

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Effect of relaxation technique versus control group on depression, stress and anxiety in patients with multiple sclerosis: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of relaxation technique versus control group on depression, stress and anxiety in patients with multiple sclerosis

##### Design

This is a randomized clinical trial, phase II, in which 88 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients with multiple sclerosis referring to Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Multiple sclerosis for at least 5 months, Literate, Ability to perform the exercise for 20 minutes daily, Residence of Hamadan city Exclusion criteria: The acute phase of the disease, Taking stimulant or psychotropic drugs, Having a hearing problem, Motor impairment or cognitive impairment

##### Intervention groups

Intervention group: Routine treatment plus Jacobson and Benson relaxation exercises at least 20 minutes daily for 8 weeks Control group: Just routine treatment

##### Main outcome variables

Primary outcome: Depression, stress, and anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N331**

Registration date: **2020-01-10, 1398/10/20**

Registration timing: **prospective**

Last update: **2020-01-10, 1398/10/20**

Update count: **0**

##### Registration date

2020-01-10, 1398/10/20

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-03-18, 1398/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of relaxation technique versus control group on depression, stress and anxiety in patients with multiple sclerosis: a randomized clinical trial

##### Public title

Effect of relaxation technique versus control group on depression, stress and anxiety in patients with multiple sclerosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 18 to 65 years, Multiple sclerosis for at least 5 months, Literate, Ability to perform exercise for 20 minutes daily, Residence of Hamadan city

**Exclusion criteria:**

Acute phase of the disease, Taking stimulant or psychotropic drugs, Having hearing problem, Motor impairment or cognitive impairment

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **88**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

**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 Hamadan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2019-12-07, 1398/09/16

**Ethics committee reference number**

IR.UMSHA.REC.1398.735

**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**

Depression, stress and anxiety

**Timepoint**

Before the intervention and 4 and 8 weeks after that

**Method of measurement**

By using DASS-21 standard questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Routine treatment plus Jacobson and Benson relaxation exercises at least 20 minutes daily for 8 weeks

**Category**

Treatment - Other

**2****Description**

Control group: Just routine treatment

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina Hospital in Hamadan city

**Full name of responsible person**

Forpuzan Ahmadi

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Sina Hospital, Mirzadeh Eshghi Ave.

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Fr.ahmadi267@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Forpuzan Ahmadi

**Position**

Student of Nursery

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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