

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison the effect of Benson relaxation and slowe stroke back massage behind level of anxiety and vital signs unstable angina patients.

#### Protocol summary

##### Summary

This study is a randomized clinical trial which will be done in Imam Khomeini(ra) Hospital Poldokhtar related to Lorestan University of Medical Sciences. The objectives of this study are to determine and compare the effects of Benson relaxation and slowe stroke back massage on the level of anxiety and vital signs among unstable angina patients admitted to CCU wards; therefore 114 patients with unstable angina randomly divided into 3 different groups ( 38 people in each group). Before any intervention, anxiety, and vital signs of patients in each group were measured and recorded and then intervenetion done (Benson relaxation for 20-15 minutes and masage for 10 minutes in the first two days of hospitalization) in the two groups. In the control group no such intervention performed. After intervention, the severity of anxiety and the vital signs would be measured and recorded . the results will be compared and analysed in three groups . Data collection tool is a questionnaire.Which consists of three parts (demographic data, test anxiety Spielberger ,Check list vital signs).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201205139737N1**  
Registration date: **2012-05-31, 1391/03/11**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-05-31, 1391/03/11

##### Registrant information

Name

Zeinab Ahmadipour

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 1620 0147

##### Email address

ahmadipourz@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Lorestan University of Medical Ssciences

##### Expected recruitment start date

2012-05-25, 1391/03/05

##### Expected recruitment end date

2012-09-26, 1391/07/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of Benson relaxation and slowe stroke back massage behind level of anxiety and vital signs unstable angina patients.

##### Public title

Comparison the effect of Benson relaxation and slowe stroke back massage behind level of anxiety and vital signs unstable angina patients.

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: age 75-18 years old; interest in massage and relaxation program participation; lack of physical illness that Masazhslamt endanger a person's spinal cord injury or surgery such as history; not having

psoriasis (burn) bones (fractures) entered into the neck, back and sacrum; lack of drug and alcohol addiction; lack of corporate programs of relaxation; massage and similar techniques, lack of psychological problems (delirium, etc.); no history of hospitalization in CCU and no action Apart from anti-anxiety routine interventions (opioids and benzodiazepines) to create peace. Exclusion criteria: lack of patient cooperation and withdrew from the intervention; unstable conditions according to the patient's physician and any complications that arise during massage therapy or health-threatening.

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **114**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### 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

Lorestan University of Medical Sciences Ethics Committee

##### Street address

Khorram Abad road km 5 - Boroujerd - opposite the village Kahrizak - Integrated Medical Sciences

##### City

Poldokhtar

##### Postal code

6851836865

#### Approval date

2012-05-13, 1391/02/24

#### Ethics committee reference number

66375/200

## Health conditions studied

### 1

#### Description of health condition studied

Unstable angina

#### ICD-10 code

I20.0

#### ICD-10 code description

Unstable angina

## Primary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Before and immediately after intervention

#### Method of measurement

Spielberger questionnaire

### 2

#### Description

Vital signs

#### Timepoint

Before and immediately after intervention

#### Method of measurement

Heart monitoring device

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Before intervention to 15 minutes on goals, the length of study, how Benson relaxation and massage, and their effects on anxiety and overall appearance of life, clarifications necessary separately to each unit of study is given and after obtaining consent, the questionnaire personal information is collected through interviews with patients and medical records. The level of anxiety by Spielberger anxiety questionnaire and through interviews with patients by trained research associate who is a nurse (other than the researcher or user intervention) is determined The vital signs (systolic and diastolic blood pressure, pulse, respiration) and examined by using electronic heart monitoring device SAADAT models by caliber engineer medical equipment, in three groups by the research partners, will review and ensure the reliability intera observer is involved in the massage group, massage therapy can be administered by a trained researcher.(ICC), confirmed it in writing to the Scientific Advisor to be announced Inter class correlation (ICC), confirmed it in writing to the scientific Advisor to be announced. Massage using massage oil and warm hands in a day and time period 10 minutes in the first 2 days of hospitalization, in the absence of patient privacy will be maintained within the coronary care unit.

#### Category

Other

## 2

### Description

Relaxation group, first individually and face to face how to do Relaxation training then the researcher to practice your Relaxation process the client performs and the client was asked that same day to do a Relaxation time, which lasts 15-20 minutes intervention also about 20 minutes first 2 days of hospitalization, is done. Benson Relaxation skills conducted a researcher in the samples using four criteria, each of which is 2 point will be assessed these criteria included being a quiet place, close your eyes, breathe slow and motionless limbs were being if the samples 7 points from 8 points to gain the necessary skills in applying the huge intervention after learning points and relaxation by the patient, the level of anxiety and the patients vital signs review and will be recorded.

### Category

Other

## 3

### Description

Standard treatment is usually performed in the control group And you have not done any kind of intervention And only 15 minutes from their anxiety and changes in vital signs are measured

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini(ra) Hospital poldokhtar

##### Full name of responsible person

mohammad gholami

##### Street address

Dormitory Basij -Imam Khomeini(ra) Hospital poldokhtar

##### City

poldokhtar

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Full name of responsible person

mohammad hassan kaiedi

##### Street address

Khorram Abad road km 5 - Boroujerd - Lorestan University of Medical Sciences Complex, Department of Research and Technology

##### City

Khorram Abad road

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Lorestan University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Lorestan University of Medical Sciences

#### Full name of responsible person

Zeinab Ahmadipour

#### Position

Student of Nursing Care

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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Mohammad Gholami

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MSc in Nursing

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Zeinab Ahmadipour

**Position**

MSc student of nursing care

**Other areas of specialty/work**

**Street address**

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**City**

Khorram Abad

## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*