

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparing the effect of eye mask and self selected music on the level of anxiety and hemodynamic indices in patients undergoing cardiac angiography

Protocol summary

Study aim

Comparing the effect of eye mask and self selected music on the level of anxiety and hemodynamic indices in patients undergoing cardiac angiography

Design

Clinical trial with control group with parallel, double blind, randomized, and blocked; 360 patients in total, and 90 patients in each group, inclusive of loss.

Settings and conduct

Location: Fatemeh Zahra Hospital, Sari Hospital, Shahid Lavasani Hospital, Tehran. Anxiety assessment with a questionnaire, 10 min before the intervention and 20 min after the end of intervention, by an external evaluator and recording vital signs immediately before intervention, as soon as they were placed on the angiographic bed and 5 min after the intervention and immediately after Completion of the doctor's work and 20 min after the intervention by the researcher in all four groups. Doubles: An evaluator and statistician.

Participants/Inclusion and exclusion criteria

Entry: 18 years and older, patient conscious, candid for coronary artery angiography, Score higher than 32 after responding to anxiety inventory, willingness to participate in the study, physician's permission Music playback, No drug consuming for four hours and soothing at least one hour before the intervention, non-use of antipsychotics, lack of cognitive impairment, and lack of significant visual and auditory problems. Exit: Pregnancy, Acute pain, Illiterate patients and low levels of illiteracy, angiography history, Earn 73 anxiety score, Emergency Angiography, Medical personnel.

Intervention groups

Group A: Putting eyes mask on the patient's eyes. Group B: Play the desired music through the headphones for the patient. Group C: Putting eyes on the patient's eyes and music playback through headphones at the same time, .Group D: without any intervention.

Main outcome variables

Social-Demographic Information Questionnaire; Clinical Questionnaire; Spielberger Anxiety Inventory.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190328043132N1**

Registration date: **2019-04-23, 1398/02/03**

Registration timing: **retrospective**

Last update: **2019-04-23, 1398/02/03**

Update count: **0**

Registration date

2019-04-23, 1398/02/03

Registrant information

Name

sanaz esfandiary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 8916

Email address

hjafari@mazums.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

2018-12-21, 1397/09/30

Actual recruitment end date

2019-03-10, 1397/12/19

Trial completion date

2019-03-10, 1397/12/19

Scientific title

Comparing the effect of eye mask and self selected music on the level of anxiety and hemodynamic indices in patients undergoing cardiac angiography

Public title

Comparing the effect of eye mask and self selected music on the level of anxiety and hemodynamic indices in patients undergoing cardiac angiography

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 and above. Patient is alert and able to verbal communication and eye contact, Candidate for coronary artery angiography, Earning score above 32 after responding to the Spielberger state-trait anxiety inventory, willingness to participate in the study, Desire to hear music, Allow physician to play music, Tendency to close the eye. No drug consuming for four hours and soothing at least one hour before the intervention, Non-use of antipsychotics, Lack of cognitive impairment, The absence of significant visual and auditory problems

Exclusion criteria:

Pregnancy. The presence of acute pain in the part of the body, Uneducated and very low literacy patients, Patients with angiography history, Get an anxiety score of 73 up, Emergency Angiography, Medical personnel.

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 360

Actual sample size reached: 360

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are selected by random method and will be randomly divided into four groups. Group A (eye mask), Group B (self selected music) Group C (Receiver of self Selected Music and eye mask at the same time) And group D (control group). The design of this research is in the form of parallel groups, In this case, a comparison is made between the two randomly assigned groups. One group faces certain treatment and the other group is not faced. Participants in the study period remain in the examined and control groups. The necessity of the third group in this study (Receiver of self Selected Music and eye mask at the same time) is based on a clinical trial with factorial designs. So that they compare the two

therapies simultaneously with the control group, and the third group will receive both treatments to examine the interference effects of the two treatments. The random allocation of patients in each of the four groups is performed using random block and all random variables are used to create the block. The random allocation of patients in each of the four groups is performed using random block and all random variables are used to create the block. Each block is assigned a number from 1 to 24 and These numbers are placed in the pieces of the cases for selection, and according to the sample size, N times randomly selected a nut, and again the vertebrae is returned to the lottery cycle to complete the number of members of the groups To make.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding in this study is as follows: An assessment that completes the anxiety questionnaire before and after the intervention, and the statistician who studies the results is unaware of the process of doing the research (blinded) This knowledge, while the researcher is aware of the type of intervention devoted to the participants in the research, does not affect the analysis of the data.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Nasibeh Nursing College, Vesal street, Amir Mazandarani Blv

City

sari

Province

Mazandaran

Postal code

4816715793

Approval date

2018-12-11, 1397/09/20

Ethics committee reference number

IR.MAZUMS.REC.1397.3096

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

Coronary artery disease

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

The percent of people who have a Spielberger anxiety scores above 32.

Timepoint

Anxiety levels 10 minutes before intervention and 20 minutes after intervention.

Method of measurement

Spielberger State Trait Anxiety Inventory

Secondary outcomes

1

Description

Hemodynamic indices(blood pressure, hear rate, respiratory rate)

Timepoint

Immediately before, immediately after placement on the angiographic bed and 5 minutes after the intervention and immediately after the doctor completes the work, and 20 minutes after the end of the intervention

Method of measurement

Poyandegan Rah Saadat monitor digital and cuff pressure meter to it.

Intervention groups

1

Description

Intervention group: A(eye mask)

Category

Other

2

Description

Intervention group: B(self selected music)

Category

Other

3

Description

Intervention group: C(eye mask and self selected music at the same time)

Category

Other

4

Description

Control group: whit out intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra hospital

Full name of responsible person

Samad Golshani

Street address

Next to the Blood Transfusion Organization, Army Blvd,Imam Hossein Square.

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2

Recruitment center

Name of recruitment center

SHaheed Lavasany Hospital

Full name of responsible person

Syed Ali Jamalian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

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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

Sari University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Jafary Hedayat

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available