

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The Effect of Emotion Regulation Training based on Gross model on Alexithymia and Emotional Adjustment in Patients with Multiple Sclerosis (MS)

Protocol summary

Study aim

Determine effect of emotion regulation training based on Gross model on alexithymia and emotional adjustment in patients with Multiple Sclerosis (MS)

Design

After approving the plan in the university research vice chancellor and receiving the code of ethics from the university research committee, the researcher refers to the clinics affiliated to Shiraz University of Medical Sciences, and after obtaining informed consent from the participants, the demographic information form and questionnaires Will be completed by participants. From the participants who have all the criteria for inclusion in the study, 50 people will be randomly selected and these people will be re-assigned to the intervention and control groups using block randomization method. The intervention group participates in 8 sessions of emotion regulation training based on Gross model. The control group will receive the routine interventions provided in the clinics during this period.

Settings and conduct

The environment of this research is all clinics affiliated to Shiraz University of Medical Sciences, where training sessions will be held in the training halls of the centers.

Participants/Inclusion and exclusion criteria

MS diagnosed by a neurologist who is not in the advanced stage of the disease; ability to read and write; no serious psychiatric illness (psychotic disorders); no use of psychotropic drugs; ability to participate in training; not attending training sessions excitement over the past six months.

Intervention groups

The intervention group participated in 8 emotion regulation training sessions based on Gross model. The time of each session is 90 minutes. The control group participates in educational interventions provided by the relevant associations

Main outcome variables

Improve the level of emotional adjustment and adjust the level of emotions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047691N1**

Registration date: **2020-08-20, 1399/05/30**

Registration timing: **prospective**

Last update: **2020-08-20, 1399/05/30**

Update count: **0**

Registration date

2020-08-20, 1399/05/30

Registrant information

Name

Narges Bayatfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3232 1320

Email address

n_bayatfar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Emotion Regulation Training based on Gross model on Alexithymia and Emotional Adjustment in Patients with Multiple Sclerosis (MS)

Public title

Effect of Emotion Regulation Training in MS patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having MS diagnosed by a neurologist who is not in an advanced stage of the disease Ability to writing and reading No serious psychiatric illness (psychotic disorders) Ability to participate in training Do not use psychedelics Lack of participation in emotion regulation training sessions during the last six months

Exclusion criteria:

Patients who are in the advanced stage of the disease. Intolerance of group activities.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the participants, those who meet all the criteria for entering the study will be randomly selected 50 people, who will be redistributed using the block randomization method in two groups of intervention and control. Each block size is 4.

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 Shiraz University of Medical Sciences

Street address

Hazrat Fatemeh School of Nursing and Midwifery, Namazi Square

City

Shiraz

Province

Fars

Postal code

7333245724

Approval date

2020-05-05, 1399/02/16

Ethics committee reference number

IR.SUMS.REC.1399.236

Health conditions studied**1****Description of health condition studied**

Emotion Regulation in Patient with MS

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****Description**

Improve the level of emotional adjustment and adjust the level of emotions

Timepoint

Start of intervention and one month after the end of the intervention

Method of measurement

Toronto Alexithymia Questionnaire and Rabio Emotional Adjusment Questionnaire

Secondary outcomes

empty

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

Intervention group: Interventions include eight Groos-based emotion regulation training sessions, held in groups (two sessions per week). The duration of each session was 90 minutes, with the first 30 minutes including the therapist's speech, the middle 30 minutes devoted to group discussion, and the final 30 minutes including reviewing assignments and debugging.

Category

Lifestyle

2

Description

Control group: During this period, they do not receive emotion regulation intervention

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Shiraz subspecialty clinic

Full name of responsible person

Ladan Zarshenas

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Shiraz- Namazi square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abas Rezaian Zade

Street address

Shiraz, Zand St., Central Building of the University of Medical Sciences

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Narges Bayatfar

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Full name of responsible person

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available