Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of sound therapy on pain , anxiety level and hemodinamic 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

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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, Aghdasea
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
Street address
Education Departeman of Velayat, Arag Squer, Aghdasea
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TEHRAN
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
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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