

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The Effects of Massage and Exercise Therapy on Walking, Balance, Quality of Life, Fatigue, Spasticity and Pain in Multiple Sclerosis

Protocol summary

Summary

The aim was to evaluate the effects of massage therapy on pain, fatigue, spasticity, balance, gait, and quality of life in patients with multiple sclerosis and compare with effects after exercise therapy or massage-exercise therapy. In this Single Blinded Randomized Controlled Trial 48 patients RR MS OR SP MS with EDSS between 2-6 were randomly assigned to four subgroups as MT, ET, MET or control group. Patients received three 30 min intervention per week for five weeks. The MT group received a standard Swedish massage. Included in the ET group were a combined set of strength, stretch, endurance, and balance training. Patients in the MET received a combined set of massage-exercise. Patients in the control group were asked to continue their standard medical care. Examiner was blinded to grouping. Patients in study were blinded to existence of other groups and therapies. Outcome measurement were assessed pre-intervention and immediately after intervention completion. Primary outcome measures included: EDSS, Spasticity, Fatigue Severity, Pain, Quality of Life, Static Balance, Dynamic Balance, Gait Velocity, Gait Endurance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051413335N1**

Registration date: **2013-07-20, 1392/04/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-20, 1392/04/29

Registrant information

Name

Solmaz Rezaie

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1337 7823

Email address

rezaie.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Massage and Exercise Therapy on Walking, Balance, Quality of Life, Fatigue, Spasticity and Pain in Multiple Sclerosis

Public title

The effect of massage and Exercise Therapy in Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Major inclusion criteria to study: Confirm MS with neurologist; RR MS OR SP MS; EDSS between 2-6; Ability to walk with or without assist; Ability to stand with or

without assist; Absence any Underlying disease include: Rheumatic disease, Orthopedic Diseases, Metabolic diseases or other neurologic diseases; Non-use antispastic drugs; Women in study Not to be pregnant; Patients haven't open or infected wounds on skin; Patients Don't participate in other studies; Patients have no Recurrence in 6 month ago Major exclusion criteria to study: Severe or suddenly neurologic symptoms

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 48

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

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, University city, Ahvaz

City

Ahvaz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

ETH-494

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

EDSS

Timepoint

before intervention and after 15 session intervention

Method of measurement

Expanded Disability Severity Status-numerical

2

Description

Spasticity

Timepoint

before intervention and after 15 session intervention

Method of measurement

Modified ashworth scale- numerical

3

Description

Fatigue Severity

Timepoint

before intervention and after 15 session intervention

Method of measurement

Fatigue Severity Scale

4

Description

Pain

Timepoint

before intervention and after 15 session intervention

Method of measurement

Visual Analogue Scale

5

Description

Quality of Life

Timepoint

before intervention and after 15 session intervention

Method of measurement

Quality of Life Multiple Sclerosis -54

6

Description

Static Balance

Timepoint

before intervention and after 15 session intervention

Method of measurement

Berg Balance Scale

7

Description

Dynamic Balance

Timepoint

before intervention and after 15 session intervention

Method of measurement

Timed Up and Go-Ssecond

8**Description**

Gait Velocity

Timepoint

before intervention and after 15 session intervention

Method of measurement

Timed 10-meter Walk-Second

9**Description**

Gait Endurance

Timepoint

before intervention and after 15 session intervention

Method of measurement

2-Mintue Walking-Meter

Secondary outcomes

empty

Intervention groups**1****Description**

Control Group-continue medical care and usual physical therapy program be done with delay and after 5 weeks

Category

Other

2**Description**

Massage Group- swedish massage for lower extremity for 30 minutesin per session during 15 sessions in 5 weeks

Category

Treatment - Other

3**Description**

Exercise Group-exercises for 30 minutesin per sessions for 15 sessions during 5 weeks-exercises include:

- 1.Weighted Straight Leg Rising
- 2.Forward Lunge
- 3.treadmill treaning
- 4.progressive resistance cycling
- 5.balancing exercise
- 6.stretching exercise

Category

Rehabilitation

4**Description**

Massage and Exercise Group- combination of 15 minutes massage of lower extremity and 15 minutesexercise therapy for 15 sessions during 5 weeks- exercises include: 1.Weighted Straight Leg Rising 2.Forward Lunge

3.treadmill treaning 4.progressive resistance cycling

5.balancing exercise 6.stretching exercise

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Khuzestan Community of Multiple Sclerosis

Full name of responsible person

Solmaz Rezaie

Street address

Ground Floor, Faculty of Rehabilitation Sciences ,Ahvaz Jundishapur University of Medical Sciences, Ahvaz

City

Ahvaz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi

Street address

Ground Floor, Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences, University City, Ahvaz

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Ahvaz Jundishapur 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****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Solmaz Rezaie

Position

Master Degree in Physical Therapy

Other areas of specialty/work**Street address**

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Web page address**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