

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Compare the effects of reflexology and relaxation on physical and mental symptoms in women with multiple sclerosis

#### Protocol summary

##### Summary

This study is a single-blind randomized clinical trial that is done on 75 patients with multiple sclerosis referred to MS clinic of Ayatollah Kashani Hospital. After simple non-random sampling, participants were randomly assigned by minimization method to three groups: reflexology (25 patients), relaxation (25 patients) and control (25 patients). In the experimental groups was performed foot reflexology and relaxation intervention (Jacobson and Benson) within 4 weeks, twice a week for 40 minutes and the control group were received only routine medical treatment as directed by a doctor. Data was collected via Demographic information questionnaire, fatigue severity scale (FSS), numerical pain scale (NRS) and questionnaire (DASS-21), before, immediately after and two months after interventions in all three groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014050117387N2**

Registration date: **2014-07-01, 1393/04/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-07-01, 1393/04/10

##### Registrant information

###### Name

Fatemeh Nazari

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 7589

###### Email address

nazari@nm.mui.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Isfahan University of Medical Sciences

###### Expected recruitment start date

2013-06-09, 1392/03/19

###### Expected recruitment end date

2013-08-21, 1392/05/30

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Compare the effects of reflexology and relaxation on physical and mental symptoms in women with multiple sclerosis

###### Public title

Compare the effects of reflexology and relaxation on physical and mental symptom multiple sclerosis

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion criteria : Women aged 18-50 years suffering from MS (relapsing-remitting, primary progressive and secondary progressive); MS final diagnosis by neurologists based on McDonald criteria with the elapse of at least 6 months from relevant diagnosis; tendency to participate in the research; no previous participation at treatment sessions of complementary medicine methods such as reflexology, relaxation, massage for the last 6 months; to feel chronic pain in at least one body organs, previous use of pain medication and Numerical Rating Scale (NRS); having the fatigue severity score of equal to

and over 4 based on fatigue severity scale( FSS); have high scores of depression (more than 13), anxiety (more than 9) and stress (more than 18) based on DASS-21 scale; acquisition of scores 0-5.5 based on the Expanded Disability Status Scale( EDSS); not being in the menstruation period, nonexistence of deformity, callus or corn in the feet, feet lesion or cleft, active thrombosis or phlebitis, Varicose veins, record of latest ankle trauma, sprain, fracture, feet palm inflammation or infection; no affliction with diseases other than MS such as febrile acute or bodily chronic (flu, cardiac disabling, glands, respiratory, hepatic, skeletomuscular, renal), mental or psychic disorders such as severe depression, speech or hearing disorder; no addiction to narcotics and psychotropic; not being a member to the treatment crew (physician, nurse); to feel chronic pain in at least one body organs; previous use of pain medication and Numerical Rating Scale (NRS) pain score more 4 for at least 6 months; no pregnancy or no willingness to be pregnant and after taking of informed written consent. Exclusion criteria: No wanting to continue cooperation in research, use another CAM either current; absence of more than two session's acute relapse of the disease one month preceding ordering the study period or within study .

**Age**

From **18 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **75**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences.Hezar Jerib st,  
,Isfahan, Iran

**City**

Isfahan

**Postal code****Approval date**

2013-05-06, 1392/02/16

**Ethics committee reference number**

392094

**Health conditions studied****1****Description of health condition studied**

multiple sclerosis

**ICD-10 code**

G35-G37

**ICD-10 code description**

Demyelinating diseases of the central nervous system

**Primary outcomes****1****Description**

Physical symptoms (pain,fatigue)

**Timepoint**

Before, immediately and two months after interventions

**Method of measurement**

Questionnaire

**2****Description**

Mmental symptoms (stress ,anxiety , depression)

**Timepoint**

Before, immediately and two months after interventions

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the experimental groups were performed foot reflexology and relaxation intervention (Jacobson and Benson) within 4 weeks, twice a week for 40 minutes

**Category**

Treatment - Other

**2****Description**

The control group was received only care and routine medical treatment as directed by a doctor.

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

MS clinic of Ayatollah Kashani Hospital in Isfahan.

**Full name of responsible person**

**Street address**

**City**

Isfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research Deputy Isfahan University of Medical Sciences

**Full name of responsible person**

Fateme Nazari

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib st, Isfahan, Iran

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research Deputy 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**

Fateme Nazari

**Position**

MSc Nursing, Faculty member, School of Nursing and Midwifery

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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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*