Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison Of The Effectiveness Of Acceptance And Commitment Based Therapy With Schema Therapy On Depression, Health Anxiety, Adaptive Behavior And Psychological Hardiness In Patients With MS In Isfahan During The Covid-19 Epidemic

Protocol summary

Study aim
A comparative study of the effectiveness of acceptance and commitment therapy with schema therapy on depression, health anxiety, adaptive behavior, and psychological hardiness in patients with multiple sclerosis in Isfahan during the Covid-19 epidemic.

Design
This is a three-arm, parallel-group, semi-experimental trial. Participants will be randomly assigned to two intervention groups (ACT or Schema Therapy) or a waitlist control group.

Settings and conduct
The study will be conducted in Isfahan, Iran. Participants will be randomly assigned to ACT, Schema Therapy, or a waitlist control group. Interventions include 8 weekly 2-hour sessions, with outcomes assessed at baseline, post-intervention, and follow-up by blinded assessors using concealed computerised randomisation.

Participants/Inclusion and exclusion criteria
Participants in this study will include patients diagnosed with Multiple Sclerosis (MS) confirmed by a neurologist, aged between 18 and 60 years, who are able to read and write in Persian, have a stable medical condition without acute relapse during the last month, and provide informed consent to attend group therapy sessions. Exclusion criteria will be the presence of severe psychiatric disorders such as psychosis or bipolar disorder, current participation in other psychological interventions, substance abuse or dependence, cognitive impairments interfering with participation, and absence from more than two intervention sessions.

Intervention groups
This study includes three groups: two intervention groups receiving 8 weekly 2-hour sessions of ACT or Schema Therapy, and a waitlist control group attending a 2-hour MS educational workshop.

Main outcome variables
Depression scores; Health anxiety scores; Adjustment behavior scores; Psychological resilience scores

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250807066781N1**
Registration date: **2025-09-02, 1404/06/11**
Registration timing: **prospective**

Last update: **2025-09-02, 1404/06/11**
Update count: **0**

Registration date
2025-09-02, 1404/06/11

Registrant information

Name
lotfollah saberian
Name of organization / entity
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Iran (Islamic Republic of)
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+98 913 591 1725
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-09-23, 1404/07/01
Expected recruitment end date
2026-02-20, 1404/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison Of The Effectiveness Of Acceptance And Commitment Based Therapy With Schema Therapy On Depression, Health Anxiety, Adaptive Behavior And Psychological Hardiness In Patients With MS In Isfahan During The Covid-19 Epidemic

Public title
Comparison Of The Effectiveness Of Acceptance And Commitment Based Therapy With Schema Therapy On Depression, Health Anxiety, Adaptive Behavior And Psychological Hardiness In Patients With MS In Isfahan During The Covid-19 Epidemic.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of MS based on medical records or neurologist criteria. Age: 18 to 60 years. Education level: Minimum literacy (to complete questionnaires). Clinical status: Mild to moderate depression (based on standard questionnaire) Written consent: Informed willingness to participate in research.
Exclusion criteria:
Having severe psychiatric disorders Changing psychiatric or neurological medications during the study Concurrent participation in other psychological treatments Missing more than two therapy sessions Unwillingness to continue cooperation or withdrawal of consent Having a serious physical illness that prevents you from continuing your sessions
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were randomly assigned to one of three groups—Acceptance and Commitment Therapy (ACT), Schema Therapy, or Waitlist Control—in a 1:1:1 ratio. To ensure balance and control for potential confounders, randomization was stratified by gender (male/female) and disease severity (EDSS < 3.5 vs. ≥ 3.5). Within each stratum, variable block sizes (3, 6, and 9) were used to generate the allocation sequence. The random sequence was generated by an independent researcher using computer-based random number generation with a fixed seed to allow reproducibility. Allocation concealment was achieved through the use of sequentially numbered, opaque, sealed envelopes (SNOSE), prepared for each stratum. After informed consent was obtained and baseline assessment (T1) was completed, the study coordinator opened the next envelope corresponding to the participant's stratum to determine group assignment. Outcome assessors at post-test (T2) and follow-up (T3) were blinded to participants' group allocation to reduce bias. Data analysis followed the intention-to-treat principle, and participant flow through each stage of the study was documented using a CONSORT flow diagram.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of psychological interventions, it was not possible to blind the participants to the type of treatment they received. However, to minimize bias, the study was conducted in a single-blind manner. Specifically, the outcome assessor who was responsible for data collection and analysis was blinded to the group allocation (Acceptance and Commitment Therapy vs. Schema Therapy). This procedure was implemented to enhance the accuracy of assessments and reduce the influence of researcher or participant expectations on the study outcomes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Islamic Azad University Zahedan Branch
Street address
Islamic Azad University, Zahedan Branch
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
7617779515
Approval date
2025-07-26, 1404/05/04
Ethics committee reference number
IR.IAU.ZAH.REC.1404.040

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
Timepoint
pre and post interventions
Method of measurement
Beck depression questionaire

Secondary outcomes

1

Description
anxiety
Timepoint
pre and post intervention
Method of measurement
Beck Anxiety Inventory

2

Description
Adaptive Behavior
Timepoint
pre and post intervention
Method of measurement
Lambert Adaptive Behavior Scale

3

Description
Hardiness
Timepoint
pre and post intervention
Method of measurement
Long & Goulet hardiness questionaire

Intervention groups

1

Description
Intervention group: Acceptance and Commitment Therapy (ACT) group:Participants in this group will attend structured group sessions based on the ACT approach. The intervention focuses on enhancing acceptance of internal experiences, fostering present-moment awareness, clarifying personal values, and promoting commitment to adaptive behaviors.
Category
Treatment - Other

2

Description
Intervention group: Schema Therapy group:Participants in this group will attend group sessions based on Young's schema therapy model. The intervention emphasizes identifying and modifying early maladaptive schemas and supporting patients in developing healthier emotional and behavioral patterns.
Category
Treatment - Other

3

Description
Control group: Participants in the control group received only their routine medical care throughout the study period and did not attend any of the psychological intervention sessions (Acceptance and Commitment Therapy or Schema Therapy). To address ethical considerations, access to similar therapeutic services was provided to these participants after the completion of the study.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan MS Association
Full name of responsible person
Ahmad Famil Dardashti
Street address
2nd Floor, Basat Building, Beginning of West Hasht Behesht Street, Neshat Street, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mehdi Shahreki
Street address
Islamic Azad University, Zahedan Branch Complex,

Daneshgah (University) Street, Zahedan, Sistan and Baluchestan Province, Iran

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Province
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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
Private

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
Lotfollah Saberian

Position
Student

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

"Study results along with anonymized participant data"

When the data will become available and for how long

"From the time of publication until one year thereafter"

To whom data/document is available

"All researchers and clinical specialists"

Under which criteria data/document could be used

"For clinical and research purposes"

From where data/document is obtainable

Formal request to the corresponding author

What processes are involved for a request to access data/document

Initially discussed within the research team, and ultimately, the data will be shared upon approval

Comments