Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Dalance, 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)

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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 drags; 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 Feghhi
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
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Person responsible for updating data

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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