

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of foot reflexology on sleep quality, fatigue and anxiety in patients with MS

Protocol summary

Study aim

The effect of foot reflexology on patients with MS

Design

In this study, 60 patients with MS with entry criteria are selected. Patients are randomly assigned to control and intervention groups using random numbers. Each group was assigned a code to hide the groups.

Settings and conduct

Janbazan Clinic of Arak City

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 50 years old; conscious informed consent of the patient; EDSS is less than or equal to 4: Expanded Disability Status Scale (EDSS) scale that measures the severity of MS patient disability. Exit criteria: the presence of deformity or ulcer in the areas of massage on the palms of the feet; there is a burn, fungal infection, varice and warts, cornea and any kind of numbness in the leg; having problems with the legs, including problems with blood flow (confirmed by the cardiologist); use of hypnotic and antipyretic drugs, antidepressants and analgesics during the study; anemia, renal failure, liver, diabetes, thyroid disorders and urinary tract infection; use of other alternative and alternative methods during the study; patient's lack of consent to continue cooperation.

Intervention groups

In the intervention group, patients will undergo 8 reflexology sessions twice a week for 4 weeks. Each session is performed for 30 minutes and for each foot for 15 minutes, including 5 minutes for general massage of the foot and 10 minutes for massage on the pituitary glands, hypothalamus, pineal gland on the thumb and continue with massage On the solar cell will be done. Patients in the control group do not receive any reflexology intervention on the part of the researcher. At the end of the eighth week, the same questionnaires will be filled in before the intervention.

Main outcome variables

Quality of sleep fatigue anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038211N3**

Registration date: **2018-05-07, 1397/02/17**

Registration timing: **prospective**

Last update: **2018-05-07, 1397/02/17**

Update count: **0**

Registration date

2018-05-07, 1397/02/17

Registrant information

Name

Fahime Davodabady

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on sleep quality, fatigue and anxiety in patients with MS

Public title

Effect of foot reflexology in MS

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with MS who have Expanded Disability Status Scale (EDSS) are equal to or less than 4. Patients with MS aged 18 to 50 years old Conscious informed consent of the patient

Exclusion criteria:

There is any problem in the foot massage areas Use of other complementary and alternative methods during the study Anemia, renal failure, liver failure, diabetes, thyroid disorders and urinary tract infection Sleeping and sedative medications, antidepressants and analgesics during the study Having problems with the legs, including problems with blood flow (confirmed by the cardiologist) The presence of burn, fungal infection, varicose veins, warts, corns and any kind of numbness in the leg The presence of deformity or ulcer in the area of massage on the palms of the feet

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

Individuals with entry criteria are divided into two intervention and control groups according to the random numbers table. The people of the intervention group A and the control group B are called. Before and after the intervention, the information is collected by the evaluator of the outcome that is unaware of the grouping of the groups. Data analysis is also done by someone who is unaware of the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

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Markazi

Postal code

Arak University of M

Approval date

2018-02-14, 1396/11/25

Ethics committee reference number

IR.ARAKMU.REC.1396.316

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**

Sleep quality with Pittsburgh Sleep Quality Questionnaire

Timepoint

Measurement of sleep quality at the beginning of the study and the end of the fourth week after the intervention began

Method of measurement

Pittsburgh Sleep Quality Questionnaire

2**Description**

Fatigue with Fatigue Impact Scale MS

Timepoint

Measurement of fatigue at the beginning of the study and the end of the fourth week after the intervention began

Method of measurement

Fatigue Impact Scale MS

3

Description

Anxiety with State-Trait Anxiety Inventory (STAI)

Timepoint

Measurement of anxiety at the beginning of the study and the end of the fourth week after the intervention began

Method of measurement

State-Trait Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients will undergo 8 reflexology sessions 2 times a week for 4 weeks. Each session is performed for 30 minutes and for each foot for 15 minutes, including 5 minutes for general massage of the foot and 10 minutes for massage on the pituitary glands, hypothalamus, pineal gland on the thumb and continue with massage. On the solar cell will be done. Patient caregiver is given general massage and pressure points to ensure that the correct work is done to ensure patient comfort and comfort due to the difficulty of travel and the cost of reflexology associated with the patient at home. This is done twice a week for 4 weeks and afternoon, and we will be contacted for follow up and reminders with patients and fellows by telephone and SMS.

Category

Treatment - Other

2

Description

Control group: Patients do not receive any reflexology intervention from the researcher. To unify the interventions, the patient is required to take a total of 8 sessions of the supine position twice a week for 4 weeks without pressure for 30 minutes each Touch the feet for 15 minutes. At the end of the eighth session, the same questionnaires will be filled in before the intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Janbazan clinic

Full name of responsible person

Fahimeh Davodabady

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fahimeh Davodabady

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available