

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of Emotional Expression Technique on anxiety, heart rate, blood pressure and arterial oxygen saturation among the hospitalized elderly patients before coronary angiography

Protocol summary

Study aim

Determining the effect of emotional freedom technique on anxiety, heart rate, blood pressure and arterial blood oxygen saturation before angiography in the elderly.

Design

Parallel group randomized trial in which participants will be divided into two groups by permuted block randomization. Sample size was calculated 52.

Settings and conduct

Participants will be selected through hospitalized patients in CCU and post angiography wards of Al-Zahra Heart Hospital in Shiraz. Before the angiography, the people in the intervention group will receive the emotion release technique for 15 minutes. Patient's level of anxiety, blood pressure, heart rate and oxygen saturation will be measured and recorded before and immediately after intervention. Patients in the control group will receive routine wards care and their level of anxiety, blood pressure, heart rate and oxygen saturation will be measured and recorded at two intervals of 15 minutes.

Participants/Inclusion and exclusion criteria

Oriented, hospitalized elderly people who are candidate for non-emergency angiography. Also elderly who have a negative history of sedative and anti-anxiety drug use

Intervention groups

In the intervention group, before angiography, emotional freedom technique is performed for the patients and the patient's level of anxiety, blood pressure, heart rate and oxygen saturation will be checked. The control group will receive routine care and at the same intervals that the outcome variables are measured in the intervention group, they are also measured in the control group.

Main outcome variables

level of anxiety, blood pressure, heart rate and arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190727044347N3**

Registration date: **2021-07-13, 1400/04/22**

Registration timing: **prospective**

Last update: **2021-07-13, 1400/04/22**

Update count: **0**

Registration date

2021-07-13, 1400/04/22

Registrant information

Name

Fatemeh Shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Emotional Expression Technique on anxiety, heart rate, blood pressure and arterial oxygen saturation among the hospitalized elderly patients before coronary angiography

Public title

The Effect of Emotional Expression Technique on anxiety, heart Rate, blood pressure and oxygen saturation before Coronary Angiography

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Elderly patients between 60 to 90 years old People who are willing to participate in research and fill out the informed consent form Elderly patients who are hospitalized in the cardiac care units and are candidate for non-emergency angiography or the elderly who refer to the angiography ward by prior appointment. People who are fully aware and able to communicate People who have not undergone other invasive procedures such as esophageal echocardiography before angiography. People undergoing coronary angiography for the first time

Exclusion criteria:

Positive history of cognitive and psychological disorders at the time of the study based on the initial patient assessment. Taking sedatives, anti-anxiety, anti-depressants, narcotics, corticosteroids and other drugs affecting the autonomic nervous system and endocrine system before (8 hours before angiography) Drug addiction, sedatives and alcohol consumption. Emergency angiography and unstable condition of the client Having pain before angiography

Age

From **60 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting eligible individuals to participate in the study based on inclusion criteria, these individuals will be assigned to two study groups based on double randomized permutation block with foursome blocks. The random list is generated by a statistician using "Random Allocation" software. Foursome blocks are the combination of different status such as: ABBA, BAAB, BABA, ABAB, BBAA, AABB. Using random list that is generated by computer, blocks are selected for forming the two study groups.

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 Shiraz University of Medical Sciences

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-05-29, 1400/03/08

Ethics committee reference number

IR.SUMS.REC.1400.209

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

Angiography in elderlies

ICD-10 code

I97

ICD-10 code description

Intraoperative and postprocedural complications and disorders of circulatory system, not elsewhere classified

Primary outcomes**1****Description**

Anxiety level

Timepoint

Before and after the intervention, (before the angiography)

Method of measurement

Spielberger State Anxiety Inventory

2**Description**

The level of arterial oxygen saturation

Timepoint

Before and after the intervention, (before the angiography)

Method of measurement

pulse oximetry

3**Description**

heart rate

Timepoint

Before and after the intervention, (before the angiography)

Method of measurement

Pulse oximetry

4**Description**

Blood Pressure

Timepoint

Before and after the intervention, (before the angiography)

Method of measurement

blood pressure monitor

Secondary outcomes

empty

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

Intervention group: one hour before angiography, the emotional freedom technique will be explained to the patients of the intervention group and they will be taught how to perform the intervention. The procedure is as follows: at each stage before the intervention, a short interview will be conducted with the patient and the unpleasant factors that cause him /her discomfort in that situation, will be determined. Then, by focusing on these unpleasant situational factors, a series of indoctrination and positive sentences are taught to the patient, and the patient tries to accept his/her problem and relax him/herself by repeating these positive and indoctrination sentences. In addition, seven positive, non-annoying blows to each of the patient's meridian points are struck by the patient himself while repeating the positive inductive sentences. The intervention group will receive the emotion release technique for 15 minutes.

Category

Treatment - Other

2**Description**

Control group: The control group will receive routine care and at the same intervals that the outcome variables are measured in the intervention group, they are also measured in the control group.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra Heart Charity Hospital and Shahid Hejazi Children Hospital

Full name of responsible person

Hojjatollah Roosta

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Web page address<https://hfhc.sums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Abbas Rezaianzadeh

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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

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Shirazi
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Assistant professor
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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable