

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of effleurage massage and foot reflexology training on quality of life in patients with multiple sclerosis

Protocol summary

Study aim

Determining the effect of Effleurage massage and reflexology training on the quality of life of patients with MS

Design

a two-arm parallel-group randomized trial with accidental 45 participants by the Random number table

Settings and conduct

The study site is in Qom and, the study will include three groups of Effleurage, reflexology, and control for eight weeks and three times a week.

Participants/Inclusion and exclusion criteria

Participants in the study of patients with multiple sclerosis 18 years and older in both men and women who have equal or higher pain and fatigue scores of 4 and an Expanded disability scale of 2-6 and are willing to participate in the study.

Intervention groups

In the Effleurage massage group, using two drops of sweet almond oil, the Effleurage massage will be done by the caregiver in the thigh and hip muscles and leg and sole for 10 minutes on each leg. In the foot reflexology group: reflective points on the head, neck, solar plexus, pelvis, shoulders, pituitary gland, hip, adrenal glands, which will be marked by a marker on the sole, by the index finger and thumb, deep pressure 2-3 mm, the intended time for pressing the reflecting points for each foot will be 10 minutes. Control group: Members of this group will lubricate each sole for 10 minutes with emollient ointment, so the length of each session in these three groups will be 20 minutes.

Main outcome variables

Pain, fatigue, ability to walk, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210723051959N1**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Fatemeh Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3784 6180

Email address

fafa_ak@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-22, 1400/05/31

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of effleurage massage and foot reflexology training on quality of life in patients with multiple sclerosis

Public title

The effect of effleurage massage and foot reflexology training on quality of life in patients with multiple sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with MS, in the age group of 18 years and older, are members of the Qom MS Association and please to participate in this study. Fatigue score equal to or Greater than four according to Fatigue Severity Scale Pain score equal to or Greater than four, according to the Analogue Visual Scale (Vas) Extensive disability score 2-6 according to the Expanded Disability Status Scale Ability to walk comfortably at least 10 meters, with support if needed Ability to stand for at least 60 seconds, with an attendant if needed patients who have not used complementary therapies in the last six months patients who are not prohibited from massage and do not have wounds and skin problems that interfere with the message those who do not have fractures, thrombosis, and arthritis in the foot area No drug addiction

Exclusion criteria:

Pregnancy and taking it during the study Inability to massage by the companion hypotension, unstable cardiovascular conditions If the patient informs the researcher that they used Analgesics or antidepressants during the study, will be excluded them History of hypothyroidism Neuromuscular diseases

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of 45 patients in use according to inclusion and exclusion criteria, randomly into three intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Qom University of Medical Sciences

Street address

No. 83, 1/1 Alley, Safashahr St, Qom town

City

Qom

Province

Ghoush

Postal code

93456-37169

Approval date

2021-07-13, 1400/04/22

Ethics committee reference number

IR.MUQ.REC.1400.063

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Disseminated Multiple Sclerosis

Primary outcomes

1

Description

quality of life

Timepoint

Before the intervention and at the end of the Study

Method of measurement

MSQOL-54(Multiple Sclerosis Quality of Life-54)

Secondary outcomes

1

Description

Pain score

Timepoint

Before the intervention, after each intervention session, at the end of the study

Method of measurement

Visual analogue scale

2

Description

Fatigue score

Timepoint

Before the intervention, after each intervention session, at the end of the study

Method of measurement

Fatigue Severity Scale

3

Description

Walking speed

Timepoint

Before the intervention and at the end of the study

Method of measurement

Timed 25-Foot Walk

4

Description

Fatigue score

Timepoint

Before the intervention and at the end of the study

Method of measurement

Fatigue Impact Scale

Intervention groups

1

Description

Effleurage massage will be performed in the patient's home and place suitable in terms of humidity and heat by the caregiver. Effleurage massage with two Drops of Sweet almonds oil will be done for 10 minutes on each leg to prepare the person and create relaxation in the thigh and hip muscles and calf and sole muscles. Effleurage massage will include slow, rhythmic, and gentle movements, usually blood flow to the heart. And a superficial pressure will be applied by the palm to the skin of the patient's body during reciprocating movements, so the total duration of the session will be 20 minutes

Category

Rehabilitation

2

Description

Intervention group 2: in the Reflexology group, using a silicone marker, reflective points on the head, neck, solar plexus, pelvis, shoulders, pituitary gland, hip, adrenal glands, On the sole, by the index finger and thumb, pressure with a depth of 2-3 mm and regular rhythm and round and approaching the two toes and pointing will be done at the point of reflection, the time allotted for the pressure of the reflective points for each The foot will be 10 minutes, so the total duration of the massage in each session will be 20 minutes. Then the FSS fatigue score will be measured by the caregiver immediately after each session and, the pain scores one hour and, the results will be sent to the researcher via SMS by the caregiver.

Category

Rehabilitation

3

Description

Control group: to simulate the processes performed in the intervention groups, will lubricate each sole with

emollient ointment for 10 minutes 3 times a week for eight weeks, so the length of Each session in this group will be 20 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Association of Patients with Multiple Sclerosis in Qom

Full name of responsible person

Fakhruddin Hejazi

Street address

27th Alley, Honarestan st, Qom

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ghous University of Medical Sciences

Full name of responsible person

Mohammad Khandan

Street address

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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

Ghous 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**

Ghoum University of Medical Sciences

Full name of responsible person

Mahsa Haji Mohammad Hosseini

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ghoum University of Medical Sciences

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Position

Associate professor

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Fatemeh Akbari

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the original and secondary consequence

When the data will become available and for how long

6 months after accepting of article

To whom data/document is available

Researchers working at the university and scientific institutions

Under which criteria data/document could be used

Requires data to do similar research

From where data/document is obtainable

Fatemeh Akbari: fafa_ak@yahoo.com Mahsa Haji Hosseini: MAHSA.NMSPRG@GMAIL.COM

What processes are involved for a request to access data/document

Email / Check the reason for content request and file / approval by the executive and colleagues / send the file

Comments