

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The effect of foot reflexology on fatigue, sleep quality, physiological indices and electrocardiogram changes in acute myocardial infarction patients

Protocol summary

Study aim

The effect of foot reflexology on fatigue, sleep quality, physiological indices and electrocardiogram changes in acute myocardial infarction patients

Design

A clinical trial with control group, parallel group randomized trial, a single blinded

Settings and conduct

Setting: CCU wards in Al-Zahra Hospital, Data collector and statistician are blind.

Participants/Inclusion and exclusion criteria

The inclusion criteria were having acute myocardial infarction, being 18-75 years old, speak Persian language and oriented to time, person and place. The patients with infectious or bleeding ulcer in their legs, having previous history of cardiovascular diseases, inability to tolerate foot reflexology; and physical disability would be excluded.

Intervention groups

Intervention group: The patient lays on a bed in a quiet environment. The therapist places at the below of the patient's bed and each foot receives a reflexology for 15 minutes. reflexology will be done in three consecutive days at 4 pm. In order to do reflexology, firstly, the sweet almond oil is used. Then the reflexology would be done on following points the sleep points consisted of the thumb and Solar plexus, the inner and outer edges, soles and heel to the ankle of the foot which relate to the fatigue. Moreover, reflexology would be done on both the soles, between the shoulder line and diaphragm line in heart and chest reflex areas. The control group does not receive any type of reflexology. This group receives routine care such as the intervention group.

Main outcome variables

Fatigue, sleep quality, physiological indices and electrocardiogram changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130616013690N8**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name

Masoume Rambod

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4258

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on fatigue, sleep quality, physiological indices and electrocardiogram changes in acute myocardial infarction patients

Public title

The effect of foot reflexology on acute myocardial infarction patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed with acute myocardial infarction Being 18 years old or above Speak Persian language being orient to time, person and place

Exclusion criteria:

Infection or bleeding ulcer in the patient legs Having previous history of cardiovascular diseases Inability to tolerate foot reflexology Having physical disability

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Firstly, the patients are included in the study using convenience sampling. Then, a random block with four block is used to randomly assign patients into the both groups. Block list is provided by the "Create a block randomization list" software. Each block is then placed inside an envelope and numbered. In this way, after selecting a patient, a numbered envelope is opened, the patient is allocated into the intervention or control groups based on the contents of envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

To conducting blinding, assistant researcher who collects data before and after the intervention, as well as statistician who analyzes the data, are blinded to the groups and the assignment of individuals in the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice chancellor for research affairs, seven floor, Shiraz University of Medical Science, beside Helal Ahmar, Zand Ave, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Approval date

2021-02-28, 1399/12/10

Ethics committee reference number

IR.SUMS.REC.1399.1278

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction

ICD-10 code

ST elevati

ICD-10 code description

121

Primary outcomes

1

Description

Fatigue

Timepoint

30 minutes before the intervention and four days after the intervention at 8:00 A.M.

Method of measurement

Multidimensional Fatigue Inventory

2

Description

Quality of sleep

Timepoint

30 minutes before the intervention and four days after the intervention at 8:00 A.M.

Method of measurement

Pittsburgh Sleep Quality Index

3

Description

Physiological indices

Timepoint

30 minutes before the intervention and every day from

second to fourth days at 7 A.M.

Method of measurement

Digital heart monitoring device

4

Description

Temperature

Timepoint

30 minutes before the intervention and every day from second to fourth days at 7 A.M

Method of measurement

MASTECH Non Contact Infrared Medical Thermometer

5

Description

peripheral blood oxygen saturation level

Timepoint

30 minutes before the intervention and every day from second to fourth days at 7 A.M

Method of measurement

Pulse Oximeter

6

Description

Electrocardiogram changes

Timepoint

30 minutes before the intervention and every day from second to fourth days at 7 A.M.

Method of measurement

Digital heart monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient lays on a bed in a quiet environment. The therapist places at the below of the patient's bed and each foot receives a reflexology for 15 minutes. reflexology will be done in three consecutive days at 4 pm. In order to do reflexology, firstly, the sweet almond oil is used. Then the reflexology would be done on following points the sleep points consisted of the thumb and Solar plexus, the inner and outer edges, soles and heel to the ankle of the foot which relate to the fatigue. Moreover, reflexology would be done on both the soles, between the shoulder line and diaphragm line in heart and chest reflex areas.

Category

Prevention

2

Description

Control group: The control group does not receive any type of reflexology. This group receives routine care such

as the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Heart Center

Full name of responsible person

Masoume Rambod

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Nursing and Midwifery University, Namazee Sq, Zand Ave, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaieanzadeh

Street address

Vice chancellor for research affairs of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

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71348-14336

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vcrdep@sums.ac.ir

Grant name

21255

Grant code / Reference number

21255

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Masoume Rambod

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Primary outcomes would be shared.

When the data will become available and for how long

Starting 6 months after publication article

To whom data/document is available

People and researchers working in academic institutions

Under which criteria data/document could be used

Data are provided for information only.

From where data/document is obtainable

Data is available via email rambodma@yahoo.com.

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

Data is available via email rambodma@yahoo.com.

Comments

