Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Street address
Shiraz- Namazi squre
City
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7332456127
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Abas Rezaiyan Zade
Street address
Shiraz, Zand St., Central Building of the University of Medical Sciences
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71345-1978
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rezaiana@sums.ac.ir
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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Associate professor
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Student

Latest degree
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Other areas of specialty/work
Nursery

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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