

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment the effect of music on anxiety and physiologic variable in patients with acute coronary syndrome admitted to coronary care unit (C.C.U) In Valiasr Hospital, of Eghlid city in 2011- 2012

Protocol summary

Summary

Objective: To determine the effect of music on anxiety and physiological variables in patients with acute coronary syndrome admitted to the coronary care unit, Vali- Asr hospital, Eghlid city. Design: Cross- Sectional study of a clinical trial during the period October 2011 to July 2012 in Vali- Asr hospital, Eghlid city, in coronary care unit on 70 patients who met the study was conducted. Setting and conduct: Patients were randomly divided into two groups, music therapy and control group. In music group two days and 20 minutes a day between the hours of 9-11 am, music with Mp3 Player and headphones for each subject was broadcast. To investigate the physiological state of patient's respiratory rate uncounted in one minute and in order to control blood pressure and pulse rate were used digital monitor. STAI anxiety questionnaire was completed by patients before and immediately after the intervention. Participants including major eligibility criteria: Inclusion criteria Knowledge of time and place and person, Literate, Stable hemodynamic status during the intervention, allowing the Physician to effluence the music and Exclusion criteria for hearing impaired, ill, being accustomed to listening to music, receiving narcotic drugs 4 hours and tranquilizer 1 hour prior to completing the questionnaire, and unwillingness to participate in the test. Intervention: In the intervention group, music with MP3 Player and headphones for each subject was broadcast. Before the intervention and immediately after the intervention, with anxiety Inventory STAI, patient anxiety was measured and also before the intervention and immediately after the intervention, patients' vital signs were recorded. Main outcome measures (variables): anxiety and vital signs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211207844N2**

Registration date: **2013-01-08, 1391/10/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-08, 1391/10/19

Registrant information

Name

Mansour Arab

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1320 5179

Email address

marab@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2011-10-06, 1390/07/14

Expected recruitment end date

2012-07-04, 1391/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of music on anxiety and physiologic variable in patients with acute coronary syndrome admitted to coronary care unit (C.C.U) In Valiasr Hospital, of Eghlid city in 2011- 2012

Public title

Assessment the effect of music on anxiety and physiologic variable in patients with acute coronary syndrome admitted to coronary care unit (C.C.U) In Valiasr Hospital, of Eghlid city in 2011- 2012

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Knowledge of time and place and person; Literate; Stable hemodynamic status during the intervention and allowing the Physician to effluence the music Exclusion criteria: Hearing impaired; Ill; Being accustomed to listening to music; Receiving narcotic drugs 4 hours and tranquilizer 1 hour prior to completing the questionnaire and unwillingness to participate in the test

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 75

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 Vice chancellor for research, Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jahad Blvd, Somayye Crossroads,

Shariaati St, Kerman

City

Kerman

Postal code**Approval date**

2011-10-12, 1390/07/20

Ethics committee reference number

437/90

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

Anxiety

ICD-10 code

f00-f99

ICD-10 code description

Mental and behavioural disorders

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

Anxiety

Timepoint

Before intervention and immediately after intervention

Method of measurement

Spiilberger questionnaire

2**Description**

Vital sign

Timepoint

Before intervention and immediately after intervention

Method of measurement

Digital manitor device

Secondary outcomes

empty

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

In the control group, it is not certain

Category

Diagnosis

2**Description**

Two hours and 20 minutes a day between the hours of 11-9 am music with Mp3 Player and headphone for each subject were distributed.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital, Eghlid city, Fars province

Full name of responsible person

Seid Alireza Moniri

Street address

Shahid beheshti Blvd, Valiasr hospital, Eghlid city, Fars province

City

Eghlid

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, kerman University of Medical Sciences

Full name of responsible person

Dr. Malekpour Afshar

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jahad Blvd, Somayye Crossroads, Shariaati St, Kerman

City

kerman

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, kerman 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

Razi Nursing and Midwifery School, Kerman University of Medical Sciences

Full name of responsible person

Mansour Arab

Position

MSN/ Lecturer of Nursing

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

Razi Nursing and Midwifery School, Haft Bagh Alavi Highway, Kerman

City

kerman

Postal code

7618147867

Phone

+98 34 1320 5179

Fax**Email**

marab@kmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Razi Nursing and Midwifery School, Kerman University of Medical Sciences

Full name of responsible person

Mansour Arab

Position

MSN/ Lecturer of Nursing

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

Razi Nursing and Midwifery School, Haft Bagh Alavi Highway, Kerman

City

kerman

Postal code

7618147867

Phone

+98 34 1320 5179

Fax**Email**

marab@kmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Razi Nursing and Midwifery School, Kerman University of Medical Sciences

Full name of responsible person

Mansour Arab

Position

MSN/ Lecturer of Nursing

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

Razi Nursing and Midwifery School, Haft Bagh Alavi Highway, Kerman

City

kerman

Postal code

7618147867

Phone

+98 34 1320 5179

Fax**Email**

marab@kmu.ac.ir

Web page address

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