Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effectiveness of cognitive behavioral group therapy on early maladaptive schemas, functional flexibility, distress tolerance, and self-differentiation of women undergoing drug treatment

Protocol summary

Study aim
Determining the effectiveness of cognitive behavioral group therapy on early maladaptive schemas, functional flexibility, distress tolerance, and self-differentiation in women undergoing drug treatment with multiple sclerosis in Ahvaz.

Design
A controlled clinical trial with parallel groups, double-blind, randomized, on 40 patients. The rand function of Excel software was used for randomization.

Settings and conduct
Using purposive sampling, after referring to the Ahvaz MS Association and conducting a clinical interview by a clinical specialist, initially, 40 of them were selected by simple random sampling (drawing). Then, they were divided into 2 groups of 20 people and finally, they were assigned to the experimental group and the control group by simple random sampling. Blinding was not performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range 20 to 40 years, women with MS, no participation in other psychotherapy sessions at least one month before the study. Inclusion criteria: absence of more than two sessions, simultaneous participation in other psychological treatments, unwillingness to continue treatment.

Intervention groups
The Intervention Group Includes Women Undergoing Pharmacological Treatment With Multiple Sclerosis in Ahvaz City, Who Receive the Intervention: Cognitive Behavioral Group Therapy on Early Maladaptive Schemas, Action Flexibility, Distress Tolerance, and Self-Differentiation. The Comparison Group Includes Women Undergoing Pharmacological Treatment With Multiple Sclerosis in Ahvaz City, Who Receive the Intervention: (Receiving Standard Pharmacological Treatment and Not Receiving Cognitive Behavioral Group Therapy)

Main outcome variables
Early maladaptive schemas, functional flexibility, distress tolerance, and self-differentiation in women undergoing drug treatment for multiple sclerosis.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250529065966N1**
Registration date: **2025-07-26, 1404/05/04**
Registration timing: **prospective**

Last update: **2025-07-26, 1404/05/04**
Update count: **0**

Registration date
2025-07-26, 1404/05/04

Registrant information

Name
fatmeh deynavizadeh
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-07-31, 1404/05/09
Expected recruitment end date
2025-12-30, 1404/10/09
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effectiveness of cognitive behavioral group therapy on early maladaptive schemas, functional flexibility, distress tolerance, and self-differentiation of women undergoing drug treatment

Public title

The effect of cognitive behavioral group therapy on early maladaptive schemas, functional flexibility, distress tolerance, and self-differentiation in women.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 20 to 40 years for women with MS Definitive diagnosis of MS by a specialist doctor Signing a written consent form to participate in the research and adhere to treatment Minimum education: Diploma

Exclusion criteria:

Attending other psychotherapy sessions at least one month before the study Substance use and lack of psychotic symptoms and a history of brain diseases such as brain tumors

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The control group will not receive any intervention during the research, but to prevent factors that threaten the internal validity of the research, such as compensatory competition in the control group or demoralization, they will be assured that they will receive problem-solving skills training in the next round (after data collection).

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Ahvaz Branch

Street address

Golestan Highway - Farhang City - Islamic Azad University, Ahvaz Unit

City

AHWAZ

Province

Khouzestan

Postal code

3733361349

Approval date

2024-12-24, 1403/10/04

Ethics committee reference number

IR.IAU.AHVAZ.REC.1403.421

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

Early maladaptive schemas: Deep, dysfunctional thought patterns and beliefs that are formed early in life and can cause psychological problems.

Timepoint

At the beginning of the study (before the intervention) and after about a month and a half of receiving the cognitive behavioral therapy intervention

Method of measurement

Young's Early Maladaptive Schemas Questionnaire

Secondary outcomes

1

Description

Functional flexibility: A person's ability to adapt their behaviors and attitudes to different situations and changing circumstances.

Timepoint

At the beginning of the study (before the intervention) and after about a month and a half of receiving the cognitive behavioral therapy intervention

Method of measurement

Functional Flexibility Questionnaire: Connor and Davidson (2003)

2

Description
At the beginning of the study (before the intervention) and after about a month and a half of receiving the cognitive behavioral therapy intervention
Timepoint
At the beginning of the study (before the intervention) and after about a month and a half of receiving the cognitive behavioral therapy intervention
Method of measurement
Distress Tolerance Questionnaire: Simmons and Gahr (2005)

3

Description
Self-differentiation: The ability of an individual to maintain their identity and independence in close relationships, without losing connection and intimacy.
Timepoint
At the beginning of the study (before the intervention) and after about a month and a half of receiving the cognitive behavioral therapy intervention
Method of measurement
Skowron and Friedlander Differentiation Questionnaire:

Intervention groups

1

Description
Type of intervention: In addition to receiving standard medication for multiple sclerosis (as prescribed by a specialist), this group participates in 12 sessions of cognitive-behavioral group therapy (CBT). Sessions are held weekly, each session lasting 90 minutes, at the counseling center. The intervention includes identifying and modifying early maladaptive schemas, training in functional flexibility, distress tolerance, and self-differentiation skills. Sessions are conducted by an experienced clinical psychologist trained in cognitive-behavioral therapy in groups (6 to 10 people per group).
Category
N/A

2

Description
Control group: The comparison group includes women undergoing drug treatment for multiple sclerosis in Ahvaz who receive the intervention (receiving standard drug treatment and not receiving cognitive behavioral group therapy). Also, there will be no intervention for the control group. However, to prevent threats to the internal validity of the test, the intervention will be implemented for them after the end of the study. After completing the training period, both the experimental and control groups (40 people) will be re-assessed by questionnaires that measure the dependent variables (early maladaptive schemas, functional flexibility, distress tolerance, self-differentiation) as a post-test, and finally, after one month of the post-test, both groups will be re-assessed.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University, Ahvaz Unit
Full name of responsible person
Sasan Bavi
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Sponsors / Funding sources

1

Sponsor
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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

Sasan Bavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Fatmeh Deynavizadeh

Position

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable