

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3323 2163

##### Email address

parvinmoradi798@gmail.com

##### 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**

Shiraz

**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

#### Street address

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

#### City

Shiraz

#### Province

Fars

#### Postal code

۱۳۳۱۱-۷۱۹۳۶

#### Phone

+98 71 3647 4332

#### Fax

#### Email

nemazee\_inf@sums.ac.ir

## 2

### Recruitment center

#### Name of recruitment center

Faghihi Hospital

#### Full name of responsible person

Seyed Mohammad Kazem Tadayon

#### Street address

Shiraz - Karim Khan Zand Boulevard - next to the medical school

#### City

Shiraz

#### Province

Fars

#### Postal code

۷۱۳۴۸۴۶۱۱۴

#### Phone

+98 71 3235 1087

#### Fax

#### Email

FaghihiHsp@Sums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Seyed Vahid Hoseini

#### 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

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#### Postal code

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#### Phone

+98 71 3481 4336

#### Email

info@sums.ac.ir

#### 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

Fars

**Postal code**

1978-71345

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najafisa@yahoo.com

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Saeid Najafi

**Position**

Faculty instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Shiraz University of Medical Sciences, Hazrat Fatemeh School of Nursing and Midwifery, Department of Internal Medicine, Surgery and Emergency Medicine

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**Province**

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Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Saeid Najafi

**Position**

Faculty instructor

**Latest degree**

Master

**Other areas of specialty/work**

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**City**

Shiraz

**Province****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Parvin Moradikashkoli

**Position**

University student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Namazi Square Namazi Hospital, Nursing School, Shiraz Town

**City**

Shiraz

**Province**

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**Postal code**

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**Phone**

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**Fax****Email**

parvinmoradi798@gmail.com

**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