Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of (EMDR) and Positive Psychotherapy in Depression and Quality of Life in Men and Women with MS

Protocol summary

Study aim
Comparing the effectiveness of desensitization treatment with eye movements and reprocessing with positive psychotherapy in reducing depressive symptoms and increasing the quality of life in women and men with Multiple sclerosis.

Design
Clinical trial with control group, with parallel groups, single-blind, randomized, phase 2 on 45 patients, and individual randomization was used.

Settings and conduct
Qazvin City, Bo Ali Hospital, the sampling method in the present study will be voluntary sampling, which will be randomly assigned to 2 experimental groups and a control group. First, the scores in depression and quality of life are determined with the pre-test, then after the implementation of the desired therapeutic interventions, the post-test will be performed to check their effectiveness.

Participants/Inclusion and exclusion criteria
Participants must have MS;The participants must be between the ages of 18 and 60 years oldm; and have the physical and mental ability to attend therapy intervention sessions; be interested in participating in the research: and fill out the informed consent form; They are assured that whenever Those who want can withdraw from the research; not receiving psychological treatments for at least 6 months before the intervention sessions or during the interventions.

Intervention groups
There are two intervention groups and a control group, a pre-test about quality of life and depression disorder is supposed to be taken from all three groups, then one group will not receive any intervention as a control group, and the second group will receive therapeutic intervention EMDR, and in the third group, positive psychotherapy treatment intervention is performed, then post-test is performed in all three groups.

Main outcome variables
Depression and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221228056957N1**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **prospective**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date
2023-02-28, 1401/12/09

Registrant information

Name
Azam Hoseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-16, 1401/12/25

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the Effectiveness of (EMDR) and Positive Psychotherapy in Depression and Quality of Life in Men and Women with MS

Public title
Treatment (AMDR) and Positive Psychotherapy in Depression and Quality of Life in Men and Women with MS.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Suffering from Multiple Sclerosis Having at least middle school education to understand the concepts treatment Obtaining informed consent to explain the proceess of therapeutic interventionand research Providing the necessary explanation about the necessity of attending treatment sessions Having the physical and mental ability to attend the treatment intervention sessions No receive psychological treatments for at least 6 months before intervention sessions Having an age rang of 18 to 60 years

Exclusion criteria:
Having less than middle school education Receiving psychological treatments during 6 months before starting the therapeutic intervention Being less than 18 or more than 60 years old

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The research will include voluntary sampling, wich will be randomly assigned to two experimental groups and one control group. First,the scores in depression and quality of life are determined with the pre-test, then after the implementation of the desired therapeutic intervention, the post-test will be implemented to check their effectiveeness.To calculate the sampel size in the semi - experimental research, the tableprepared by cohen in used (Cohen, 1986), (Dr. Zohra Sarmad et al.). In this research, the significance level is 0/05 and the power of the test is 0/84, in this research, 45 qualified peple are included in the research and they are randomly divided in to three groups of peple, two experimental groups and one control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
participants

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Islamic Azad University of Rodehen

Street address
Ayatollah Khamenei Blvd., Islamic Azad University., University complex., Rodehen., Iran

City
rodehen

Province
Tehran

Postal code
3973188981

Approval date
2022-11-30, 1401/09/09

Ethics committee reference number
IR.IAU.R.REC.1401.069

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 score

Timepoint
Before the intervention, after the intervention and 3 months after the intervention.

Method of measurement
Beck questionnaire

2

Description
Quality of life score

Timepoint
Before the intervention, after the intervention and 3 months after the intervention

Method of measurement
The Beck questionnaire is used to measure depression and the quality of life questionnaire of multiple sclerosis patients.

Secondary outcomes

1

Description
Anxiety score
Timepoint
Before and after study
Method of measurement
Kattle questionnaire

Intervention groups

1

Description
The first group consists of 15 participants, which is a treatment method of desensitization with eye movements and reprocessing, which includes 8 sessions:1-taking history, 2-preparation, 3-evaluation, 4-desensitization, 5-installation (replacement), 6 - Body scan, 7- Closure, 8- Re-evaluation. (Shapiro; 2001).
Category
Treatment - Other

2

Description
Intervention group: The second group consists of 15 participants, in which positive psychotherapy intervention is performed, positive psychology training sessions based on Seligman, Rashid and Park (2006) protocol, includes 8 sessions:1- Introduction and orientation 2- Personal capabilities and using them in a new way, 3- Cultivating positive emotions and mentioning blessings and things in life, 4- Personal heritage and having a purpose and goal in life, 5- Letters and visits of thanks, 6- Relationships Social positivity and happiness in life, 7- Working with peaceful reflection and avoiding haste, 8- Celebration and happiness and stabilization of happiness.
Category
Treatment - Other

3

Description
Control group: the third group which consists of 15 people, no therapeutic intervention is performed in this group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Buali Sina hospital
Full name of responsible person
Azam hoseini
Street address
No. 25,17Azadi Ave., Alvand Town., Qazvin province., Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
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Ayatollah Khamenei Blvd., Islamic Azad university., University complex., Rodehen., Iran
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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
Islamic Azad University
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
Islamic Azad University

Full name of responsible person
Azam

Position
PhD student / hospital supervisor

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Position
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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