Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 (25patients), 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

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Name of organization / entity

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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 ,anexity , 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
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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