Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology on constipation in patients with MS

Protocol summary

Study aim
Determine the effect of foot reflexology on constipation in patients with MS

Design
Clinical trial with control group, Blind, randomized, with 54 patients

Settings and conduct
Janbazan Clinic of Arak

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 50 years; informed consent, EDSS Expanded Disability Status Scale that measures the severity of MS patient disability less or equal to 4 . Constipation according to Rome IV criteria and doctor's approval. Exclusion criteria: the presence of deformity or ulcer in the areas of massage on the palms of the feet; burn, use of hypnotic and antipyretic drugs, the presence of obstructive diseases of the gastrointestinal tract, inflammatory intestinal diseases, hypothyroidism, hyperparathyroidism, hypopituitarism expressed by the patient, irritable bowel syndrome according to physician confirmation, use of other complementary and alternative methods during the study.

Intervention groups
In the intervention group, patients takes 12 reflexology sessions twice a week for 6 weeks. Each session is 15 minutes massage for each leg, and includes 5 minutes for general massage of the foot and 10 minutes for massage on the gastrointestinal tract (stomach, liver, small intestine) and affecting the constipation. in the control group, Patients do not receive any reflexology intervention. To unify the interventions, the caregiver of patient is required to touch on the feet for total of 12 sessions twice a week for 6 weeks without pressure.

Main outcome variables
Constipation and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180103038211N5**
Registration date: **2018-10-20, 1397/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-20, 1397/07/28**
Update count: **0**

Registration date
2018-10-20, 1397/07/28

Registrant information

Name
Fahime Davodabady

Name of organization / entity

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Iran (Islamic Republic of)

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+98 86 3226 7610

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-10-22, 1397/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology on constipation in patients with MS

Public title
The effect of reflexology on constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with MS who have Expanded Disability Status Scale (EDSS) equal or less than 4. Patients with MS aged 18 to 50 years old Informed consent

Exclusion criteria:

Use of other complementary and alternative methods during the study History of Hypothyroidism, hyperparathyroidism, hypopituitarism declared by the patient 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 plantar area Irritable bowel syndrome confirmed by a doctor Gastrointestinal obstructive diseases, inflammatory digestive diseases

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Study population consists of patients who were registered in the MS center. Subjects were invited in the study with invitation letter. The Subjects with entry criteria were selected by simple sampling methods. Each person was given a number from 1 to n and then were assigned with using random numbers randomly to either an experimental or a control group

Blinding (investigator's opinion)

Double blinded

Blinding description

Individuals with entry criteria are divided into intervention and control groups according to the random numbers table. One of the groups is A and the other is called B. Before and after the intervention, the information is collected by the evaluator of the outcome that is unaware of the Classification of the groups. Data analysis is also done by someone who is unaware of the allocation of groups. The control group also receive similar (but not effective) intervention so are unaware of the allocation to the intervention or control group.

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

Province

Markazi

Postal code

6941-7-38481

Approval date

2018-05-06, 1397/02/16

Ethics committee reference number

IR.ARAKMU.REC.1397.038

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

Constipation

Timepoint

At the beginning of the study and at the end of the sixth week after the intervention began

Method of measurement

Constipation Assessment Scale (CAS)

2

Description

Quality of Life

Timepoint

At the beginning of the study and at the end of the sixth week after the intervention began

Method of measurement

Quality of life SF36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The study group receives 12 reflexology sessions for 30 minutes, twice a week for 6 weeks. Reflexology massage time is for 15 minutes, for each leg and includes general massage of the feet, and then massage the points related to the digestive tract (stomach, liver, small intestine and large) and affecting constipation. The reflexology is taught to the patient's caregiver and the accuracy of reflexology is ensured. Then reflexology is performed by the patient's caregiver at home for this period. We communicate with patients and follows through telephone and SMS.

Category

Treatment - Other

2

Description

Control group: Patients do not receive any reflexology intervention from the researcher. To unify the interventions, patient's caregiver touches the patient's foot surface for 30 minutes, twice a week for 6 weeks and also this patientes takes routine constipation treatment by the doctor.

Category

Treatment - Other

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
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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