

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative of the effect of foot reflexology massage and progressive muscle relaxation on anxiety in patients with acute coronary syndrome.

Protocol summary

Study aim

Determination and Comparison of the Effect of Reflective Massage and Progressive Muscle Relaxation on Anxiety in Patients with Acute Coronary Syndrome.

Design

A randomized clinical trial using blocking and sealed envelopes with parallel groups, without blinding with a sample size of 90 people (two 45-person randomized groups).

Settings and conduct

Sampling will perform among hospitalized patients in the cardiac care unit of Imam Hossein Hospital and Khatam Al-Anbia Hospital in Shahroud. Patients will be divided into two groups. Due to the nature of the study and the type of intervention, participants cannot be blinded. But data collectors and data analysts will be unaware of the patients' placement in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having mild anxiety based on questionnaire criteria; full alertness and ability to communicate; age: 18 to 75 years old; the patient has been hospitalized for at least 24 hours; stabilize patient status for sampling; having acute Coronary Syndrome. Exclusion criteria: En Dangerous arrhythmies and CPR cases in the ward; having a history of using psychotropic drugs based on patient statements and cases; drug and alcohol addiction citing the case; having a history of reflective massage and relaxation and psychotherapy; fractures, wounds and skin problems and the possibility of DVT at the Massage location; starting effective medicines in anxiety before intervention.

Intervention groups

Group A: Reflexive Foot Massage. Group B: Progressive Muscle Relaxation

Main outcome variables

Spielberger Anxiety Inventory (STAI) will be used in these patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191222045854N1**

Registration date: **2020-01-09, 1398/10/19**

Registration timing: **prospective**

Last update: **2020-01-09, 1398/10/19**

Update count: **0**

Registration date

2020-01-09, 1398/10/19

Registrant information

Name

Maryam Bigom Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3237 2675

Email address

mb.hosseini@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative of the effect of foot reflexology massage and progressive muscle relaxation on anxiety in patients with acute coronary syndrome.	
Public title	the effect of foot reflexology massage and progressive muscle relaxation on anxiety.
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Having mild anxiety based on questionnaire criteria Full alertness and ability to communicate Age:18 to 75 years old The patient has been hospitalized for at least 24 hours Stabilize patient status for sampling Having acute Coronary Syndrome Exclusion criteria: Dangerous arrhythmies and CPR cases in the ward Having a history of using psychotropic drugs based on patient statements and cases Drug and alcohol addiction citing the case Having a history of reflective massage and relaxation and psychotherapy Fractures, wounds and skin problems and the possibility of DVT at the Massage location Starting effective medicines in anxiety before intervention
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: 90
Randomization (investigator's opinion)	Randomized
Randomization description	The method of randomization is tetragonal blocking and the randomization tool is the sealed envelope. An statistic expert will accomplish the randomization sequence by using the suitable software. Sampling will be done sequentially. In order to concealment, given a code to each one, which the main researcher will not be aware.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	<u>1</u> Ethics committee Name of ethics committee Ethics committee of Shahroud University of Medical Sciences Street address Shahrood University Of Medical Sciences, 7th Tir Square, Shahrood City Shahrood Province Semnan Postal code 3614773947 Approval date 2019-12-29, 1398/10/08 Ethics committee reference number IR.SHMU.REC.1398.120 Health conditions studied <u>1</u> Description of health condition studied Anxiety in Acute Coronary Syndrome Patients ICD-10 code F40-48 ICD-10 code description Anxiety
Primary outcomes	<u>1</u> Description Anxiety in Acute Coronary Syndrome Patients Timepoint At baseline (before intervention) and three days after intervention Method of measurement Spiel Berger Anxiety Inventory
Secondary outcomes	empty
Intervention groups	<u>1</u> Description In group A, foot reflexology massage is performed for 3 days every 30 minutes 2 times a day and anxiety levels are measured and then the data will be analyzed. Category Other <u>2</u> Description In group B, progressive muscle relaxation is performed

for 3 days every 20 minutes 2 times a day. Anxiety levels are measured and the data are analyzed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Maryam Bigom Hosseini

Street address

Emam Ave, Emam Hossein Hospital

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Shahrood

Province

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2

Recruitment center

Name of recruitment center

Khatam Al-Anbia Hospital

Full name of responsible person

Maryam Bigom Hosseini

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Tehran Ave, Khatam Al-Anbia Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

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vcr@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Maryam Bigom Hosseini

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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

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

Yes - There is 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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

The obtained data after intervention on 90 participants in Imam Hossein and Khatam Al Anbia hospitals can be shared after unidentifiable individuals.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academies and scientific institutions, could access to data and documentation

Under which criteria data/document could be used

To promote and extend the subject under study from other aspects and to compare the results with other relevant scientific results, it is permissible to use documentation and data to improve the level of care.

From where data/document is obtainable

Hosseini_maf22@yahoo.com

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

After reviewing the reason of requesting to access documentation and data by the researcher, the data and documentation file will be sent to the researcher (one month after submitting the request).

Comments