Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of Compassion-focused Acceptance and Commitment Therapy on Experiential avoidance, Self-care, Pain self-efficacy and pain catastrophizing in Patients with Multiple Sclerosis

Protocol summary

Study aim
The present study was conducted to investigate the effectiveness of compassion-focused acceptance and commitment therapy on experiential avoidance, self-care, pain self-efficacy and pain catastrophizing in patients with multiple sclerosis.

Design
The clinical trial consisted of experimental and control groups, without blinding, randomized, and conducted on 36 patients. Randomization was performed using the rand function in Microsoft Excel software.

Settings and conduct
The clinical trial was conducted at the educational therapeutic center of Boali Sina in Sari County.

Participants/Inclusion and exclusion criteria
- Diagnosis of multiple sclerosis (MS) by a neurologist. - More than one month since the diagnosis of MS. - Higher than primary education level. - Age between 18 and 61 years old. - No history of serious psychiatric illness (psychosis) or hospitalization in a psychiatric hospital. - No substance abuse or addiction. - Willingness and informed consent to participate in the research project.

Intervention groups
Two groups of patients with criteria for inclusion were used. Group 1 was our experimental group and received cognitive-behavioral therapy, while Group 2 served as the control group and received no intervention.

Main outcome variables
The results of this research indicate that Acceptance and Commitment Therapy focused on compassion can be an effective treatment for patients with multiple sclerosis. It can be taught in relevant centers and implemented for use.

General information

Reason for update

Acronym
CFACT for MS

IRCT registration information
IRCT registration number: **IRCT20240217061032N1**
Registration date: **2024-04-25, 1403/02/06**
Registration timing: **retrospective**

Last update: **2024-04-25, 1403/02/06**
Update count: **0**

Registration date
2024-04-25, 1403/02/06

Registrant information

Name
Mehdi Ebrahimpour Azizi
Name of organization / entity
University of Mohaghegh Ardabili
Country
Iran (Islamic Republic of)
Phone
+98 11 3533 8953
Email address
mehdii.ebrahimpour@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2023-11-21, 1402/08/30

Actual recruitment start date
2023-10-27, 1402/08/05

Actual recruitment end date
2023-11-21, 1402/08/30

Trial completion date
2023-11-22, 1402/09/01

Scientific title
The effectiveness of Compassion-focused Acceptance and Commitment Therapy on Experiential avoidance, Self-care, Pain self-efficacy and pain catastrophizing in Patients with Multiple Sclerosis

Public title
Effectiveness of Compassion-Focused Acceptance and Commitment Therapy in Patients With Multiple Sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Be diagnosed with MS based on the diagnosis of a neurologist More than a month has passed since the diagnosis of MS Literacy level higher than cycle Be between the ages of 18 and 61 Willingness and informed consent to participate in the research project Expansion Disability status score (EDSS) between 0 and 5

Exclusion criteria:
Having a history of serious mental illness (psychotic) and a history of hospitalization in a mental hospital Drug addiction Lack of informed consent to participate in the research project

Age
From **18 years** old to **61 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**
Actual sample size reached: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Volunteers to participate in the project were divided into two random groups, experimental and control, using the rand function of Excel software, using a simple randomization method. Concealment was not used and we only used the experimental and control groups to evaluate the applied psychological intervention.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study follows a basic design and is of the experimental type with a pretest-posttest control group design. There were two groups in this study: experimental and control. Pretests were administered to both the experimental and control groups, after which the experimental group received a psychological intervention, while the control group simply remained on the waiting list. Finally, posttests were administered to both groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mohaghegh University

Street address
University of Mohaghegh Ardabili, Daneshgah Street, Ardabil , Iran

City
Ardabil

Province
Ardabil

Postal code
۱۱۳۶۷ - ۵۶۱۹۹

Approval date
2023-09-26, 1402/07/04

Ethics committee reference number
IR.UMA.REC.1402.029

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
Expanded Disability Status Scale (EDSS)

Timepoint
Before the start of the intervention - after the start of the intervention

Method of measurement
Medical examination

2

Description
AAQ-II

Timepoint
Before the start of the intervention - after the start of the intervention

Method of measurement
Questionnaire

3

Description
Self-care questionnaire by Morvati Sharif Abad et al.

Timepoint
Before the start of the intervention - after the start of the intervention
Method of measurement
questionnaire

4

Description
Pain self-efficacy questionnaire (Nicolas, 2007)
Timepoint
Before the start of the intervention - after the start of the intervention
Method of measurement
questionnaire

5

Description
Pain Catastrophizing Scale (PCS)
Timepoint
Before the start of the intervention - after the start of the intervention
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receiving 10 sessions of one and a half hours of on Compassion Focused Acceptance and Commitment Therapy, taken from the book Compassion-focused therapy for ACT therapists by Dennis Tirch.
Category
Behavior

2

Description
Control group: did not receive any treatment and were only on the waiting list
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu-Ali Sina Teaching Hospital
Full name of responsible person
Mohammad Baghbanian
Street address
Bu-Ali Sina Teaching Hospital, Pasdaran Blvd, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4815838477
Phone
+98 11 3334 3014
Fax
Email
Mohammadbaghbanian@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Mohaghegh Ardabili
Full name of responsible person
Ali Sheykholeslami
Street address
University of Mohaghegh Ardabili, Daneshgah Street, Ardabil , Iran
City
Ardabil
Province
Ardabil
Postal code
56199-13131
Phone
+98 11 3150 5622
Email
Sheykholeslami@uma.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Mohaghegh Ardabili
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
University of Mohaghegh Ardabili
Full name of responsible person
Mehdi Ebrahimpour Azizi
Position
Student
Latest degree

Master

Other areas of specialty/work
Psychology

Street address
12 Tawheed Alley, Sharifi Boulevard, Babolsar, Mazandaran, Iran

City
Babolsar

Province
Mazandaran

Postal code
4741756476

Phone
+98 11 3533 8953

Email
mehdii.ebrahimpour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Mohaghegh Ardabili

Full name of responsible person
Nader Hajloo

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
University of Mohaghegh Ardabili, Daneshgah Street, Ardabil , Iran

City
Ardabil

Province
Ardabil

Postal code
۱۱۳۶۷ - ۵۶۱۹۹

Phone
+98 45 3150 0000

Email
hajloo53@uma.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
University of Mohaghegh Ardabili

Full name of responsible person
Mehdi Ebrahimpour Azizi

Position
Student

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
12 Tawheed Alley, Sharifi Boulevard,

City
Babolsar

Province
Mazandaran

Postal code
4741756476

Phone
+98 11 3533 8953

Email
mehdii.ebrahimpour@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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Documents will be made available to references without mentioning their names upon request.

When the data will become available and for how long
The access period starts 6 months after the results are published.

To whom data/document is available
University professors and researchers.

Under which criteria data/document could be used
If used to get ideas and do similar designs

From where data/document is obtainable
Apply to my university email

What processes are involved for a request to access data/document
The request of the person who wishes will be applied after checking the conditions during 1 week

Comments