Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of training based on Leventhal's self-regulation model on anxiety, stress, depression and illness Perception in women with multiple sclerosis

Protocol summary

Study aim

The aim is to investigate the effect of training based on Leventhal's self-regulation model on anxiety, stress, depression and understanding of the disease in women with multiple sclerosis.

Design

The randomized clinical trial has a parallel intervention and control group, without blinding, on 64 MS patients. Sealedenvelope site and blocks of four were used for randomization.

Settings and conduct

This study will be conducted on women with MS and in the MS Association of Central Province. in a way that includes two control and intervention groups in the form of pre-test and post-test on two occasions. After randomizing the sample size in two groups; In addition to routine training, people in the intervention group will receive self-regulation training based on the Levant model in four to five non-simultaneous sessions and in two to three simultaneous sessions, and in the control group, they will receive only the usual training provided by the clinic's treatment staff. will be

Participants/Inclusion and exclusion criteria

Women aged 18 to 50 with MS who have been diagnosed with MS for at least one year and do not have any other disease or disorder.

Intervention groups

In addition to routine training, people in the intervention group will receive self-regulation training based on the Levant model in four to five non-simultaneous sessions and in two to three simultaneous sessions, and in the control group, they will receive only the usual training provided by the clinic's treatment staff.

Main outcome variables

Stress, anxiety and depression and understanding of the disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220703055351N3**
Registration date: **2024-02-11, 1402/11/22**
Registration timing: **prospective**

Last update: **2024-02-11, 1402/11/22**
Update count: **0**

Registration date

2024-02-11, 1402/11/22

Registrant information

Name

Mahsa Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-19, 1402/11/30

Expected recruitment end date

2024-07-20, 1403/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of training based on Leventhal's self-regulation model on anxiety, stress, depression and illness Perception in women with multiple sclerosis

Public title
The effect of training based on Leventhal's self-regulation model on anxiety, stress, depression and illness Perception in women with multiple sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Examination of the disease based on the medical record and expert diagnosis Age between 18-50 years A history of illness of at least one year Access to a smartphone and having media literacy (ability to work with a smartphone) Not being in the relapse stage Not suffering from any other acute or chronic disease based on self-report and medical record, ability to speak (speech and hearing) Not having dementia and known mental disorders based on the person's statements and medical record Patients should not receive other education related to methods of dealing with stress, anxiety and depression Minimum literacy Obtaining a score of 0-5.5 on the Extended Disability Status Scale Not suffering from other autoimmune diseases (psoriasis, myasthenia gravis) Not suffering from neurological diseases (Parkinson, epilepsy)

Exclusion criteria:
Inability of the patient to continue participating in the research for any reason (accident, death or migration to another city) Unwillingness to continue cooperation pregnancy drug use Physical limitations Making specific changes during the study in people's lifestyle or treatment process

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random blocks will be used in order to conceal the randomized allocation of concealment and balance during and after the study. For this purpose, the site sealedenvelope is used. The total sample size, the number of studied groups, and the number of blocks in question (blocks of 4) will be entered on the mentioned site, and its output will be a randomized list including the number of samples separated by the studied groups (control and intervention). Then, the eligible research samples will be selected and based on the priority of reference, each of them will be assigned a code, and by matching that number with the random block allocation list, the patients participating in the research will be assigned to theintervention group and the control group

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
Research Ethics Committees of Arak University of Medical Sciences

Street address
Malek St.Arak

City
Arak

Province
Markazi

Postal code
3813944438

Approval date
2024-01-10, 1402/10/20

Ethics committee reference number
IR.ARAKMU.REC.1402.199

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
Stress is one of the consequences of MS.

Timepoint
Once before the intervention, once immediately after the intervention, four weeks after the intervention

Method of measurement
stress, anxiety and depression questionnaire

2

Description
Anxiety is one of the consequences of MS.

Timepoint
Once before the intervention, once immediately after the intervention, four weeks after the intervention
Method of measurement
stress, anxiety and depression questionnaire

3

Description
Depression is one of the consequences of MS.
Timepoint
Once before the intervention, once immediately after the intervention, four weeks after the intervention
Method of measurement
stress, anxiety and depression questionnaire

4

Description
The understanding of the disease is the influencing factor on how patients deal with their disease.
Timepoint
Once before the intervention, once immediately after the intervention, four weeks after the intervention
Method of measurement
Brief Illness Perception Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to routine training, people in the intervention group will receive self-regulation training based on the Levantal model in four to five offline sessions through virtual networks as a group and two to three online sessions through Skype as a group. did Each offline session will be multimedia and average 20 minutes, and each online session will be lecture and average 15 minutes. All sessions will be designed based on the two cognitive and emotional dimensions of Leventhal's self-regulation model and will be designed within 5 weeks.
Category
Other

2

Description
Control group: Only the usual training provided by the clinic's treatment staff is received.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical centers affiliated to Arak University of Medical Sciences
Full name of responsible person
Mahsa Hosseini
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Dawood Hekmat Po
Street address
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Mahsa Hosseini

Position
Nursing student of Arak University of Medical Sciences

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Position
Nursing master's student

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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable