Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The Effect of Emotional Freedom Technique on Sleep, Low Back Pain and Blood Pressure in the Elderly Patient Hospitalized After Coronary Angiogaphy in Alzahra Cardiology hospital 2020

Protocol summary

Study aim
Determining the effect of Emotional Freedom Technique on Sleep, Low Back Pain and Blood Pressure of Elderly Hospitalized Patient After Coronary Angiogaphy

Design
Parallel group randomized trial in which participants will be divided into two groups by permuted block randomization. Sample size was calculated 68.

Settings and conduct
After the angiography, the people in the intervention group will receive the emotion release technique three times, once after the angiography and immediately after the patient enters the ward, once an hour later, and the third stage at 8 pm.Patient's pain level and blood pressure will be measured and recorded before and immediately after each intervention. The next morning, a sleep quality questionnaire will be completed for patients.Patients in the control group receive routine ward care and at the same time set for the intervention group, pain level and blood pressure will be measured and recorded at two intervals of 15 minutes. Also, before angiography and the next day after the angiography, the sleep quality questionnaire will be completed for both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: oriented, hospitalized elderly people who are candidate for non-emergency angiography for the first time. Exclusion criteria: cognitive and psychological disorders; vision impairment, sleep problems and back pain; drug addiction; sedatives and narcotics abuse; active bleeding or need for cardiopulmonary resuscitation.

Intervention groups
Patients in the intervention group, after performing angiography and entering the ward, will receive the emotion release technique three times immediately after entering the ward, one hour later and at 8 pm that night. Patients in the control group receive routine ward care.

Main outcome variables
Blood pressure; The severity of low back pain; The quality of sleep

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190727044347N2**
Registration date: **2021-03-14, 1399/12/24**
Registration timing: **prospective**

Last update: **2021-03-14, 1399/12/24**
Update count: **0**

Registration date
2021-03-14, 1399/12/24

Registrant information

Name
Fatemeh Shirazi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-03-21, 1400/01/01
Expected recruitment end date
2021-06-20, 1400/03/30
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Emotional Freedom Technique on Sleep, Low Back Pain and Blood Pressure in the Elderly Patient Hospitalized After Coronary Angiogaphy in Alzahra Cardiology hospital 2020

Public title

The Effect of Emotional Freedom Technique on Sleep, Low Back Pain and Blood Pressure in the Elderly patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly Patients between 60 to 90 years old Elderly patients admitted to the cardiac care units and candidate for non-emergency angiography People who want to participate in research and fill out the informed consent form People who are fully aware and able to communicate People who have not undergone other invasive procedures such as esophageal echocardiography before angiography. Elderlies who have only angiography and do not have right heart catheterization People undergoing coronary angiography for the first time

Exclusion criteria:

Having positive history of sleep disorders and taking medication before hospitalization based on the initial patient assessment form. Having known cognitive and psychological disorders at the time of the study based on the initial patient assessment form. Taking sedatives and analgesics before (8 hours before) and after angiography The need for cardiopulmonary resuscitation during angiography. Having visual impairment that prevents the selection of the correct position in the pain assessment tool (based on the initial patient assessment form). Having active hemorrhage with hemodynamic disorders that resulted in blood transfusion during and after angiography. Dangerous rhythm disorder immediately after catheterization. Having low back pain on admission. Addiction to drug, sedatives and alcohol drinks.

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: **68**

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

Research 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

2020-12-26, 1399/10/06

Ethics committee reference number

IR.SUMS.REC.1399.1023

Health conditions studied

1

Description of health condition studied

Hospitalized elderlies after angiography

ICD-10 code

I97

ICD-10 code description

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

Primary outcomes

1

Description

The quality of sleep

Timepoint

The beginning of the study (before the intervention) and

the day after the intervention

Method of measurement

The St. Mary's Hospital Sleep Questionnaire (SMHS)

2

Description

Low Back Pain

Timepoint

Patients' low back pain is measured before and after the three times intervention . The intervention will be performed once immediately after the patient enters the ward, once an hour later and the third stage will be performed at 8 pm on the same night. Patients in the control group at the same times set for the intervention group, the level of pain will be measured and recorded in two time intervals with an interval of 15 minutes.

Method of measurement

Visual scale for pain intensity

3

Description

Blood Pressure

Timepoint

Patients' blood pressure is measured before and after the three times intervention. The intervention will be performed once immediately after the patient enters the ward, once an hour later and the third time will be performed at 8 pm on the same night. In the control group at the same times set for the intervention group, blood pressure will be measured and recorded in two time intervals with an interval of 15 minutes.

Method of measurement

Digital model amron 3 blood pressure monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 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 is conducted with the patient and the unpleasant factors that cause him 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 problem and relax himself 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 therapist or the patient himself while repeating the positive inductive sentences. The intervention group will receive the emotion release technique three times ،In this way, this technique will be performed once after angiography and immediately after the patient enters the ward. The second stage is the intervention one hour after the patient enters the ward and the third stage will be done at 20:00 that night.

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

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Heart Charity Hospital and Shahid Hejazi Childrenl and Hejazi Children Hospital

Full name of responsible person

Dr Hojjatollah Roosta

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

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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