# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of effectiveness of interpretation bias correction training and acceptance and commitment therapy (ACT) on cognitive-behavioral and emotional symptoms of patients with multiple sclerosis (M.S).

## Protocol summary

**Study aim**

To compare the effectiveness of interpretation bias correction training and acceptance and commitment therapy on the cognitive-behavioral and emotional symptoms of patients with multiple sclerosis (MS).

**Design**

A clinical trial with a control group, using parallel groups, is conducted in a non-blinded manner on 54patients, with randomization performed using www.randomization.com.

**Settings and conduct**

Patients with MS who are members of the MS Association of Urmia will be randomly assigned to intervention and control groups using simple randomization, provided they meet the eligibility criteria.

**Participants/Inclusion and exclusion criteria**

The inclusion criteria for the study comprised a diagnosis of MS, an age range of 18 to 45years, possession of at least a high school diploma, and the necessity for identifying impairments in cognitive-behavioral and emotional symptoms assessed through interviews and tests. The exclusion criteria included concurrent treatment with other therapies, the emergence of symptoms due to substance use or bereavement, and a history of receiving similar interventions.

**Intervention groups**

Intervention group1: Over 4 weeks and each week 2 sessions of 90 minutes will be intervened. In the form of cognitive behavioral therapy, patients are taught to identify their negative interpretations and then be able to reconstruct them into more logical interpretations. Intervention group2:Over 4 weeks and each week 2 sessions of 90 minutes will be intervened. The content of these sessions will include 6 main axes of the acceptance and commitment approach along with the use of related metaphors in the sessions. Control group: In this research, no intervention is carried out for the control group and initially it is considered solely for measurement and observation.

**Main outcome variables**

cognitive bias; profile of psychosis; emotional information processing; M.S. self-efficacy; acceptance of illness.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20241026063497N1**
Registration date: **2025-05-13, 1404/02/23**
Registration timing: **retrospective**

Last update: **2025-05-13, 1404/02/23**
Update count: **0**

**Registration date**

2025-05-13, 1404/02/23

**Registrant information**

**Name**

saleh sadighi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 11 4308 0317

**Email address**

s.sadighi@urmia.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-12-30, 1403/10/10

**Expected recruitment end date**

2025-01-09, 1403/10/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of effectiveness of interpretation bias correction training and acceptance and commitment therapy (ACT) on cognitive-behavioral and emotional symptoms of patients with multiple sclerosis (M.S).

**Public title**

Comparison of effectiveness of interpretation bias correction training and acceptance and commitment therapy on patients with multiple sclerosis

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Must have a definitive diagnosis of multiple sclerosis. Must be at least 18 and at most 45 years old. Have at least a diploma. Damage in cognitive, behavioral and emotional symptoms examined in this research should be diagnosed by interview and test.

**Exclusion criteria:**

Receive other concurrent treatment. The symptoms are due to drug use and bereavement. Have a history of receiving similar interventions.

**Age**

From **18 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method was considered as simple randomization with individual random units. Subsequently, the final sample was divided into two experimental groups and one control group. The randomization process was carried out using the website www.randomization.com.

**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 Ethical Committee of Urmia University

**Street address**

University of Urmia, 11 km Sero Road, Azerbaijangharbi Province - Urmia

**City**

urmia

**Province**

West Azarbaijan

**Postal code**

5756151818

**Approval date**

2024-05-18, 1403/02/29

**Ethics committee reference number**

IR.URMIA.REC.1403.006

## 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**

cognitive bias

**Timepoint**

Before the intervention, the last intervention session and 2 months after the last intervention session

**Method of measurement**

Cognitive bias questionnaire of Woody, Chambless and Glass

### 2

**Description**

profile of psychosis

**Timepoint**

Before the intervention, the last intervention session and 2 months after the last intervention session.

**Method of measurement**

Depression, Anxiety, Stress Scale (DASS) Lavibond and Lavibond

### 3

**Description**

emotional information processing

**Timepoint**

Before the intervention, the last intervention session and

2 months after the last intervention session

**Method of measurement**

Emotional Information Processing Questionnaire Baker et al.'s

**4**

**Description**

M.S self-efficacy

**Timepoint**

Before the intervention, the last intervention session and 2 months after the last intervention session

**Method of measurement**

Multiple Sclerosis Self-Efficacy Questionnaire (MSSS)

**5**

**Description**

acceptance of illness

**Timepoint**

Before the intervention, the last intervention session and 2 months after the last intervention session

**Method of measurement**

Disease Acceptance Scale (ALS)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group 1: Training in interpretation bias modification: In the present study, while providing necessary explanations to patients and ensuring the confidentiality of their information, patients are trained over 4 weeks with 2 individual sessions of 90 minutes each per week in the form of cognitive-behavioral therapy to identify their negative interpretations and then be able to reconstruct them into more logical interpretations. The term 'interpretation bias' in this research refers to individuals' tendency to interpret ambiguous and neutral events negatively and threateningly. This bias can manifest in various areas such as social relationships, health, and job performance. During therapy sessions, various cognitive-behavioral techniques are used, such as thought recording, Socratic questioning, identifying cognitive errors (especially errors related to interpretation), providing supporting and opposing evidence, creating alternative perspectives, and behavioral exercises.

**Category**

Rehabilitation

**2**

**Description**

Acceptance and Commitment Therapy: In the present study, while providing the necessary explanations to the group members and ensuring the confidentiality of their information, patients are treated in a group setting and over 4 weeks, with 2 sessions per week lasting 90 minutes, under Acceptance and Commitment Therapy. The content of these sessions includes the 6 main components of the Acceptance and Commitment approach, along with the use of metaphors related to the sessions and practical exercises. During the sessions, various metaphors are used to facilitate understanding of Acceptance and Commitment approach concepts. For example, the metaphor of "quicksand" is used to show that trying to control unpleasant thoughts and feelings can lead to becoming more submerged in them, the metaphor of the "bus" is used to show that thoughts and feelings are the passengers on the bus and the individual is the driver and can choose their route, and the metaphor of "tug-of-war with a monster" is used to show that fighting unpleasant thoughts and feelings takes a lot of energy and it is better to drop the rope. During the sessions, the therapist plays the role of a facilitator and helps the members to identify their values, set committed goals, and face their unpleasant experiences with more acceptance and flexibility. The therapist also provides a safe and supportive environment so that members can share their experiences and support each other.

**Category**

Rehabilitation

**3**

**Description**

Control group: In this study, no intervention is performed for the control group, and it is initially considered solely for measurement and observation purposes.

**Category**

Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Urmia MS Association

**Full name of responsible person**

Simin Mahmod Akhgar

**Street address**

46 Unit, 4th Floor, Almas Gharb Building, Keshtegar Street, Urmia

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5713613948

**Phone**

+98 44 3224 6764

**Email**

anjomanmsurmia@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Urmia University
**Full name of responsible person**
Abbas Banj Shafiei
**Street address**
University of Urmia, 11 km Sarv Road, West Azerbaijan Province - Urmia
**City**
urmia
**Province**
West Azarbaijan
**Postal code**
5756151818
**Phone**
+98 44 3277 0555
**Email**
a.banjshafiei@urmia.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Urmia 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**
Urmia University
**Full name of responsible person**
Saleh Sadighi
**Position**
PhD Student
**Latest degree**
Master
**Other areas of specialty/work**
Psychology
**Street address**
Mir building, 55.3 Side alley, 55 Darya, Kelkaser, Amol
**City**
Amol
**Province**
Mazandaran
**Postal code**
4617139606
**Phone**
+98 11 4308 0317
**Email**
salehsadighi@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Urmia University
**Full name of responsible person**
Saleh Sadighi
**Position**
PhD student
**Latest degree**
Master
**Other areas of specialty/work**
Psychology
**Street address**
Mir building, 55.3 Side alley, 55 Darya, Kelakaser, Amol
**City**
Amol
**Province**
Mazandaran
**Postal code**
4617139606
**Phone**
+98 11 4308 0317
**Email**
salehsadighi@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Urmia University
**Full name of responsible person**
Saleh Sadigi
**Position**
PhD student
**Latest degree**
Master
**Other areas of specialty/work**
Psychology
**Street address**
Mir building, 55.3 Side alley, 55 Darya, Kelkaser, Amol.
**City**
Amol
**Province**
Mazandaran
**Postal code**
4617139606
**Phone**
+98 11 4308 0317
**Email**
salehsadighi@gmail.com

## 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**

Pre-test, Post-test, Retention test

**When the data will become available and for how long**

6 months after the results are published

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

Can be used for therapists in this field as well as researchers of review research, meta-analysis, etc.

**From where data/document is obtainable**

Saleh Sadighi

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

Official Request Letter.

**Comments**