

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of combination effect of Benson's relaxation technique and Foot bath on Quality of Sleep and Anxiety in patients with Acute Coronary Syndrom

#### Protocol summary

##### Study aim

Comparison of combination effect of Benson's relaxation technique and Foot bath on Quality of Sleep and Anxiety in patients with Acute Coronary Syndrom

##### Design

Four groups clinical trials, With a control group, Randomized by senary random block with no permutations with 64 patient

##### Settings and conduct

64 Patients referring to the cardiac care units of the Shahid Rajaee hospital of Gachsaran, through continuous sampling will enter to study. The Benson relaxation method will be performed by the patient on the day after the training. Instructions for doing these steps will be provided through the audio file by the researcher. The warm Foot baths will perform up to 10 cm above the ankle with 40 ° C water for 30 minutes, 1hour before bedtime. The patients in the combined group are asked to first bath their feet in water for 30 minutes and then Perform relaxation for 20 minutes in accordance with the above mentioned protocols. In the control group, nothing will be done in 3 consecutive nights of intervention, Interventions will take place for three consecutive days. All groups will receive regular care of the unit. The SMHSQ and Beck's questionnaire will be completed for three days.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Diagnosis of acute coronary syndrome that 24-48 hours passed from the time they began to be hospitalized 2-ack of acute or chronic psychiatric or anxiety disorders 3-At least reading and writing skills 4-Age 65-32 years old 5-Complete alert 6-A score of 25-16 (moderate anxiety) was obtained based on Beck's questionnaire Exclusion criteria: 1-Failure to motivate the patient to continue cooperation 2-Exacerbation of the disease for a period of intervention 3-Death of the patient

##### Intervention groups

Four groups of Benson's muscle relaxation, Foot bath, Combination group and control

##### Main outcome variables

Quality of Sleep- Anxiety

#### General information

##### Reason for update

##### Acronym

ACS

##### IRCT registration information

IRCT registration number: **IRCT20190126042497N1**

Registration date: **2019-02-05, 1397/11/16**

Registration timing: **prospective**

Last update: **2019-02-05, 1397/11/16**

Update count: **0**

##### Registration date

2019-02-05, 1397/11/16

##### Registrant information

##### Name

Hoda Arianpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3620 1449

##### Email address

hoda.aryanpour@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-07, 1397/11/18

##### Expected recruitment end date

2019-04-07, 1398/01/18  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of combination effect of Benson's relaxation technique and Foot bath on Quality of Sleep and Anxiety in patients with Acute Coronary Syndrom

**Public title**  
combination effect of Benson's relaxation technique and Foot bath on Quality of Sleep and Anxiety

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with Acute Coronary Syndrome lack of anxiety or chronic psychiatric disorder First time admission in CCU ward Passed at least one night from the patient's hospitalization having written knowingly informed consent Interest in program participation lack of acute or chronic illness At least reading and writing skills Age 65-32 years old Having healthy health (hearing and legs) Complete alert lack of membership in medical treatment services A score of 25-16 (moderate anxiety) was obtained based on Beck's questionnaire Sleeping and relaxing medications are the same Lack of mental and motor disorders Not having eczema or any type of ulcer in your legs Not having diabetic ulcer or diabetic neuropathy diagnosis lack of corporate programs of relaxation; Foot bath and similar techniques

**Exclusion criteria:**

Failure to motivate the patient to continue cooperation Exacerbation of the disease for a period of intervention Death of the patient

**Age**  
From **32 years** old to **65 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients with acute coronary syndrome are selected by non probabilistic sampling, but randomly assigned to four intervention groups. In this method, all four states of the group are written on 16 cards and each will be placed in a sealed envelope. These packs are placed in a box, and the researcher does not know which groups of items are to be examined before choosing any of the envelopes. Prior to exposing the units, the researcher assisted in removing one of the envelopes from the box, in which of the 4 illnesses that entered the study would

be included.  
**Blinding (investigator's opinion)**  
Not blinded  
**Blinding description**  
**Placebo**  
Not used  
**Assignment**  
Factorial  
**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Yasouj University of Medical Sciences

**Street address**

Dr. Shahid Motahari Blvd., Yasouj University of Medical Sciences

**City**

Yasouj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

75917-41417

**Approval date**

2018-12-22, 1397/10/01

**Ethics committee reference number**

IR.YUMS.REC.1397.133

**Health conditions studied**

**1**

**Description of health condition studied**

Sleep

**ICD-10 code**

F51.2

**ICD-10 code description**

Nonorganic disorder of the sleep-wake schedule

**2**

**Description of health condition studied**

Anxiety

**ICD-10 code**

F41.9

**ICD-10 code description**

Anxiety disorder, unspecified

**Primary outcomes**

**1**

**Description**

Quality of Sleep

## Timepoint

Measurement of Sleep Quality before the onset of intervention and on the morning of the third, fourth and fifth day of admission after the start of Benson's relaxation & Foot bath

## Method of measurement

St Mary's Hospital Sleep Questionnaire (SMHSQ)

## 2

### Description

anxiety

### Timepoint

Measurement of Anxiety before the onset of intervention and on the morning of the third, fourth and fifth day of admission after the start of Benson's relaxation & Foot bath

### Method of measurement

Beck Anxiety Inventory (BAI)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Benson relaxation technique: The Benson's muscle relaxation is performed by the patient in six steps. 1- Stay in a comfortable position 2. Close eyes. 3. Expansion the muscles of the body from the tip to the head 4. Performing the inhale through the nose and exhaling through the mouth and whisper the word desired when exhaling. 5- Perform the above steps for 20 minutes, then open the eyes and do not move for a few minutes. 6. Lack of worry and ignoring disturbing thoughts during relaxation. During the intervention, remove the disturbing thoughts from your mind as much as possible and choose a word that has always reminded him of calm, such as (God, love, sea). Instructions for doing these steps will be provided through the MP3 player and headphones. In this audio file, the instructions are set for 20 minutes and there is no need to set the clock to determine the method duration. In this file, 30 seconds before the completion of the technique, a gentle song will be put to inform the patient about the end of the procedure. To perform muscle relaxation by pulling the curtains at the patient's bed, the patient's privacy is observed and the privacy of the person and providing a quiet and silent environment for sitting with the department's officials is coordinated so that nobody gets into the patient's unit. One day after training the procedures In addition to the usual care of the department, Benson's relaxation procedure is performed every night before bedtime for three consecutive days by patients and supervised by the researcher.

#### Category

Behavior

### 2

#### Description

Intervention group: the warm Foot baths will perform for three consecutive nights for patients with 40 ° C water for 30 minutes, 1hour before bedtime. Legs up to 10 cm above the ankle will dip in a special plastic container. SMHSQ questionnaire and Beck Anxiety Inventory (BAI) questionnaire will be completed every day during the 7 to 8 am.

#### Category

Other

### 3

#### Description

Intervention group: Combination: The patients in the combined group are asked to first bath their feet in water for 30 minutes and then Perform relaxation for 20 minutes in accordance with the above mentioned protocols.

#### Category

Behavior

### 4

#### Description

Control group: In the control group, nothing will be done in 3 consecutive nights of intervention, but The SMHSQ questionnaire will be completed for three days and each day during 7 to 8 am.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Rajaei hospital

##### Full name of responsible person

Hoda Arianpour

##### Street address

Shahid Rajaei hospital, Parastar Ave., Beladian St., Gachsaran Town

##### City

Gachsaran

##### Province

Kohgiluyeh-va-Boyer-Ahmad

##### Postal code

75917-41417

##### Phone

+98 74 2222 4811

##### Email

hoda.aryanpour@yums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

**Full name of responsible person**

Dr.Ali MousaviZadeh

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hoda.aryanpour@yums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Hoda Arianpour

**Position**

MS of Nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific  
inquiries**

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**Full name of responsible person**

Marzieh Hosseini

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**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Hoda Arianpour

**Position**

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**Latest degree**

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**Other areas of specialty/work**

Nursery

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

General data such as demographic variables and outcomes under study will be published.

**When the data will become available and for how long**

Get started 6 months after printing results

**To whom data/document is available**

All researchers working in academic and scientific institutions who want the results of the study will be allowed to receive the data

**Under which criteria data/document could be used**

Data can be used to enhance science and use results in research

**From where data/document is obtainable**

School of Nursing & Midwifery, Rashid Yasemi St, Vali Asr St, Tehran 00982143651000 nsahraea@gmail.com

**What processes are involved for a request to access data/document**

Once requested, the data will be delivered electronically or in person within one week.

**Comments**