

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation the comparative effect of Bensons Relaxation and Back Massage on Anxiety in patients undergoing Coronary Angiography

Protocol summary

Study aim

Comparison of the effect of Benson relaxation and back massage methods on anxiety in patients undergoing cardiac angiography

Design

Clinical trial has two intervention groups and a control group. The sample size of the study was calculated using Torabi et al.'s research and the formula for determining the sample size and considering a 10% drop, 35 people were calculated for each group. Therefore, the total sample size of the research will be equal to 105 people. Sampling will be random-block type.

Settings and conduct

Research environment: Cardiac Intensive Care Unit of Namazi and Faghihi Hospitals affiliated to Shiraz University of Medical Sciences
Research community: All angiography candidates referred to Namazi and Faghihi hospitals affiliated to Shiraz University of Medical Sciences
This study is a block-randomized clinical trial in which the mean scores of anxiety, blood pressure, pulse rate and respiration in the three groups of Benson relaxation, back massage and control group are examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Ability to communicate with the patient • Be at least 18 years old or older
Absence in acute conditions of the disease
No hearing problems and muscle paralysis • Do not prohibit touching with a doctor's opinion • No cognitive and mental disorders • Only undergo an angiography plan
Do not use drugs, sedatives and alcohol before angiography without a doctor's prescription
Exclusion criteria: • Acute physical condition of the patient • Patient dissatisfaction and desire to continue massage therapy or muscle relaxation

Intervention groups

For one group of intervention groups, Benson relaxation method will be taught and for the other group, back massage will be performed. No intervention is performed for the control group.

Main outcome variables

Anxiety_Blood pressure_Pulse rate _ Breathing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220406054435N1**

Registration date: **2022-06-26, 1401/04/05**

Registration timing: **prospective**

Last update: **2022-06-26, 1401/04/05**

Update count: **0**

Registration date

2022-06-26, 1401/04/05

Registrant information

Name

Parvin Moradikashkoli

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the comparative effect of Bensons Relaxation and Back Massage on Anxiety in patients undergoing Coronary Angiography

Public title

The effect of Benson relaxation and back massage on anxiety in angiography patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient's ability to communicate Be at least 18 years old or older Absence in acute conditions of the disease Do not prohibit touching with a doctor's opinion Only undergo an angiographic plan Do not take drugs, sedatives and alcohol before angiography without a doctor's prescription

Exclusion criteria:

Hearing problems and muscle paralysis Cognitive and mental disorders

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple block randomization with block size 6 will be used to place patients in the three groups (massage by the a professional, Benson relaxation technique, and control group). For this purpose, in each block of 6, 2 items will be randomly assigned to the Benson intervention group, 2 items to the massage group and 2 items to the control group. Then, for the next 6 patients, it will be decided randomly in the next block that each patient should be assigned into which group. This process will be proceeded for the next 6 patients until the required number of participants are sampled for the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Codes assigned to patients in three groups will be kept in sealed envelopes and provided to the ward secretary. Patients will not know about these codes. Moreover, the statistician won't be aware of the participants' group.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz, Zand St., in front of Palestine St., the central building of Shiraz University of Medical Sciences

City

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Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Approval date

2021-12-20, 1400/09/29

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1400.048

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

Cardiac angiography

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety score in Spielberger questionnaire

Timepoint

Measurement of anxiety before the intervention and half an hour after the intervention

Method of measurement

Spielberger Anxiety Questionnaire

Secondary outcomes

empty

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

Intervention group: Benson relaxation: In this group, before the intervention, vital signs including blood pressure, pulse rate and respiration are measured using the equipment in the ward, the correctness of which has already been checked. The patient is then placed in a quiet, supine position and closed his eyes when the

patient's private environment is provided. The patient receives non-verbal music with headphones and tries to relax his muscles from the toes to the head and then relax, and the patient is instructed to try to do this piece by piece and While tightening and relaxing the muscles, visualize them in your mind and breathe through your nose, and while breathing, listen to the breathing sounds and repeat a word. This takes 15 to 20 minutes.

Category

Behavior

2

Description

Intervention group: Back massage: Participants will be asked to lie on their backs and unveiled around the bed for patient privacy during the intervention. Also, for male patients, massage will be performed by a male massager and for female patients by a female massager. During the massage, sheets will be stretched on the patient and he will be stripped step by step. The massager, who has already received the necessary training, first warms his hands and soaks them in almond oil. Then massage the back for 20 minutes for the patient. Massage is done by static massage, superficial stretching technique, stretching massage, lymphatic surface emptying technique, transverse rubbing technique, and myofascial release technique, which is performed with efflux (gentle pressure and immersion of the body in oil). Study outcome variables are vital signs (respiration rate, pulse rate and blood pressure) and anxiety, which will be assessed using calibrated devices and the Spielberger Anxiety Inventory.

Category

Treatment - Devices

3

Description

Control group: No intervention: They will not receive any intervention and will only be provided with routine nursing training.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Ahmad Hosseinzadeh

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Shiraz, Zand St., Namazi Square, Namazi Educational and Medical Center

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

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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

Shiraz 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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

Not applicable

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