

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of massage therapy on mental-health co-morbidity and complications related to quality of life in people with MS-a randomized controlled clinical trial

Protocol summary

Study aim

Investigating the effect of massage therapy on psycho-physical complications and co-morbidity related to quality of life in people with MS.

Design

An unblinded community-based, randomized, controlled clinical trial with a parallel groups. Participants in this Phase III of clinical trial study included 70 patients with MS.

Settings and conduct

The present study will be carried out at the Neuromuscular Rehabilitation Center of Semnan University of Medical Sciences. Because of the nature of the study, the participants are not blind to the division into groups, but statisticians and evaluators split the participants into groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 16 years; At least the reading and writing skills; Confirmation of a recurrent or secondary progressive MS disease by a specialist; EDSS scores ranging from 0/3 to 0/7; Ability to stand without assistance for at least 60 seconds (if necessary with auxiliary equipment); The ability to walk 10 meters safely with or without auxiliary equipment. Exclusion criteria: Deep vein thrombosis (DVT) Uncontrolled; Uncontrolled high blood pressure (systolic blood pressure 180 mm Hg on diastolic 100 mm Hg); Confirmation of unstable angina and / or heart attack (myocardial infarction) during the past month; Diabetes.

Intervention groups

Intervention group: The participants in this group receive the Swedish standard massage by trained physiotherapists. The program provides massage therapists for approximately 70 minutes each week for two sessions, for a period of 6 weeks, in a quiet room, on a massage table, they will receive a massage therapist. Control group: They receive their routine treatments

Main outcome variables

Health-related quality of life; Pain; Fatigue; Muscular spasticity; Stress, anxiety and depression; Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170114031942N7**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Aynollah Naderi

Name of organization / entity

Shahrood University of Technology

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-06-07, 1397/03/17

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of massage therapy on mental-health co-morbidity and complications related to quality of life in people with MS-a randomized controlled clinical trial

Public title
Massage therapy and MS

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 16 years At least the reading and writing skills Confirmation of a recurrent or secondary progressive MS disease by an specialist EDSS scores ranging from 0/3 to 0/7 Ability to stand without assistance for at least 60 seconds (if necessary with auxiliary equipment) The ability to walk 10 meters safely with or without auxiliary equipment
Exclusion criteria:
 Deep vein thrombosis (DVT) Uncontrolled Uncontrolled high blood pressure (systolic blood pressure 180 mm Hg on diastolic 100 mm Hg) Confirmation of unstable angina and / or heart attack (myocardial infarction) during the past month Diabetes Arthritis, injuries or non-fixed fractures of the lower limbs Other injuries or neurological diseases Pregnancy or intending to get pregnant Get a massage in the past six months or get physical therapy program before the start of the study Inability to easily get out of the wheelchair and go to the massage table Lack of regular participation in massage sessions

Age
From **16 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are firstly enrolled by one of the research colleagues. Then, an independent assessor, blinded person who has no further involvement in the study creates a random allocation sequence using a computer Software prior to the initiation of the study that use to randomize participants with 1:1 allocation ratio. A block randomization design (block size of 2,4,6) are applied to ensure an equal number of participants in each group. Group allocation are concealed in sequentially numbered, opaque, sealed envelopes, and corresponding envelopes are opened after enrolled participants complete all baseline assessments.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences And Health Services

Street address

No. 2, Damghan road, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

99951- 35198

Approval date

2018-02-06, 1396/11/17

Ethics committee reference number

IR.SEMUMS.REC.1396.215

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

Health-related quality of life

Timepoint

Health-related quality of life is measured at beginning of the study and 6 weeks after starting the massage therapy

Method of measurement

Health-related quality of life measured by MSQoL Multiple Sclerosis Quality of Life-54

2

Description

Pain

Timepoint

Pain is measured at beginning of the study and 6 weeks after starting the massage therapy

Method of measurement

The pain is measured by visual analog scale.

3

Description

Fatigue

Timepoint

Fatigue is measured at beginning of the study and 6 weeks after starting the massage therapy

Method of measurement

Fatigue is measured by the fatigue intensity index

4

Description

Muscular spasticity

Timepoint

Muscular spasticity is measured at beginning of the study and 6 weeks after starting the massage therapy

Method of measurement

Muscular spasticity measured by the Modified Ashors Scale.

5

Description

Stress, anxiety and depression

Timepoint

Stress, anxiety and depression is measured at beginning of the study and 6 weeks after starting the massage therapy

Method of measurement

Stress, anxiety and depression are measured by the short scale of depression, anxiety and stress.

6

Description

Sleep quality

Timepoint

Sleep quality is measured at beginning of the study and 6 weeks after starting the massage therapy

Method of measurement

Sleep quality is assessed by the Pittsburgh Sleep Quality Index.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants in this group receive the Swedish standard massage by trained physiotherapists. The program provides massage therapists for approximately 70 minutes each week for

two session, for a period of 6 weeks, in a quiet room, on a massage table, they will receive a massage therapist.

Category

Rehabilitation

2

Description

Control group: They receive their routine treatments

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan University of Medical Sciences and Health Services

Full name of responsible person

Atefe Aminian far

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Technology

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Grant name

Shahroud University of Technology

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Shahroud University of Technology
Proportion provided by this source
50
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

2

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Semnan University of Medical Sciences and Health Services

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

50

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
Shahrood University of Technology
Full name of responsible person
Aynollah Naderi
Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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