Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+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 a 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
Ethic 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
۱۴۳۳۶ - 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

Tempreture

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

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

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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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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