

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)

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+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

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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6517838695

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+98 81 3827 4184

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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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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

Street address

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

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Person responsible for scientific 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 updating data

Contact

Name of organization / entity

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