

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of sound therapy on pain , anxiety level and hemodynamic variables of Patients undergoing Angioplasty coronay

Protocol summary

Summary

One of the most common complications in patients undergoing invasive cardiac interventions is anxiety. The aim of the study was to investigate the effect of sound therapy on patients' anxiety, Pain and hemodynamic parameters during percutaneous transluminal coronary angioplasty. This was a randomized controlled trial. A purposive sample of 113 patients who were undergo coronary angioplasty was recruited. Inclusion criteria: being desired for participating in the study; undergoing PTCA for the first time. Patients who chose to withdraw from the study, needed emergency intervention for treating cardiac dysrhythmias, or needed to undergo emergency open-heart surgery were excluded. Patients were randomly allocated to either the control or the experimental groups. we collected patients' demographic data .The universal pain scale VAS and the anxiety pretest is performed by using the SSAI. In the experimental group, patients received a 20-to-40-minute sound therapy intervention consisted of music (light instrumental music albums by Johann Sebastian Bach and Mariko Makino) and the Quran (Ayatalkorsi) by using a digital MP3 player and a headphone. Patients in the control group received the routine care of the study setting which consisted of no music therapy intervention. Study data were collected by using a demographic questionnaire, the Spielberger's State Anxiety Inventory consists of twenty questions, Pain scale VAS and a data sheet for documenting hemodynamic parameters. The demographic questionnaire consisted of thirteen items on patients' demographic characteristics. Patients' hemodynamic parameters were monitored at five time-points. The anxiety and Pain posttest was also performed thirty minutes after PTCA.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014043014770N2**

Registration date: **2014-10-03, 1393/07/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-03, 1393/07/11

Registrant information

Name

Masomeh Forooghy

Name of organization / entity

Baghiyatalah University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Faculty of Nursing, Baqiyatallah University of Medical Sciences and Behavioral Research Center, Baqiyatallah University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sound therapy on pain , anxiety level and hemodinamic variables of Patients undergoing Angioplasty coronay

Public title
The effect of sound therapy on pain , anxiety level and hemodinamic variables of Patients undergoing Angioplasty coronay

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria : undergoing PTCA for the first time; being able to understand and speak Persian; having an age of 40–85 years; having no hearing impairment; hving no drug or alcohol addiction; having no previous history of complicated gross surgeries; receiving no anxiolytic medication during the past six months; having no history of severe psychological disorder during the past six months; needing no emergency cardiac catheterization; Patients with first coronary angioplasty. Exclusion Criteria: Patients who chose to withdraw from the study, needed emergency intervention for treating cardiac dysrhythmias ; or needed to undergo emergency open-heart surgery were excluded from the study;

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **113**

Randomization (investigator's opinion)
Randomized

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 Baqiyatallah University of Medical Sciences

Street address

Sheikh Bahaee Street, Molasadra Street

City

Tehran

Postal code

Approval date

2014-01-05, 1392/10/15

Ethics committee reference number

34th Session- 340/3/6770 س

Health conditions studied

1

Description of health condition studied

Diseases of the circulatory system

ICD-10 code

I70, I79

ICD-10 code description

Diseases of arteries, arterioles and capillaries

Primary outcomes

1

Description

Anexity

Timepoint

befor and after invention

Method of measurement

Spielberger's State Anxiety Inventory(SSAI)

Secondary outcomes

1

Description

hemodinamic variables and pain

Timepoint

before, during and after

Method of measurement

manitoring and pain Scale VAS

Intervention groups

1

Description

In the experimental group, patients received sound therapy intervention consisted of music and the Quran by using a digital MP3 player and a headphone.

Category

Other

2

Description

Patients in the control group received the routine care of the study setting which consisted of no music therapy intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghyatallah Hospital

Full name of responsible person

Elaheh Motahedian Tabrizi

Street address

Education Departeman of Velayat, Arag Squer,
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City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Baqiyatallah University
and Behavioral Sience Research Center, Baqiyat

Full name of responsible person

Mokhtari Jamileh

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Education Departeman of Velayat, Arag Squer,
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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 Baqiyatallah University and
Behavioral Sience Research Center, Baqiyat

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**

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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