Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of acceptance and commitment group therapy with emotion regulation on the severity of worry, alexithymia, resilience, and psychological well-being of female patients with multiple sclerosis in Ahvaz.

Protocol summary

Study aim

Explaining the difference in the effectiveness of acceptance and commitment group therapies with emotion regulation on the severity of worry, alexithymia, resilience, and psychological well-being of female patients with multiple sclerosis in Ahvaz

Design

Three-group quasi-experimental (clinical trial with control group, with parallel groups, purposive sampling, with randomized assignment on 45 patients.

Settings and conduct

A randomized controlled clinical trial was conducted in the Ahvaz MS Association, a women's society, purposive sampling, 45 participants in three groups (15 in each group), random assignment to groups, and standard questionnaires were completed in two pre- and post-test phases. Blinding was not possible. Group 1 (ACT): Received group therapy based on acceptance and commitment in 8 weekly 90-minute sessions. Group 2 (ERT): Received group therapy based on emotion regulation in 8 weekly 90-minute sessions. Group 3 (Control): No psychological intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria:: No diagnosis of severe personality and clinical disorders, no substance or alcohol abuse. Exclusion critera:: Participation in other psychotherapy programs, receiving medication during the study period.

Intervention groups

1. Acceptance and Commitment Therapy Group: Experimental Group 1, the treatment protocol is implemented in 8 90-minute sessions, one session per week. 2. Emotion regulation-based therapy group: Experimental group 2. The treatment protocol is implemented in 9 90-minute training sessions, one session per week. 3.گروه کنترل: هیچگونه درمانی صورت نمی گیرد .

Main outcome variables

1. Resilience: It refers to the dynamic process of positive adaptation to difficult and unpleasant experiences. 2. Intensity of worry: It is a component of anxiety and is defined as the anticipation and expectation of unpleasant events in the future.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250929067413N1**
Registration date: **2025-10-28, 1404/08/06**
Registration timing: **prospective**

Last update: **2025-10-28, 1404/08/06**
Update count: **0**

Registration date

2025-10-28, 1404/08/06

Registrant information

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Zahra Mousavimoghadam

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-21, 1404/09/30

Expected recruitment end date

2026-02-14, 1404/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of acceptance and commitment group therapy with emotion regulation on the severity of worry, alexithymia, resilience, and psychological well-being of female patients with multiple sclerosis in Ahvaz.

Public title

Investigating the effect of group psychological therapies on reducing anxiety and improving mental health in women with multiple sclerosis (MS).

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Female Definitive diagnosis of multiple sclerosis (MS) Ability to participate regularly in group meetings

Exclusion criteria:

Having a severe psychiatric disorder Participation in other concurrent psychological interventions Unwillingness to continue cooperation Reluctance to fill out questionnaires

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization and Allocation Concealment Method and Process The randomization unit in this study was individual; meaning that each participant was independently and separately assigned to one of the two treatment groups. To maintain and balance the number of participants in the groups, a block randomization unit method with a block size of 4 was used. Randomization sequence using a random number tableIt was standardized and manually generated. In this sequence, the numbers 1 and 2 represented the treatment groups, respectively, and the allocation was based on randomly extracted numbers to maintain equal composition between the groups (15 people in each group). The construction of this sequence was done by an individual independent of the research team to avoid possible bias. To conceal allocation, opaque, sealed, and numbered envelopes were used. Each group code was placed inside the envelope, and participants received their respective envelopes in the order they arrived. After registering and obtaining written consent, their respective envelopes wereThe study was open-trial; therefore, after allocation, the treatment group was visible to the participant and therapist, but complete concealment was maintained until the moment of allocation.

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 Islamic Azad University

Street address

Shahid Danesh Town, No. 49, Farhangian St.

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Province

Khouzestan

Postal code

6478175224

Approval date

2025-09-11, 1404/06/20

Ethics committee reference number

IR.IAU.AHVAZ.REC.1404.452

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

Resilience: In this study, resilience refers to the score that subjects obtain based on their responses to the Connor and Davidson Resilience Scale (2003).

Timepoint

It is measured with a pre-test and post-test before the start of the intervention and 8 weeks after the start of

the intervention.

Method of measurement

The Connor Davidson Resilience Scale has 25 items that are scored on a Likert scale from zero (completely false) to five (always true). The options on this scale are scored as follows: Complete false = 0 Rarely true = 1 Sometimes true = 2 Often true = 3 Always true = 4 Therefore, the test score range is between 0 and 100. Higher scores indicate greater resilience of the subject.

2

Description

Worry intensity: In this study, worry intensity refers to the score that subjects obtain based on their responses to the Penn State Worry Questionnaire.

Timepoint

It is measured with a pre-test and post-test before the start of the intervention and 8 weeks after the start of the intervention.

Method of measurement

The Penn State Worry Questionnaire was developed in 1990 by Zinberg and Barlow. It is a self-assessment tool for diagnosing the trait of worry and consists of 16 items.These items are designed to capture dimensions of generality, severity, and uncontrollability of pathological worry. Each item is rated on a 5-point scale (1 = not at all true of me to 5 = very true of me). The standard questionnaire has a scoring range of 16 to 80. In eleven itemsHigher scores indicate more worry. The other five items indicate no problems with worry, and these items are reverse scored. The reverse-scored items include questions 1-3-8-10-11. Scores of 16 to 39 indicate low worry; scores of 40 to 59 indicate moderate worry; and scores of 60 to 80 indicate high worry.

Secondary outcomes

1

Description

Psychological well-being: Psychological well-being refers to the score that each subject obtained from responding to the psychological well-being questionnaire (Ryff Psychological Well-being Scale 1989).

Timepoint

It is measured with a pre-test and post-test before the start of the intervention and 8 weeks after the start of the intervention.

Method of measurement

Ryff Psychological Well-being Scale (1989) Short Form: This questionnaire has 18 questions and is derived from the original form with 120 questions. This version includes:There are 6 factors: independence (questions 9-12-18), mastery of the environment (questions 1-4-6), personal growth (questions 7-15-17), positive relationship with others factor (3, 11, 13), purpose in life (questions 5-14-16), and self-acceptance (questions 2-8-10). The scoring range of this questionnaire is based on a six-choice Likert scale.In this case, the options are: I completely disagree (1 point), I somewhat disagree (2 points), I slightly disagree (3 points), I slightly agree (4 points), I somewhat agree (5 points), I completely agree (6 points). Of course, this scoring method is reversed for questions 1, 3, 4, 5, 9, 10, 13, 17. The lowest score is 18 and the highest score is 108.

2

Description

Emotional alexithymia: The score that participants obtain on the Toronto Alexithymia Scale-20.

Timepoint

It is measured with a pre-test and post-test before the start of the intervention and 8 weeks after the start of the intervention.

Method of measurement

In this scale, the construct of alexithymia is assessed in three subscales: difficulty in recognizing emotions, difficulty in describing emotions, and externally oriented thinking. The first subscale consists of 7 items (14-13-9-7-6-3-1) that assess the subject's ability to identify emotions and differentiate between emotions and physical sensations. The second subscale has 5 items.(17-12-11-4-2) which measures a person's ability to express emotions and whether or not they are able to express their feelings in words. The third subscale has 8 items (20-19-18-16-15-10-8-5) and examines the degree to which a person is introspective and deeply involved in their own and others' inner feelings.

Intervention groups

1

Description

First intervention group: (Acceptance and Commitment Therapy sessions): For members of this group, the acceptance and commitment therapy protocol was implemented in 8 90-minute training sessions, one session per week, with PowerPoint, audio, and short videos. All six components of therapy, including acceptance, faultfinding, self, mindfulness, values clarification, and commitment, will be implemented in the form of metaphors and exercises as homework.The acceptance and commitment treatment intervention was adapted from the Hayes (1999) manual and the acceptance and commitment program for chronic pain by Woolz and Sorrell (2008), which will be implemented in 8 90-minute sessions. The content of the acceptance and commitment treatment intervention has been used and validated in the study of Parvizian, Sharifi, Shekarkan, and Ghazanfari (2019). Below is a brief description of the intervention.The intervention is committed and accepted: First session: welcoming patients, introducing the therapist, introducing group members with the aim of getting to know each other and creating a good relationship in the group, introducing group members to the research topic, brief explanation about MS, patients answering research questionnaires, practicing mindfulness, presenting home exercises. Second session: reviewing the contents of the first session, receiving feedbackFrom patients, familiarization with the concept of resilience and psychological well-

being using the brainstorming method, summarizing the discussion, practicing conscious breathing, presenting home exercises. Third session: Reviewing the contents of the previous session and receiving feedback from patients, expressing bus metaphors, 70th birthdayBirthday, Tombstone, and Values Card (The Values Card is a life compass based on the Ross Harris Happiness Trap Card set by Ali Sahebi and Mehdi Eskandari. This set consists of 59 values cards and 13 action cards, which can be used to(The ability to direct the intervention method) Presentation of home practice. Session 4: Reviewing the assignment and reviewing the materials of the previous session, understanding the concept of acceptance in ACT, using the metaphors of the flower garden and the bus, we clarify that acceptance means giving space and creating a place for painful feelings, desires, and emotions without fighting and putting them aside, and clarifying thatThis does not mean loving or wanting them, it is simply creating space for them, mindfulness, providing home practice. Session 5: Reviewing the previous session and receiving feedback from patients, mindfulness practice, examining committed action from the perspective of ACT, which is a value-based action and evokes a wide range of desirable and undesirable thoughts and feelings; therefore, actionCommitted means doing the actions that are necessary to have a worthwhile life, even if they involve pain and suffering. Discussion of resilience and emotional alexithymia and their components, as well as the relationship between their level of influence on committed action. Practice conscious breathing. Presentation of home exercises. Session 6: Review of the previous session and receiving feedback from patients. Explanation of the concept.Fusion (fusion, holding thoughts firmly) and teaching how to break down using metaphors of river leaves, radio, etc., defining the goal in ACT and its difference from value, summarizing the discussions raised in the session, practicing conscious breathing, presenting home exercises. Session 7: Reviewing the previous session and getting feedback from patients, practicing mindfulness and emphasizing being in the moment.Now, examining the values of the group members, discussing internal and external obstacles to achieving values, discussing setting short-term and long-term goals according to life values, practicing conscious breathing. Session 8: A brief review of previous sessions, explaining the nature of ACT training, which is acceptance and commitment to action, value-centeredness of life, and being committed to one's values.Patients' responses to the resilience, alexithymia, anxiety severity, and psychological well-being questionnaires again as a post-test, and thanking the patients for participating in the study.

Category

Lifestyle

2

Description

Intervention group: Intervention Group 2: Content of emotion regulation therapy sessions for experimental group members 2. The emotion regulation therapy protocol will be implemented in 9 90-minute training sessions, one session per week, with PowerPoint, audio, and short videos. This intervention will be implemented with a technical approach based on the Linehan approach (2008) and the emotion regulation techniques of Leahy et al. (2020) after validation.Implemented these interventions in the target population. The following is a brief description of the emotion regulation intervention: Session 1: Administering pre-tests, explaining and providing a general description of the goals and programs of the training course. Session 2: Describing emotions and training in emotion awareness. Session 3: Describing emotion regulation, recognizingCognitive techniques and strategies in regulating positive emotions. Session Four: Strategies of note for changing thinking (re-evaluation) and accepting the situation. Session Five: Training and implementing the technique of confrontational thoughts. Strategies of note for changing thinking (re-evaluation). Session Six: Strategies of note for planning activities and seeing realities as pleasant. Session Seven: Training andImplementing the technique of enhancing emotional awareness. Session 8: Training and implementing the technique of de-catastrophizing. Strategies of interest: relaxation and meditation. Session 9: Strategies of interest: cognitive framing and problem solving. Session 10: Summarizing the training sessions and implementing the post-test.

Category

Lifestyle

3

Description

Control group: No intervention was performed for the control group and the control group remained on the waiting list.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Khuzestan MS Patients Support Association

Full name of responsible person

Bahareh Nedamat

Street address

Golestan Alley, Golestan Hospital, Faculty of Rehabilitation

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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6134937333
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p_taghipour@iauahvaz.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad 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
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Zahra Mousavi Moghadam
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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

No - There is not 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

Information on primary and secondary outcomes will be collected using questionnaires. All data will be recorded in standard data collection forms and then imported into SPSS software as an Excel file for statistical analysis. Documents such as informed consent, protocol, etc.Intervention and patient education guides will also be prepared and maintained. To maintain confidentiality, data will be coded and stored anonymously, and only the principal investigator and the statistical analysis team will have access to them.

When the data will become available and for how long

Access begins 6 months after completion of data collection and final analysis.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Data were collected to investigate the effectiveness of group psychological treatments on psychological parameters of patients with multiple sclerosis. These data may be used in the future for research purposes such as secondary analyses, development of treatment methods, scientific articles, and clinical education. Reuse of data is permitted only with written permission from the principal investigator and approval from the ethics committee. All data will be stored anonymously and no identifying information will be made available to individuals outside the research. Also, use of data in the form of related projects or student theses will be subject to formal approval from the principal investigator and compliance with data confidentiality. Public release of the data is not currently considered. .

From where data/document is obtainable

Contact researcher Ms. Zahra Mousavi Moghadamz at 9160019095 or mousavimoghadamz@gmail.com

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

Any request for access to data or documentation from this study must be made formally to the researcher via email or written letter. Upon receipt of the request, the subject will be referred to the team.The research will be reviewed and, if necessary, sent to the ethics committee for comment. If approved, the applicant will be required to sign a form for data confidentiality and scientific use.Only anonymous data without identifying information is provided to the applicant. The entire process takes between 2 and 4 weeks.

Comments