Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

The effect of Swedish massage on sleep quality in patients with multiple sclerosis

Protocol summary

Study aim
Determining the effect of Swedish massage on the sleep quality of patients with multiple sclerosis

Design
A controlled, parallel-group, single-blind, randomized clinical trial on 64 patients. randomization by www.randomization.com.

Settings and conduct
The researcher will invite 64 patients to the research by visiting Ghaem hospital of Mashhad city using accessible sampling method and the participants will be divided into two groups. At the beginning of the work, the demographic information questionnaire will be completed by the research samples. Sleep quality will be measured before, after the intervention and one month after the intervention by the Pittsburgh Sleep Quality Questionnaire. In the intervention group, in addition to routine Cares, a trained member of the research team will perform Swedish massage for 8 weeks for 30 minutes. for the group Control routine Cares will be done by health professions.

Participants/Inclusion and exclusion criteria
The inclusion conditions include suffering from MS disease (previously diagnosed by a doctor through MRI, OCT, VEP and other specialized tests); consent to enter the study; visiting the MS clinic of Ghaem Hospital in Mashhad; and the ability to complete the questionnaire. Conditions of non-entry include non-cooperation to participate in massage therapy sessions; history of sensitivity and allergy; wound; erythema and abnormal swelling on the skin; pregnancy; history of surgery in the previous 6 months; and history of asthma and cardio-respiratory diseases.

Intervention groups
Control group: For the control group, routine procedures including joint physiotherapy, light exercise, and non-steroidal anti-inflammatory drugs will be performed by health professions. Intervention group: in this group, in addition to routine care, Swedish massage is performed by the researcher in 5 stages.

Main outcome variables
Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220130053882N1**
Registration date: **2023-03-04, 1401/12/13**
Registration timing: **prospective**

Last update: **2023-03-04, 1401/12/13**
Update count: **0**

Registration date
2023-03-04, 1401/12/13

Registrant information

Name
AmirReza JamshidBeigi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Swedish massage on sleep quality in patients with multiple sclerosis

Public title

The effect of Swedish massage on sleep quality in patients with multiple sclerosis

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from MS disease (previously diagnosed by a doctor through MRI, OCT, VEP and other specialized tests) Refer to the MS clinic of Ghaem Hospital in Mashhad Parents/primary caregivers or participants if they are 18 years old or older present at the time of registration to complete the questionnaire and complete the informed consent form; Farsi speaking and developmentally able to read and/or understand the questionnaire Consent to participate in the study

Exclusion criteria:

Non-cooperation to participate in massage therapy sessions History of sensitivity and allergy Ulcers, erythema and abnormal bumps on the skin Pregnancy History of surgery in the previous 6 months History of asthma and cardio-pulmonary diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization type: block Block size: 4 pieces Randomization Unit: Individual Randomization Tool: It is done by creating a random sequence of numbers using an online tool (https://www.randomizer.org). Concealment: Using sealed opaque envelopes How people enter the random chain: people are entered into the random sequence in the order of entering the study

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyst will be unaware of the intervention and control groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Nursing & Midwifery, Mashhad University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Doctor's Crossroad, Ibn Sina Street, Mashhad University of Medical Sciences , Khorasan Razavi, Iran

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Approval date

2022-10-04, 1401/07/12

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.079

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Sleep quality in the Pittsburgh Questionnaire

Timepoint

Before, immediately after and one month after the intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Two Male and Female researchers who have a Swedish professional massage certificate will perform this intervention. 30-minute Swedish massage is

performed for a total of 8 weeks in the intervention group. In the first 4 weeks, the massage is done twice a week and in the second 4 weeks, the massage is done three times a week. According to the request and convenience of the participants, the massage is done in the morning or in the evening. All participants in the intervention and control groups will receive usual MS care and treatment. A private room in Ghaem Hospital's MS Clinic will be used for intervention sessions. The room temperature will be set between 22 and 24 degrees Celsius and the humidity between 40 and 60 percent. The participant is placed in a supine position with the head elevated at 30 degrees. Swedish massage is applied. Field et al.'s protocol will be used to perform massage in five stages in the intervention group: Stage 1. effleurage Step 2. Petrissage Step 3. vibration Step 4. Tapotation Step 5. Friction

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

MS Clinic of Ghaem Hospital in Mashhad

Full name of responsible person

Amirreza Jamshidbeigi

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MS Clinic of Ghaem Hospital, Ahmadabad Blvd, Mashhad, Razavi Khorasan Province, Iran

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Sponsors / Funding sources

1

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Name of organization / entity

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amirreza Jamshidbeigi

Position

MSc. Medical Surgical Nursing student ,Student Research Committee, Faculty of Nursing and Midwifery,

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable