Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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
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Person responsible for updating data

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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