Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of foot reflexology massage and stroke massage on depression of patients with Myocardial Infarction

Protocol summary

Summary

This randomized, controlled clinical trial with three groups aims to compare the effects of foot reflexology massage and stroke massage on depression of patients with MI admitted to heart ward of Vali-Asr Hospital of Birjand. The patients with inclusion criteria (first time MI; age between 40 and 70 years; time passed since MI more than 48 hours; non-history of psychological problems, depression and use of anti-depressants; not having skin or neurological disorders; not having counter-indications for massage such as active infection, breakage and wound; non-addiction) will first complete Beck Depression Inventory. They will enter the study according to the score they obtain. Participants will be 60 who will be assigned into 3 groups randomly, including foot reflexology massage, stroke massage, and control groups. Intervention will be performed through 5 weeks (3 days a week, 2 sessions per day in the morning and afternoon; 30 sessions in total) in the intervention groups by the researcher during hospitalization or continued at home by the patient's main companion if approved by the researcher. The controls will simply get informed of not using anti-depressants. The patient will be excluded from the study in case s/he or his/her main companion does not have the tendency to continue; or in case a physical problem happens to them, inhibiting them from continuation. After the fifth session, the inventory will be completed again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060817756N2**
Registration date: **2016-06-14, 1395/03/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-06-14, 1395/03/25

Registrant information

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Mohammad Bagher Roozgar
Name of organization / entity
Birjand University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2016-09-28, 1395/07/07

Expected recruitment end date

2016-10-28, 1395/08/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of foot reflexology massage and stroke massage on depression of patients with Myocardial Infarction

Public title

Effects of foot reflexology massage and stroke massage on depression

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: first time MI; time passed since MI more than 48 hours; non-history of psychological problems, depression and use of anti-depressants; not having skin or neurological disorders; not having counter-indications for massage such as active infection, breakage and wound; non-addiction; at least 6 hours passed from use of narcotic drugs and tranquilizers. Exclusion criteria: The patient or his/her main companion does not have the tendency to continue; a physical problem happens to them, inhibiting them from continuing the study

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Ethics Committee of Birjand University of Medical Sciences

Street address
Birjand University of Medical Sciences, Ayatollah Ghaffari Street

City
Birjand

Postal code

Approval date
2016-04-23, 1395/02/04

Ethics committee reference number
Ir.bums.1395.4

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
f32

ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Depression

Timepoint
5 weeks from the start of treatment

Method of measurement
Beck Depression Score

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group (foot reflexology massage): Upon completing pre-test, which will be taken using Beck Depression Inventory, the group will go through 5 weeks of foot reflexology massage (3 days a week, 2 sessions per day in the morning and afternoon; 30 sessions in total) by the researcher during hospitalization or continued at home by patient’s main companion if approved by the researcher. At the end of the fifth week, the inventory will be completed again.

Category
Rehabilitation

2

Description
The second intervention group (stoke massage): Upon completing pre-test, which will be taken using Beck Depression Inventory, the group will go through 5 weeks of stroke massage (3 days a week, 2 sessions per day in the morning and afternoon; 30 sessions in total) by the researcher during hospitalization or continued at home by patient’s main companion if approved by the researcher. At the end of the fifth week, the inventory will be completed again.

Category
Rehabilitation

3

Description
Control group: The members will enter the study in similar lines with other groups; however, they will not receive any intervention associated with depression during the study. At the end of the fifth week, they will

complete the inventory again.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-Asr Hospital, Cardiology Department

Full name of responsible person

Zeinab Saremi

Street address

Vali-Asr Hospital, Ghaffari St.

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Birjand University of Medical Sciences

Full name of responsible person

Dr Asghar Zarban

Street address

Deputy of Reserach, Birjand University of Medical Sciences, Ghaffari St.

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research and Technology, Birjand 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

Faculty of Nursing and Midwifery, Birjand University of Medical Sciences

Full name of responsible person

Zeinab Saremi

Position

Master Student of Medical-Surgical Nursing

Other areas of specialty/work

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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