Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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

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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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Full name of responsible person

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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

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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