

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The effects of reflexology on chronic low back pain intensity in nurses

#### Protocol summary

##### Summary

This study was double-blind a clinical trial. The study population consisted of 50 female and male nurses suffering from chronic low back pain working in hospitals affiliated with Isfahan University of Medical Sciences. This research has been conducted to investigate the effect of reflexology on chronic low back pain intensity. Nurses were included if they had, chronic non-specific back pain diagnosed by a neurosurgery specialist for more than 3months, healthy feet without injury or damage. The subjects were excluded if they, were pregnant or lactating, or had a vascular disease, thrombo phlebitis or diseases such as urinary tract infection or kidney stones (with pain in the lower back). The participants were randomized and divided into two groups of reflexology and non-specific massage. A questionnaire three section by researcher was made and completed through interviews. The 40 minute sessions of interventions were performed three times a week for two weeks. Pain intensity was measured by Numerical Analogue Scale for pain before and immediately after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201108217391N1**

Registration date: **2016-06-05, 1395/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-05, 1395/03/16

##### Registrant information

##### Name

Maryam Eghbali Babadi

##### Name of organization / entity

Isfahan University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7539

##### Email address

eghbali@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2010-04-05, 1389/01/16

##### Expected recruitment end date

2010-07-20, 1389/04/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of reflexology on chronic low back pain intensity in nurses

##### Public title

The effect of Reflexology on chronic low back pain

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Nurses were included if they had low back pain; chronic non-specific back pain diagnosed by a neurosurgery specialist for more than 3months; healthy feet without injury or damage; and willingness to participate in the study. On the other hand, subjects were excluded if they had participated in another clinical research during the past 3 months; had an experience or knowledge of reflexology; were pregnant or lactating; used other methods of complementary therapy during

the study; or had a vascular disease; thrombophlebitis or diseases such as urinary tract infection or kidney stones (with pain in the lower back). exclusion criteria: They were also excluded if any physical damage; making the subjects unable to continue their participation; was made or if they used new medical treatments (new drugs effective on pain; physical therapy or other methods).

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 50

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Other

#### Other design features

Total of 50 nurses with chronic back pain were selected by simple random sampling method. They were then randomly numbered. Afterwards, individuals with odd and even numbers were assigned to the reflexology and nonspecific massage groups, respectively

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezar Jerib Street, Isfahan University of Medical Sciences

##### City

Isfahan

##### Postal code

009881746-73461

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

IR.MUI.REC.1389.3.008

## Health conditions studied

### 1

#### Description of health condition studied

low back pain

#### ICD-10 code

M54.5

#### ICD-10 code description

Low back pain

## Primary outcomes

### 1

#### Description

Low back pain

#### Timepoint

Before and Immediately after the intervention

#### Method of measurement

Numerical Analogue Scale of Pain

## Secondary outcomes

### 1

#### Description

NO

#### Timepoint

Before intervention and Immediately after intervention

#### Method of measurement

McGill Mlzak questionnaire

## Intervention groups

### 1

#### Description

Intervention group: In this group, reflexology performed 3 times a week for two continuous weeks and each session was 40 minutes. In this group, a simple massage from the lower legs to the ankles, soles and finally toes. Then specific reflexology was performed on all reflex points on the feet.

#### Category

Prevention

### 2

#### Description

Control group: In this group, simple and nonspecific massage performed 3 times a week for two continuous weeks and each session was 40 minutes. However, simple massaging was not followed by deep stimulation of reflexology points in this group.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Al-Zahra Hospitals

**Full name of responsible person**

**Street address**

**City**

ISFAHAN

2

**Recruitment center**

**Name of recruitment center**

Kashani Hospitals

**Full name of responsible person**

**Street address**

**City**

Isfahan

## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Isfahan University of Medical Sciences

**Full name of responsible person**

peyman adibi

**Street address**

Isfahan University of Medical Sciences

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for research of Isfahan 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**

Isfahan University Of Medical Sciences

**Full name of responsible person**

reza safari

**Position**

MSc Student

**Other areas of specialty/work**

**Street address**

Isfahan University Of Medical Sciences.School Of Nursing And Midwifery

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**Web page address**

## Person responsible for scientific inquiries

**Contact**

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Isfahan University Of Medical Sciences

**Full name of responsible person**

Maryam Eghbali Babadi

**Position**

PhD Candidate And academic member

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Isfahan University of Medical Sciences

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fatemeh nazari

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Academic member- PhD Candidate

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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*