

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Evaluating the effectiveness of acceptance and commitment therapy with a focus on compassion and yoga exercises on self-management, difficulty in emotion regulation, pain acceptance and pain catastrophizing in multiple sclerosis patients.

#### Protocol summary

##### Study aim

Determining the equivalence of acceptance and commitment-based therapy focusing on compassion and yoga exercises on self-management, difficulty in emotion regulation, pain acceptance and pain catastrophizing in multiple sclerosis patients.

##### Design

A clinical trial with a control group and two other groups, a blind strain, by available sampling method, on 45 patients.

##### Settings and conduct

This study is conducted on MS patients, and the setting for the group receiving acceptance and commitment therapy with a focus on compassion is the MS Association and the group doing yoga exercises is a yoga club.

##### Participants/Inclusion and exclusion criteria

Entry conditions: definitive diagnosis based on neurological examinations and magnetic resonance imaging by a specialist doctor; not suffering from other neurological and chronic diseases at the same time; Not suffering from psychological disorders. Non-entry conditions: suffering from other neurological and chronic diseases; suffering from severe psychological disorders at the same time; Taking psychiatric and psychoactive drugs

##### Intervention groups

One group receives Compassion-Focused Acceptance and Commitment Therapy, which is a third-wave therapy that combines an Acceptance and Commitment Therapy approach with a Compassion-Focused Therapy approach. A group of yoga exercises that combine asana (movement), pranayama (breath control), relaxing meditation. The control group receives no treatment approach..

##### Main outcome variables

Self management ; Difficulty in regulating emotions;  
Acceptance of pain; Pain catastrophizing

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230222057491N1**

Registration date: **2023-03-06, 1401/12/15**

Registration timing: **prospective**

Last update: **2023-03-06, 1401/12/15**

Update count: **0**

##### Registration date

2023-03-06, 1401/12/15

##### Registrant information

##### Name

Farhad Jahangiri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 4250 6423

##### Email address

jahangirifarhad3@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-11, 1401/12/20

##### Expected recruitment end date

2023-03-19, 1401/12/28

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluating the effectiveness of acceptance and commitment therapy with a focus on compassion and yoga exercises on self-management, difficulty in emotion regulation, pain acceptance and pain catastrophizing in multiple sclerosis patients.

**Public title**  
Comparison of the effect of therapy based on acceptance and commitment with a focus on compassion and yoga exercises on MS patients

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Definitive diagnosis based on neurological examinations and magnetic resonance imaging by a specialist doctor  
Not suffering from other neurological and chronic diseases at the same time  
Absence of mild cognitive problems by short mental state test  
Absence of severe psychological disorders  
Membership in the Multiple Sclerosis Association  
Age range from 26 to 44 years  
Literacy for reading and writing  
**Exclusion criteria:**  
Suffering from other neurological and chronic diseases  
Suffering from severe psychological disorders at the same time  
Having cognitive problems  
Taking psychiatric and psychoactive drugs  
No membership in the Multiple Sclerosis Association  
Age less than 26 and more than 44 years  
Lack of literacy

**Age**  
From **26 years** old to **44 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **45**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Available sampling and individual randomization unit. In this study, using non-residential sampling methods available and voluntarily, citing previous research records and valid research books of 45 are selected as statistical samples. In this study we have three groups, people are randomly in each group as I explain below. Group 1 receive admission-based and commitment treatment focusing on compassion, the second group performs yoga exercises, and the third group is a control group that does not receive any treatment. 45 pieces of paper are numbered from number 1 to 45, group one from 1 to 15 and Group two are from 16 to 30 and Group 3 from number 31 to 45. Participants are unaware of

what group numbers are. We urge people to draw one of the papers that are unclear, and the number that each person has to show in which group is randomly placed.

**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**  
Ethics committee of Borujerd Islamic Azad University of Medical Science  
**Street address**  
Imam Khomeini University Complex, Nawab. 3 km Yadgar Imam Road, Nawab Square, Borujerd  
**City**  
Borujerd  
**Province**  
Lorestan  
**Postal code**  
6915136335

**Approval date**  
2023-02-12, 1401/11/23

**Ethics committee reference number**  
IR.IAU.B.REC.1401.053

**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**  
Self-management is a score that the subject receives through the self-management scale of MS patients (revised) by Bishop and Frain (2011). This self-report tool is compiled in 24 items and 5 subscales. The higher the person's score, the higher the level of self-management. The range of changes in this tool is between 24 and 120.

**Timepoint**  
At the beginning of the study, that is, before the

intervention in the form of a pre-test and after the intervention in the form of a post-test and then in the follow-up

#### **Method of measurement**

The Multiple Sclerosis Self-Management Scale-Revised (MSSM-R)

## **2**

#### **Description**

Difficulty in emotion regulation is the score that the subject receives through the difficulty of emotion regulation scale by Gratz and Roemer (2004). This self-report tool has 36 items and 6 subscales. Higher scores mean more difficulty in emotional regulation.

#### **Timepoint**

At the beginning of the study, that is, before the intervention in the form of a pre-test and after the intervention in the form of a post-test and then in the follow-up

#### **Method of measurement**

Difficulties in Emotion Regulation Scale

## **3**

#### **Description**

Acceptance of pain is the score that the subject receives from the Chronic Pain Acceptance Questionnaire - Revised by McCracken et al. (2004). The questionnaire has 20 items and two factors of participation in activity and desire for pain have been identified in this questionnaire. To obtain a total score, we add the scores of each factor together. Higher scores indicate higher levels of acceptance.

#### **Timepoint**

At the beginning of the study, that is, before the intervention in the form of a pre-test and after the intervention in the form of a post-test and then in the follow-up.

#### **Method of measurement**

Chronic Pain Acceptance Questionnaire - Revised

## **4**

#### **Description**

Pain catastrophizing is a score that the subject receives through the pain catastrophizing scale of Sullivan et al. (1995). This questionnaire contains 13 statements about the person's thoughts and feelings during past painful experiences, which has subscales of rumination, magnification, and helplessness. Questions are scored on a 5-point Likert scale, and a higher total score indicates a higher level of catastrophizing thoughts and feelings.

#### **Timepoint**

At the beginning of the study, that is, before the intervention in the form of a pre-test and after the intervention in the form of a post-test and then in the follow-up.

#### **Method of measurement**

Pain Catastrophizing Scale

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: This group includes MS patients who receive treatment based on acceptance and commitment with a focus on compassion. The sessions include one pre-session and ten treatment sessions. It lasts 72 days in total. The pre-meeting is related to getting to know the group members and each other, checking the reasons for participation and expectations, the necessity of psychotherapy, introducing the approach, stating the rules and structure of the meetings, obtaining written consent and performing the pre-test, and the next ten treatment sessions will receive therapeutic intervention. . The first session: performing awareness training (body observation exercise), establishing a therapeutic alliance (metaphor of 2 mountains), expressing control as a performance measurement problem (metaphor of sand pool), introducing emotion regulation systems and assigning homework. It takes a total of 72 days. The second session: reviewing homework, practicing mindfulness, getting to know the old and new brain, introducing the dimensions of compassion and the three competitors of kindness (metaphor of the mother cat), creating creative frustration (metaphor of pressing the work board), training to create a blameless perspective and determine Homework. Third session: 3rd: Reviewing assignments, doing a brief mindfulness practice, creating sensitivity to human suffering in the context of the present, extending conscious mind compassion to the outside world and developing sensitivity to the disturbances of the present, practicing compassionate attention, filling in the daily compassionate worksheet and reviewing experiences and assigning homework. The fourth session: reviewing assignments, practicing compassionate attention, teaching and creating compassionate disruption, applying the metaphor of the freeway of the mind, and practicing the white room in a compassionate context, and assigning homework. Fifth: Homework Review, Compassionate Mindfulness Practice, Compassionate Intention Training, Compassionate Letting Go Metaphor, Ending War Practice Rope, and Homework Assignments. Sixth: Review assignments, practice compassionate attention, provide necessary training about the observer self in a compassionate context with an emphasis on empathy and compassion as a common human sense, the metaphor of the sky and the weather, perform the 2-chair technique for the inner critic and compassionate self, and determine Homework. The seventh session is reviewing homework, practicing mindfulness, teaching and freely choosing compassionate values with an emphasis on health care and the importance of loving relationships, determining life values in a context of compassion in the nine domains (compass of life), magic wand metaphors and Mind reading machine and homework assignments. Eighth session: Reviewing assignments, practicing

mindfulness, teaching committed action in line with compassionate values with an emphasis on healing human suffering, children's practice on the bus, setting 4 goals and how to deal with obstacles to action, and setting homework. Ninth session: Reviewing assignments , practicing awareness attention, cultivating a kind mind in the framework of functional contextualism, practicing kind self-imagery, practicing communicating with different aspects of oneself and setting homework. Tenth session: reviewing homework, doing awareness attention practice, reviewing and summarizing the contents, thanks and appreciation and post-test implementation.

**Category**

Treatment - Other

**2****Description**

Intervention group: This group includes people who have been definitively diagnosed with MS through neurological examinations and magnetic resonance imaging, which have been confirmed by a specialist doctor and are recorded in the MS register. The members of this group do 24 sessions of yoga exercises. The time interval of the meetings is once every three days and it lasts 72 days in total.

**Category**

Treatment - Other

**3****Description**

Control group: people in this group do not undergo any psychological treatment or yoga exercises and remain on the waiting list. After the completion of the treatment sessions, at the same time as the other groups, they will be given a pre-test, post-test and follow-up test. are compared. Also, after 60 days, the subjects will answer the questions of the questionnaires again as a follow-up step.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Borujerd MS Association

**Full name of responsible person**

Fatemeh Yarahmadi

**Street address**

MS Association ., Special Medical Center of Borujerd Islamic Azad University, Resalat St, Shahid Molla Aghaei Ave ,Shahid Torabi blvd, phase 8 , Andisheh Town, Borujerd

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Library building, Imam Khomeini University Complex, Nawab.3 km Yadgar Imam Road, Nawab Square, Borujerd

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**Web page address****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**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Farhad Jahangiri

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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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**

Total data

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

A few months after the results were published

**To whom data/document is available**

Researchers and all those who read articles

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

For scientific research

**From where data/document is obtainable**

For academic and scientific journals

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

Online search process

**Comments**