Faghihi Hospitals, affiliated with Shiraz University of Medical Sciences, 70 patients who are eligible to participate in the study, having obtained the written consent, are studied. The patients are selected by convenience sampling and then they are randomly allocated to experimental and control groups. The patients in the experimental group receive music by headphone for 30 minutes about half of an hour before the echocardiography, while the control group does not receive any intervention and the routine care are done for them. Anxiety level is measured by spielberge's questionnaire and vital signs (blood pressure, pulse, and respiration) before and after the intervention and for the control group before and after the routine cares.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409148505N9**

Registration date: **2016-05-31, 1395/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-31, 1395/03/11

Registrant information

Name

Seyed Saeed Najafi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-10-10, 1394/07/18

Expected recruitment end date

2015-12-09, 1394/09/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of music therapy on anxiety level and Vital Signs of patients candidate for trans esophageal Echocardiography

Public title

The effect of music on patient's anxiety in echocardiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in research; Ability to read and write; Having hemodynamic stability; obtaining 31 points of higher from Spielberg er anxiety questionnaire Exclusion criteria: history of known mental illness; psychiatric medicine use; Trans esophageal echocardiography cancellation for any reason other than anxiety; withdrawal of patient from the study; hearing disorder; participation in problem solving

skill training course; Stress management and yoga in the last 6 months; New crisis like the death of close relatives, Divorce of the patient or his/her parents in the last 6 months; taking sedative and analgesic 3 hours before intervention; Drug addiction; Having pain; Reluctance and unwillingness to listen to music.

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical Research Ethics Committee of Shiraz
University of Medical sciences Sciences

Street address

Central building of Shiraz University of Medical
Sciences, Zand street

City

Shiraz

Postal code

71345-1978

Approval date

2015-08-24, 1394/06/02

Ethics committee reference number

IR.SUMS.Rec.1394.286

Health conditions studied**1****Description of health condition studied**

transesophageal echocardiography

ICD-10 code

IX

ICD-10 code description

Cardiovascular System Diseases

Primary outcomes**1****Description**

anxiety

Timepoint

before music therapy and transesophageal
echocardiography and immediately after music therapy

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes**1****Description**

Blood pressure

Timepoint

before music therapy and transesophageal
echocardiography and immediately after music therapy

Method of measurement

sphyngomonometer

Intervention groups**1****Description**

Intervention group receives music by headphone for 30
minutes about half of an hour before the esophageal
echocardiography

Category

Other

2**Description**

The control group receives routing care .

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Faghihi & Nemazie hospitals affiliated with
Shiraz University of Medical Sciences

Full name of responsible person

Seyed Said Najafi

Street address

N0. 1132, street 23/1 , Valiasr Avenue, Rahmat blvd

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Sayed Basir Hashemi

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Central Building of Shiraz University of Medical Sciences, Zand street , Shiraz Fars Iran, Islamic Republic Of

City

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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

Vice Chancellor for research of Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Fatemeh(PBUH) School of Nursing and Midwifery, Shiraz University of Medical Sciences,Namazi Square

Full name of responsible person

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Position

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Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty