

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of relaxation on pain, fatigue and quality of life in women with multiple sclerosis

Protocol summary

Summary

Objective: Effect of relaxation on pain, fatigue and quality of life in women with multiple sclerosis. Design: Randomized clinical trial at two groups of intervention and control. The studied population: Patients of woman with multiple sclerosis who will refer to MS Association, Sample population: 70 people at two groups of intervention and control. Setting: patients with multiple sclerosis who will refer to MS Association with following criteria to be studied: (a) definite diagnosis of multiple sclerosis by neurologist; (b) age 20-45; (c) do not have acute illness; (d) EDSS (Expanded Disability Status Scale) is equal or less than 4/5; (e) to have pain and fatigue symptoms. The patients will be excluded from the study with the following criteria: (a) being disable to continue for participating in sessions for any reason; (b) being hospitalized. Interventions: relaxation will be done in way of Jacobson on 12 sessions of forty to sixty minutes, during four weeks at intervention group. Patients will be received routine cares at control group. Measurement of main outcome: pain, fatigue and life's quality will be studied in accordance with questionnaires as follows: (a) pain will be evaluated by visual pain scale before and eight weeks after intervention; (b) fatigue will be evaluated in accordance with fatigue severity scale questionnaire before and eight weeks after intervention; (c) life's quality will be evaluated in accordance with 54 items questionnaire of life's quality of multiple sclerosis patients before and eight weeks after intervention.

General information

Acronym

ms

IRCT registration information

IRCT registration number: **IRCT201302109759N3**

Registration date: **2013-04-01, 1392/01/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-01, 1392/01/12

Registrant information

Name

Ali Bikmoradi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0439

Email address

bikmoradi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice_chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-03-10, 1391/12/20

Expected recruitment end date

2013-05-10, 1392/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of relaxation on pain, fatigue and quality of life in women with multiple sclerosis

Public title

Effect of relaxation on Patients with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: (a) certain diagnosis of multiple sclerosis by neurologist; (b) age between 20-45; (c) not to be in acute phase of disease; (d) EDSS (Expanded Disability Status Scale) which is equal or less than 4/5 according to neurologist's view; (e) to have pain and fatigue symptoms. Exclusion criteria: (a) lack of ability to participate in the relaxation sessions for any reason; (b) to be hospitalized in hospital.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, the balanced block randomization will be used and the patients allocated in two groups of intervention (body relaxation) and control (routine cares).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Human Subject Review Board of Hamadan
University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shaheed
Fahmideh Ave.

City

Hamadan

Postal code

6517838698

Approval date

2013-02-14, 1391/11/26

Ethics committee reference number

4025/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

pain

Timepoint

Before and after intervention

Method of measurement

Visual pain Scale

2

Description

Fatigue

Timepoint

Before and after intervention

Method of measurement

Fatigue Severity Scale for patient with multiple sclerosis

3

Description

Quality of life

Timepoint

Before and after intervention

Method of measurement

MSQoL-54 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: in the control group the patients will be received only routine cares.

Category

Other

2

Description

Intervention group: relaxation will be done in way of Jacobson under 12 forty to sixty minute sessions during four weeks at intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan Association for Support of Patients with Multiple Sclerosis

Full name of responsible person

Azadeh Zafari

Street address

Shahid Fahmideh Ave., School of Nursing and Midwifery, Hamadan University of Medical Sciences

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr. Ahmad Tavilani

Street address

Shaheed Fahmideh Ave., Hamadan University of Medical Sciences,

City

Hamadan

Grant name

از محل یک درصد بودجه طرح های تحقیقاتی دانشگاه

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

Yes

Title of funding source

Vice-chancellor of Research and Technology, Hamadan 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

Hamadan University of Medical Sciences, Nursing and Midwifery School

Full name of responsible person

Dr. Ali Bikmoradi

Position

Medical Education Management

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

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PhD of Medical Education Management

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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