

# 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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**Other areas of specialty/work****Street address**

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bikmoradi@umsha.ac.ir;abeikmoradi@yahoo.com

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www.umsha.ac.ir

## 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

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PhD of Medical Education Management

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## Person responsible for updating data

### Contact

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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*