Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Schema Therapy on Quality of Life and Psychological Well-being in Women with Multiple Sclerosis

Protocol summary

Study aim
To determine the effectiveness of schema therapy on quality of life and psychological well-being in women with multiple sclerosis (MS).

Design
This study will be conducted as a quasi-experimental trial with a pretest, posttest, and follow-up design and a control group; allocation to groups will be performed by simple random assignment with a 1:1 ratio.

Settings and conduct
This study will be conducted at Imam Ali Psychiatric and Neurological Specialty Clinic, Zanjan, during the second half of the Iranian year 1405. Participants will be recruited through convenience sampling and randomly allocated to two groups; a pretest will be administered; the experimental group will then receive 15 intervention sessions; a posttest will follow, and a follow-up assessment will be conducted two months later.

Participants/Inclusion and exclusion criteria
Inclusion: women who have a confirmed diagnosis of multiple sclerosis by a specialist physician; are aged 20 to 60 years; will provide informed consent; have at least a high school education; will be receiving pharmacological treatment for MS; will not be receiving concurrent psychotherapy. Exclusion: those who have an acute or chronic psychiatric disorder; will be absent from more than two treatment sessions.

Intervention groups
Experimental group: will receive 15 weekly 90-minute group schema therapy sessions based on Young's protocol. Control group: will receive no intervention; will be offered the intervention after study completion.

Main outcome variables
Quality of life (measured with the Multiple Sclerosis Quality of Life Questionnaire, MSQOL-54) and psychological well-being (measured with the 18-item short form of the Ryff Psychological Well-Being Scale) will be assessed at pretest, posttest, and follow-up.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260927071205N1**
Registration date: **2026-10-14, 1405/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-14, 1405/07/22**
Update count: **0**

Registration date
2026-10-14, 1405/07/22

Registrant information
Name
Mojtaba Rahnamazadeh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-14, 1405/07/22

Expected recruitment end date
2026-12-13, 1405/09/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effectiveness of Schema Therapy on Quality of Life and Psychological Well-being in Women with Multiple Sclerosis

Public title
Effect of Schema Therapy on Quality of Life and Psychological Well-being in Women with MS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of multiple sclerosis by a specialist physician Age between 20 and 60 years Informed consent to participate At least a high school education Receiving pharmacological treatment for MS Not receiving concurrent psychotherapy
Exclusion criteria:
Acute or chronic psychiatric disorder Absence from more than two treatment sessions
Age
From **20 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
After determining the sample size, 30 participants will be randomly allocated, using simple random assignment by lottery, into two equal groups of experimental and control (15 participants each).
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 Committee of Islamic Azad University, Ayatollah Amoli Branch
Street address
No. 40, Fajr 11, Noor Street
City
Amol
Province
Mazandaran
Postal code
4616915686
Approval date
2025-09-02, 1404/06/11
Ethics committee reference number
IR.IAU.AMOL.REC.1404.136

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
Quality of life (measured with the Multiple Sclerosis Quality of Life Questionnaire, MSQOL-54) and psychological well-being (measured with the 18-item short form of the Ryff Psychological Well-Being Scale) will be assessed at pretest, posttest, and follow-up
Timepoint
Pretest (before the intervention), posttest (immediately after the 15th session), and follow-up (two months after the end of the intervention)
Method of measurement
uality of life using the Multiple Sclerosis Quality of Life-54 (MSQOL-54) questionnaire, and psychological well-being using the 18-item short form of Ryff's Psychological Well-Being Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in this group receive "Group Schema Therapy" based on Young's standard protocol for MS patients. The program consists of 15 weekly 90-minute sessions (total of 15 weeks) as follows: Phase 1: Assessment and Psychoeducation (Sessions 1–4)Objectives: Identifying Early Maladaptive Schemas (e.g., Defectiveness, Dependence, Self-Sacrifice) and developing an understanding of the relationship between schemas and disease experiences.Activities:Session 1: Introduction to therapy and group principles, completion of the YSQ-S3 questionnaire, reviewing the patient's life history and its connection to schemas.Session 2: Analysis of schemas activated by the illness (e.g., "I am worthless" due to physical disability), psychoeducation

on the concept of "Schema Modes" (Vulnerable Child, Punitive Parent).Sessions 3 & 4: Utilization of the "Historical Imagery" technique to explore the roots of schemas (e.g., childhood rejection experiences).Phase 2: Schema Change and Cognitive Restructuring (Sessions 5–10)Objectives: Weakening maladaptive schemas and strengthening the "Healthy Adult" mode.Activities: Session 5: Schema dialogue: Dialoguing with the "Defectiveness" schema as a separate entity.Session 6: "Letter Therapy" exercise: Writing letters to schemas from the perspective of the Healthy Adult.Sessions 7 & 8: Cognitive restructuring using belief challenge worksheets (e.g., replacing "I am a burden to others" with "I am valuable despite my limitations").Sessions 9 & 10: "Limited Emotional Catharsis" technique to reduce anger toward the body.Phase 3: Reinforcing Adaptive Behaviors and Relapse Prevention (Sessions 11–15)Objectives: Replacing maladaptive behavioral patterns with healthy behaviors.Activities:Session 11: Designing a "Behavioral Plan" to reduce excessive self-sacrifice (e.g., saying no to unreasonable requests from others).Session 12: Role-playing to practice constructive social interactions. Sessions 13 & 14: Chair technique practice for schema modes: Dialogue between the "Vulnerable Child" and the "Healthy Adult".Session 15: Reviewing achievements, formulating a long-term self-care plan, and final assessment (Young, 2023).

Category
Behavior

2

Description
Control group: Control group: Participants in this group receive no psychological intervention during the study period and are placed on a waiting list. For ethical considerations, after the completion of the study, post-test, and follow-up assessments, an abbreviated course of Schema Therapy will be offered to the control group.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Ali (AS) Specialized Psychiatry and Mental Health Clinic

Full name of responsible person
Mojtaba Rahnamazadeh

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No. 40, Fajr 11, Noor Street

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Esmaeil Fattahi

Street address
Islamic Azad University, Ayatollah Amoli Branch, University Access Road, 5th kilometer of the old Amol-Babol road, Amol, Mazandaran

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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
Mojtaba Rahnamazadeh

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
To protect participants' confidentiality, and in accordance with the informed consent, which permits the use of data only for the purposes of this study, there is no plan to share individual participant data. Results will be reported at the group level.
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