

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigate the effect of massage therapy on fatigue in patients with Multiple Sclerosis (MS)

Protocol summary

Summary

Aim: This study aim is to investigate the effect of massage therapy on fatigue in patients with multiple sclerosis in Samenolhojaj Special diseases center of Kerman City. Design: Clinical trial with random allocation of patients in case and control groups Participants: 80 patients with Multiple Sclerosis are introduced to the study based on the inclusions and exclusions criteria. Main inclusion criteria are no history of massage therapy, score of 36 and higher with fatigue severity scale and disease duration of more than six months. Main exclusion criteria are affliction with other physical and mental disorders and increase the severity of MS during the study. Intervention: Patients in intervention group will receive massage therapy and the control group receive usual care of treatment center. Outcome: Evaluation of fatigue severity score and the effectiveness of massage therapy, before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611217844N11**

Registration date: **2017-09-03, 1396/06/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-03, 1396/06/12

Registrant information

Name

Mansour Arab

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1320 5179

Email address

marab@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kerman University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate the effect of massage therapy on fatigue in patients with Multiple Sclerosis (MS)

Public title

The effect of massage therapy on fatigue of patients with Multiple Sclerosis (MS)

Purpose

Supportive

Inclusion/Exclusion criteria

Main inclusion criteria: No history of massage therapy; Score of 36 and higher with fatigue severity scale; Disease duration of more than six months Main exclusion criteria: Affliction with other physical and mental disorders; Increase the severity of MS during the study

Age

No age limit

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The random allocation method is roll of a dice

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Science

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jihad Blvd, Somayye Crossroads, Shariati St, Kerman

City

Kerman

Postal code

Approval date

2013-04-06, 1392/01/17

Ethics committee reference number

k/92/487

Health conditions studied

1

Description of health condition studied

Fatigue

ICD-10 code

R53

ICD-10 code description

Malaise and fatigue

Primary outcomes

1

Description

Fatigue severity

Timepoint

Before and after of massage therapy

Method of measurement

Fatigue Severity Scale

Secondary outcomes

1

Description

The effectiveness of massage therapy

Timepoint

Before and after of each massage therapy session

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Patients in intervention group received massage therapy. Masseur is a family member who is trained by a physiotherapist. Massage therapy sessions are provided for 20 minutes, 3 times a week, over a period of four weeks.

Category

Other

2

Description

Patients in the control group received usual care of treatment center

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Samenolhojaj Special Diseases Center of Kerman City

Full name of responsible person

Mr Ganjali Khani

Street address

Samenolhojaj Special Diseases Center, Shahid Rajaei St, Qaem Crossroads, Shariati St, Kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kerman University of Medical Sciences

Full name of responsible person

Dr Malek Pour Afshar

Street address

Vice chancellor for research, Kerman University of
Medical Sciences, Jihad Blvd, Somayye Crossroads,
Shariaati St, Kerman

City

Kerman

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 of Kerman 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

Razi Nursing and Midwifery School

Full name of responsible person

Mansour Arab

Position

MSN/ Lecturer of Nursing

Other areas of specialty/work

Street address

Razi Nursing and Midwifery School, Haft Bagh Alavi
Highway, Kerman

City

Kerman

Postal code

Phone

+98 34 3132 5000

Fax

Email

marab112004@yahoo.com

Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Razi Nursing and Midwifery School

Full name of responsible person

Mansour Arab

Position

MSN/ Lecturer of Nursing

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact

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Street address

City

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Phone

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Fax

Email

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