

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

Street address

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

City

Khoram abad

Postal code

Phone

+98 66 1620 0147

Fax

+98 66 1620 0149

Email

www.ahmadipourz@yahoo.com

Web page address

www.lums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Mohammad Gholami

Position

MSc in Nursing

Other areas of specialty/work

Street address

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

City

Khoram abad

Postal code

1483877397

Phone

+98 66 1620 0147

Fax

+98 66 1620 0149

Email

mohammad13565@yahoo.com

Web page address

www.lums.ac.ir

Postal code

Phone

00896616200147

Fax

+98 66 1620 0149

Email

ahmadipourz@yahoo.com

Web page address

www.lums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Zeinab Ahmadipour

Position

MSc student of nursing care

Other areas of specialty/work

Street address

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

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