

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The Effect of Foot Reflexology on Disability and Pain Intensity in Chronic Low Back Pain

Protocol summary

Summary

This study is an investigation of the influence of foot reflexology on pain intensity and disability in patients with low back pain. In this quasi-experimental design, we recruited 150 men with chronic low back pain returnee to Baghiatallah hospital in Tehran, who were able to communicate in Persian, were literacy and had history of low back pain for about 3 months and excluded from study if had not consent for study and used tobacco and alcohol. Participants were selected by purposive sampling and then were divided into three groups using random allocation method: intervention group (foot reflexology was applied in real points once a week for three weeks), control (without any intervention) and placebo (sham foot reflexology was applied low pressure in all points once a week for three weeks). Data were collected by Roland- Morris Disability Questionnaire, Visual Analog Scale and Mc-Gill Questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904304431N1**

Registration date: **2013-02-28, 1391/12/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-28, 1391/12/10

Registrant information

Name

Mahdi Rezvani Amin

Name of organization / entity

Baghiatallah University

Country

Iran (Islamic Republic of)

Phone

+98 54 1241 9085

Email address

rezvaniamin@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Baghiatallah University of Medical Sciences

Expected recruitment start date

2010-03-11, 1388/12/20

Expected recruitment end date

2010-07-13, 1389/04/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Foot Reflexology on Disability and Pain Intensity in Chronic Low Back Pain

Public title

The Effect of Foot Reflexology on Low Back Pain

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Able to communicate in Persian; having literacy; health of the legs and history of low back pain more than three months. Exclusion criteria: Patient was not consent to continue participation in the study; death; use of drug, alcohol and tobacco addiction.

Age

From **19 years** old to **85 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baghiatallah University of Medical Sciences

Street address

Baghiatallah Hospital, Mollasadra avenue, Vanak Square

City

Tehran

Postal code

Approval date

2010-04-08, 1389/01/19

Ethics committee reference number

354

Health conditions studied

1

Description of health condition studied

Chronic low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain intensity

Timepoint

Before of intervention, three weeks and six weeks after intervention

Method of measurement

Short Form Mc-Gill Pain Questionnaire

Secondary outcomes

1

Description

Disability

Timepoint

Before of intervention, three weeks and six weeks after intervention

Method of measurement

Roland Morris Questioner

Intervention groups

1

Description

In intervention group, foot reflexology was applied in real points related to low back pain in once a week for three weeks

Category

Other

2

Description

In placebo group, foot reflexology was applied in all point of sole with pressure lower than intervention group

Category

Placebo

3

Description

In control group, do not apply any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiatallah Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baghiatallah University of Medical Sciences, Nursing College

Full name of responsible person

Dr. Ebadi

Street address

Araj Square, Aghdasie

City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Baghiatallah University of Medical Sciences, Nursing College

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
Baghiatallah University of Medical Sciences

Full name of responsible person
Masoud Sirati Nir

Position
Master of science in nursing, Teacher

Other areas of specialty/work
Street address
Aghdasie, Araj Square, Baghiatallah Nursing College

City
Tehran

Postal code
Phone
+98 21 2221 8639

Fax
Email
sirati.info@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Baghiatallah University of Medical Sciences

Full name of responsible person
Mahdi Rezvani Amin

Position

Master of science in nursing

Other areas of specialty/work
Street address
No 4, Hashemi st, Jamaran Avenue, Niavaran Highway

City
Tehran

Postal code
Phone
+98 937 818 8100

Fax
Email
rezvaniamin@bmsu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Baghiatallah University of Medical Sciences

Full name of responsible person
Mahdi Rezvani Amin

Position
Master of science

Other areas of specialty/work
Street address
No 4, Hashemi st, Jamaran Avenue, Niavaran Highway

City
Tehran

Postal code
Phone
+98 937 818 8100

Fax
Email
rezvani.1386@yahoo.com

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