

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison effect of Reflexology and Effleurage massage on the severity of fatigue and insomnia in Multiple Sclerosis patients

Protocol summary

Study aim

Determine and compare the effect of Reflexology and Effleurage Massage on the severity of fatigue and insomnia of patients with Multiple Sclerosis

Design

This research is a randomized clinical trial with control group. The sample size is 90. In this study, a non-invasive non-pharmacological method is used.

Settings and conduct

This study was conducted to compare the effects of two methods of non-pharmacological treatment Reflexology and Effleurage massage on fatigue and sleeplessness of patients referring to MS Society of Ahvaz. Sampling was performed based on entry criteria and cut-off point for data collection and intervention. Reflexology and massage of the eyelids, and use the Fatigue Intensive and Insomnia Inventory before and after the intervention and collect data from them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range 18 - 50 years old; willingness to participate in the study, and full awareness and health of the member. A score of 45 up to fatigue and gain a score of 22 up from the state of insomnia. Exit criteria: increased severity of disease; recurrent disease during the process, and failure to follow the patient's or accompanying massage program and reflexology. The accompanying benchmark includes willingness to collaborate, literacy, and writing; the ability of the hands to massage the hands.

Intervention groups

Reflexology group, Effleurage massage group and control group

Main outcome variables

Reflexology, Fallage Massage, Fatigue, Insomnia Severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190423043355N1**

Registration date: **2019-05-19, 1398/02/29**

Registration timing: **prospective**

Last update: **2019-05-19, 1398/02/29**

Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

Abdollah Poursamad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 5118

Email address

ab_poursamad@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-31, 1398/03/10

Expected recruitment end date

2019-08-01, 1398/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of Reflexology and Effleurage massage on the severity of fatigue and insomnia in Multiple Sclerosis patients

Public title

Effect Reflexology and Effleurage on fatigue and insomnia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range is 50-18 years. Expressed willingness to participate in the study. Full vigilance on the health of the legs and the lack of physical damage to the organs and spine. Failure to have any motion sickness that impairs the performance of tests. Not having surgery in the legs and legs in the last six months. Lack of previous participation in complementary therapy sessions in the past six months A definitive diagnosis of MS by a neurologist who has been at least six months since it was diagnosed. Earn 45 or more points of fatigue and gain a score of 22 up from the state of insomnia

Exclusion criteria:

Increase the severity of the disease so that it affects the severity of fatigue and insomnia. Recurrence of the disease and changes in the process of the disease so that the patient becomes hospitalized. Failure to follow the massage or reflexology program by the patient or his companion for any reason.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Invited individuals are invited to enter the study and will be assigned to the study groups through random allocation of the block. Thus, in the beginning, according to the number of studied groups (three groups of two groups of subjects and one control group), the number of samples in each block is 3, and accordingly the number of blocks caused by all modes The ordering of individuals, by calculating the factorial of the number of samples per block, is 24 blocks, and the blocks involve the probable ordering of individuals, taking into account A for intervention 1 (reflexology) and B for intervention 2 (Forlo Ragh massage) and C for the control group Is being developed

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**

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj-Shahid Motahari Blvd.-Yasouj University of Medical Sciences

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2019-04-22, 1398/02/02

Ethics committee reference number

IR.YUMS.REC.1398.007

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**

Fatigue severity scale in FSS Fatigue Severity questionnaire

Timepoint

Before the intervention and two months after the intervention

Method of measurement

Fatigue severity scale

Secondary outcomes**1****Description**

Insomnia severity score

Timepoint

Before the intervention and two months after the intervention

Method of measurement

insomnia severity index questionnaire

Intervention groups

1

Description

Intervention group: Reflexology

Category

Treatment - Other

2

Description

Intervention group: Effleurage massage

Category

Treatment - Other

3

Description

Control group: Control

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Multiple Sclerosis Society of Ahwaz

Full name of responsible person

Abdullah Poursamad

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Golestan Avenue, Ahwaz Jundishapur University of
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Abdullah Poursamad

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available