

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

Street address

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

City

Isfahan

Postal code

Phone

+98 31 1792 2948

Fax

Email

nazari@nm.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Fateme Nazari

Position

MSc Nursing

Other areas of specialty/work

Street address

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

City

Isfahan

Postal code

Phone

+98 31 1792 2948

Fax

Email

nazari@nm.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Fateme Nazari

Position

Other areas of specialty/work

Street address

City

Isfahan

Postal code

Phone

+98 31 1792 2948

Fax

Email

nazari@nm.mui.ac.ir

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