Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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