

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The Comparison between of foot and hand reflexology on anxiety in patients with angiography candidates

Protocol summary

2015-01-16, 1393/10/26

Summary

The aim of this study was to compare the effects of posted shortly feet reflexology massage and hands reflexology massage on anxiety patients undergoing coronary angiography. In this randomized clinical trial, 135 candidates of angiography were randomly allocated to three groups (first week for foot reflexology, second week for hand reflexology massage, third week for control group and again this random allocation is repeated) into experimental and control groups (35 patients in each group). The study will be conducted on female patients candidates for angiography in patients admitted to Kosar hospital in Semnan. Sampling begins after explaining the objectives of the study and obtaining informed consent from patients in different groups. In the foot and hand reflexology massage groups, patients were placed in a comfortable position and either feet or hands are massaged for ten minutes. Spielberger standard questionnaire and hemodynamic parameters will be gathered before and after intervention, and one minute after angiography. The control group will not receive any type of intervention and only anxiety and hemodynamic parameters will be measured after twenty minutes interval. The researchers and data monitoring committee will not become aware of what sort of intervention the patients have been received.

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahed University Vice chancellor for research

Expected recruitment start date

2014-10-14, 1393/07/22

Expected recruitment end date

2015-01-10, 1393/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412087529N6**

Registration date: **2015-01-16, 1393/10/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Scientific title

The Comparison between of foot and hand reflexology on anxiety in patients with angiography candidates

Public title

Effect of massage on the level of anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

nclusion criteria: the desire to participate in the study; having no previous history of angiography; having no order of emergency angiography; having 20 number

anxiety; age over 18 years old;; health in the legs and hands; patients not taking the narcotic drug alcohol, ; having no previous history of mental disorder; not using anticoagulation medications; No diabetes; Do not have the risk of deep vein thrombosis. Exclusion criteria: injury or infection at the site of reflex zone therapy; anxiolytic or hypnotic drugs in the 8 hours before reflex zone therapy; condition of hemodynamic is unstable; transfer of patient to intensive care unit and cardiopulmonary resuscitation of the patient.

Age

From **18 years** old to **80 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The patients are randomly allocated in to the three study groups: foot reflexology massage, hand reflexology massage and control group (35 patients in each group). Random allocated to intervention and control groups, assign patients were given this manner: (first week for foot reflexology, second week for hand reflexology massage, third week for control group and again this random allocation is repeated)The researchers and data monitoring committee will not become aware of what sort of intervention the patients receive.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way , Tehran ,Iran

City

Tehran

Postal code**Approval date**

2014-09-09, 1393/06/18

Ethics committee reference number

4/629

Health conditions studied**1****Description of health condition studied**

Anxiety in patients with angiographic candidates

ICD-10 code

F40-48

ICD-10 code description

Neurotic, stress-related and somatoform disorders

Primary outcomes**1****Description**

satisfaction

Timepoint

30 minutes after angiography

Method of measurement

satisfaction Visual Analog Scale

2**Description**

Anxiety

Timepoint

Before intervention , one minute after intervention, and one minute after angiography

Method of measurement

Spielberger questionnaire

3**Description**

Blood pressure

Timepoint

Before intervention , one minute after intervention, and one minute after angiography

Method of measurement

phygmomanometer

4**Description**

Respiratory rate

Timepoint

Before intervention , one minute after intervention, and one minute after angiography

Method of measurement

Checklist

5**Description**

Pulse rate

Timepoint

Before intervention , one minute after intervention, and one minute after angiography

Method of measurement

Checklist

6

Description

Oxygen saturation

Timepoint

Before intervention , one minute after intervention, and one minute after angiography

Method of measurement

pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

In foot reflexology massage group is done 20 minutes.(10 minutes for per foot). massage techniques on reflex points of the pituitary, spinal cord and solar plexus .reflection of the pituitary is in inner edge of middle portion in the first Knucklebone of the big in plantar plantar, solar plexus is in end of the first metatarsal bone in foot and reflection of the spinal cord is in the inner edge of the foot, starting from the end of the first Knucklebone of the thumb and leads to heel. The level of anxiety (measured by using spielburger questionnaire) and hemodynamic parameters (recorded in a checklist) are used before intervention , one minute after intervention, and one minute after angiography

Category

Other

2

Description

In hand reflexology massage group is done 20 minutes.(10 minutes for per hand).In the hand Reflexology group for the points massage, including the pituitary gland and solar plexus is performed. The level of anxiety (measured by using spielburger questionnaire) and hemodynamic parameters (recorded in a checklist) are used before and after intervention, while and after angiography

Category

Treatment - Other

3

Description

control group without any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital in Semnan university of medical sciences

Full name of responsible person

Dr.Kamran Godus

Street address

Semnan university of medical sciences;Golestan street;Semnan;Iran

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University Vice chancellor for research

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way , Tehran ,Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University Vice chancellor for research

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

Shahed University

Full name of responsible person

Fatemeh Heidari

Position

MSC

Other areas of specialty/work

Street address

Shahed University-Tehran, Iran

City

Tehran

Postal code

021

Phone

+98 21 51210

Fax

Email

fatemeh_heidari19@yahoo.com , nrejah@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way , Tehran ,Iran

City

Tehran

Postal code

Phone

+98 21 51210

Fax

Email

nrejah@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way , Tehran ,Iran

City

Tehran

Postal code

1591715314

Phone

00

Fax

Email

Web page address

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