Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Jalal Poorolajal
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
Student of Nursery
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Person responsible for updating data

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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